

CLINICAL TRIALS OF DRUGS IN ITALY

10th National Report
2011



Agenzia Italiana del Farmaco

AIFA



Agenzia Italiana del Farmaco

AIFA

CLINICAL TRIALS OF DRUGS IN ITALY

**10th National Report
2011**

AUTHORS

**Italian Medicines Agency
Research and Clinical Trial Unit**

National Monitoring Centre on Clinical Trials of Drugs (OsSC)

WORKGROUP

Chief of OsSC Project:

C. Tomino, Head of Research and Clinical Trial Unit – AIFA

Chief of Technological Infrastructure:

M. De Rosa, Health Care Systems Department – CINECA

AIFA, Research and Clinical Trial Unit – Rome

A. Galluccio (Coord.), *P. Aita*, *R. Coppari*, *S. de Gregori*, *F. Guglielmi*, *M. Lastella*, *R. Maione*,
M. Marchetti, *A. Misticoni Consorti*, *L. Scarchilli*

CINECA – Casalecchio di Reno (BO)

E. Rinieri (Coord.), *G. Contino*, *E. Fedozzi*, *L. Pazzi*, *A. Ramenghi*, *F. Ronchetti*, *L. Verri*

*We hereby thank Farindustria (Pharmaceutical Companies Association),
IMS (Intercontinental Marketing Services), ISS (National Institute of Health),
ISTAT (National Institute of Statistics)
and OsMed (National Observatory for Pharmaceutical Use) for their contribution*

10th National Report – 2011

data from 1st January 2006 to 31st December 2010
available on Clinical Research Portal <http://ricerca-clinica.agenziafarmaco.it/>

Any reproduction or diffusion of the information herein is prohibited unless accompanied by its source
and completeness of any information used.



Sergio Pecorelli, *President*
Guido Rasi, *Director General*

■ Overview

Italy and the evolution of clinical trials of drugs	17
10 th National Report on Clinical Trials of Drugs	18
Table 1 Total pharmaceutical turnover (values ex factory) – 2010	20
Table 2 Gross expenses borne by National Health Service per therapeutic classification – 2010	21
Table 3 Investments and number of researchers in R&D in the pharmaceutical industry – 2010	22

■ Clinical trials

Summary of main results 2006-2010	25
Table 4 Clinical trials per year: comparison EU with Italy	26
Table 5 Clinical trials per status (2006-2010)	27
Table 6 Clinical trials per year and outcome of the single opinion (Ethics committee's evaluation of the coordinating centre)	27
Table 7 Clinical trials with favourable single opinion per year and status	28
Table 8 Clinical trials with favourable single opinion concluded per year	28
Table 9 Clinical trials with favourable single opinion and early conclusion per year and reasons	29
Table 10 Forecast and enrolled patients in concluded clinical trials per phase	30
Table 11 Forecast and enrolled patients in regularly concluded clinical trials per phase	31
Table 12 Forecast and enrolled patients in concluded clinical trials sponsored by profit Sponsors per phase	32
Table 13 Forecast and enrolled patients in regularly concluded clinical trials sponsored by profit Sponsors per phase	33
Table 14 Forecast and enrolled patients in concluded clinical trials sponsored by no profit Sponsors per phase	34
Table 15 Forecast and enrolled patients in concluded clinical trials sponsored by no profit Sponsors per phase	35
Table 16 International multi-center clinical trials – Forecast patients in Italy and EU	36
Table 17 International multi-center clinical trials – Average number of forecast patients per clinical trial in Italy and EU	36
Table 18 Clinical trials per design	37
Table 19 Clinical trials per design - details	37
Table 20 Controlled clinical trials per comparator product	37
Table 21 Clinical trials per year and phase	38
Chart A Clinical trials per year and phase	38
Table 22 Mono-centre and multi-centre clinical trials per year	39
Chart B Mono-centre and multi-centre (national and international) clinical trials	39
Table 23 National and international multi-centre clinical trials per year	40
Chart C Multi-centre clinical trials per coordinating country	40
Table 24 Mono-centre and multi-centre clinical trials per phase	41
Table 25 Clinical trials per forecast patient gender	41
Table 26 Clinical trials per forecast age group	41
Table 27 Clinical trials per drug typology	42
Table 28 Clinical trials per drug category	42
Table 29 Clinical trials per therapeutic classification and phase	43

Table 30	Clinical trials per therapeutic classification – ATC up to 2 nd level.....	44
Table 31	Clinical trials per therapeutic classification – ATC up to 5 th level and Phases I, II and III.....	48
Table 32	Clinical trials per therapeutic area and phase (% in rows).....	70
Table 33	Clinical trials per therapeutic area and phase (% in columns).....	71
Chart D	Clinical trials per therapeutic area.....	72
Table 34	Mono-centre and multi-centre clinical trials per therapeutic area.....	73
Table 35	Clinical trials per year and profit / no profit Sponsors.....	74
Chart E	Clinical trials per year and profit / no profit Sponsors.....	74
Table 36	Clinical trials per therapeutic area and profit / no profit Sponsors (% in rows).....	75
Table 37	Clinical trials per therapeutic area and profit / no profit Sponsors (% in columns).....	76
Table 38	Clinical trials per profit Sponsor.....	77
Chart F	Clinical trials per profit Sponsor.....	87
Table 39	Clinical trials per typology of no profit Sponsor.....	88
Table 40	Clinical trials per no profit Sponsor.....	89
Chart G	Clinical trials per no profit Sponsor.....	96
Table 41	Clinical trials per typology of participating centre.....	97
Table 42	Clinical trials per typology of participating centre and phase.....	97
Chart H	Clinical trials per participating centre's region.....	98
Table 43	Clinical trials per participating centre's province.....	99
Table 44	Clinical trials per participating centre.....	100
Table 45	Clinical trials per participating centre ordered by region and province.....	102
	Phase I clinical trials 2006-2010.....	132
Table 46	Phase I clinical trials per year.....	132
Table 47	Phase I clinical trials - First in human per year.....	132
Table 48	Mono-centre and multi-centre Phase I clinical trials per year.....	133
Table 49	Multi-centre national and international Phase I clinical trials per year.....	133
Table 50	Phase I clinical trials per typology of Sponsor: profit / no profit.....	134
Table 51	Phase I clinical trials per year and profit / no profit Sponsors.....	134
Table 52	Phase I clinical trials per therapeutic area.....	135
Table 53	Phase I clinical trials per typology of participating centre.....	136
	Objectives of the clinical trials 2006-2010.....	137
Table 54	Clinical trials per objective.....	137
Table 55	Clinical trials per objective and phase (% of total CT per phase).....	138
Table 56	Mono-centre and multi-centre clinical trials per objective.....	139
Table 57	National and international multi-centre clinical trials per objective.....	140
Table 58	Clinical trials per objective and profit / no profit Sponsor.....	141
Table 59	Clinical trials per objective and therapeutic area.....	142
	Clinical trials with orphan drugs and on rare diseases 2006-2010.....	143
Table 60	Clinical trials with orphan drugs per year.....	143
Table 61	Clinical trials with orphan drugs per year and phase.....	143
Table 62	Mono-centre and multi-centre clinical trials with orphan drugs per year.....	144
Table 63	National and international multi-centre clinical trials with orphan drugs per year.....	144
Table 64	Clinical trials with orphan drugs per typology of Sponsor: profit / no profit.....	145
Table 65	Clinical trials with orphan drugs per year and profit / no profit Sponsor.....	145

Table 66	Clinical trials with orphan drugs per therapeutic area	146
Table 67	Clinical trials with orphan drugs per typology of participating centre	147
	Clinical trials on rare diseases	148
Table 68	Clinical trials on rare diseases per therapeutic area	148
	Substantial amendments to clinical trials 2009-2010	149
Table 69	Substantial amendments per year of clinical trial's single opinion issuing	149
Table 70	Substantial amendments per phase	149
Table 71	Substantial amendments per authorisation procedure	150
Table 72	Substantial amendments per typology	151
	Analysis on the following substantial amendment typology:	
	"Modifications to CTA form / protocol / other documents or urgent safety measures"	152
Table 72 a	Details per typology	152
Table 72 b	Details per typology and profit / no profit Sponsor	152
Table 72 c	Details per reason	153
Table 72 d	Details per reason and profit / no profit Sponsor	154
Table 73	Substantial amendments per therapeutic area	155
Table 74	Substantial amendments per typology of Sponsor: profit / no profit	156
Table 75	Substantial amendments per profit Sponsor	157
Table 76	Substantial amendments per no profit Sponsor	158

■ Analysis

	Clinical trials on female population	
	Summary of main results 2006-2010	163
	Clinical trials exclusively involving women	164
Table 77	Clinical trials exclusively involving women per year and phase	164
Table 78	Clinical trials exclusively involving women per forecast age group	164
Table 79	Clinical trials exclusively involving women per therapeutic area	165
Table 80	Clinical trials exclusively involving women per therapeutic area and phase	166
Table 81	Clinical trials exclusively involving women per therapeutic classification – ATC up to 5 th level	167
Table 82	Clinical trials exclusively involving women per participating centre's region	173
Table 83	Clinical trials exclusively involving women per typology of Sponsor: profit / no profit	174
Table 84	Clinical trials exclusively involving women per objective	174
	Clinical trials involving pregnant women	175
Table 85	Clinical trials involving pregnant women per year and phase	175
Table 86	Clinical trials involving pregnant women per forecast age group	175
Table 87	Clinical trials involving pregnant women per therapeutic area	176
Table 88	Clinical trials involving pregnant women per therapeutic area and phase	177
Table 89	Clinical trials involving pregnant women per therapeutic classification – ATC up to 2 nd level	178
Table 90	Clinical trials involving pregnant women per typology of Sponsor: profit / no profit	180
Table 91	Clinical trials involving pregnant women per objective	180

	Clinical trials involving breastfeeding women	181
Table 92	Clinical trials involving breastfeeding women per year and phase	181
Table 93	Clinical trials involving breastfeeding women per forecast age group	181
Table 94	Clinical trials involving breastfeeding women per therapeutic area	182
Table 95	Clinical trials involving breastfeeding women per therapeutic area and phase	183
Table 96	Clinical trials involving breastfeeding women per therapeutic classification – ATC up to 2 nd level	184
Table 97	Clinical trials involving breastfeeding women per typology of Sponsor: profit / no profit	186
Table 98	Clinical trials involving breastfeeding women per objective	187
	Clinical trials involving patients incapable of validly submitting their consent	
	Summary of main results 2006-2010	191
Table 99	Clinical trials involving patients incapable of validly submitting their consent per year and phase	192
Table 100	Clinical trials involving patients incapable of validly submitting their consent per forecast age group	192
Table 101	Clinical trials involving patients incapable of validly submitting their consent per therapeutic area	193
Table 102	Clinical trials involving patients incapable of validly submitting their consent per therapeutic classification – ATC up to 2 nd level	194
Table 103	Clinical trials involving patients incapable of validly submitting their consent per typology of Sponsor: profit / no profit	197
Table 104	Clinical trials involving patients incapable of validly submitting their consent per objective	198

■ **Observational studies**

	Summary of main results 1st March – 31st December 2010	201
Table 105	Studies per status	201
Table 106	Studies per typology	202
Table 107	Studies per structure where study is performed	202
Table 108	Studies per design	202
Table 109	Studies per typology of applicant	203
Table 110	Studies per typology of applicant coinciding with Sponsor: profit / no profit Sponsor	203
Table 111	Studies per typology of applicant not coinciding with Sponsor	204
Table 112	Studies per source of finance	204
Table 113	Studies per objective	204
Table 114	Studies per main objective	205
Table 115	Studies per aim	205
Table 116	Studies per therapeutic area	206
Table 117	Studies per therapeutic classification – ATC up to 2 nd level	207
Table 118	Studies per therapeutic classification – ATC 5 th level	209
Table 119	Studies per coordinating centre	214

■ Ethics committees

Summary of main results 2007-2010	219
Table 120 Ethics committees per region and inhabitants	220
Chart I Ethics committees per region	221
Table 121 Members of Ethics Committees per professional qualification	222
Analysis on time necessary to issue the single opinion and the acceptance/ refusal of the single opinion	223
Table 122 Single opinion per outcome and year	223
Table 123 Average time to issue the single opinion per year	223
Table 124 Acceptance/refusal of the single opinion per outcome and year	224
Table 125 Median times to issue the acceptance/refusal of the single opinion per year	224
Table 126 Ethics committees' activity per region	225
Table 127 Single opinions and average times to issue the opinion per Ethics committee and year	226
Table 128 Acceptance/refusal of the single opinion and median times to issue the opinion per Ethics committee and year	236

■ Appendix 1

Legislation	253
-------------------	-----

■ Appendix 2

Glossary	259
----------------	-----

■ Appendix 3

Training	269
----------------	-----



■ Foreword

Given the results, it's reasonably simple to say that establishing the National Monitoring Centre on Clinical Trials of Drugs - OsSC – has been a positive step forward. Not only has Italy availed itself of an innovative body for monitoring its pharmacological research, but it has also paved the way for concepts and ideas that are currently being adopted in numerous other countries.

The underlying theme of this entire project has been the concept of “service” to the community (scientific and non); having linked every health structure, including Ethics committees, has been an enormous leap forward, favoured by the rapid evolution of technologies, and certainly boosted by a desire for scientific and cultural development.

In Europe, Italy has been the first country to “open” its registry to the public; the so-called Ottawa Statement, which stipulates which content of research needs to be made public, has been fully embraced by national institutions. Their aim has been to provide citizens with information, in many cases useful for them to interact with clinical research centres to verify the possibility of a citizen being an “active part” in new pharmacological research.

The OsSC has been connected to the European data-warehouse EudraCT since 2004, pursuant to the European directive 2001/20; this has given us the possibility to compare our work with other colleagues and other “research” cultures. Nevertheless, national qualities were certainly taken into consideration given that Italy was included in the group of countries that shall develop the European data-warehouse under the supervision of the European Medicines Agency (EMA).

As a result, numerous sister projects have sprung from the original project; indeed, observational studies have now their own registry, which can certainly be improved, which will soon enable the scientific community to be informed on these kind of important post-marketing researches.

All this has been enclosed in what can be considered as a “portal” of clinical research, where anyone can access numerous publicly useful facts.

Having set up this important registry has enabled us to “monitor” the types of national clinical research over a period of time, identifying grey areas where a prudent country would earmark some investment. This is the focus of the AIFA research projects: over 200 projects in public health structures have been financed to date. These projects are beginning to provide interesting results that could somewhat alter clinical practices in forthcoming years.

Another forthcoming groundbreaking leap shall be the introduction of an online computerised management system for all documentation related to the start-up and running of all clinical experimentation. The e-submission project, which has attracted numerous volunteers that we'd like to thank publicly, has reached the final stages of the tests and in the following months it shall be representing the national benchmark, newly placing Italy among the pioneering countries for maximum use of technologies (at least in this sector).

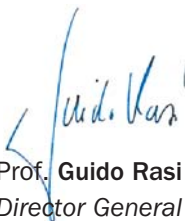
The information in this 10th National Report illustrates the reaching of one of the OsSC's targets: to represent a tool for managing an activity which is fundamental both for boosting knowledge and providing quality assistance, based essentially on research.

It is often difficult and sometimes pointless to measure gains and losses, however the experience of this 10-year project undisputedly shows that even in the complex Public Administration a long-term intelligent management and development project can be set up, and looked upon admiringly from abroad. Naturally, this is thanks to the numerous people who have given their efforts, professionalism and selflessness to the projects, and who never forgot that they were proud owners of unique Italian creativity in the world.



In the forthcoming years our objective shall be to never waste energy and efforts, continuing to “serve” the community in the best way possible, putting professionalism and hopefully further successful ideas on the table.

Enjoy reading,



Prof. Guido Rasi
Director General
Italian Medicines Agency



Dott. Carlo Tomino
Head of Research and Clinical Trial Unit
Italian Medicines Agency



Overview





Italy and the evolution of clinical trials of drugs

The National Report on clinical trials of drugs has reached its tenth edition. This is a significant update of qualitative and quantitative information regarding Italian clinical research highly anticipated by the entire pharmaceutical industry.

Despite the fact that in 2010 there weren't so many legislations published, it is worth noticing that the groundwork for a legislative decree approved by the cabinet in March contains a significant section dedicated to clinical research. This shall represent a considerable task for the supervisory authorities and the Ministry of Health to enact a more flexible legislation, simpler and competitive that governs clinical research for the future. The contents of the legislative decree can be summarised as below:

- shuffling and reorganisation of Ethics committees;
- identification of authorised centre's requirements for clinical trials from phase 0 to phase IV;
- identification of the means of supporting activation and optimisation of clinical centres dedicated to phase 0 and phase I clinical trials, both on patients as well as on healthy volunteers;
- simplification of the red tape concerning applications for an Ethics committee's opinion and its evaluation of a clinical study, specifically concerning:
 - computerised procedures to manage the documentation related to the application to be submitted for the Ethics committee's opinion and for the start up of clinical trials;
 - procedures for the recognition of clinical trials carried out abroad;
 - authorisation procedures for carrying out clinical trials with particular medical products;
- revision of the alert system for adverse reactions and events which may occur during the trial;

- development of a national roll to coordinate every activity and strategy concerning clinical experimentation on drugs;
- defining the evaluation procedure and authorisation process for a clinical experimentation by:
 - identifying the role of the competent authority;
 - identifying the role of the legal representative of the health structure where the clinical trial is intended to be carried out;
 - identification of the tasks and aims of the Ethics committees from a national, regional and local point of view;
 - defining the minimum contents to be presented in the contracts for clinical trials;
- use of computerised support systems for clinical trials that foresee:
 - evaluation systems for the performance of public health structures concerning clinical trials;
 - completion of a consultation website for public access;
 - using the OsSC to exchange documentation regarding clinical trials using predefined forms available on the system;
- identifying the criteria for setting up Post-Graduate studies on carrying out and managing controlled clinical trials (research doctor and data manager).

Likewise, the much anticipated e-submission project has almost been completed. This shall enable the OsSC to operate as an integrated system for the computerised preparing and sending of applications to the competent authorities and Ethics committees for their single opinions in a format pursuant to the European guidelines. The same "CTA" Ministerial Decree introduced further procedures and forms, for communicating the Ethics committee's decisions to the OsSC and for monitoring trials (start-up and closure of clinical centres). This platform shall undergo a new phase of testing that will be started up by the end of this year by the representatives of the technical roundtables, and gradually extended to every operator in the OsSC.

The aim is to introduce the e-submission project as an instrument to simplify bureaucracy, stan-



standardise the procedures and reduce time for sending documentation and decisions to the Ethics committees and competent authorities.

■ 10th National Report on Clinical Trials of Drugs

The studies taken into consideration in this 10th Report are those the Ethics committee of the coordinating centre has submitted its approving data to the OsSC (trials with pending or negative evaluations have been excluded).



Clinical trials

The data in question refers to those submitted to the OsSC between 1st January 2006 and 31st December 2010.

It is worth remembering that recent innovations have been introduced concerning the elaboration and presentation of tables:

- a different elaboration of the ATC classification of experimental drugs has been published. To date, registration to a OsSC study was definable by a 5th level ATC for the active ingredient: the table groups, for every 2nd ATC level, a list of molecules inversely ordering them by numerosness and their relative number of phase I, II and III studies where the molecule has been used;

- tables on trials per profit and no profit Sponsors have been illustrated with decreasing number of studies for the period 2006-2010. Each Sponsor is reported with the partial number of studies for the period 2006-2010.

Analysis on clinical trials

Continuing the consolidated tradition of providing details on certain aspects, some points deemed important by the scientific community have been analysed.

Phase I clinical trials: a significant revival of this specific type of study is particularly visible. Numbers have gone from 2.4 to 8.0% of all clinical trials per year in just a handful of years. This is largely due to new procedures introduced by the Italian National Health Institute (competent authority for these studies), enabling to reduce the time needed for evaluation to the lowest international ones. Corporate Sponsors presented approximately 80% of these studies.

Objectives of the clinical study: these are inevitably related to the trial phase. What strikes us immediately is how the number of studies aiming at evaluating efficacy grows progressively (from phase I to III). What remains a high figure is the number related to safety (>85%). It's worth noting the portions relating to pharmacokinetics, pharmacodynamics and pharmacogenetics studies.

Orphan drugs and rare diseases: there has been a progressive growth in the number of studies in this sector over the last five years. They have gone from 5.3 to 10.0% of all clinical trials per year, highlighting the interest this sector offers. Almost every study has been a multicentre one (96.3%) and numerous have been international (87.2%). Given the difficulty to recruit, Sponsors have opted for this typology of study. The therapeutic area most covered has been oncology, where numerous rare diseases have been the focus of the studies.

Substantial amendments: it is worth underlining that each study is subject to more than one substantial amendment. Specifically the report



states the number as being 1:2.59. This is extremely burdensome on the Ethics committees, and it's concentrated on changes to the Clinical Trial Application (80.2%), to the protocol or other documents concerning the study. The main reasons are safety, rights, wellbeing or integrity of the persons participating in the trial or modifications to how the clinical study should be managed or carried out.

Ethics committees

Also this year, this section contains detailed analyses of the regional distribution and on time to issue single opinions (for the coordinating centre) and to issue acceptance / refusal of the single opinion (for satellite centres). The reference period goes from 1st January 2007 to 31st December 2010.

Tables following:

Table 1

Total pharmaceutical turnover
(values ex factory) – 2010

Table 2

Gross expenses borne by National Health Service
per therapeutic classification – 2010

Table 3

Investments and number of researchers
in R&D in the pharmaceutical industry – 2010



**Table 1****Total pharmaceutical turnover (values ex factory) – 2010**

Country	Total turnover (pharmacies and hospitals in million)	%
USA	232,452*	39.5
Japan	64,668*	11.0
EU countries	134,694	22.9
Germany	30,134	5.1
France	29,342	5.0
Italy	19,964	3.4
Spain	16,575	2.8
United Kingdom	15,317	2.6
Greece	3,759	0.6
Belgium	3,152	0.5
The Netherlands	3,121	0.5
Sweden	3,022	0.5
Portugal	2,411	0.4
Austria	2,088	0.4
Finland	1,979	0.3
Denmark	1,939	0.3
Ireland	1,891	0.3
Switzerland **	2,746	0.5
Norway **	1,350	0.2
Others	152,263	25.9
Total	588,173 *	100.0

* source IMS

** non-EU countries

Source Farindustria.

**Table 2****Gross expenses borne by National Health Service per therapeutic classification – 2010**

Therapeutic classification – ATC 1 st level		Total expenses (€ million)	Cost pro-capita (€)	%
C	Cardiovascular system	4,657	77.2	35.9
A	Alimentary tract and metabolism	2,014	33.4	15.5
N	Nervous system	1,454	24.1	11.2
J	General antiinfectives for systemic use	1,095	18.1	8.4
R	Respiratory system	1,095	18.1	8.4
B	Blood and blood forming organs	609	10.1	4.7
M	Musculo-skeletal system	594	9.8	4.6
L	Antineoplastic and immunomodulating agents	450	7.5	3.5
G	Genito urinary system and sex hormones	423	7.0	3.3
H	Systemic hormonal preparations, excluding sex hormones and insulins	223	3.7	1.7
S	Sensory organs	221	3.7	1.7
V	Various	75	1.2	0.6
D	Dermatologicals	61	1.0	0.5
P	Antiparasitic products, insecticides and repellents	12	0.2	0.1
Total		12,983	215.1	100.0

Source OsMed - Osservatorio Nazionale sull'Impiego dei Medicinali.

**Table 3*****Investments and number of researchers in R&D in the pharmaceutical industry – 2010***

Country	Investment (€ million)	%	Researchers	%
Germany	5,379	8.4	20,240	9.1
United Kingdom	4,976	7.8	26,000	11.7
France	4,964	7.7	22,212	10.0
Switzerland	4,320	6.7	8,463	3.8
Belgium	1,809	2.8	3,438	1.5
Italy	1,240	1.9	6,050	2.7
Denmark	1,102	1.7	7,468	3.3
Spain	967	1.5	5,121	2.3
Sweden	746	1.2	5,134	2.3
The Netherlands	550	0.9	4,743	2.1
Austria	280	0.4	1,521	0.7
Ireland	260	0.4	2,600	1.2
Finland	255	0.4	1,378	0.6
Norway	96	0.1	600	0.3
Others	469	0.7	1,714	0.8
Europe	27,413	42.8	116,682	52.3
USA	28,190	44.0	78,950	35.4
Japan	8,499	13.3	27,362	12.3
Total	64,102	100.0	222,994	100.0

Source Farindustria.

Clinical trials





Summary of main results 2006-2010

There have been 7,441 clinical trials approved by the coordinating Ethics committee between 1st January 2000 and 31st December 2010, entered in the OsSC. The following table illustrates their breakdown per year:

Year	# CT
2000	557
2001	605
2002	560
2003	568
2004	624
2005	664
2006	778
2007	795
2008	878
2009	752
2010	660
Total	7,441

This section of 10th National Report illustrates the data concerning the clinical trials approved by the coordinating Ethics committee since 1st January 2006, therefore analysing this last five years' activity.

As illustrated in the table above, there was a drop of 12.2% on the previous year concerning the

number of clinical trials. This drop was principally in the mono-centre studies.

However, this fact should be considered on a European scale: in 2010 every EU country faced a drop in the number of clinical trials approved, reaching a mere 4,193. Italy accounts for 660 of these (15.7%); this figure is identical to 2007 data when Italy performed 795 (15.8%) studies of the 5,028 studies carried out in Europe.

The number of phase I and II studies is still increasing compared to the total number of clinical trials in Italy, accounting for 45.4% in the last year (compared to 43.2% in 2009). Phase III studies reached 42.1% of clinical trials in 2010.

The percentage of multi-centre studies reached 83% of the total in 2010, with 75.4% of these being international studies.

The majority of drugs tested were chemical ones (79.4%), with a constant growth of biological/biotechnical ones (26.4%).

For each therapeutic classification, the principal molecules studied in phases I, II and III had a 5th ATC level when they were inserted in the OsSC, are listed. An analysis of patients enrolled in clinical trials shows that Italy represents 21.8% of the European total (17.9% in 2006).

Oncology is the therapeutic area mostly studied (30%), with its closest runner-ups being cardiology/vascular diseases (9.3%), neurology (9.1%) and immunology/Infectious diseases (7.8%).

A relevant section has been dedicated to the centres involved in the clinical trials and their distribution per region and province. This highlights the large number of Lombardy centres performing clinical trials (in line with their high number of centres).



What used to be considered special analysis in previous editions (phase I studies, objectives of the clinical trials, studies on orphan drugs, rare diseases and substantial amendments) have become integrating parts of this Report. Instead, specific analyses have been made this year concerning female population and those incapable of giving their consent validly.

This year witnesses for the first time the inclusion of the analysis on observational studies. The national database shall be complete including this typology of research. This is fundamental to fully un-

derstand the use of new (and not only) drugs in a real practical clinical daily environment.

Lastly, an analysis on Ethics committees; despite the efforts to aggregate them so as to reach operative efficiency, Ethics committees remain too numerous often determining an unmanageable situation (especially concerning the acceptance/refusal of an opinion). With respect to the foregoing, we shall study with the assistance of regional administrations the guidelines to realign Italy to international standards.

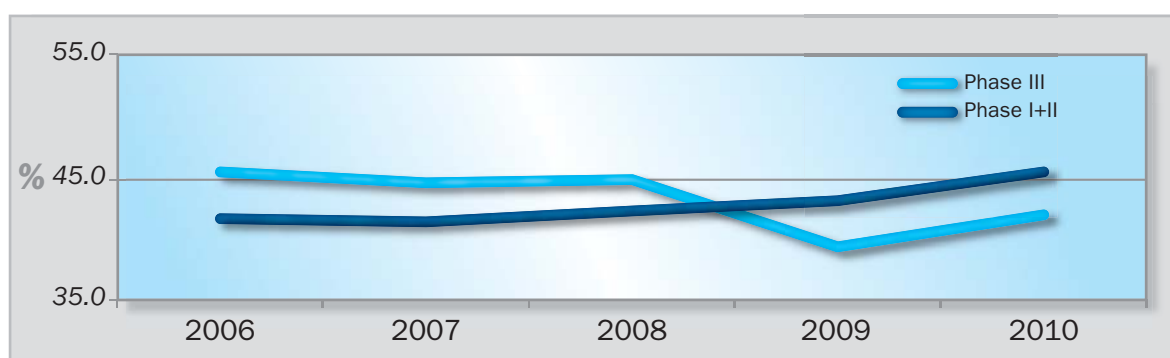


Table 4

Clinical trials per year: comparison EU with Italy

Year	CT in EU	CT in Italy	% Italy/EU
2007	5,028	795	15.8
2008	4,618	878	19.0
2009	4,491	752	16.7
2010	4,193	660	15.7

The number of clinical trials in the EU according to EudraCT was reported in the Concept Paper drafted by the European Commission following the revision of the Directive on clinical trials 2001/20/EC (http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf).

The number of clinical trials performed in Italy comes from the OsSC.

**Table 5*****Clinical trials per status (2006-2010)***

Status	CT
CT with favourable single opinion	3,863
CT with unfavourable single opinion	106
CT with suspended single opinion	57
CT revoked prior to the single opinion	52
CT not authorised by ISS	3
CT not authorised by AIFA	1

Table 6
***Clinical trials per year and outcome of the single opinion
(Ethics committee's evaluation of the coordinating centre)***

Total CT (with favourable and unfavourable SO): 3,969

Year	Favourable SO	Unfavourable SO	Total
2006	778	15	793
2007	795	20	815
2008	878	16	894
2009	752	25	777
2010	660	30	690
Total	3,863	106	3,969

**Table 7*****Clinical trials with favourable single opinion per year and status***

CT: 3,848 (excluding suspended ones)

Year	In approval phase		Open		Concluded		Total	
	CT	%	CT	%	CT	%	CT	%
2006	81	10.4	195	25.1	502	64.5	778	100.0
2007	93	11.8	265	33.5	433	54.7	791	100.0
2008	112	12.9	387	44.4	372	42.7	871	100.0
2009	190	25.3	404	53.9	156	20.8	750	100.0
2010	341	51.8	274	41.6	43	6.5	658	100.0
Total	817	21.2	1,525	39.6	1,506	39.1	3,848	100.0

In approval phase: with favourable single opinion but not started-up yet (in any centre).

Open: with single opinion and start up in at least one centre.

Concluded: fully concluded.

Table 8***Clinical trials with favourable single opinion concluded per year***

CT: 1,506

Year	Regular conclusion		Early conclusion		Total	
	CT	%	CT	%	CT	%
2006	361	71.9	141	28.1	502	100.0
2007	306	70.7	127	29.3	433	100.0
2008	228	61.3	144	38.7	372	100.0
2009	91	58.3	65	41.7	156	100.0
2010	18	41.9	25	58.1	43	100.0
Total	1,004	66.7	502	33.3	1,506	100.0

**Table 9****Clinical trials with favourable single opinion and early conclusion per year and reasons**

CT: 502

Year	Safety		Lack of efficiency		IMP * quality		Enrolment difficulty		Lack of start-up		Removal of SO		Other	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	10	7.1	29	20.6	0	0.0	46	32.6	15	10.6	0	0.0	53	37.6
2007	10	7.9	26	20.5	0	0.0	47	37.0	12	9.4	1	0.8	51	40.2
2008	15	10.4	22	15.3	3	2.1	35	24.3	34	23.6	4	2.8	49	34.0
2009	7	10.8	14	21.5	1	1.5	18	27.7	14	21.5	1	1.5	21	32.3
2010	4	16.0	6	24.0	2	8.0	6	24.0	11	44.0	0	0.0	4	16.0

* Investigational Medicinal Product

The same clinical trial may have numerous reasons for an early conclusion and therefore shall be counted more than once.



The following analysis is focussed on patients forecast and actually enrolled in clinical trials: every clinical trial that was concluded in OsSC in the 2006-2010 period is taken into consideration. Please refer to the corresponding CTA on latest effective amendment for details on patients forecast in Italy.

Table 10**Forecast and enrolled patients in concluded clinical trials per phase**

CT: 1,506 of which 1,448 (96.1%) have reported the effective number of patients enrolled in the study

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# CT	59	4.1	525	36.3	662	45.7	163	11.3	39	2.7	1,448	100.0
Patients												
# Forecast patients for enrolment in Italy	1,054	1.0	22,702	22.3	52,964	52.1	23,793	23.4	1,084	1.1	101,597	100.0
# Patients effectively enrolled in Italy	575	0.9	13,962	21.8	38,419	60.0	10,049	15.7	1,024	1.6	64,029	100.0
Variance	479	1.3	8,740	23.3	14,545	38.7	13,744	36.6	60	0.2	37,568	100.0
Average number of forecast patients to be enrolled per CT in Italy	18		43		80		146		28		70	
Average number of patients effectively enrolled per CT in Italy	10		27		58		62		26		4	
Average variance per CT	8		17		22		84		2		26	

**Table 11****Forecast and enrolled patients in regularly concluded clinical trials per phase**

CT: 1,004

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# Clinical trials	41	4.1	346	34.5	458	45.6	122	12.2	37	3.7	1,004	100.0
Patients												
# Forecast patients for enrolment in Italy	620	0.9	15,827	22.6	40,581	57.9	11,986	17.1	1,024	1.5	70,038	100.0
# Patients effectively enrolled in Italy	496	0.9	12,211	21.4	33,684	59.2	9,521	16.7	1,024	1.8	56,936	100.0
Variance	124	0.9	3,616	27.6	6,897	52.6	2,465	18.8			13,102	100.0
Average number of forecast patients to be enrolled per CT in Italy	15		46		89		98		28		70	
Average number of patients effectively enrolled per CT in Italy	12		35		74		78		28		57	
Average variance per CT	3		10		15		20				13	

**Table 12****Forecast and enrolled patients in concluded clinical trials sponsored by profit Sponsors per phase**

CT: 1,214 of which 1,156 (95.2%) have reported the effective number of patients enrolled in the study

Profit Sponsors: 222

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# Clinical trials	54	4.7	375	32.4	590	51.0	100	8.7	37	3.2	1,156	100.0
Patients												
# Forecast patients for enrolment in Italy	884	1.3	14,209	21.1	40,684	60.4	10,585	15.7	1,036	1.5	67,398	100.0
# Patients effectively enrolled in Italy	497	0.9	10,106	18.6	35,039	64.5	7,686	14.2	974	1.8	54,302	100.0
Variance	387	3.0	4,103	31.3	5,645	43.1	2,899	22.1	62	0.5	13,096	100.0
Average number of forecast patients to be enrolled per CT in Italy	16		38		69		106		28		58	
Average number of patients effectively enrolled per CT in Italy	9		27		59		77		26		47	
Average variance per CT	7		11		10		29		2		11	

**Table 13**

Forecast and enrolled patients in regularly concluded clinical trials sponsored by profit Sponsors per phase

CT: 831

Profit Sponsors: 178

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# Clinical trials	38	4.6	259	31.2	422	50.8	77	9.3	35	4.2	831	100.0
Patients												
# Forecast patients for enrolment in Italy	538	0.9	10,827	18.5	37,489	64.2	8,562	14.7	976	1.7	58,392	100.0
# Patients effectively enrolled in Italy	420	0.9	9,218	18.8	31,166	63.5	7,331	14.9	974	2.0	49,109	100.0
Variance	118	1.3	1,609	17.3	6,323	68.1	1,231	13.3	2		9,283	100.0
Average number of forecast patients to be enrolled per CT in Italy	14		42		89		111		28		70	
Average number of patients effectively enrolled per CT in Italy	11		36		74		95		28		59	
Average variance per CT	3		6		15		16				11	

**Table 14**

Forecast and enrolled patients in concluded clinical trials sponsored by no profit Sponsors per phase

CT: 292

No profit Sponsors: 82

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# Clinical trials	5	1.7	150	51.4	72	24.7	63	21.6	2	0.7	292	100.0
Patients												
# Forecast patients for enrolment in Italy	170	0.5	8,493	24.8	12,280	35.9	13,208	38.6	48	0.1	34,199	100.0
# Patients effectively enrolled in Italy	78	0.8	3,856	39.6	3,380	34.7	2,363	24.3	50	0.5	9,727	100.0
Variance	92	0.4	4,637	18.9	8,900	36.4	10,845	44.3	- 2		24,472	100.0
Average number of forecast patients to be enrolled per CT in Italy	34		57		171		210		24		117	
Average number of patients effectively enrolled per CT in Italy	16		26		47		38		25		33	
Average variance per CT	18		31		124		172		- 1		84	

**Table 15**

Forecast and enrolled patients in concluded clinical trials sponsored by no profit Sponsors per phase

CT: 173

No profit Sponsors: 50

	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Clinical trials												
# Clinical trials	3	1.7	87	50.3	36	20.8	45	26.0	2	1.2	173	100.0
Patients												
# Forecast patients for enrolment in Italy	82	0.7	5,000	42.9	3,092	26.5	3,424	29.4	48	0.4	11,646	100.0
# Patients effectively enrolled in Italy	76	1.0	2,993	38.2	2,518	32.2	2,190	28.0	50	0.6	7,827	100.0
Variance	6	0.2	2,007	52.6	574	15.0	1,234	32.3	- 2	- 0.1	3,819	100.0
Average number of forecast patients to be enrolled per CT in Italy	27		57		86		76		24		67	
Average number of patients effectively enrolled per CT in Italy	25		34		70		49		25		45	
Average variance per CT	2		23		16		27		- 1		22	



The following tables have been elaborated on international multi-centre clinical trials with a favourable single opinion that report the number of forecast patients and involve Italy and other EU countries.

Table 16***International multi-center clinical trials – Forecast patients in Italy and EU***

CT with centres exclusively in EU: 408 of which 406 (99.5%)
with number of patients in EU greater than those in Italy

Year	CT	Forecast patients in Italy	Forecast patients in EU (including Italy)	% patients Italy / EU
2006	64	3,562	19,897	17.9
2007	99	9,103	52,531	17.3
2008	99	6,474	32,720	19.8
2009	75	10,420	49,182	21.2
2010	69	4,425	20,265	21.8
Total	406	33,984	174,595	19.5

Table 17***International multi-center clinical trials – Average number of forecast patients per CT in Italy and EU***

Year	CT	Forecast patients in Italy	Average number of forecast patients per CT in Italy	Forecast patients in EU (including Italy)	Average number of forecast patients per CT in EU (including Italy)
2006	64	3,562	56	19,897	311
2007	99	9,103	92	52,531	531
2008	99	6,474	65	32,720	331
2009	75	10,420	139	49,182	656
2010	69	4,425	64	20,265	294
Total	406	33,984	84	174,595	430

**Table 18*****Clinical trials per design***

Total CT: 3,863

Design	CT	%
Controlled	2,631	68.1
Not controlled	1,232	31.9
Total	3,863	100.0

Table 19***Clinical trials per design-details***

Total CT: 3,863 of which 2,380 (61.6%) with specified design

Design-detail	CT	%
Randomised	2,480	64.2
Parallel groups	2,145	55.5
Double blind	1,386	35.9
Open	1,020	26.4
Cross over	162	4.2
Single blind	90	2.3

The information concerning the clinical trial design is not univocal; therefore one trial may be associated to more than one design.

Table 20***Controlled clinical trials per comparator product***

Controlled CT: 2,631 of which 2,488 (94.6%) with specified comparator product

Comparator product	CT	% of controlled CT
Placebo	1,167	44.4
Other drug(s)	1,051	39.9
Same drug with different dosage	326	12.4
Other	479	18.2

The information concerning the comparator product is not univocal; therefore one trial may be associated to more than one comparator product.

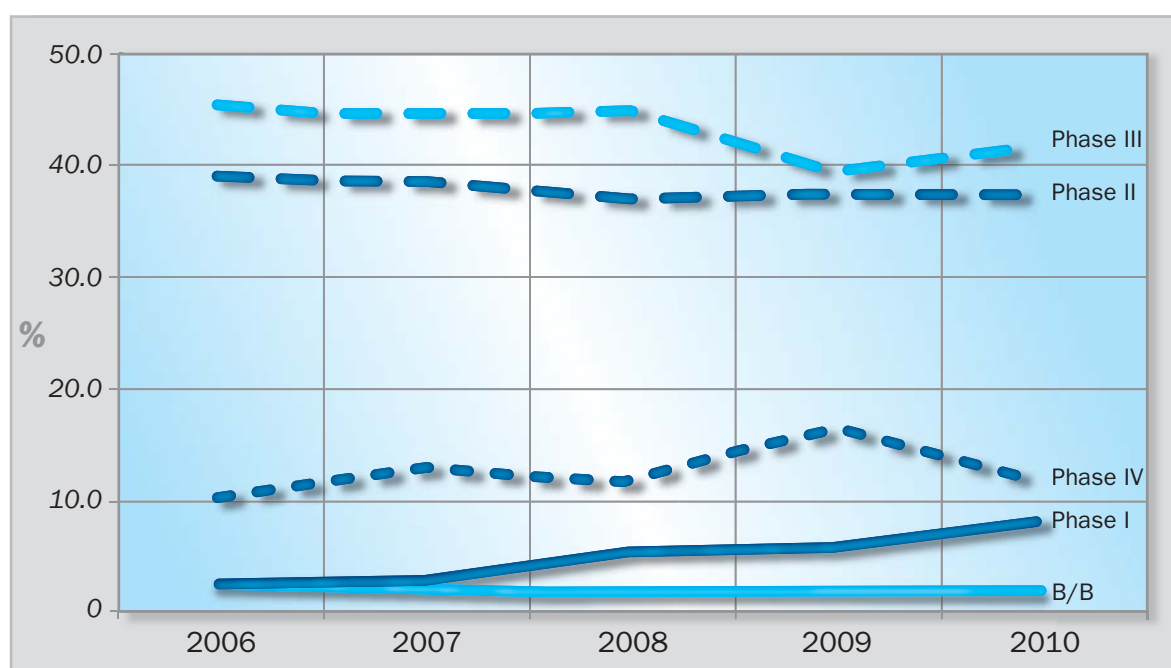
**Table 21****Clinical trials per year and phase**

Total CT: 3,863

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	19	2.4	305	39.2	355	45.6	81	10.4	18	2.3	778	100.0
2007	22	2.8	307	38.6	355	44.7	103	13.0	8	1.0	795	100.0
2008	46	5.2	326	37.1	395	45.0	104	11.8	7	0.8	878	100.0
2009	43	5.7	282	37.5	296	39.4	124	16.5	7	0.9	752	100.0
2010	53	8.0	247	37.4	278	42.1	77	11.7	5	0.8	660	100.0
Total	183	4.7	1,467	38.0	1,679	43.5	489	12.7	45	1.2	3,863	100.0

Chart A**Clinical trials per year and phase**

Total CT: 3,863



**Table 22*****Mono-centre and multi-centre clinical trials per year***

Total CT: 3,863

Year	Mono-centre		Multi-centre		Total	
	CT	%	CT	%	CT	%
2006	167	21.5	611	78.5	778	100.0
2007	162	20.4	633	79.6	795	100.0
2008	186	21.2	692	78.8	878	100.0
2009	167	22.2	585	77.8	752	100.0
2010	112	17.0	548	83.0	660	100.0
Total	794	20.6	3,069	79.4	3,863	100.0

Chart B***Mono-centre and multi-centre (national and international) clinical trials***

Total CT: 3,863



■ International multi-centre CT 57.5%

■ National multi-centre CT 21.9%

■ Mono-centre CT 20.6%

**Table 23*****National and international multi-centre clinical trials per year***

Multi-centre CT: 3,069

Year	National multi-centres CT		International multi-centres CT		Total	
	CT	%	CT	%	CT	%
2006	181	29.6	430	70.4	611	100.0
2007	166	26.2	467	73.8	633	100.0
2008	209	30.2	483	69.8	692	100.0
2009	155	26.5	430	73.5	585	100.0
2010	135	24.6	413	75.4	548	100.0
Total	846	27.6	2,223	72.4	3,069	100.0

Chart C***Multi-centre clinical trials per coordinating country***

Multi-centre CT: 3,069



■ International CT coord. Italy 7.7% ■ National CT 27.6% ■ International CT coord. other/unspecified 1.9%
 ■ International CT coord. USA 21.7% ■ International CT coord. Europe (excl. Italy) 41.1%

**Table 24*****Mono-centre and multi-centre clinical trials per phase***

Total CT: 3,863

Phase	Mono-centre CT		Multi-centre CT		Total	
	CT	%	CT	%	CT	%
Phase III	160	20.2	1,519	49.5	1,679	100.0
Phase II	356	44.8	1,111	36.2	1,467	100.0
Phase IV	207	26.1	282	9.2	489	100.0
Phase I	28	3.5	155	5.1	183	100.0
Bioeq / Biod	43	5.4	2	0.1	45	100.0
Total	794	100.0	3,069	100.0	3,863	100.0

Table 25***Clinical trials per forecast patient gender***

Total CT: 3,863

Gender	CT	%
Female & male	3,365	87.1
Female	314	8.1
Male	184	4.8
Total	3,863	100.0

Table 26***Clinical trials per forecast age group***

Total CT: 3,863 of which 3,846 (99.6%) with age specified

Age group	CT	%
Adults (from 19 to 64 years of age)	3,549	92.3
OAPs (65+ years of age)	2,945	76.6
Minors (from 13 to 18 years of age)	351	9.1
Children (up to 12 years of age)	334	8.7

Enrolled subjects could fall into more than one age group; therefore the same trial may be counted more than once.

**Table 27*****Clinical trials per drug typology***

Total CT: 3,863 of which 3,849 (99.6%) with ATC and typology of at least one test drug specified

Typology	CT	%
Chemical active ingredient	3,055	79.4
Biological/biotechnological active ingredient	1,016	26.4

The same clinical trial can involve more than one test drug and therefore shall be counted in more than one drug typology.

Table 28***Clinical trials per drug category***

Total CT: 3,863 of which 3,844 (99.5%) with ATC and category of at least one test drug specified

Category	CT	%
Immunological medicinal product (vaccine, allergen, immune sera)	250	6.5
Radiopharmaceutical medicinal product	59	1.5
Other extractive medicinal product	57	1.5
Plasma derived medicinal product	28	0.7
Somatic cell therapy medicinal product	20	0.5
Herbal medicinal product	11	0.3
Gene therapy medicinal product	10	0.3
Homeopathic medicinal product	5	0.1
Medicinal product containing GMOs	4	0.1
Other	2,068	53.8

The same clinical trial can involve more than one test drug and therefore shall be counted in more than one drug category.

**Table 29*****Clinical trials per therapeutic classification and phase***

Total CT: 3,863 of which 3,849 (99.6%) with ATC of at least one test drug specified

Therapeutic classification ATC 1 st level		CT	%					
			Phase I	Phase II	Phase III	Phase IV	Bioeq/ Biod	Total
L	Antineoplastic and immunomodulating agents	1,511	8.7	52.9	34.4	3.8	0.1	100.0
		446	0.9	26.7	48.9	21.5	2.0	100.0
N	Nervous system	348	4.9	33.3	45.7	15.2	0.9	100.0
J	General antiinfectives for systemic use	317	1.3	28.7	55.2	13.9	0.9	100.0
A	Alimentary tract and metabolism							
B	Blood and blood forming organs	277	5.8	24.5	52.0	17.7	0.0	100.0
C	Cardiovascular system	262	0.4	22.5	52.7	19.8	4.6	100.0
V	Various	248	4.4	39.9	36.3	19.0	0.4	100.0
H	Systemic hormonal preparations, excluding sex hormones and insulins	157	3.8	36.3	40.8	18.5	0.6	100.0
M	Musculo-skeletal system	147	2.7	35.4	44.2	10.2	7.5	100.0
R	Respiratory system	128	0.0	23.4	58.6	15.6	2.3	100.0
G	Genito urinary system and sex hormones	95	0.0	28.4	49.5	22.1	0.0	100.0
S	Sensory organs	85	2.4	36.5	45.9	14.1	1.2	100.0
D	Dermatologicals	47	4.3	36.2	38.3	21.3	0.0	100.0
P	Antiparasitic products, insecticides and repellents	9	11.1	33.3	33.3	22.2	0.0	100.0

The same clinical trial can involve more than one test drug and therefore shall be counted in more than one ATC classification.

**Table 30*****Clinical trials per therapeutic classification – ATC up to 2nd level***

Total CT: 3,863 of which 3,849 (99.6%) with ATC of at least one test drug specified

Therapeutic classification ATC up to 2 nd level		CT	% of ATC 1 st level	% of CT with spec. ATC (3,849)
L	Antineoplastic and immunomodulating agents	1,511		39.3
L01	Antineoplastic agents	1,111	73.5	28.9
L04	Immunosuppressants	282	18.7	7.3
L03	Immunostimulants	162	10.7	4.2
L02	Endocrine therapy	40	2.6	1.0
N	Nervous system	446		11.6
N07	Other nervous system drugs	94	21.1	2.4
N06	Psychoanaleptics	80	17.9	2.1
N02	Analgesics	78	17.5	2.0
N03	Antiepileptics	63	14.1	1.6
N01	Anesthetics	56	12.6	1.5
N05	Psycholeptics	46	10.3	1.2
N04	Anti-Parkinson drugs	43	9.6	1.1
J	General antiinfectives for systemic use	348		9.0
J05	Antivirals for systemic use	179	51.4	4.7
J01	Antibacterials for systemic use	66	19.0	1.7
J07	Vaccines	62	17.8	1.6
J02	Antimycotics for systemic use	24	6.9	0.6
J06	Immune sera and immunoglobulins	17	4.9	0.4
J04	Antimycobacterials	3	0.9	0.1
A	Alimentary tract and metabolism	317		8.2
A10	Drugs used in diabetes	144	45.4	3.7
A07	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	45	14.2	1.2
A16	Other alimentary tract and metabolism products	29	9.1	0.8
A02	Drugs for acid related disorders	18	5.7	0.5
A11	Vitamins	18	5.7	0.5
A04	Antiemetics and antinauseants	17	5.4	0.4
A03	Drugs for functional gastrointestinal disorders	11	3.5	0.3
A05	Bile and liver therapy	11	3.5	0.3
A09	Digestives, including enzymes	10	3.2	0.3
A06	Laxatives	6	1.9	0.2
A08	Antiobesity preparations, excluding diet products	5	1.6	0.1



Therapeutic classification ATC up to 2 nd level	CT	% of ATC 1 st level	% of CT with spec. ATC (3,849)
A01 Stomatological preparations	4	1.3	0.1
A12 Mineral supplements	3	0.9	0.1
B Blood and blood forming organs	277		7.2
B01 Antithrombotic agents	133	48.0	3.5
B02 Antihemorrhagics	62	22.4	1.6
B03 Antianemic preparations	42	15.2	1.1
B05 Blood substitutes and perfusion solutions	24	8.7	0.6
B06 Other hematological agents	17	6.1	0.4
C Cardiovascular system	262		6.8
C09 Agents acting on the renin-angiotensin system	75	28.6	1.9
C10 Lipid modifying agents	62	23.7	1.6
C01 Cardiac therapy	55	21.0	1.4
C02 Antihypertensives	26	9.9	0.7
C03 Diuretics	23	8.8	0.6
C08 Calcium channel blockers	17	6.5	0.4
C07 Beta blocking agents	14	5.3	0.4
C04 Peripheral vasodilators	8	3.1	0.2
C05 Vasoprotectives	7	2.7	0.2
V Various	248		6.4
V03 All other therapeutic products	122	49.2	3.2
V08 Contrast media	37	14.9	1.0
V09 Diagnostic radiopharmaceuticals	35	14.1	0.9
V01 Allergens	19	7.7	0.5
V10 Therapeutic radiopharmaceuticals	17	6.9	0.4
V06 General nutrients	12	4.8	0.3
V04 Diagnostic agents	6	2.4	0.2
V07 All other non-therapeutic products	2	0.8	0.1
H Systemic hormonal preparations, excluding sex hormones and insulins	157		4.1
H02 Corticosteroids for systemic use	91	58.0	2.4
H01 Pituitary and hypothalamic hormones and analogues	37	23.6	1.0
H05 Calcium homeostasis	20	12.7	0.5
H03 Thyroid therapy	10	6.4	0.3
M Musculo-skeletal system	147		3.8
M01 Antiinflammatory and antirheumatic products	59	40.1	1.5
M05 Drugs for treatment of bone diseases	42	28.6	1.1
M03 Muscle relaxants	25	17.0	0.6



Therapeutic classification ATC up to 2 nd level		CT	% of ATC 1 st level	% of CT with spec. ATC (3,849)
M09	Other drugs for disorders of the musculo-skeletal system	14	9.5	0.4
M02	Topical products for joint and muscular pain	6	4.1	0.2
M04	Antigout preparations	3	2.0	0.1
R	Respiratory system	128		3.3
R03	Drugs for obstructive airway diseases	81	63.3	2.1
R07	Other respiratory system products	17	13.3	0.4
R05	Cough and cold preparations	16	12.5	0.4
R06	Antihistamines for systemic use	11	8.6	0.3
R01	Nasal preparations	4	3.1	0.1
G	Genito urinary system and sex hormones	95		2.5
G04	Urologicals	54	56.8	1.4
G03	Sex hormones and modulators of the genital system	36	37.9	0.9
G02	Other gynaecologicals	8	8.4	0.2
S	Sensory organs	85		2.2
S01	Ophthalmologicals	83	97.6	2.2
S03	Ophthalmological and otological preparations	2	2.4	0.1
D	Dermatologicals	47		1.2
D07	Corticosteroids, dermatological preparations	11	23.4	0.3
D11	Other dermatological preparations	9	19.1	0.2
D03	Preparations for treatment of wounds and ulcers	5	10.6	0.1
D05	Antipsoriatics	5	10.6	0.1
D06	Antibiotics and chemotherapeutics for dermatological use	5	10.6	0.1
D01	Antifungals for dermatological use	3	6.4	0.1
D02	Emollients and protectives	3	6.4	0.1
D08	Antiseptics and disinfectants	3	6.4	0.1
D10	Anti-acne preparations	3	6.4	0.1
D04	Antipruritics, including antihistamines, anesthetics, etc.	1	2.1	0.0
P	Antiparasitic products, insecticides and repellents	9		0.2
P01	Antiprotozoals	6	66.7	0.2
P03	Ectoparasitocides, including scabicides, insecticides and repellents	2	22.2	0.1
P02	Anthelmintics	1	11.1	0.0

**Note Table 30**

The total number of ATC 1st level clinical trials ("CT" column) is higher than the number indicated in the subtitle because the same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

Likewise, regarding each therapeutic classification, the total number of ATC 2nd level clinical trials ("CT" column) can be higher than the ATC 1st level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

**Table 31****Clinical trials per therapeutic classification – ATC up to 5th level and Phases I, II and III**

Phase I, II and III CT: 3,329 of which 1,982 (59.5%)
with ATC 5th level of at least one test drug specified

The table does not include active ingredients that were not classifiable as
ATC 5th level when they were inserted in the OsSC.

L - Antineoplastic and immunomodulating agents

CT: 1,452 of which 988 (68.0%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
L01	Antineoplastic agents	740	8.8	62.7	28.5	100.0
L01XC07	Bevacizumab	85	3.5	62.4	34.1	100.0
L01XA01	Cisplatin	75	9.3	66.7	24.0	100.0
L01CD02	Docetaxel	67	11.9	70.1	17.9	100.0
L01DB01	Doxorubicin	62	9.7	71.0	19.4	100.0
L01XC02	Rituximab	58	10.3	67.2	22.4	100.0
L01BC05	Gemcitabin	49	10.2	63.3	26.5	100.0
L01AA01	Cyclophosphan	47	6.4	70.2	23.4	100.0
L01BC06	Capecitabine	45	6.7	77.8	15.6	100.0
L01CD01	Paclitaxel	43	16.3	51.2	32.6	100.0
L01XA03	Oxaliplatin	39	7.7	82.1	10.3	100.0
L01BC02	Fluorouracile	38	0.0	78.9	21.1	100.0
L01XC03	Trastuzumab	38	10.5	65.8	23.7	100.0
L01BA04	Pemetrexed	36	8.3	75.0	16.7	100.0
L01CA04	Vinorelbine	32	3.1	90.6	6.3	100.0
L01XX32	Bortezomib	32	6.3	78.1	15.6	100.0
L01XA02	Carboplatine	31	16.1	58.1	25.8	100.0
L01XC06	Cetuximab	31	3.2	67.7	29.0	100.0
L01XE05	Sorafenib	30	13.3	63.3	23.3	100.0
L01AX03	Temozolomide	28	3.6	78.6	17.9	100.0
L01XX19	Irinotecan	26	7.7	61.5	30.8	100.0
L01XE01	Imatinib	23	8.7	73.9	17.4	100.0
L01AA03	Melphalan	19	10.5	57.9	31.6	100.0
L01BC01	Cytarabine	18	0.0	94.4	5.6	100.0
L01CB01	Etoposide	18	5.6	61.1	33.3	100.0
L01XE03	Erlotinib	16	12.5	50.0	37.5	100.0
L01DB03	Epirubicin	15	13.3	73.3	13.3	100.0
L01XE04	Sunitinib	15	0.0	53.3	46.7	100.0
L01XE06	Dasatinib	15	40.0	46.7	13.3	100.0
L01XE07	Lapatinib	15	20.0	53.3	26.7	100.0
L01CA02	Vincristine	14	7.1	57.1	35.7	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
L01BB05 Fludarabine	12	25.0	41.7	33.3	100.0
L01AD05 Fotemustine	11	9.1	90.9	0.0	100.0
L01BA01 Metotrexato	11	0.0	54.5	45.5	100.0
L01XC08 Panitumumab	10	0.0	80.0	20.0	100.0
L01XE08 Nilotinib	10	10.0	50.0	40.0	100.0
L01CX01 Trabectedine	9	11.1	55.6	33.3	100.0
L01DC01 Bleomicine	9	0.0	66.7	33.3	100.0
L01DC03 Mitomicine	9	0.0	88.9	11.1	100.0
L01XE10 Everolimus	9	0.0	44.4	55.6	100.0
L01CA01 Vinblastine	8	0.0	62.5	37.5	100.0
L01AA06 Ifosfamide	7	14.3	85.7	0.0	100.0
L01AX04 Dacarbazina	7	0.0	28.6	71.4	100.0
L01XC04 Alemtuzumab	7	0.0	42.9	57.1	100.0
L01AA09 Bendamustina	6	16.7	66.7	16.7	100.0
L01BB06 Clofarabine	6	16.7	66.7	16.7	100.0
L01XX17 Topotecan	6	16.7	83.3	0.0	100.0
L01AB01 Busulfano	5	40.0	20.0	40.0	100.0
L01BC53 Tegafur. combinations	5	0.0	100.0	0.0	100.0
L01XE09 Temsirolimus	5	0.0	100.0	0.0	100.0
L01AB02 Treosulfan	4	25.0	50.0	25.0	100.0
L01AC01 Thiotepa	4	25.0	50.0	25.0	100.0
L01DC04 Ixabepilone	4	25.0	50.0	25.0	100.0
L01AA02 Chlorambucil	3	0.0	100.0	0.0	100.0
L01AD01 Carmustine	3	0.0	66.7	33.3	100.0
L01BB04 Cladribine	3	0.0	33.3	66.7	100.0
L01BC07 Azacitidine	3	0.0	33.3	66.7	100.0
L01DB02 Daunorubicin	3	0.0	66.7	33.3	100.0
L01XE11 Pazopanib	3	0.0	33.3	66.7	100.0
L01XX14 Tretinoin	3	0.0	33.3	66.7	100.0
L01BB02 Mercaptopurine	2	0.0	100.0	0.0	100.0
L01DB06 Idarubicin	2	0.0	50.0	50.0	100.0
L01DB07 Mitoxantrone	2	0.0	50.0	50.0	100.0
L01XB01 Procarbazine	2	0.0	50.0	50.0	100.0
L01XC05 Gemtuzumab	2	0.0	50.0	50.0	100.0
L01XC10 Ofatumumab	2	0.0	100.0	0.0	100.0
L01XE02 Gefitinib	2	0.0	50.0	50.0	100.0
L01XE90 Masitinib	2	0.0	0.0	100.0	100.0
L01XX05 Hydroxycarbamide	2	0.0	50.0	50.0	100.0
L01XX24 Pegaspargase	2	0.0	50.0	50.0	100.0
L01XX27 Arsenic trioxide	2	0.0	0.0	100.0	100.0
L01XX38 Vorinostat	2	0.0	50.0	50.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
L01XX38	Vorinostat	2	0.0	50.0	50.0	100.0
L01BA05	Pralatrexate	1	100.0	0.0	0.0	100.0
L01BB03	Tioguanine	1	0.0	100.0	0.0	100.0
L01BC08	Decitabine	1	0.0	100.0	0.0	100.0
L01BC52	Fluorouracil combinations	1	0.0	100.0	0.0	100.0
L01CA03	Vindesine	1	0.0	100.0	0.0	100.0
L01CA05	Vinflunine	1	0.0	100.0	0.0	100.0
L01DA01	Dactinomycin	1	0.0	0.0	100.0	100.0
L01XC09	Catumaxomab	1	0.0	100.0	0.0	100.0
L01XD02	Verteporfin	1	0.0	100.0	0.0	100.0
L01XD04	Aminolevulinic acid	1	0.0	0.0	100.0	100.0
L01XD05	Temoporfin	1	0.0	100.0	0.0	100.0
L01XX02	Asparaginase	1	0.0	100.0	0.0	100.0
L01XX08	Pentostatin	1	0.0	100.0	0.0	100.0
L01XX11	Estramustine	1	0.0	100.0	0.0	100.0
L01XX23	Mitotane	1	0.0	0.0	100.0	100.0
L01XX25	Bexarotene	1	100.0	0.0	0.0	100.0
L01XX28	Imatinib	1	0.0	100.0	0.0	100.0
L01XX33	Celecoxib	1	0.0	0.0	100.0	100.0
L01XX34	Erlotinib	1	0.0	100.0	0.0	100.0
L01XX36	Oblimersen	1	0.0	0.0	100.0	100.0
L01XX39	Romidepsin	1	0.0	100.0	0.0	100.0
L04	Immunosuppressants	178	3.9	43.8	52.2	100.0
L04AX04	Lenalidomide	32	12.5	56.3	31.3	100.0
L04AA18	Everolimus	29	6.9	58.6	34.5	100.0
L04AA06	Mycophenolic Acid	13	0.0	46.2	53.8	100.0
L04AA04	Antithymocyte Immune Globulin	11	9.1	36.4	54.5	100.0
L04AB02	Infliximab	11	0.0	27.3	72.7	100.0
L04AB04	Adalimumab	11	0.0	9.1	90.9	100.0
L04AA10	Sirolimus	10	0.0	80.0	20.0	100.0
L04AC07	Tocilizumab	10	0.0	10.0	90.0	100.0
L04AD02	Tacrolimus	9	0.0	33.3	66.7	100.0
L04AB05	Certolizumab pegol	7	0.0	0.0	100.0	100.0
L04AX02	Thalidomide	7	0.0	85.7	14.3	100.0
L04AA01	Ciclosporin	6	0.0	50.0	50.0	100.0
L04AA24	Abatacept	6	0.0	33.3	66.7	100.0
L04AA25	Eculizumab	6	0.0	100.0	0.0	100.0
L04AB01	Etanercept	5	0.0	40.0	60.0	100.0
L04AC02	Basiliximab	5	0.0	40.0	60.0	100.0
L04AD01	Ciclosporin	4	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
L04AX01 Azathioprine	3	0.0	0.0	100.0	100.0
L04AA17 Adalimumab	2	0.0	0.0	100.0	100.0
L04AB06 Golimumab	2	0.0	0.0	100.0	100.0
L04AC03 Anakinra	2	0.0	50.0	50.0	100.0
L04AA08 Daclizumab	1	0.0	0.0	100.0	100.0
L04AA13 Leflunomide	1	0.0	0.0	100.0	100.0
L04AA15 Alefacept	1	0.0	100.0	0.0	100.0
L04AA22 Abetimus	1	0.0	0.0	100.0	100.0
L04AA23 Natalizumab	1	0.0	0.0	100.0	100.0
L04AC08 Canakinumab	1	0.0	100.0	0.0	100.0
L04AX03 Methotrexate	1	0.0	100.0	0.0	100.0
L03 Immunostimulants	96	5.2	56.3	38.5	100.0
L03AB11 Peginterferon alfa-2a	18	5.6	44.4	50.0	100.0
L03AB10 Peginterferon alfa-2b	13	15.4	23.1	61.5	100.0
L03AA02 Filgrastim	11	0.0	81.8	18.2	100.0
L03AA10 Lenograstim	10	0.0	80.0	20.0	100.0
L03AA13 Pegfilgrastim	10	0.0	80.0	20.0	100.0
L03AC01 Aldesleukin	10	0.0	60.0	40.0	100.0
L03AB07 Interferon beta-1a	7	0.0	14.3	85.7	100.0
L03AA09 Sargramostim	6	16.7	66.7	16.7	100.0
L03AB04 Interferone alfa-2a	6	16.7	83.3	0.0	100.0
L03AB05 Interferone alfa-2b	3	33.3	66.7	0.0	100.0
L03AX13 Glatiramer Acetate	3	0.0	33.3	66.7	100.0
L03AB01 Interferon Alfa Natural	2	0.0	50.0	50.0	100.0
L03AB08 Interferon beta-1b	2	0.0	50.0	50.0	100.0
L03AB03 Interferon gamma	1	0.0	0.0	100.0	100.0
L03AX16 Plerixafor	1	100.0	0.0	0.0	100.0
L03AX49 Other Cytokine and Immunomodulating agents	1	0.0	100.0	0.0	100.0
L02 Endocrine therapy	30	0.0	53.3	46.7	100.0
L02BG04 Letrozolo	11	0.0	63.6	36.4	100.0
L02AE04 Triptorelin	7	0.0	57.1	42.9	100.0
L02BA03 Fulvestrant	6	0.0	83.3	16.7	100.0
L02AE02 Leuprorelin	5	0.0	40.0	60.0	100.0
L02BG06 Exemestan	3	0.0	66.7	33.3	100.0
L02BA01 Tamoxifene	2	0.0	0.0	100.0	100.0
L02BB03 Bicalutamide	2	0.0	0.0	100.0	100.0
L02AE03 Goserelin	1	0.0	0.0	100.0	100.0
L02BG03 Anastrozole	1	0.0	0.0	100.0	100.0
L02BX02 Degarelix	1	0.0	100.0	0.0	100.0

**N – Nervous system**CT: 341 of which 157 (46.0%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
N06	Psychoanaleptics	37	0.0	45.9	54.1	100.0
N06BX12	Acetylcarnitine	7	0.0	71.4	28.6	100.0
N06DA02	Donepezil	6	0.0	66.7	33.3	100.0
N06DX01	Memantine	6	0.0	66.7	33.3	100.0
N06AB05	Paroxetine	4	0.0	50.0	50.0	100.0
N06AX22	Agomelatine	3	0.0	33.3	66.7	100.0
N06BA09	Tomoxetine	3	0.0	0.0	100.0	100.0
N06DA03	Rivastigmine	3	0.0	33.3	66.7	100.0
N06AX17	Milnacipran	2	0.0	0.0	100.0	100.0
N06AX21	Duloxetine	2	0.0	50.0	50.0	100.0
N06AB10	Escitalopram	1	0.0	0.0	100.0	100.0
N06AX05	Trazodone	1	0.0	0.0	100.0	100.0
N06DA04	Galantamine	1	0.0	0.0	100.0	100.0
N02	Analgesics	32	3.1	31.3	65.6	100.0
N02AB03	Fentanyl	7	0.0	0.0	100.0	100.0
N02AX02	Tramadol	5	20.0	40.0	40.0	100.0
N02AE01	Buprenorfine	4	0.0	25.0	75.0	100.0
N02AA05	Oxycodone	3	0.0	33.3	66.7	100.0
N02BA11	Diflunisal	2	0.0	100.0	0.0	100.0
N02BE01	Paracetamol	2	0.0	50.0	50.0	100.0
N02CC04	Rizatriptan	2	0.0	0.0	100.0	100.0
N02AA01	Morphine	1	0.0	0.0	100.0	100.0
N02AA55	Oxycodone combinations	1	0.0	0.0	100.0	100.0
N02AX52	Tramadol combinations	1	0.0	100.0	0.0	100.0
N02BG08	Ziconotide	1	0.0	100.0	0.0	100.0
N02BG10	Nabiximols	1	0.0	100.0	0.0	100.0
N02CA07	Lisuride	1	0.0	0.0	100.0	100.0
N02CC01	Sumatriptan	1	0.0	100.0	0.0	100.0
N02CC07	Frovatriptan	1	0.0	0.0	100.0	100.0
N01	Anesthetics	26	0.0	11.5	88.5	100.0
N01BB09	Ropivacaine	10	0.0	0.0	100.0	100.0
N01AX03	Ketamine	6	0.0	0.0	100.0	100.0
N01AH06	Remifentanyl	4	0.0	0.0	100.0	100.0
N01AX10	Propofol	3	0.0	0.0	100.0	100.0
N01AH03	Sufentanyl	2	0.0	0.0	100.0	100.0
N01BB02	Lidocaine	2	0.0	50.0	50.0	100.0
N01BB10	Levobupivacaine	2	0.0	50.0	50.0	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
N01AH01 Fentanil	1	0.0	0.0	100.0	100.0
N01AX15 Xenon	1	0.0	100.0	0.0	100.0
N01BA04 Cloroprocaine	1	0.0	0.0	100.0	100.0
N03 Antiepileptics	26	0.0	30.8	69.2	100.0
N03AG01 Valproic Acid	5	0.0	40.0	60.0	100.0
N03AX14 Levetiracetam	5	0.0	40.0	60.0	100.0
N03AX16 Pregabalin	5	0.0	0.0	100.0	100.0
N03AX15 Zonisamide	4	0.0	25.0	75.0	100.0
N03AX18 Lacosamide	3	0.0	0.0	100.0	100.0
N03AF04 Eslicarbazepine	2	0.0	50.0	50.0	100.0
N03AF02 Oxcarbazepine	1	0.0	100.0	0.0	100.0
N03AX11 Topiramate	1	0.0	100.0	0.0	100.0
N05 Psycholeptics	16	0.0	43.8	56.3	100.0
N05AN01 Lithium	4	0.0	75.0	25.0	100.0
N05AD01 Haloperidol	2	0.0	50.0	50.0	100.0
N05AE04 Ziprasidone	2	0.0	0.0	100.0	100.0
N05AH04 Quetiapin	2	0.0	0.0	100.0	100.0
N05AX13 Paliperidone	2	0.0	0.0	100.0	100.0
N05AD03 Melperone	1	0.0	100.0	0.0	100.0
N05AH03 Olanzapine	1	0.0	0.0	100.0	100.0
N05AX08 Risperidone	1	0.0	100.0	0.0	100.0
N05AX12 Aripiprazolo	1	0.0	0.0	100.0	100.0
N05CD08 Midazolam	1	0.0	100.0	0.0	100.0
N04 Anti-Parkinson drugs	15	0.0	33.3	66.7	100.0
N04BC05 Pramipexol	5	0.0	20.0	80.0	100.0
N04BA02 Levodopa and Decarboxylase Inhibitor	3	0.0	33.3	66.7	100.0
N04BC04 Ropinirole	2	0.0	50.0	50.0	100.0
N04BC09 Rotigotine	2	0.0	0.0	100.0	100.0
N04BD02 Rasagiline	2	0.0	50.0	50.0	100.0
N04BA03 Levodopa, Decarboxylase Inhibitor and COMT Inhibitor	1	0.0	0.0	100.0	100.0
N04BA05 Melevodopa and Decarboxylase Inhibitor	1	0.0	0.0	100.0	100.0
N04BC07 Apomorphine	1	0.0	100.0	0.0	100.0
N04BX02 Entacapone	1	0.0	0.0	100.0	100.0
N07 Other nervous system drugs	12	0.0	58.3	41.7	100.0
N07XX02 Riluzole	3	0.0	100.0	0.0	100.0
N07AX02 Choline Alfoscerate	2	0.0	100.0	0.0	100.0
N07XX04 Hydroxybutyric Acid	2	0.0	0.0	100.0	100.0
N07BA03 Varenicline	1	0.0	0.0	100.0	100.0
N07BB04 Naltrexone	1	0.0	100.0	0.0	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
N07BB49 Drugs used in alcohol addiction – various	1	0.0	100.0	0.0	100.0
N07XX03 Xaliproden	1	0.0	0.0	100.0	100.0
N07XX99 Other drugs of the nervous system – various combinations	1	0.0	0.0	100.0	100.0

J – General anti-infectives for systemic useCT: 292 of which 200 (68.5%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
J05 Antivirals for systemic use	106	5.7	35.8	58.5	100.0
J05AB04 Ribavirin	31	6.5	45.2	48.4	100.0
J05AE03 Ritonavir	24	0.0	29.2	70.8	100.0
J05AE10 Darunavir	11	0.0	36.4	63.6	100.0
J05AE06 Lopinavir	8	0.0	25.0	75.0	100.0
J05AE08 Atazanavir	7	0.0	42.9	57.1	100.0
J05AE09 Tipranavir	6	0.0	16.7	83.3	100.0
J05AG01 Nevirapine	6	16.7	33.3	50.0	100.0
J05AX08 Raltegravir	6	0.0	50.0	50.0	100.0
J05AX09 Maraviroc	6	16.7	33.3	50.0	100.0
J05AF07 Tenofovir disoproxil	5	0.0	20.0	80.0	100.0
J05AF30 Nucleoside and nucleotide reverse transcriptase inhibitors	5	0.0	40.0	60.0	100.0
J05AR03 Tenofovir Disoproxil and Emtricitabine	5	0.0	20.0	80.0	100.0
J05AF10 Entecavir	4	0.0	25.0	75.0	100.0
J05AG03 Efavirenz	4	25.0	25.0	50.0	100.0
J05AH02 Oseltamivir	4	25.0	25.0	50.0	100.0
J05AE07 Fosamprenavir	3	0.0	33.3	66.7	100.0
J05AF08 Adefovir dipivoxil	3	0.0	0.0	100.0	100.0
J05AR02 Lamivudine and Abacavir	3	0.0	0.0	100.0	100.0
J05AF05 Lamivudine	2	0.0	0.0	100.0	100.0
J05AR01 Zidovudine and Lamivudine	2	0.0	0.0	100.0	100.0
J05AR06 Emtricitabine. Tenofovir Disoproxil and Efavirenz	2	0.0	0.0	100.0	100.0
J05AB06 Ganciclovir	1	0.0	0.0	100.0	100.0
J05AB14 Valganciclovir	1	0.0	0.0	100.0	100.0
J05AE01 Saquinavir	1	0.0	100.0	0.0	100.0
J05AE02 Indinavir	1	0.0	100.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
J05AE49	Proteasitis inhibitors - various	1	0.0	0.0	100.0	100.0
J05AF09	Emtricitabine	1	0.0	100.0	0.0	100.0
J05AG04	Etravirina	1	0.0	0.0	100.0	100.0
J05AX49	Other anitvirals - various	1	0.0	100.0	0.0	100.0
J01	Antibacterials for systemic use	36	8.3	44.4	47.2	100.0
J01MA17	Prulifloxacin	6	50.0	16.7	33.3	100.0
J01AA02	Doxycycline	4	0.0	100.0	0.0	100.0
J01MA14	Moxifloxacin	4	0.0	25.0	75.0	100.0
J01XX08	Linezolid	3	0.0	66.7	33.3	100.0
J01XX09	Daptomycin	3	0.0	33.3	66.7	100.0
J01CR02	Amoxicillin and Enzyme Inhibitor	2	0.0	50.0	50.0	100.0
J01AA07	Tetracycline	1	0.0	100.0	0.0	100.0
J01AA08	Minocycline	1	0.0	100.0	0.0	100.0
J01CA04	Amoxicillin	1	0.0	100.0	0.0	100.0
J01DA11	Ceftazidime	1	0.0	100.0	0.0	100.0
J01DB04	Cefazolin	1	0.0	0.0	100.0	100.0
J01DC04	Cefaclor	1	0.0	0.0	100.0	100.0
J01DD04	Ceftriaxone	1	0.0	100.0	0.0	100.0
J01DD13	Cefpodoxime	1	0.0	0.0	100.0	100.0
J01DD14	Ceftibuten	1	0.0	0.0	100.0	100.0
J01DE01	Cefepime	1	0.0	100.0	0.0	100.0
J01DF01	Aztreonam	1	0.0	0.0	100.0	100.0
J01DH02	Meropenem	1	0.0	100.0	0.0	100.0
J01DH03	Ertapenem	1	0.0	0.0	100.0	100.0
J01FA09	Clarithromycin	1	0.0	100.0	0.0	100.0
J01FA10	Azithromycin	1	0.0	0.0	100.0	100.0
J01GB01	Tobramycin	1	0.0	0.0	100.0	100.0
J01GB03	Gentamicin	1	0.0	100.0	0.0	100.0
J01GB06	Amikacin	1	0.0	100.0	0.0	100.0
J01MA12	Levofloxacin	1	0.0	0.0	100.0	100.0
J07	Vaccines	30	3.3	56.7	40.0	100.0
J07BB02	Influenza, Purified Antigen	14	0.0	85.7	14.3	100.0
J07AH06	Meningococcus B, Outer Membrane Vesicle Vaccine	4	0.0	75.0	25.0	100.0
J07BD54	Measles with Mumps, Rubella and Varicella, live attenuated	4	0.0	0.0	100.0	100.0
J07BC01	Hepatitis B. Purified Antigen	2	50.0	0.0	50.0	100.0
J07AH07	Meningococcus C, Purified Polysaccharides Antigen Conjugated	1	0.0	100.0	0.0	100.0
J07AJ52	Pertussis, Purified Antigen, combinations with Toxoids	1	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
J07AL01	Pneumococcus, Purified Polysaccharides Antigen	1	0.0	0.0	100.0	100.0
J07AL02	Pneumococcus, Purified Polysaccharides Antigen Conjugated	1	0.0	0.0	100.0	100.0
J07AP01	Typhoid, Oral, live attenuated	1	0.0	100.0	0.0	100.0
J07BK02	Zoster, live attenuated	1	0.0	0.0	100.0	100.0
J07CA02	Diphtheria-Pertussis-Poliomyelitis-Tetanus	1	0.0	0.0	100.0	100.0
J07CA99	Bacterial and viral vaccines, combinations	1	0.0	0.0	100.0	100.0
J02	Antimycotics for systemic use	18	11.1	50.0	38.9	100.0
J02AA01	Amphotericin B	8	0.0	87.5	12.5	100.0
J02AC03	Voriconazole	4	0.0	0.0	100.0	100.0
J02AX06	Anidulafungin	4	0.0	0.0	100.0	100.0
J02AC01	Fluconazole	3	0.0	0.0	100.0	100.0
J02AC04	Posaconazole	2	100.0	0.0	0.0	100.0
J02AX05	Micafungin	2	0.0	50.0	50.0	100.0
J02AX04	Caspofungin	1	0.0	100.0	0.0	100.0
J06	Immune sera and immunoglobulins	10	0.0	40.0	60.0	100.0
J06BA02	Immunoglobulins, normal human, for intravascular administration	4	0.0	25.0	75.0	100.0
J06BA01	Immunoglobulins, normal human, for extravascular administration	3	0.0	66.7	33.3	100.0
J06BB04	Hepatitis B immunoglobulin	2	0.0	0.0	100.0	100.0
J06BB09	Cytomegalovirus immunoglobulin	1	0.0	100.0	0.0	100.0
J04	Antimycobacterials	3	0.0	66.7	33.3	100.0
J04AB02	Rifampicin	2	0.0	50.0	50.0	100.0
J04AK01	Pyrazinamide	1	0.0	100.0	0.0	100.0
J04AK02	Etambutol	1	0.0	100.0	0.0	100.0

A – Alimentary tract and metabolismCT: 270 of which 142 (52.6%) with ATC 5th level of at least on test drug specified

Therapeutic Classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
A10	Drugs used in diabetes	56	1.8	23.2	75.0	100.0
A10BA02	Metformin	21	0.0	28.6	71.4	100.0
A10BH01	Sitagliptin	6	0.0	33.3	66.7	100.0
A10BG03	Pioglitazone	5	0.0	20.0	80.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
A10AB01	Insulin (human) quick acting	4	0.0	25.0	75.0	100.0
A10BG02	Rosiglitazone	4	0.0	25.0	75.0	100.0
A10BX04	Exenatide	4	0.0	25.0	75.0	100.0
A10AE04	Insulin glargine	2	0.0	50.0	50.0	100.0
A10BH03	Saxagliptin	2	0.0	0.0	100.0	100.0
A10BX07	Liraglutide	2	0.0	0.0	100.0	100.0
A10AB06	Insulin glulisine	1	100.0	0.0	0.0	100.0
A10AC01	Insulin (human) medium acting	1	0.0	0.0	100.0	100.0
A10AC04	Insulin lispro	1	0.0	0.0	100.0	100.0
A10AD05	Insulin aspart	1	0.0	0.0	100.0	100.0
A10AF01	Insulin (human)	1	0.0	100.0	0.0	100.0
A10BB01	Glibenclamide	1	0.0	0.0	100.0	100.0
A10BD07	Metformin e sitagliptin	1	0.0	0.0	100.0	100.0
A10BH02	Vildagliptin	1	0.0	0.0	100.0	100.0
A07	Antidiarrheals, intestinal antiinflammatory/antiinfective agents	27	3.7	29.6	66.7	100.0
A07EC02	Mesalazine	8	0.0	12.5	87.5	100.0
A07EA06	Budesonide	5	0.0	20.0	80.0	100.0
A07AA11	Rifaximin	3	33.3	66.7	0.0	100.0
A07FA01	Lactic acid producing organisms	3	0.0	33.3	66.7	100.0
A07AA09	Vancomycin	2	0.0	100.0	0.0	100.0
A07EA03	Prednisone	2	0.0	50.0	50.0	100.0
A07AA02	Nystatin	1	0.0	0.0	100.0	100.0
A07BA01	Medicinal charcoal	1	0.0	0.0	100.0	100.0
A07EA07	Beclometasone	1	0.0	0.0	100.0	100.0
A07EB01	Cromoglicic acid	1	0.0	0.0	100.0	100.0
A02	Drugs for acid related disorders	15	0.0	40.0	60.0	100.0
A02BC02	Pantoprazole	4	0.0	0.0	100.0	100.0
A02BC05	Esomeprazole	3	0.0	100.0	0.0	100.0
A02BC04	Rabeprazole	2	0.0	0.0	100.0	100.0
A02AA04	Magnesium hydroxide	1	0.0	0.0	100.0	100.0
A02BA04	Nizatidine	1	0.0	100.0	0.0	100.0
A02BB01	Misoprostole	1	0.0	0.0	100.0	100.0
A02BC01	Omeprazole	1	0.0	0.0	100.0	100.0
A02BX05	Bismuth subcitrate	1	0.0	100.0	0.0	100.0
A02BX13	Alginic acid	1	0.0	100.0	0.0	100.0
A11	Vitamins	10	0.0	40.0	60.0	100.0
A11CC05	Colecalciferol	5	0.0	20.0	80.0	100.0
A11CC07	Paracalcitol	2	0.0	100.0	0.0	100.0
A11GA01	Ascorbic acid (vitamin C)	1	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
A11HA03	Tocopherol (vitamin E)	1	0.0	0.0	100.0	100.0
A11HA04	Riboflavin (vitamin B2)	1	0.0	100.0	0.0	100.0
A04	Antiemetics and antinauseants	9	0.0	33.3	66.7	100.0
A04AD12	Aprepitant	5	0.0	0.0	100.0	100.0
A04AA01	Ondansetron	2	0.0	0.0	100.0	100.0
A04AA03	Tropisetron	2	0.0	100.0	0.0	100.0
A04AD11	Nabilone	1	0.0	100.0	0.0	100.0
A16	Other alimentary tract and metabolism products	7	0.0	42.8	57.2	100.0
A16AA01	Levocarnitine	3	0.0	33.3	66.7	100.0
A16AX07	Sapropterin	2	0.0	50.0	50.0	100.0
A16AX01	Tiotoxic acid	1	0.0	100.0	0.0	100.0
A16AX06	Miglustat	1	0.0	0.0	100.0	100.0
A09	Digestives, including enzymes	6	0.0	33.3	66.7	100.0
A09AA02	Multienzymes (lipase, protease, etc.)	6	0.0	33.3	66.7	100.0
A05	Bile and liver therapy	4	0.0	50.0	50.0	100.0
A05AA02	Ursodeoxycholic acid	4	0.0	50.0	50.0	100.0
A01	Stomatological preparations	3	0.0	66.7	33.3	100.0
A01AB22	Doxycycline	1	0.0	100.0	0.0	100.0
A01AB23	Minocycline	1	0.0	0.0	100.0	100.0
A01AC02	Dexamethasone	1	0.0	100.0	0.0	100.0
A06	Laxatives	3	0.0	0.0	100.0	100.0
A06AD65	Macrogol, combinations	3	0.0	0.0	100.0	100.0
A12	Mineral supplements	3	0.0	100.0	0.0	100.0
A12CC08	Magnesium pidolate	2	0.0	100.0	0.0	100.0
A12CA01	Sodium chloride	1	0.0	100.0	0.0	100.0
A03	Drugs for functional gastrointestinal disorders	1	0.0	0.0	100.0	100.0
A03FA01	Metoclopramide	1	0.0	0.0	100.0	100.0
A08	Antiobesity preparations, excluding diet products	1	0.0	0.0	100.0	100.0
A08AX01	Rimonabant	1	0.0	0.0	100.0	100.0

**B – Blood and blood forming organs**CT: 228 of which 130 (57.0%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
B01	Antithrombotic agents	54	1.9	24.1	74.1	100.0
B01AC04	Clopidogrel	9	0.0	11.1	88.9	100.0
B01AB05	Enoxaparin	4	0.0	0.0	100.0	100.0
B01AC11	Iloprost	4	0.0	50.0	50.0	100.0
B01AC21	Treprostinil	4	0.0	0.0	100.0	100.0
B01AE07	Dabigatran etexilate	4	0.0	25.0	75.0	100.0
B01AX05	Fondaparinux	4	0.0	0.0	100.0	100.0
B01AX06	Rivaroxaban	4	25.0	50.0	25.0	100.0
B01AB04	Dalteparin	3	0.0	0.0	100.0	100.0
B01AB02	Antithrombin III	2	0.0	100.0	0.0	100.0
B01AB06	Nadroparin	2	0.0	50.0	50.0	100.0
B01AC06	Acetylsalicylic acid	2	0.0	0.0	100.0	100.0
B01AC16	Eptifibatide	2	0.0	50.0	50.0	100.0
B01AC17	Tirofiban	2	0.0	100.0	0.0	100.0
B01AD02	Alteplase	2	0.0	0.0	100.0	100.0
B01AD10	Drotrecogin alfa	2	0.0	50.0	50.0	100.0
B01AD11	Tenecteplase	2	0.0	0.0	100.0	100.0
B01AA03	Warfarin	1	0.0	0.0	100.0	100.0
B01AB01	Heparin	1	0.0	0.0	100.0	100.0
B01AB10	Tinzaparin	1	0.0	0.0	100.0	100.0
B01AB11	Sulodexide	1	0.0	0.0	100.0	100.0
B01AC13	Abciximab	1	0.0	0.0	100.0	100.0
B01AC22	Prasugrel	1	0.0	100.0	0.0	100.0
B01AD04	Urokinase	1	0.0	100.0	0.0	100.0
B01AE06	Bivalirudin	1	0.0	0.0	100.0	100.0
B02	Antihemorrhagics	41	17.1	31.7	51.2	100.0
B02BD02	Coagulation factor VIII	12	25.0	8.3	66.7	100.0
B02BC30	Combinations	9	0.0	22.2	77.8	100.0
B02BD04	Coagulation factor IX	3	33.3	33.3	33.3	100.0
B02BD07	Coagulation factor XIII	3	0.0	33.3	66.7	100.0
B02BX04	Romiplostim	3	0.0	100.0	0.0	100.0
B02AB03	C1-inhibitor	2	0.0	100.0	0.0	100.0
B02BD08	Eptacog alfa (activated)	2	50.0	50.0	0.0	100.0
B02BX05	Eltrombopag	2	50.0	50.0	0.0	100.0
B02BB01	Human fibrinogen	1	0.0	0.0	100.0	100.0
B02BD01	Coagulation factor IX, II, VII and X in combination	1	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
B02BD03	Factor VIII inhibitor bypassing activity	1	0.0	0.0	100.0	100.0
B02BD05	Coagulation factor VII	1	0.0	100.0	0.0	100.0
B02BD06	Von Willebrand factor and coagulation factor VIII in combination	1	100.0	0.0	0.0	100.0
B02BD09	Nonacog alfa	1	100.0	0.0	0.0	100.0
B03	Antianemic preparations	24	0.0	16.7	83.3	100.0
B03XA01	Erythropoietin	11	0.0	18.2	81.8	100.0
B03XA03	Methoxy polyethylene glycol-epoetin beta	6	0.0	16.7	83.3	100.0
B03XA02	Darbepoetin alfa	5	0.0	0.0	100.0	100.0
B03AA07	Ferrous sulfate	2	0.0	50.0	50.0	100.0
B03BB01	Folic acid	1	0.0	0.0	100.0	100.0
B05	Blood substitutes and perfusion solutions	12	0.0	41.7	58.3	100.0
B05BA02	Fat emulsions	4	0.0	50.0	50.0	100.0
B05AA01	Serum albumin	3	0.0	66.7	33.3	100.0
B05BA01	Amino acids	2	0.0	50.0	50.0	100.0
B05AA07	Hydroxyethylstarch	1	0.0	0.0	100.0	100.0
B05BA03	Carbohydrates	1	0.0	0.0	100.0	100.0
B05BC01	Mannitol	1	0.0	0.0	100.0	100.0
B05CB01	Sodium chloride	1	0.0	0.0	100.0	100.0
B05XA03	Sodio cloruro	1	0.0	0.0	100.0	100.0
B05XA05	Magnesium Sulfate	1	0.0	0.0	100.0	100.0

C – Cardiovascular systemCT: 198 of which 125 (63.1%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
C09	Agents acting on the renin-angiotensin system	44	0.0	15.9	84.1	100.0
C09XA02	Aliskiren	11	0.0	18.2	81.8	100.0
C09CA03	Valsartan	8	0.0	0.0	100.0	100.0
C09BA15	Zofenopril and diuretics	4	0.0	0.0	100.0	100.0
C09CA01	Losartan	4	0.0	25.0	75.0	100.0
C09AA15	Zofenopril	3	0.0	0.0	100.0	100.0
C09AA04	Perindopril	2	0.0	100.0	0.0	100.0
C09AA05	Ramipril	2	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
C09AA07 Benazepril	2	0.0	0.0	100.0	100.0
C09CA04 Irbesartan	2	0.0	50.0	50.0	100.0
C09CA06 Candesartan	2	0.0	0.0	100.0	100.0
C09AA02 Enalapril	1	0.0	0.0	100.0	100.0
C09BA12 Delapril and diuretics	1	0.0	0.0	100.0	100.0
C09BB02 Enalapril and lercanidipine	1	0.0	0.0	100.0	100.0
C09BB04 Perindopril and amlodipine	1	0.0	0.0	100.0	100.0
C09CA07 Telmisartan	1	0.0	100.0	0.0	100.0
C09CA08 Olmesartan medoxomil	1	0.0	0.0	100.0	100.0
C09DA01 Losartan and diuretics	1	0.0	0.0	100.0	100.0
C09DB01 Valsartan and amlodipine	1	0.0	0.0	100.0	100.0
C09DB02 Olmesartan medoxomil and amlodipine	1	0.0	0.0	100.0	100.0
C09DB04 Telmisartan and amlodipine	1	0.0	0.0	100.0	100.0
C10 Lipid modifying agents	35	0.0	28.6	71.4	100.0
C10AA05 Atorvastatin	10	0.0	40.0	60.0	100.0
C10AA07 Rosuvastatin	7	0.0	28.6	71.4	100.0
C10AA01 Simvastatin	4	0.0	25.0	75.0	100.0
C10AB05 Fenofibrate	3	0.0	66.7	33.3	100.0
C10AD02 Nicotinic acid	3	0.0	66.7	33.3	100.0
C10AX06 Omega-3-triglycerides	3	0.0	0.0	100.0	100.0
C10BA02 Simvastatin and ezetimibe	3	0.0	0.0	100.0	100.0
C10AA04 Fluvastatin	2	0.0	50.0	50.0	100.0
C10AX09 Ezetimibe	2	0.0	0.0	100.0	100.0
C10AA03 Pravastatin	1	0.0	0.0	100.0	100.0
C10AD06 Acipimox	1	0.0	0.0	100.0	100.0
C01 Cardiac therapy	23	0.0	30.4	69.6	100.0
C01CA19 Fenoldopam	6	0.0	50.0	50.0	100.0
C01EB17 Ivabradine	4	0.0	0.0	100.0	100.0
C01EB10 Adenosine	2	0.0	0.0	100.0	100.0
C01EB19 Icatibant	2	0.0	50.0	50.0	100.0
C01AA05 Digoxin	1	0.0	100.0	0.0	100.0
C01BC04 Flecainide	1	0.0	0.0	100.0	100.0
C01CA03 Norepinephrine	1	0.0	100.0	0.0	100.0
C01CA17 Midodrine	1	0.0	0.0	100.0	100.0
C01CX08 Levosimendan	1	0.0	0.0	100.0	100.0
C01DX19 Nesiritide	1	0.0	0.0	100.0	100.0
C01EB13 Acadesine	1	0.0	0.0	100.0	100.0
C01EB15 Trimetazidine	1	0.0	0.0	100.0	100.0
C01EB18 Ranolazine	1	0.0	100.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
C02	Antihypertensives	11	0.0	18.2	81.8	100.0
C02KX02	Ambrisentan	4	0.0	25.0	75.0	100.0
C02AC01	Clonidine	3	0.0	33.3	66.7	100.0
C02KX01	Bosentan	3	0.0	0.0	100.0	100.0
C02DD01	Nitroprussiate	1	0.0	0.0	100.0	100.0
C03	Diuretics	11	0.0	18.2	81.8	100.0
C03AA03	Hydrochlorothiazide	5	0.0	0.0	100.0	100.0
C03XA01	Tolvaptan	2	0.0	0.0	100.0	100.0
C03BA11	Indapamide	1	0.0	0.0	100.0	100.0
C03CA01	Furosemide	1	0.0	100.0	0.0	100.0
C03DA01	Spironolactone	1	0.0	100.0	0.0	100.0
C03DA04	Eplerenone	1	0.0	0.0	100.0	100.0
C07	Beta blocking agents	9	0.0	55.6	44.4	100.0
C07AA05	Propranolol	5	0.0	60.0	40.0	100.0
C07AB07	Bisoprolol	2	0.0	100.0	0.0	100.0
C07AB12	Nebivolol	2	0.0	50.0	50.0	100.0
C07AB02	Metoprolol	1	0.0	0.0	100.0	100.0
C07AG02	Carvedilol	1	0.0	100.0	0.0	100.0
C08	Calcium channel blockers	8	0.0	12.5	87.5	100.0
C08CA01	Amlodipine	5	0.0	0.0	100.0	100.0
C08CA05	Nifedipine	2	0.0	50.0	50.0	100.0
C08CA08	Nitrendipine	1	0.0	0.0	100.0	100.0
C04	Peripheral vasodilators	1	0.0	100.0	0.0	100.0
C04AX33	Cilostazol	1	0.0	100.0	0.0	100.0

V – VariousCT: 200 of which 80 (40.0%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
V03	All other therapeutic products	43	0.0	65.1	34.9	100.0
V03AF04	Calcium levofolinate	16	0.0	87.5	12.5	100.0
V03AC03	Deferasirox	9	0.0	66.7	33.3	100.0
V03AC02	Deferiprone	5	0.0	80.0	20.0	100.0
V03AF03	Calcium folinate	5	0.0	60.0	40.0	100.0
V03AB23	Acetylcysteine	2	0.0	0.0	100.0	100.0
V03AB32	Glutathione	2	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			
		Phase I	Phase II	Phase III	Total
V03AF01 Mesna	2	0.0	100.0	0.0	100.0
V03AF08 Palifermin	2	0.0	0.0	100.0	100.0
V03AB17 Methylthioninium chloride	1	0.0	0.0	100.0	100.0
V03AC01 Deferoxamine	1	0.0	100.0	0.0	100.0
V03AE02 Sevelamer	1	0.0	0.0	100.0	100.0
V08 Contrast media	17	0.0	52.9	47.1	100.0
V08DA05 Sulfur Hexafluoride	5	0.0	60.0	40.0	100.0
V08CA11 Gadofosveset	3	0.0	66.7	33.3	100.0
V08AB09 Iodixanol	2	0.0	50.0	50.0	100.0
V08CA08 Gadobenidic acid	2	0.0	0.0	100.0	100.0
V08AB04 Iopamidol	1	0.0	100.0	0.0	100.0
V08AB10 Iomeprol	1	0.0	0.0	100.0	100.0
V08AC02 Iotroxidic acid	1	0.0	100.0	0.0	100.0
V08CA09 Gadobutrol	1	0.0	0.0	100.0	100.0
V08CB03 Iron oxide, nanoparticles	1	0.0	100.0	0.0	100.0
V01 Allergens	9	0.0	0.0	100.0	100.0
V01AA02 Grass pollen	4	0.0	0.0	100.0	100.0
V01AA20 Various	3	0.0	0.0	100.0	100.0
V01AA03 House dust	1	0.0	0.0	100.0	100.0
V01AA05 Tree pollen	1	0.0	0.0	100.0	100.0
V10 Therapeutic radiopharmaceuticals	7	0.0	85.7	14.3	100.0
V10XX02 Ibritumomab tiuxetan	6	0.0	100.0	0.0	100.0
V10BX02 Samarium-153Sm- lexidronam	1	0.0	0.0	100.0	100.0
V09 Diagnostic radiopharmaceuticals	4	0.0	100.0	0.0	100.0
V09GA04 Technetium-99mTc- human albumin	3	0.0	100.0	0.0	100.0
V09IX05 Fluorodopa (18F)	1	0.0	100.0	0.0	100.0
V04 Diagnostic agents	1	0.0	100.0	0.0	100.0
V04CJ01 Thyrotropin	1	0.0	100.0	0.0	100.0

H – Systemic hormonal preparations, excluding sex hormones and insulins

CT: 127 of which 106 (83.5%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level	CT (Phase I-II-III)	%			Total
		Phase I	Phase II	Phase III	
H02 Corticosteroids for systemic use	72	5.6	51.4	43.1	100.0
H02AB07 Prednisone	33	6.1	48.5	45.5	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
H02AB02	Dexamethasone	28	7.1	67.9	25.0	100.0
H02AB04	Methylprednisolone	9	0.0	33.3	66.7	100.0
H02AB08	Triamcinolone	3	0.0	0.0	100.0	100.0
H02AB06	Prednisolone	2	0.0	0.0	100.0	100.0
H02AB09	Hydrocortisone	1	0.0	100.0	0.0	100.0
H01	Pituitary and hypothalamic hormones and analogues	20	5.0	35.0	60.0	100.0
H01CB02	Octreotide	9	11.1	44.4	44.4	100.0
H01CB03	Lanreotide	5	0.0	0.0	100.0	100.0
H01AC01	Somatropin	3	0.0	66.7	33.3	100.0
H01AX01	Pegvisomant	2	0.0	0.0	100.0	100.0
H01BA04	Terlipressin	1	0.0	100.0	0.0	100.0
H01BB02	Oxytocin	1	0.0	0.0	100.0	100.0
H01CC02	Cetrorelix	1	0.0	0.0	100.0	100.0
H05	Calcium homeostasis	10	0.0	20.0	80.0	100.0
H05BX01	Cinacalcet	4	0.0	50.0	50.0	100.0
H05AA02	Teriparatide	2	0.0	0.0	100.0	100.0
H05BX02	Paracalcitol	2	0.0	0.0	100.0	100.0
H05AA03	Parathyroid hormone	1	0.0	0.0	100.0	100.0
H05BA01	Calcitonin (salmon synthetic)	1	0.0	0.0	100.0	100.0
H03	Thyroid therapy	4	0.0	75.0	25.0	100.0
H03AA01	Levothyroxine sodium	2	0.0	50.0	50.0	100.0
H03AA02	Liothyronine sodium	2	0.0	100.0	0.0	100.0

M – Musculo-skeletal systemCT: 121 of which 57 (47.1%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
M05	Drugs for treatment of bone diseases	22	4.5	22.7	72.7	100.0
M05BA08	Zoledronic acid	12	8.3	33.3	58.3	100.0
M05BX03	Strontium ranelate	5	0.0	0.0	100.0	100.0
M05BA02	Clodronic acid	2	0.0	0.0	100.0	100.0
M05BX04	Denosumab	2	0.0	0.0	100.0	100.0
M05BA06	Ibandronic acid	1	0.0	100.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
M01	Antiinflammatory and antirheumatic products	17	5.9	47.0	47.1	100.0
M01AH01	Celecoxib	5	0.0	60.0	40.0	100.0
M01AE17	Dexketoprofen	3	33.3	33.3	33.3	100.0
M01AH05	Etoricoxib	3	0.0	33.3	66.7	100.0
M01AC06	Meloxicam	2	0.0	100.0	0.0	100.0
M01AB05	Diclofenac	1	0.0	0.0	100.0	100.0
M01AB15	Ketorolac	1	0.0	0.0	100.0	100.0
M01AE01	Ibuprofen	1	0.0	0.0	100.0	100.0
M01AX05	Glucosamine	1	0.0	100.0	0.0	100.0
M03	Muscle relaxants	15	0.0	33.3	66.7	100.0
M03AX01	Botulinum toxin	10	0.0	30.0	70.0	100.0
M03BX01	Baclofen	2	0.0	0.0	100.0	100.0
M03AC11	Cisatracurium	1	0.0	0.0	100.0	100.0
M03BX05	Hiocolchicoside	1	0.0	100.0	0.0	100.0
M03BX09	Eperisone	1	0.0	100.0	0.0	100.0
M02	Topical products for joint and muscular pain	2	0.0	100.0	0.0	100.0
M02AA05	Benzidamine	1	0.0	100.0	0.0	100.0
M02AA15	Diclofenac	1	0.0	100.0	0.0	100.0
M04	Antigout preparations	1	0.0	100.0	0.0	100.0
M04AA01	Allopurinol	1	0.0	100.0	0.0	100.0
M09	Other drugs for disorders of the musculo-skeletal system	1	0.0	0.0	100.0	100.0
M09AX01	Hyaluronic acid	1	0.0	0.0	100.0	100.0

R – Respiratory systemCT: 105 of which 56 (53.3%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
R03	Drugs for obstructive airway diseases	34	0.0	26.5	73.5	100.0
R03BB04	Tiotropium bromide	7	0.0	14.3	85.7	100.0
R03AK07	Formoterol and other drugs for obstructive airway diseases	6	0.0	33.3	66.7	100.0
R03DC03	Montelukast	5	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
R03AC02	Salbutamol	3	0.0	33.3	66.7	100.0
R03AK06	Salmeterol and other drugs for obstructive airway diseases	2	0.0	0.0	100.0	100.0
R03CC13	Clenbuterol	2	0.0	100.0	0.0	100.0
R03DX05	Omalizumab	2	0.0	50.0	50.0	100.0
R03AC12	Salmeterol	1	0.0	0.0	100.0	100.0
R03AC13	Formoterol	1	0.0	100.0	0.0	100.0
R03AK04	Salbutamol and other drugs for obstructive airway diseases	1	0.0	0.0	100.0	100.0
R03BA01	Beclometasone	1	0.0	0.0	100.0	100.0
R03BA02	Budesonide	1	0.0	0.0	100.0	100.0
R03BA03	Flunisolide	1	0.0	0.0	100.0	100.0
R03BA99	Glycocorticoide - various	1	0.0	0.0	100.0	100.0
R03CC02	Salbutamol	1	0.0	100.0	0.0	100.0
R03DX07	Roflumilast	1	0.0	0.0	100.0	100.0
R05	Cough and cold preparations	13	0.0	30.7	69.3	100.0
R05CB01	Acetylcysteine	9	0.0	44.4	55.6	100.0
R05CB15	Erdosteine	2	0.0	0.0	100.0	100.0
R05CB03	Carbocisteine	1	0.0	0.0	100.0	100.0
R05CB05	Mesna	1	0.0	0.0	100.0	100.0
R06	Antihistamines for systemic use	6	0.0	16.7	83.3	100.0
R06AX27	Desloratadine	3	0.0	0.0	100.0	100.0
R06AD07	Mequitazine	1	0.0	0.0	100.0	100.0
R06AE09	Levocetirizine	1	0.0	0.0	100.0	100.0
R06AX28	Rupatadine	1	0.0	100.0	0.0	100.0
R01	Nasal preparations	2	0.0	0.0	100.0	100.0
R01AD09	Mometasone Furoate	1	0.0	0.0	100.0	100.0
R01AD12	Fluticasone Furoate	1	0.0	0.0	100.0	100.0
R07	Other respiratory system products	2	0.0	50.0	50.0	100.0
R07AA02	Natural phospholipids	2	0.0	50.0	50.0	100.0

**G – Genito urinary system and sex hormones**CT: 74 of which 50 (67.6%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
G04	Urologicals	30	0.0	30.0	70.0	100.0
G04BE08	Tadalafil	13	0.0	23.1	76.9	100.0
G04BE03	Sildenafil	6	0.0	33.3	66.7	100.0
G04CA02	Tamsulosin	5	0.0	40.0	60.0	100.0
G04BE09	Vardenafil	3	0.0	66.7	33.3	100.0
G04BD08	Solifenacin	2	0.0	50.0	50.0	100.0
G04BX13	Dimethyl sulfoxide	1	0.0	0.0	100.0	100.0
G04CA52	Tamsulosin and dutasteride	1	0.0	0.0	100.0	100.0
G04CB01	Finasteride	1	0.0	0.0	100.0	100.0
G04CB02	Dutasteride	1	0.0	0.0	100.0	100.0
G03	Sex hormones and modulators of the genital system	17	0.0	41.2	58.8	100.0
G03BA03	Testosterone	5	0.0	40.0	60.0	100.0
G03GA05	Follitropin alfa	5	0.0	60.0	40.0	100.0
G03AA12	Drospirenone and estrogen	2	0.0	0.0	100.0	100.0
G03AA07	Levonorgestrel and estrogen	1	0.0	100.0	0.0	100.0
G03AA10	Gestodene and estrogen	1	0.0	0.0	100.0	100.0
G03AC01	Noretisterone	1	0.0	100.0	0.0	100.0
G03CA03	Estradiol	1	0.0	0.0	100.0	100.0
G03DA03	Hydroxyprogesterone	1	0.0	100.0	0.0	100.0
G03DA04	Progesterone	1	0.0	0.0	100.0	100.0
G03DB04	Nomegestrol	1	0.0	0.0	100.0	100.0
G03GA07	Lutropin alfa	1	0.0	0.0	100.0	100.0
G03GA30	Combinations	1	0.0	0.0	100.0	100.0
G02	Other gynaecologicals	5	0.0	20.0	80.0	100.0
G02CB03	Cabergoline	3	0.0	0.0	100.0	100.0
G02AB01	Methylethergometrine	1	0.0	0.0	100.0	100.0
G02BA03	Plastic IUD with progestogen	1	0.0	100.0	0.0	100.0

**S – Sensory organs**CT: 72 of which 32 (44.4%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
S01	Ophthalmologicals	32	3.1	34.4	62.5	100.0
S01A04	Ranibizumab	5	0.0	20.0	80.0	100.0
S01LA03	Pegaptanib	4	0.0	75.0	25.0	100.0
S01BA01	Dexamethasone	3	0.0	66.7	33.3	100.0
S01EE01	Latanoprost	3	33.3	33.3	33.3	100.0
S01EC01	Acetazolamide	2	0.0	50.0	50.0	100.0
S01ED51	Timolol. combinations	2	0.0	0.0	100.0	100.0
S01EE04	Travoprost	2	0.0	0.0	100.0	100.0
S01GX08	Ketotifen	2	0.0	0.0	100.0	100.0
S01LA01	Verteporfin	2	0.0	50.0	50.0	100.0
S01AA26	Azithromycin	1	0.0	0.0	100.0	100.0
S01BC10	Nepafenac	1	0.0	0.0	100.0	100.0
S01CA01	Dexamethasone and antiinfectives	1	0.0	100.0	0.0	100.0
S01CA08	Methylprednisolone and antiinfectives	1	0.0	0.0	100.0	100.0
S01EC03	Dorzolamide	1	0.0	100.0	0.0	100.0
S01EE03	Bimatoprost	1	0.0	0.0	100.0	100.0
S01XA14	Heparin	1	0.0	100.0	0.0	100.0
S01XA16	Anecortave	1	0.0	100.0	0.0	100.0
S01XA18	Ciclosporin	1	0.0	0.0	100.0	100.0

D – DermatologicalsCT: 37 of which 19 (51.4%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
D07	Corticosteroids, dermatological preparations	7	0.0	71.4	28.6	100.0
D07AB19	Desamethasone	5	0.0	100.0	0.0	100.0
D07AB08	Desonide	1	0.0	0.0	100.0	100.0
D07AD01	Clobetasol	1	0.0	0.0	100.0	100.0
D05	Antipsoriatics	3	0.0	33.3	66.7	100.0
D05AX02	Calcipotriol	1	0.0	100.0	0.0	100.0
D05AX05	Tazarotene	1	0.0	0.0	100.0	100.0
D05AX52	Calcipotriol. combinations	1	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
D06	Antibiotics and chemotherapeutics for dermatological use	3	33.3	0.0	66.7	100.0
D06BB03	Aciclovir	2	0.0	0.0	100.0	100.0
D06BB10	Imiquimod	1	100.0	0.0	0.0	100.0
D10	Anti-acne preparations	2	0.0	0.0	100.0	100.0
D10AX30	Various combinations	1	0.0	0.0	100.0	100.0
D10BA01	Isotretinoina	1	0.0	0.0	100.0	100.0
D01	Antifungals for dermatological use	1	0.0	100.0	0.0	100.0
D01AC08	Ketoconazole	1	0.0	100.0	0.0	100.0
D04	Antipruritics, including antihistamines, anesthetics, etc	1	0.0	0.0	100.0	100.0
D04AB01	Lidocaine	1	0.0	0.0	100.0	100.0
D08	Antiseptics and disinfectants	1	0.0	0.0	100.0	100.0
D08AX99	Other insecticides and disinfectants, combinations	1	0.0	0.0	100.0	100.0
D11	Other dermatological preparations	1	0.0	100.0	0.0	100.0
D11AX15	Pimecrolimus	1	0.0	100.0	0.0	100.0

P – Antiparasitic products, insecticides and repellents

CT: 7 of which 4 (57.1%) with ATC 5th level of at least on test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III)	%			
			Phase I	Phase II	Phase III	Total
P01	Antiprotozoals	4	0.0	75.0	25.0	100.0
P01AB01	Metronidazole	2	0.0	100.0	0.0	100.0
P01BA02	Hydroxychloroquine	1	0.0	0.0	100.0	100.0
P01BC02	Mefloquine	1	0.0	100.0	0.0	100.0

The total number of ATC 2nd level clinical trials ("CT" column) is higher than the number indicated in the subtitle of each ATC classification because the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

Likewise, regarding each ATC 2nd level classification, the total number of ATC 5th level clinical trials ("CT" column) can be higher than the ATC 2nd level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

**Table 32*****Clinical trials per therapeutic area and phase (% in rows)***

Total CT: 3,863

Therapeutic area	CT	%					
		Phase I	Phase II	Phase III	Phase IV	Bioeq/Blod	Total
Oncology	1,158	10.1	54.8	32.6	2.4	0.0	100.0
Cardiology/Vascular diseases	360	0.6	22.5	52.5	21.7	2.8	100.0
Neurology	351	0.9	35.0	49.6	13.1	1.4	100.0
Immunology and infectious diseases	302	4.0	37.4	46.4	11.6	0.7	100.0
Haematology	268	9.3	52.2	32.8	5.6	0.0	100.0
Endocrinology	201	1.5	19.9	58.2	19.9	0.5	100.0
Gastroenterology	178	3.4	33.7	48.3	12.9	1.7	100.0
Respiratory system diseases	162	1.2	21.0	53.1	21.0	3.7	100.0
Nephrology/Urology	149	1.3	35.6	43.0	20.1	0.0	100.0
Ophthalmology	119	1.7	43.7	42.9	10.9	0.8	100.0
Rheumatology	110	1.8	30.0	56.4	10.0	1.8	100.0
Anaesthesiology	84	0.0	7.1	39.3	53.6	0.0	100.0
Paediatrics/Neonatology	76	0.0	26.3	50.0	23.7	0.0	100.0
Musculo-skeletal system diseases	75	4.0	20.0	46.7	18.7	10.7	100.0
Psychiatry/Psychology	67	1.5	14.9	55.2	25.4	3.0	100.0
Dermatology/Plastic surgery	67	0.0	22.4	49.3	28.4	0.0	100.0
Gynaecology and obstetrics	45	2.2	13.3	62.2	22.2	0.0	100.0
Genito urinary system	39	0.0	35.9	56.4	7.7	0.0	100.0
Traumatology and emergency medicine	21	0.0	28.6	52.4	19.0	0.0	100.0
Pharmacology/Toxicology	12	8.3	16.7	8.3	25.0	41.7	100.0
Oral and maxillofacial surgery	11	0.0	45.5	27.3	27.3	0.0	100.0
Otolaryngology	8	12.5	50.0	37.5	0.0	0.0	100.0
Total	3,863	4.7	38.0	43.5	12.7	1.2	100.0

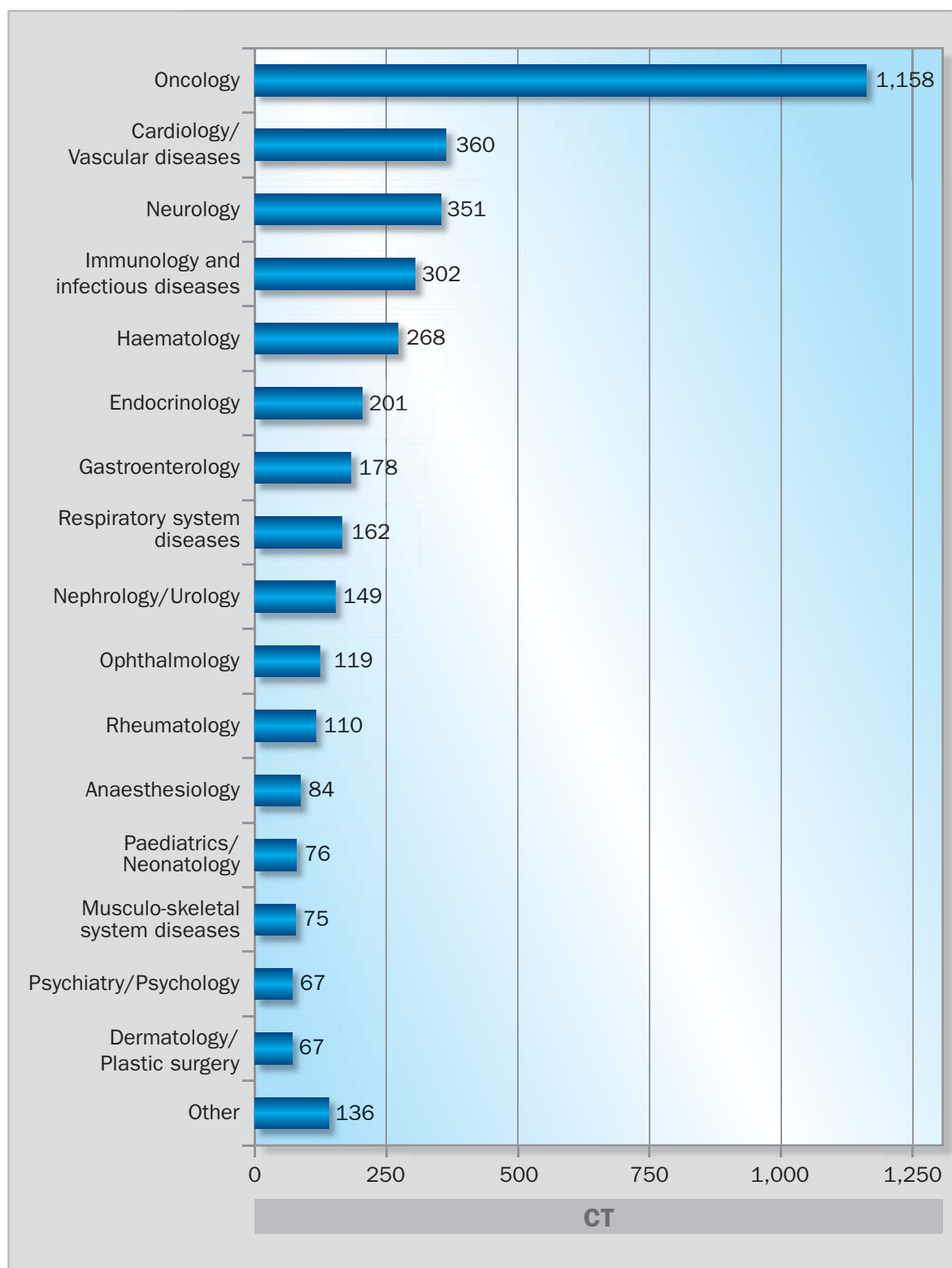
**Table 33*****Clinical trials per therapeutic area and phase (% in columns)***

Total CT: 3,863

Therapeutic area	CT	%					
		Phase I	Phase II	Phase III	Phase IV	Bioeq/Biod	Total
Oncology	1,158	63.9	43.3	22.5	5.7	0.0	30.0
Cardiology/Vascular diseases	360	1.1	5.5	11.3	16.0	22.2	9.3
Neurology	351	1.6	8.4	10.4	9.4	11.1	9.1
Immunology and infectious diseases	302	6.6	7.7	8.3	7.2	4.4	7.8
Haematology	268	13.7	9.5	5.2	3.1	0.0	6.9
Endocrinology	201	1.6	2.7	7.0	8.2	2.2	5.2
Gastroenterology	178	3.3	4.1	5.1	4.7	6.7	4.6
Respiratory system diseases	162	1.1	2.3	5.1	7.0	13.3	4.2
Nephrology/Urology	149	1.1	3.6	3.8	6.1	0.0	3.9
Ophthalmology	119	1.1	3.5	3.0	2.7	2.2	3.1
Rheumatology	110	1.1	2.2	3.7	2.2	4.4	2.8
Anaesthesiology	84	0.0	0.4	2.0	9.2	0.0	2.2
Paediatrics/Neonatology	76	0.0	1.4	2.3	3.7	0.0	2.0
Musculo-skeletal system diseases	75	1.6	1.0	2.1	2.9	17.8	1.9
Psychiatry/Psychology	67	0.5	0.7	2.2	3.5	4.4	1.7
Dermatology/Plastic surgery	67	0.0	1.0	2.0	3.9	0.0	1.7
Gynaecology and obstetrics	45	0.5	0.4	1.7	2.0	0.0	1.2
Genito urinary system	39	0.0	1.0	1.3	0.6	0.0	1.0
Traumatology and emergency medicine	21	0.0	0.4	0.7	0.8	0.0	0.5
Pharmacology/Toxicology	12	0.5	0.1	0.1	0.6	11.1	0.3
Oral and maxillofacial surgery	11	0.0	0.3	0.2	0.6	0.0	0.3
Otolaryngology	8	0.5	0.3	0.2	0.0	0.0	0.2
Total	3,863	100.0	100.0	100.0	100.0	100.0	100.0

**Chart D*****Clinical trials per therapeutic area***

Total CT: 3,863



**Table 34*****Mono-centre and multi-centre clinical trials per therapeutic area***

Total CT: 3,863

Therapeutic area	Mono-centre CT		Multi-centre CT		Total	
	CT	%	CT	%	CT	%
Oncology	180	15.5	978	84.5	1,158	100.0
Cardiology/Vascular diseases	99	27.5	261	72.5	360	100.0
Neurology	62	17.7	289	82.3	351	100.0
Immunology and infectious diseases	45	14.9	257	85.1	302	100.0
Haematology	36	13.4	232	86.6	268	100.0
Endocrinology	34	16.9	167	83.1	201	100.0
Gastroenterology	51	28.7	127	71.3	178	100.0
Respiratory system diseases	29	17.9	133	82.1	162	100.0
Nephrology/Urology	27	18.1	122	81.9	149	100.0
Ophthalmology	37	31.1	82	68.9	119	100.0
Rheumatology	8	7.3	102	92.7	110	100.0
Anaesthesiology	57	67.9	27	32.1	84	100.0
Paediatrics/Neonatology	29	38.2	47	61.8	76	100.0
Musculo-skeletal system diseases	26	34.7	49	65.3	75	100.0
Psychiatry/Psychology	12	17.9	55	82.1	67	100.0
Dermatology/Plastic surgery	15	22.4	52	77.6	67	100.0
Gynaecology and obstetrics	13	28.9	32	71.1	45	100.0
Genito urinary system	8	20.5	31	79.5	39	100.0
Traumatology and emergency medicine	6	28.6	15	71.4	21	100.0
Pharmacology/Toxicology	8	66.7	4	33.3	12	100.0
Oral and maxillofacial surgery	7	63.6	4	36.4	11	100.0
Otolaryngology	5	62.5	3	37.5	8	100.0
Total	794	20.6	3,069	79.4	3,863	100.0

**Table 35*****Clinical trials per year and profit / no profit Sponsors***

Total CT: 3,863

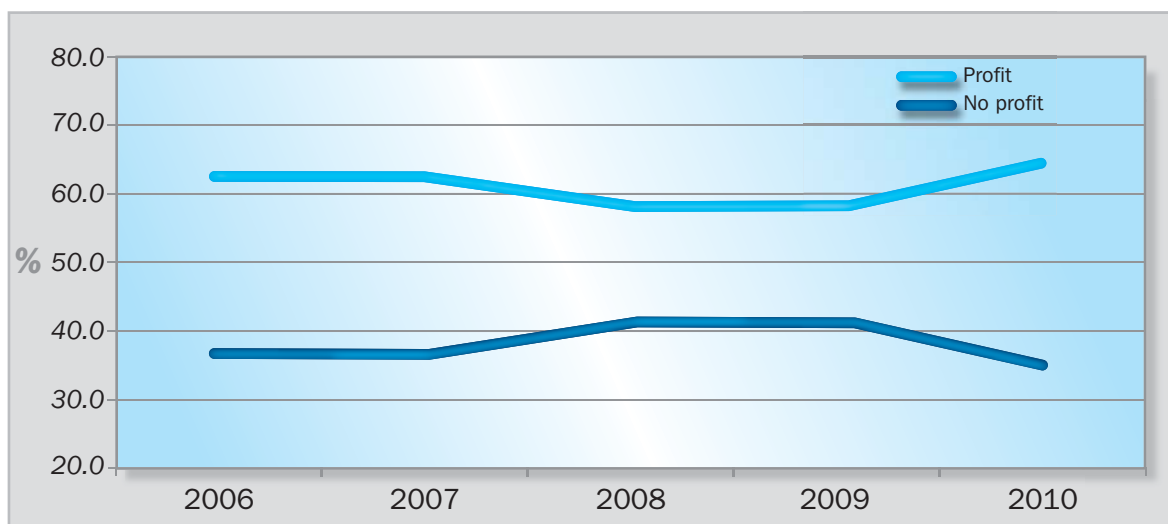
Profit Sponsors: 347

No profit Sponsors: 216

Year	Profit		No profit		Total	
	CT	%	CT	%	CT	%
2006	491	63.1	287	36.9	778	100.0
2007	502	63.1	293	36.9	795	100.0
2008	516	58.8	362	41.2	878	100.0
2009	443	58.9	309	41.1	752	100.0
2010	431	65.3	229	34.7	660	100.0
Total	2,383	61.7	1,480	38.3	3,863	100.0

Chart E***Clinical trials per year and profit / no profit Sponsors***

Total CT: 3,863



**Table 36*****Clinical trials per therapeutic area and profit / no profit Sponsors (% in rows)***

Total CT: 3,863

Therapeutic area	Profit		No profit		Total	
	CT	%	CT	%	CT	%
Oncology	667	57.6	491	42.4	1.158	100.0
Cardiology/Vascular diseases	228	63.3	261	36.7	360	100.0
Neurology	249	70.9	289	29.1	351	100.0
Immunology and infectious diseases	209	69.2	93	30.8	302	100.0
Haematology	126	47.0	142	53.0	268	100.0
Endocrinology	147	73.1	54	26.9	201	100.0
Gastroenterology	115	64.6	63	35.4	178	100.0
Respiratory system diseases	127	78.4	35	21.6	162	100.0
Nephrology/Urology	91	61.1	58	38.9	149	100.0
Ophthalmology	65	54.6	54	45.4	119	100.0
Rheumatology	96	87.3	14	12.7	110	100.0
Anaesthesiology	9	10.7	75	89.3	84	100.0
Paediatrics/Neonatology	25	32.9	51	67.1	76	100.0
Musculo-skeletal system diseases	53	70.7	22	29.3	75	100.0
Psychiatry/Psychology	54	80.6	13	19.4	67	100.0
Dermatology/Plastic surgery	47	70.1	20	29.9	67	100.0
Gynaecology and obstetrics	19	42.2	26	57.8	45	100.0
Genito urinary system	28	71.8	11	28.2	39	100.0
Traumatology and emergency medicine	13	61.9	8	38.1	21	100.0
Pharmacology/Toxicology	5	41.7	7	58.3	12	100.0
Oral and maxillofacial surgery	5	45.5	6	54.5	11	100.0
Otolaryngology	5	62.5	3	37.5	8	100.0
Total	2,383	61.7	1,480	38.3	3,863	100.0

**Table 37*****Clinical trials per therapeutic area and profit / no profit Sponsors (% in columns)***

Total CT: 3,863

Therapeutic area	Profit		No profit		Total	
	CT	%	CT	%	CT	%
Oncology	667	28.0	491	33.2	1.158	30.0
Cardiology/Vascular diseases	228	9.6	261	8.9	360	9.3
Neurology	249	10.4	289	6.9	351	9.1
Immunology and infectious diseases	209	8.8	93	6.3	302	7.8
Haematology	126	5.3	142	9.6	268	6.9
Endocrinology	147	6.2	54	3.6	201	5.2
Gastroenterology	115	4.8	63	4.3	178	4.6
Respiratory system diseases	127	5.3	35	2.4	162	4.2
Nephrology/Urology	91	3.8	58	3.9	149	3.9
Ophthalmology	65	2.7	54	3.6	119	3.1
Rheumatology	96	4.0	14	0.9	110	2.8
Anaesthesiology	9	0.4	75	5.1	84	2.2
Paediatrics/Neonatology	25	1.0	51	3.4	76	2.0
Musculo-skeletal system diseases	53	2.2	22	1.5	75	1.9
Psychiatry/Psychology	54	2.3	13	0.9	67	1.7
Dermatology/Plastic surgery	47	2.0	20	1.4	67	1.7
Gynaecology and obstetrics	19	0.8	26	1.8	45	1.2
Genito urinary system	28	1.2	11	0.7	39	1.0
Traumatology and emergency medicine	13	0.5	8	0.5	21	0.5
Pharmacology/Toxicology	5	0.2	7	0.5	12	0.3
Oral and maxillofacial surgery	5	0.2	6	0.4	11	0.3
Otolaryngology	5	0.2	3	0.2	8	0.2
Total	2,383	100.0	1,480	100.0	3,863	100.0

**Table 38*****Clinical trials per profit Sponsors***

CT: 2,383

	Profit Sponsor	CT	%	cum. %
1	Novartis	231	9.7	9.7
2	Pfizer	157	6.6	16.3
3	Roche	115	4.8	21.1
4	GlaxoSmithKline	114	4.8	25.9
5	Sanofi-Aventis	92	3.9	29.8
6	Bristol Myers Squibb	82	3.4	33.2
7	Lilly	73	3.1	36.3
8	Boehringer Ingelheim	70	2.9	39.2
9	Bayer	59	2.5	41.7
10	AstraZeneca	54	2.3	43.9
11	Amgen	49	2.1	46.0
12	Janssen-Cilag	47	2.0	48.0
13	MSD Italia	43	1.8	49.8
14	Schering Plough	39	1.6	51.4
15	Gruppo Abbott	36	1.5	52.9
16	Gruppo Merck	35	1.5	54.4
17	Merck Sharp & Dohme	35	1.5	55.9
18	Astellas	28	1.2	57.0
19	Novo Nordisk	26	1.1	58.1
20	UCB Pharma	25	1.0	59.2
21	Eisai	24	1.0	60.2
22	Pierre Fabre	23	1.0	61.1
23	Celgene	21	0.9	62.0
24	Servier	21	0.9	62.9
25	Actelion Pharmaceuticals	20	0.8	63.7
26	Gruppo Menarini	20	0.8	64.6
27	Takeda	19	0.8	65.4
28	Bracco	18	0.8	66.1
29	Chiesi	16	0.7	66.8
30	Teva	16	0.7	67.5
31	Genzyme	15	0.6	68.1
32	Gilead Sciences	15	0.6	68.7



	Profit Sponsor	CT	%	cum. %
33	Alcon	14	0.6	69.3
34	MolMed	14	0.6	69.9
35	Angelini	13	0.5	70.5
36	Italfarmaco	13	0.5	71.0
37	Biogen Idec	12	0.5	71.5
38	Gruppo Shire	12	0.5	72.0
39	Nerviano Medical Sciences	12	0.5	72.5
40	Philogen	12	0.5	73.0
41	Sigma-Tau	12	0.5	73.5
42	Allergan	11	0.5	74.0
43	Ipsen	11	0.5	74.4
44	Lundbeck	11	0.5	74.9
45	Nycomed	11	0.5	75.4
46	Pharma Mar	11	0.5	75.8
47	Gruppo Daiichi Sankyo	9	0.4	76.2
48	Sofar	9	0.4	76.6
49	Bial-Portela	8	0.3	76.9
50	IBSA	8	0.3	77.3
51	CSL Behring	7	0.3	77.5
52	Kedrion	7	0.3	77.8
53	Medivation	7	0.3	78.1
54	Alexion Pharmaceuticals	6	0.3	78.4
55	Grünenthal-Formenti	6	0.3	78.6
56	Gruppo Galenica	6	0.3	78.9
57	ImClone	6	0.3	79.1
58	Janssen Biologics B.V.	6	0.3	79.4
59	Mipham	6	0.3	79.6
60	PTC Therapeutics	6	0.3	79.9
61	Alfa Wassermann	5	0.2	80.1
62	Cephalon	5	0.2	80.3
63	Cytheris	5	0.2	80.5
64	Genentech	5	0.2	80.7
65	Mitsubishi Tanabe Pharma Corporation	5	0.2	80.9
66	Rottapharm	5	0.2	81.2
67	Sanofi Pasteur MSD	5	0.2	81.4
68	Seattle Genetics	5	0.2	81.6



	Profit Sponsor	CT	%	cum. %
69	Zambon	5	0.2	81.8
70	Abiogen	4	0.2	82.0
71	Alk Abellò	4	0.2	82.1
72	ArQule	4	0.2	82.3
73	Baxter	4	0.2	82.5
38	Cosmo	4	0.2	82.6
75	Debiopharm	4	0.2	82.8
76	Ferring	4	0.2	83.0
77	Fidia	4	0.2	83.1
78	Fresenius Biotech	4	0.2	83.3
79	Genmab	4	0.2	83.5
80	Guerbet	4	0.2	83.6
81	Iperboreal Pharma	4	0.2	83.8
82	Monterese	4	0.2	84.0
83	Newron Pharmaceuticals	4	0.2	84.1
84	Organon Italia	4	0.2	84.3
85	United Therapeutics	4	0.2	84.5
86	Allergopharma	3	0.1	84.6
87	Almirall	3	0.1	84.7
88	Basilea Pharmaceutica	3	0.1	84.9
89	Biotest	3	0.1	85.0
90	Clavis Pharma	3	0.1	85.1
91	Clinuvel Pharmaceuticals	3	0.1	85.2
92	Damor	3	0.1	85.4
93	GE Healthcare	3	0.1	85.5
94	Galderma	3	0.1	85.6
95	Gruppo Dompé	3	0.1	85.7
96	Hexal	3	0.1	85.9
97	Human Genome Sciences	3	0.1	86.0
98	Incyte	3	0.1	86.1
99	Intermune	3	0.1	86.2
100	Lofarma	3	0.1	86.4
101	NPS Pharmaceuticals	3	0.1	86.5
102	Protalix Biotherapeutics	3	0.1	86.6
103	Recordati	3	0.1	86.7
104	SIFI	3	0.1	86.9



	Profit Sponsor	CT	%	cum. %
105	Sendo-tech	3	0.1	87.0
106	Special Product's Line	3	0.1	87.1
107	Stallergenes	3	0.1	87.2
108	Swedish Orphan Biovitrium	3	0.1	87.4
109	The Medicines Company	3	0.1	87.5
110	AB Science	2	0.1	87.6
111	AVEO Pharmaceuticals	2	0.1	87.7
112	Acadia Pharmaceuticals	2	0.1	87.7
113	Achillion Pharmaceuticals	2	0.1	87.8
114	Affymax	2	0.1	87.9
115	Air Liquide	2	0.1	88.0
116	Ali Raif	2	0.1	88.1
117	Allos	2	0.1	88.2
118	Altus Pharmaceuticals	2	0.1	88.3
119	Apotex	2	0.1	88.3
120	Archimedes	2	0.1	88.4
121	Avexa	2	0.1	88.5
122	Bausch & Lomb IOM	2	0.1	88.6
123	BioCryst	2	0.1	88.7
124	BioXell	2	0.1	88.8
125	Cardiokine Biopharma	2	0.1	88.8
126	Cell Genesys	2	0.1	88.9
127	Cerexa	2	0.1	89.0
128	Chelsea Therapeutics	2	0.1	89.1
129	Cougar Biotechnology	2	0.1	89.2
130	Dr. Falk Pharma	2	0.1	89.3
131	EOS - Ethical Oncology Science	2	0.1	89.3
132	Erydel - ERYthrocyte DELivery	2	0.1	89.4
133	Essex Italia	2	0.1	89.5
134	Eurand	3	0.1	89.6
135	Farmigea	2	0.1	89.7
136	FoldRx Pharmaceuticals	2	0.1	89.8
137	GW Pharma	2	0.1	89.8
138	Genetic	2	0.1	89.9
139	Giuliani	2	0.1	90.0
140	Glycotope	2	0.1	90.1



	Profit Sponsor	CT	%	cum. %
141	Grifols Italia	2	0.1	90.2
142	ISDIN	2	0.1	90.3
143	Janssen Biologics	2	0.1	90.3
144	Jazz Pharmaceuticals	2	0.1	90.4
145	Laboratoires Thea	2	0.1	90.5
146	Leo Pharma	2	0.1	90.6
147	Light Sciences Oncology	2	0.1	90.7
148	MedImmune LLC	2	0.1	90.8
149	Merz Pharmaceuticals	2	0.1	90.9
150	Mundipharma Research	2	0.1	90.9
151	Myriad Genetics	2	0.1	91.0
152	Norgine	2	0.1	91.1
153	Novagali Pharma	2	0.1	91.2
154	Nuvelo	2	0.1	91.3
155	Ono Pharma	2	0.1	91.4
156	Orfagen	2	0.1	91.4
157	Ovation Pharmaceuticals	2	0.1	91.5
158	PDL	2	0.1	91.6
159	Polichem	2	0.1	91.7
160	Promefarm	2	0.1	91.8
161	SLA Pharma	2	0.1	91.9
162	Shionogi	2	0.1	91.9
163	Stragen	2	0.1	92.0
164	ThromboGenics	2	0.1	92.1
165	Tolerx	2	0.1	92.2
166	Vectura	2	0.1	92.3
167	ViroStatics	2	0.1	92.4
168	Viropharma	2	0.1	92.4
169	Ziopharm Oncology	2	0.1	92.5
170	4SC	1	0.0	92.6
171	AEterna Zentaris	1	0.0	92.6
172	AM Pharma	1	0.0	92.7
173	AMAG Pharmaceuticals	1	0.0	92.7
174	AOP Orphan Pharmaceuticals	1	0.0	92.7
175	Ablynx	1	0.0	92.8
176	Abraxis BioScience	1	0.0	92.8



	Profit Sponsor	CT	%	cum. %
177	Agennix	1	0.0	92.9
178	Algeta	1	0.0	92.9
179	Alimera Sciences	1	0.0	93.0
180	Amarin	1	0.0	93.0
181	Amarin Neuroscience	1	0.0	93.0
182	Ambit Biosciences	1	0.0	93.1
183	Amdipharm	1	0.0	93.1
184	Amicus Therapeutics	1	0.0	93.2
185	Andromeda Biotech	1	0.0	93.2
186	Anthera Pharmaceuticals	1	0.0	93.2
187	Antisoma	1	0.0	93.3
188	Archemix	1	0.0	93.3
189	Argenes	1	0.0	93.4
190	Arpida	1	0.0	93.4
191	Artu Biologicals	1	0.0	93.5
192	Ascendis Pharma	1	0.0	93.5
193	Aspreva Pharmaceuticals	1	0.0	93.5
194	Axcan Pharma	1	0.0	93.6
195	Axxonis Pharma	1	0.0	93.6
196	BHR Pharma	1	0.0	93.7
197	Berksam	1	0.0	93.7
198	Bio-Ker	1	0.0	93.7
199	BioAlliance Pharma	1	0.0	93.8
200	Biocon	1	0.0	93.8
201	Biomarin	1	0.0	93.9
202	Bionor Immuno	1	0.0	93.9
203	Biopartners	1	0.0	94.0
204	Bioprogress	1	0.0	94.0
205	Bioproject	1	0.0	94.0
206	Biosynexus	1	0.0	94.1
207	Braintree Laboratories	1	0.0	94.1
208	Bristol-Myers Squibb	1	0.0	94.2
209	C.T. Laboratorio Farmaceutico	1	0.0	94.2
210	CPDS - Celtic Pharma Development Services	1	0.0	94.3
211	Celltrion	1	0.0	94.3
212	Celsion	1	0.0	94.3



	Profit Sponsor	CT	%	cum. %
213	Clinipace Worldwide	1	0.0	94.4
214	Clovis Oncology	1	0.0	94.4
215	Cogentus Pharmaceuticals	1	0.0	94.5
216	Corthera	1	0.0	94.5
217	Cotherix	1	0.0	94.5
218	Crucell	1	0.0	94.6
219	Curalogic	1	0.0	94.6
220	CureVac	1	0.0	94.7
221	D-Pharm	1	0.0	94.7
222	DAC	1	0.0	94.8
223	DR - Dimensione Ricerca	1	0.0	94.8
224	Defiante	1	0.0	94.8
225	Diamyd Medical	1	0.0	94.9
226	Diatos	1	0.0	94.9
227	Dyax Corporation	1	0.0	95.0
228	Ecupharma	1	0.0	95.0
229	Edmond Pharma	1	0.0	95.0
230	EpiCept	1	0.0	95.1
231	Epifarma	1	0.0	95.1
232	Exelixis	1	0.0	95.2
233	Ferrer Internacional	1	0.0	95.2
234	FerroKin BioSciences	1	0.0	95.3
235	GPC Biotech	1	0.0	95.3
236	Galsor	1	0.0	95.3
237	Genta Development	1	0.0	95.4
238	Germed Farmaceutica	1	0.0	95.4
239	Gienne Pharma	1	0.0	95.5
240	Glenmark Pharmaceuticals	1	0.0	95.5
241	Gloucester Pharmaceuticals	1	0.0	95.6
242	Helsinn Healthcare	1	0.0	95.6
243	Hologic	1	0.0	95.6
244	Humanitas Centro Catanese di Oncologia di Catania	1	0.0	95.7
245	IBI	1	0.0	95.7
246	Impax Laboratories	1	0.0	95.8
247	Ineos Healthcare	1	0.0	95.8
248	Infinity Pharmaceuticals	1	0.0	95.8



	Profit Sponsor	CT	%	cum. %
249	Innate Pharma	1	0.0	95.9
250	Innovive Pharmaceuticals	1	0.0	95.9
251	Inspiration Pharmaceuticals	1	0.0	96.0
252	Intendis	1	0.0	96.0
253	Italchimici	1	0.0	96.1
254	Jerini	1	0.0	96.1
255	KAI Pharmaceuticals	1	0.0	96.1
256	Kowa Research Europe	1	0.0	96.2
257	Kureha	1	0.0	96.2
258	Kyowa Hakko	1	0.0	96.3
259	La Jolla Pharmaceutical Company	1	0.0	96.3
260	Laboratoire HRA Pharma	1	0.0	96.3
261	Laboratoires SMB	1	0.0	96.4
262	Laboratori Baldacci	1	0.0	96.4
263	Laboratorio Chimico Farmaceutico Sella	1	0.0	96.5
264	Laboratorio Farmacologico Milanese	1	0.0	96.5
229	Lallemand Pharma International	1	0.0	96.6
266	Lux Biosciences	1	0.0	96.6
267	MacroGenics	1	0.0	96.6
268	Marshall Edwards	1	0.0	96.7
269	Mastelli	1	0.0	96.7
270	Medac	1	0.0	96.8
271	Medestea	1	0.0	96.8
272	MediWound	1	0.0	96.9
273	Mediolanum Cardio Research	1	0.0	96.9
274	Medosan	1	0.0	96.9
275	Medtronic	1	0.0	97.0
276	Micromet	1	0.0	97.0
277	Molteni	1	0.0	97.1
278	Molteni Therapeutics	1	0.0	97.1
279	MondoGen	1	0.0	97.1
280	Mutual Pharmaceutical Company	1	0.0	97.2
281	Named	1	0.0	97.2
282	Nathura	1	0.0	97.3
283	NeuroSearch	1	0.0	97.3
284	Neurobiotec	1	0.0	97.4



	Profit Sponsor	CT	%	cum. %
285	Neurochem	1	0.0	97.4
286	Neuropharm	1	0.0	97.4
287	Nicox (Francia)	1	0.0	97.5
288	Nordic Bioscience	1	0.0	97.5
289	NovaRx	1	0.0	97.6
290	Novelos Therapeutics	1	0.0	97.6
291	Okairos	1	0.0	97.7
292	Olympus France	1	0.0	97.7
293	Oncoscience	1	0.0	97.7
294	Onyx Pharmaceuticals	1	0.0	97.8
295	Opera	1	0.0	97.8
296	Ophthotech	1	0.0	97.9
297	Opko Health	1	0.0	97.9
298	Optimer Pharmaceuticals	1	0.0	97.9
299	OraPharma	1	0.0	98.0
300	Orphanetics	1	0.0	98.0
301	Ortho-McNeil Janssen Scientific Affairs	1	0.0	98.1
302	Osiris	1	0.0	98.1
303	Oxigene	1	0.0	98.2
304	PH&T	1	0.0	98.2
305	Peptimmune	1	0.0	98.2
306	Pharmexa	1	0.0	98.3
307	Pharming Technologies	1	0.0	98.3
308	Pipex Pharmaceuticals	1	0.0	98.4
309	PregLem	1	0.0	98.4
310	Pro Aparts	1	0.0	98.4
311	Procter & Gamble	1	0.0	98.5
312	Proge Farm	1	0.0	98.5
313	Proge Medica	1	0.0	98.6
314	Progen Pharmaceuticals	1	0.0	98.6
315	Prosensa	1	0.0	98.7
316	Quest PharmaTech	1	0.0	98.7
317	Renovo	1	0.0	98.7
318	Replidyne	1	0.0	98.8
319	Rigel Pharmaceuticals	1	0.0	98.8
320	SPA - Società Prodotti Antibiotici	1	0.0	98.9



	Profit Sponsor	CT	%	cum. %
321	Sintetica	1	0.0	98.9
322	Sirtex Technology	1	0.0	99.0
323	So.Se.Pharm	1	0.0	99.0
324	Sopherion Therapeutics	1	0.0	99.0
325	Sparkle	1	0.0	99.1
326	Synta Pharmaceuticals	1	0.0	99.1
327	Taiho Pharma	1	0.0	99.2
328	Targanta Therapeutics	1	0.0	99.2
329	Therakos	1	0.0	99.2
330	Theratechnologies	1	0.0	99.3
331	Theriaca	1	0.0	99.3
332	Topigen Pharmaceuticals	1	0.0	99.4
333	TopoTarget	1	0.0	99.4
334	Trophos	1	0.0	99.5
335	Uriach	1	0.0	99.5
336	Valeant Pharmaceuticals International	1	0.0	99.5
337	Valeas	1	0.0	99.6
338	Valetudo	1	0.0	99.6
339	Vernalis Development	1	0.0	99.7
340	Verona Pharma	1	0.0	99.7
341	Vertex Pharmaceuticals	1	0.0	99.7
342	Via Pharmaceuticals	1	0.0	99.8
343	Vical	1	0.0	99.8
344	Visufarma	1	0.0	99.9
345	Viventia Biotech	1	0.0	99.9
346	WILEX	1	0.0	100.0
347	Weleda	1	0.0	100.0
	Total	2,383	100.0	

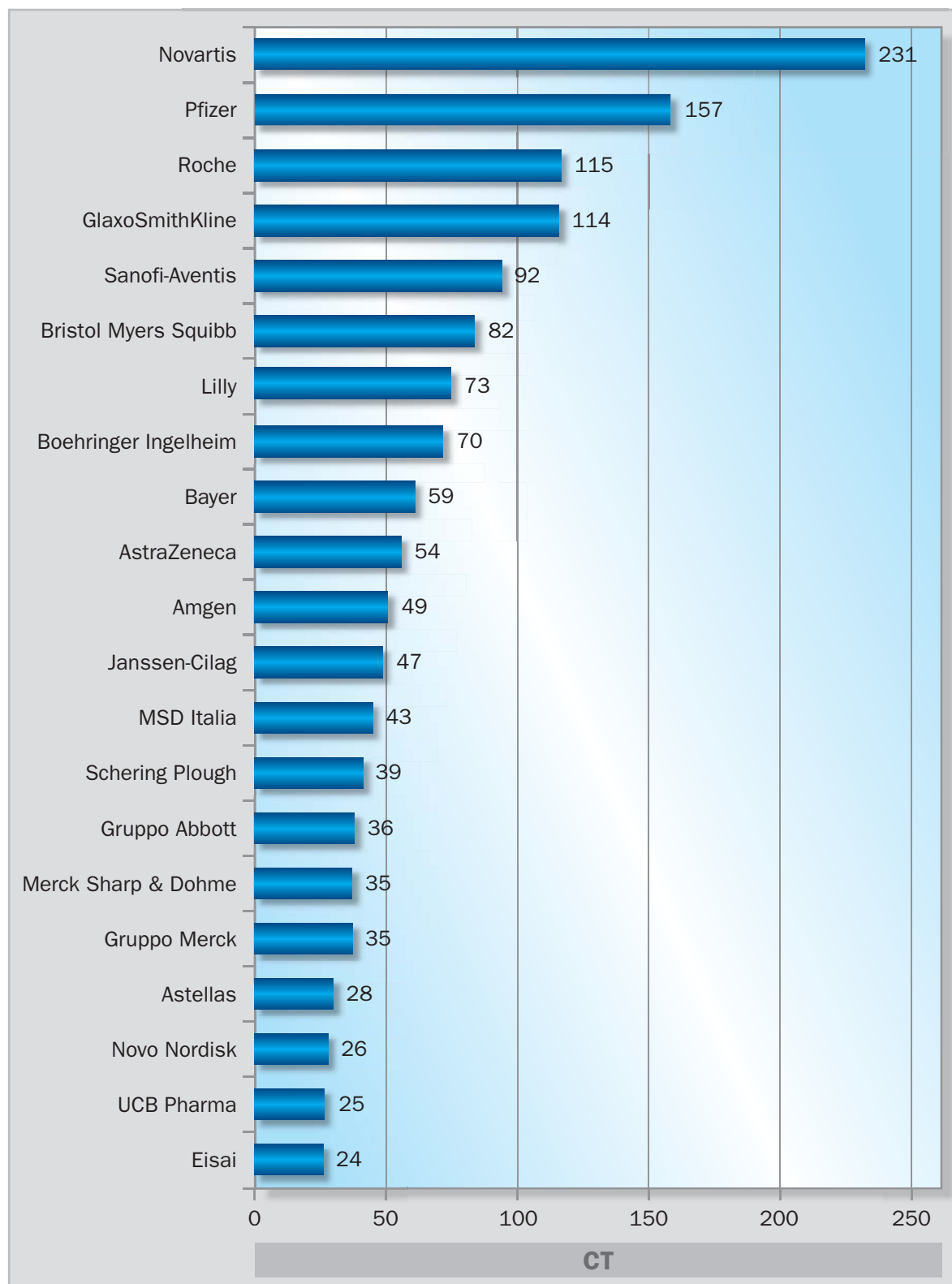
The data regarding Sponsors, their names and clinical trials associated to them, take into consideration any registered office's variation, merger, acquisition and/or incorporation.



Chart F

Clinical trials per profit Sponsor

The first 21 out of 347 profit Sponsors (6.1%) represent 60.2% of the clinical trials



**Table 39*****Clinical trials per typology of no profit Sponsor***

CT: 1,480

Typology	CT	%	No profit Sponsors
University hospital, University polyclinic and University	569	38.4	41
Public or private Scientific institute for research and care (IRCCS)	380	25.7	31
Hospital structure *	212	14.3	41
Scientific association	155	10.5	39
Foundation	77	5.2	21
Local health unit	60	4.1	32
Research institute	22	1.5	7
Government body	5	0.3	4
Total	1,480	100.0	216

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local hospitals, military hospital

**Table 40*****Clinical trials per no profit Sponsor***

CT: 1,480

	No profit Sponsor	CT	%	cum. %
1	A.O. Universitaria Policlinico Gemelli of Rome	96	6.5	6.5
2	A.O. Universitaria Policlinico S. Orsola Malpighi of Bologna	89	6.0	12.5
3	IRCCS Fondazione Centro S. Raffaele del Monte Tabor of Milan	72	4.9	17.4
4	A.O. Universitaria S. Giovanni Battista-Molinette of Turin	45	3.0	20.4
5	IRCCS Istituto Europeo di Oncologia (IEO) of Milan	37	2.5	22.9
6	A.O. Universitaria Pisana of Pisa	36	2.4	25.3
7	IRCCS Policlinico S. Matteo of Pavia	36	2.4	27.8
8	A.O. Universitaria Policlinico of Modena	33	2.2	30.0
9	IRCCS Istituto Gaslini of Genoa	31	2.1	32.1
10	Istituto di Ricerche Farmacologiche Mario Negri (Milan)	28	1.9	34.0
11	A.O. Presidio Spedali Civili of Brescia	27	1.8	35.8
12	IRCCS Istituto Nazionale dei Tumori (INT) of Milan	26	1.8	37.6
13	A.O. of Padua	23	1.6	39.1
14	A.O. Universitaria Consorziale Policlinico of Bari	21	1.4	40.5
15	A.O. Universitaria of Parma	21	1.4	42.0
16	GOIM - Gruppo Oncologico dell'Italia Meridionale (Bari)	21	1.4	43.4
17	Federico II University of Naples	21	1.4	44.8
18	A.O. Universitaria Senese of Siena	20	1.4	46.1
19	IRCCS Fondazione Istituto Neurologico Besta of Milan	19	1.3	47.4
20	IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	19	1.3	48.7
21	A.O. Ospedale S. Gerardo of Monza (MB)	18	1.2	49.9
22	IRCCS Istituti Fisioterapici Ospitalieri (IFO) of Rome	18	1.2	51.1
23	Perugia University	18	1.2	52.4
24	IRCCS Istituto Clinico Humanitas of Rozzano (MI)	17	1.1	53.5
25	A.O. Universitaria Ospedali Riuniti Umberto I - Lancisi - Salesi of Ancona	16	1.1	54.6
26	GIMEMA - Gruppo Italiano Malattie EMatologiche dell'Adulto (Rome)	16	1.1	55.7
27	A.O. Ospedali Riuniti of Bergamo	15	1.0	56.7
28	A.O. Universitaria Integrata of Verona	15	1.0	57.7
29	Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan	15	1.0	58.7
30	Fondazione Neoplasie Sangue (Turin)	15	1.0	59.7
31	A.O. Universitaria Careggi of Florence	14	0.9	60.7
32	IIL - Intergruppo Italiano Linfomi (Alessandria)	14	0.9	61.6



	No profit Sponsor	CT	%	cum. %
33	A.O. Ospedale Niguarda Ca' Granda of Milan	13	0.9	62.5
34	Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) of Meldola (FC)	13	0.9	63.4
35	Tor Vergata University of Rome	13	0.9	64.3
36	A.O. Ospedale Sacco of Milan	12	0.8	65.1
37	EORTC - European Organisation for Research and Treatment of Cancer (Belgium)	12	0.8	65.9
38	GOIRC - Gruppo Oncologico Italiano di Ricerca Clinica (Parma)	12	0.8	66.7
39	IRCCS Burlo Garofolo of Trieste	12	0.8	67.5
40	A.O. Universitaria Maggiore della Carità of Novara	11	0.7	68.2
41	A.O. Universitaria Policlinico Umberto I of Rome	11	0.7	69.0
42	A.O. Universitaria S. Luigi Gonzaga of Orbassano (TO)	11	0.7	69.7
43	A.O. Universitaria Seconda Università of Naples	11	0.7	70.5
44	GONO - Gruppo Oncologico Nord Ovest (Genoa)	10	0.7	71.1
45	GISL - Gruppo Italiano Studio Linfomi (Modena)	9	0.6	71.8
46	IRCCS Centro di Riferimento Oncologico (CRO) of Aviano (PN)	9	0.6	72.4
47	Campus Bio-Medico University of Rome	9	0.6	73.0
48	A.O. Universitaria S. Martino of Genoa	8	0.5	73.5
49	A.O. Arcispedale S. Maria Nuova of Reggio Emilia	7	0.5	74.0
50	Fondazione Michelangelo (Milan)	7	0.5	74.5
51	IRCCS Istituto Nazionale per la Ricerca sul Cancro (IST) of Genoa	7	0.5	74.9
52	IRCCS Istituto Ortopedico Rizzoli (IOR) of Bologna	7	0.5	75.4
53	Istituto Superiore di Sanità of Rome	7	0.5	75.9
54	A.O. Ospedale S. Carlo of Potenza	6	0.4	76.3
55	A.O. Ospedale S. Salvatore of Pesaro (PU)	6	0.4	76.7
56	A.O. Ospedale di Circolo e Fondazione Macchi of Varese	6	0.4	77.1
57	A.O. Universitaria Meyer of Florence	6	0.4	77.5
58	A.O. Universitaria Policlinico Monserrato of Cagliari	6	0.4	77.9
59	A.O. Universitaria S. Andrea of Rome	6	0.4	78.3
60	A.O. Universitaria S. Maria della Misericordia of Udine	6	0.4	78.7
61	IRCCS Fondazione Bietti of Rome	6	0.4	79.1
62	IRCCS Istituto Auxologico Italiano - Ospedale of Oggebbio (VB)	6	0.4	79.5
63	ITMO - Italian Trials in Medical Oncology (Milan)	6	0.4	79.9
64	Pavia University	6	0.4	80.3
65	A.O. Istituti Clinici di Perfezionamento (ICP) of Milan	5	0.3	80.7
66	Consorzio Oncotech (Naples)	5	0.3	81.0



	No profit Sponsor	CT	%	cum. %
67	E.O. Ospedali Galliera of Genoa	5	0.3	81.4
68	IRCCS Istituto Nazionale Malattie Infettive Spallanzani of Rome	5	0.3	81.7
69	Italian Sarcoma Group (Bologna)	5	0.3	82.0
70	OPDC - Otsuka Pharmaceutical Development & Commercialization (USA)	5	0.3	82.4
71	A.O. Ospedale Manzoni of Lecco	4	0.3	82.6
72	A.O. Ospedale Mauriziano Umberto I of Turin	4	0.3	82.9
73	A.O. S. Croce e Carle of Cuneo	4	0.3	83.2
74	A.O. S. Maria of Terni	4	0.3	83.4
75	A.O. of Perugia	4	0.3	83.7
76	APSS of Trento	4	0.3	84.0
77	ASL TO/2 of Turin	4	0.3	84.3
78	AUSL 1 of Massa and Carrara	4	0.3	84.5
79	AUSL 12 of Viareggio (LU)	4	0.3	84.8
80	Centro Emofilia e Trombosi Bianchi Bonomi (Milan)	4	0.3	85.1
81	Fondazione Ricerca Trapianto di Midollo Osseo (Genoa)	4	0.3	85.3
82	Fondazione del Piemonte per l'Oncologia IRCC of Candiolo (TO)	4	0.3	85.6
83	GISCAD - Gruppo Italiano per lo Studio sui Carcinomi Apparato Digerente (Arluno, MI)	4	0.3	85.9
84	IRCCS Fondazione Maugher - Istituto of Pavia	4	0.3	86.1
85	IRCCS Fondazione S. Lucia of Rome	4	0.3	86.4
86	IRCCS Istituto Dermopatico dell'Immacolata (IDI) of Rome	4	0.3	86.7
87	IRCCS Istituto Neurologico Mediterraneo (Neuromed) of Pozzilli (IS)	4	0.3	87.0
88	SICOG - Southern Italy Cooperative Oncology Group (Naples)	4	0.3	87.2
89	A.O. Cardarelli of Naples	3	0.2	87.4
90	A.O. Monaldi of Naples	3	0.2	87.6
91	A.O. Ospedale of Asola (MN)	3	0.2	87.8
92	AISSM - Associazione Italiana Studio Sindromi Mielodisplastiche (Alessandria)	3	0.2	88.0
93	ASL 2 Savonese of Savona	3	0.2	88.2
94	AUSL 4 of Prato	3	0.2	88.4
95	AUSL 6 of Livorno	3	0.2	88.6
96	AUSL 8 of Arezzo	3	0.2	88.9
97	AUSL of Rimini	3	0.2	89.1
98	Associazione QOL - ONE (Pellaro, RC)	3	0.2	89.3



	No profit Sponsor	CT	%	cum. %
99	GIMURELL - Gruppo Italiano MULTiREgionale per lo studio dei Linfomi e delle Leucemie (Turin)	3	0.2	89.5
100	IOR - Istituto Oncologico Romagnolo (Forlì)	3	0.2	89.7
101	IRCCS Centro Cardiologico Monzino of Milan	3	0.2	89.9
102	IRCCS Fondazione Istituto Neurologico Mondino of Pavia	3	0.2	90.1
103	IRCCS Istituto Oncologico Veneto (IOV) of Padova	3	0.2	90.3
104	IRCCS Policlinico S. Donato of S. Donato Milanese (MI)	3	0.2	90.5
105	Kuros Biosurgery (Switzerland)	3	0.2	90.7
106	Ospedale Sacro Cuore - Don Calabria of Negrar (VR)	3	0.2	90.9
107	Turin University	3	0.2	91.1
108	A.O. Ospedale Fatebenefratelli e Oftalmico of Milan	2	0.1	91.2
109	A.O. Ospedale S. Filippo Neri of Rome	2	0.1	91.4
110	A.O. Universitaria Arcispedale S. Anna of Ferrara	2	0.1	91.5
111	AFaR - Associazione Fatebenefratelli per la Ricerca (Rome)	2	0.1	91.6
112	AIEOP - Associazione Italiana Ematologia Oncologia Pediatrica (BO)	2	0.1	91.8
113	ASL of Salerno	2	0.1	91.9
114	AULSS 16 of Padova	2	0.1	92.0
115	AULSS 9 of Treviso	2	0.1	92.2
116	AUSL 9 of Grosseto	2	0.1	92.3
117	AUSL LE of Lecce	2	0.1	92.4
118	AUSL of Forlì	2	0.1	92.6
119	CINBO - Consorzio Interuniversitario Nazionale per la Bio-Oncologia (Chieti)	2	0.1	92.7
120	Centro Studi FADOI - Federazione delle Associazioni dei Dirigenti Ospedalieri Internisti (Rome)	2	0.1	92.8
121	EMN - European Myeloma Network (Denmark)	2	0.1	93.0
122	Fondazione Nadir (Rome)	2	0.1	93.1
123	HCF - Fondazione Italiana per la Lotta alle Malattie Cardiovascolari (Florence)	2	0.1	93.2
124	IBCSG - International Breast Cancer Study Group (Switzerland)	2	0.1	93.4
125	IELSG - International Extranodal Lymphoma Study Group (Switzerland)	2	0.1	93.5
126	IRCCS Centro di Riferimento Oncologico di Basilicata (CROB) of Rionero in Vulture (PZ)	2	0.1	93.6
127	IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Ancona	2	0.1	93.8
128	IRCCS Ospedale Casa Sollievo della Sofferenza of S. Giovanni Rotondo (FG)	2	0.1	93.9



	No profit Sponsor	CT	%	cum. %
129	IRCCS Ospedale Pediatrico del Bambino Gesù (OPBG) of Rome	2	0.1	94.1
130	Regione Lombardia - Direzione Generale Sanità	2	0.1	94.2
131	A.O. Bianchi - Melacrino - Morelli of Reggio Calabria	1	0.1	94.3
132	A.O. Brotzu of Cagliari	1	0.1	94.3
133	A.O. Civico - Di Cristina - Benfratelli of Palermo	1	0.1	94.4
134	A.O. Istituto Mediterraneo Trapianti e Terapie ad alta specializzazione (IsMeTT) of Palermo	1	0.1	94.5
135	A.O. OIRM/S. Anna of Turin	1	0.1	94.5
136	A.O. Ospedale Salvini di Garbagnate Milanese (MI)	1	0.1	94.6
137	A.O. Ospedale of Busto Arsizio (VA)	1	0.1	94.7
138	A.O. S. Anna e S. Sebastiano of Caserta	1	0.1	94.7
139	A.O. S. Paolo of Milan	1	0.1	94.8
140	A.O. Universitaria Integrata di Verona - Centro Ricerche Cliniche (CRC)	1	0.1	94.9
141	A.O. Universitaria Ospedali Riuniti of Trieste	1	0.1	94.9
142	A.O. Universitaria Policlinico - Vittorio Emanuele - Centro per la prevenzione e cura del Tabagismo (Catania)	1	0.1	95.0
143	A.O. Universitaria Policlinico - Vittorio Emanuele of Catania	1	0.1	95.1
144	AIL - Associazione Italiana contro le Leucemie-linfomi e Mielomi (Palermo)	1	0.1	95.1
145	AIOT - Associazione Italiana Oncologia Toracica (Rome)	1	0.1	95.2
146	AIPO - Associazione Italiana Pneumologi Ospedalieri (Milan)	1	0.1	95.3
147	AISAR - Associazione Italiana per lo Studio degli Antimicrobici e delle Resistenze (Milan)	1	0.1	95.3
148	AISD - Associazione Italiana per lo Studio del Dolore (L'Aquila)	1	0.1	95.4
149	AISF - Associazione Italiana per lo Studio del Fegato (Rome)	1	0.1	95.5
150	AME - Associazione Medici Endocrinologi (Udine)	1	0.1	95.5
151	AMS - Associazione Malattie del Sangue (Milan)	1	0.1	95.6
152	ARCO - Associazione per la Ricerca Clinica Oncologica (Vecchiano, PI)	1	0.1	95.7
153	ARNAS Garibaldi of Catania	1	0.1	95.7
154	ARTBC - Association Internationale pour la Recherche sur le Temps Biologique et la Chronothérapie (France)	1	0.1	95.8
155	ASL 1 Umbria of Città di Castello (PG)	1	0.1	95.9
156	ASL 3 Genovese of Genoa	1	0.1	95.9
157	ASL 3 Umbria of Foligno (PG)	1	0.1	96.0
158	ASL AT of Asti	1	0.1	96.1



	No profit Sponsor	CT	%	cum. %
159	ASL BI of Biella	1	0.1	96.1
160	ASL CN/1 of Cuneo	1	0.1	96.2
161	ASL della Provincia of Brescia	1	0.1	96.3
162	ASL of Sassari	1	0.1	96.4
163	ASREM - Zona Territoriale of Campobasso	1	0.1	96.4
164	ASUR - Zona Territoriale 5 of Jesi (AN)	1	0.1	96.5
165	AULSS 6 of Vicenza	1	0.1	96.6
166	AUSL 2 of Lucca	1	0.1	96.6
167	AUSL BA of Bari	1	0.1	96.7
168	AUSL RM/C of Rome	1	0.1	96.8
169	AUSL of Bologna	1	0.1	96.8
170	AUSL of Imola (BO)	1	0.1	96.9
171	AVAPO Ricerche - Associazione Volontari Assistenza Pazienti Oncologici (Venice)	1	0.1	97.0
172	Assistance publique Hôpitaux de Paris/Délégation à la recherche clinique et au développement (France)	1	0.1	97.0
173	Associazione SNO - Scienze Neurologiche Ospedaliere (Bologna)	1	0.1	97.1
174	Associazione italiana endocrinologia-metabolismo-ipofisi (Naples)	1	0.1	97.2
175	CHIP - Copenhagen HIV Program (Denmark)	1	0.1	97.2
176	CIPOMO - Collegio Italiano dei Primari Oncologi Medici Ospedalieri (Milan)	1	0.1	97.3
177	Cambridge University Hospitals NHS Foundation Trust (UK)	1	0.1	97.4
178	Conrad (USA)	1	0.1	97.4
179	FFCD - Fédération Francophone de Cancérologie Digestive (France)	1	0.1	97.5
180	FPP - Fondazione Paolo Procacci (Rome)	1	0.1	97.6
181	Fondazione Evidence (Milan)	1	0.1	97.6
182	Fondazione Franco e Piera Cutino (Palermo)	1	0.1	97.7
183	Fondazione Humanitas per la Ricerca (Rozzano, MI)	1	0.1	97.8
184	Fondazione Istituto S. Raffaele - Giglio of Cefalù (PA)	1	0.1	97.8
185	Fondazione Italiana Giambone per la guarigione dalla Talassemia (Castelvoturno, CE)	1	0.1	97.9
186	Fondazione Malattie Rare Baschirotto - Istituto BIRD Europe (Costozza di Longare, VI)	1	0.1	98.0
187	Fondazione SENDO - Southern Europe New Drug Organization (MI)	1	0.1	98.0
188	GITMO - Gruppo Italiano per il Trapianto di Midollo Osseo (Genoa)	1	0.1	98.1



	No profit Sponsor	CT	%	cum. %
189	Hospice Il Gelso of Alessandria	1	0.1	98.2
190	IRCCS Ospedale Oncologico of Bari	1	0.1	98.2
191	IRCCS S. Raffaele Pisana of Rome	1	0.1	98.3
192	Imperial College London (UK)	1	0.1	98.4
193	Istituto Casa di cura Abano Terme of Abano Terme (PD)	1	0.1	98.4
194	LILT - Lega Italiana per la Lotta contro i Tumori (Rome)	1	0.1	98.5
195	Medical Research Council (UK)	1	0.1	98.6
196	Medstar Research Institute/Cardiovascular Research Institute (USA)	1	0.1	98.6
197	Mukoviszidose (Germany)	1	0.1	98.7
198	NIBIT - Network Italiano per la Bio-Immunoterapia dei Tumori	1	0.1	98.8
199	ORVACS - Objectif Recherche VACCin Sida (Paris)	1	0.1	98.9
200	Ospedale Civile S. Salvatore of L'Aquila	1	0.1	98.9
201	Ospedale Clinicizzato SS. Annunziata of Chieti	1	0.1	99.0
202	Ospedale Israelitico of Rome	1	0.1	99.1
203	Ospedale S. Croce of Fano (PU)	1	0.1	99.1
204	Ospedali Civili of Lione (France)	1	0.1	99.2
205	Regensburg University Medical Centre (Germany)	1	0.1	99.3
206	SAKK - Gruppo Svizzero di Ricerca Clinica sul cancro (Switzerland)	1	0.1	99.3
207	SIA - Società Italiana di Andrologia (Rome)	1	0.1	99.4
208	SIGG - Società Italiana di Gerontologia e Geriatria (Florence)	1	0.1	99.5
209	Spanish Lung Canger Group (Spain)	1	0.1	99.5
210	TrialNet Study Group (USA)	1	0.1	99.6
211	University Children's Hospital Tuebingen (Germany)	1	0.1	99.7
212	D'Annunzio University of Chieti	1	0.1	99.7
213	Genoa University	1	0.1	99.8
214	Sassari University	1	0.1	99.9
215	Yale University (USA)	1	0.1	99.9
216	VAS - Vascular Independent Research and Education European Organization (Milan)	1	0.1	100.0
	Total	1,480	100.0	

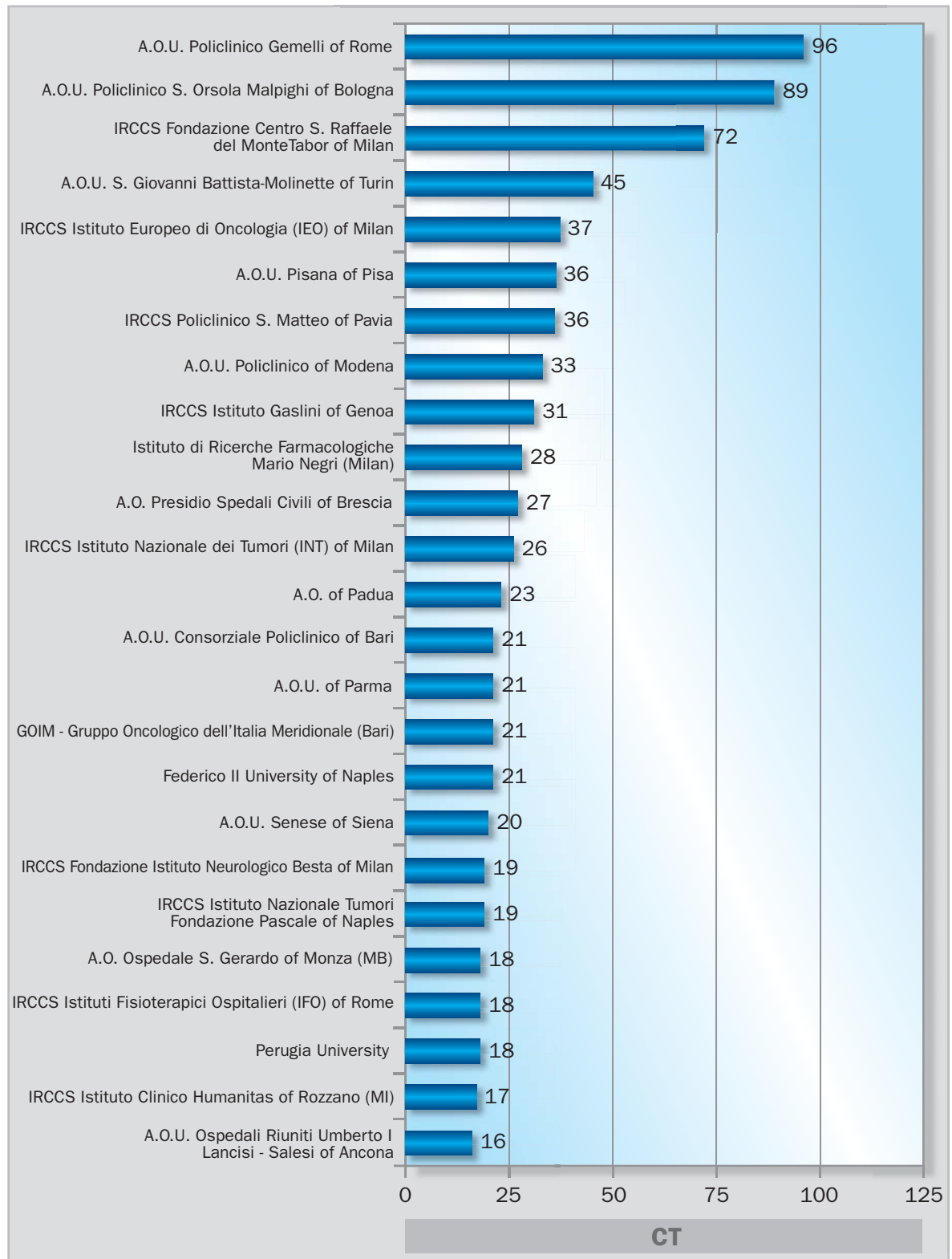
The data regarding Sponsors, their names and clinical trials associated to them, take into consideration any registered office's variation, merger, acquisition and/or incorporation.



Chart G

Clinical trials per no profit Sponsor

The first 25 out of 216 no profit Sponsors (11.6%) represent 54.6% of the clinical trials



**Table 41****Clinical trials per typology of participating centre**

Total CT: 3,863

Typology	CT	% of tot. CT (3,863)	Centres involved
University hospital, University polyclinic and University	2,898	75.0	74
Hospital structure *	2,327	60.2	538
Public or private Scientific institute for research and care (IRCCS)	2,181	56.5	60
Local health unit	633	16.4	148
Private centre **	224	5.8	37
Research institute	55	1.4	5

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

** Recognised suitable for running clinical trials of drugs

Table 42**Clinical trials per typology of participating centre and phase**

Total CT: 3,863

Typology	CT	%					
		Phase I	Phase II	Phase III	Phase IV	Bioeq/Biod	Total
University hospital, University polyclinic and University	2,898	3.5	35.0	47.9	12.2	2.5	100.0
Hospital structure *	2,327	2.7	34.4	53.0	9.8	0.4	100.0
Public or private Scientific institute for research and care (IRCCS)	2,181	5.3	37.6	49.5	7.7	1.1	100.0
Local health unit	633	1.3	28.0	58.1	12.6	1.3	100.0
Private centre **	224	0.4	30.4	64.7	3.6	2.7	100.0
Research institute	55	3.6	20.0	67.3	9.1	0.0	100.0

* Hospitals, hospitals under self-administration, assimilated or classified hospitals, private qualified health institutes acting as local hospitals, military hospital

** Recognised suitable for running clinical trials of drugs

In both tables, multi-centre clinical trials are carried out in more than one centre, and therefore the same study shall be counted in more than one typology of centre.

**Chart H*****Clinical trials per participating centre's region***

Total CT: 3,863



Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted in more than one region.

**Table 43*****Clinical trials per participating centre's province***

Total CT: 3,863

First 20 provinces out of 109

	Province	CT	% of tot. CT (3,863)	Centres involved	Average CT per centre	CT coord.	% CT coord. / total
1	Milan	1,765	45.7	46	59	800	45.3
2	Rome	1,608	41.6	59	44	529	32.9
3	Turin	833	21.6	32	33	187	22.5
4	Genoa	805	20.8	14	64	191	23.7
5	Naples	764	19.8	31	31	120	15.7
6	Bologna	725	18.8	11	69	281	38.8
7	Pavia	572	14.8	12	52	148	25.9
8	Florence	566	14.7	15	40	96	17.0
9	Padova	499	12.9	14	37	65	13.0
10	Pisa	480	12.4	8	62	187	39.0
11	Modena	431	11.2	9	51	75	17.4
12	Palermo	427	11.1	20	26	29	6.8
13	Bari	410	10.6	15	29	48	11.7
14	Catania	405	10.5	14	33	48	11.9
15	Brescia	390	10.1	18	24	67	17.2
16	Perugia	377	9.8	13	31	69	18.3
17	Bergamo	335	8.7	10	39	63	18.8
18	Siena	329	8.5	6	56	94	28.6
19	Ancona	325	8.4	14	25	54	16.6
20	Parma	293	7.6	5	61	49	16.7

Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted in more than one province in the "CT" column.

In the column "Centres involved" the number of centres participating in clinical trials is reported for each province. In this case each centre is counted only once, even if it is participating in more than one trial.

The numbers reported in the "Average CT per centre" column represent the average number of clinical trials each centre is carrying out per province. This number is calculated summing the studies performed in each centre, divided by the number of centres involved (see Table "Clinical trials per participating centre ordered by region and province").

The "CT coord." column reports the number of clinical trials whose coordinating centre is in the province (the sum of this column in the complete table corresponds to the national sample being one coordinating centre per clinical trial).

**Table 44*****Clinical trials per participating centre***

Total CT: 3,863

First 50 centres out of 862

	Centre	CT	% of tot. CT (3,863)	CT coord.	% CT coord./ total
1	IRCCS Fondazione Centro S. Raffaele del Monte Tabor of Milan	565	14.6	238	42.1
2	A.O. Universitaria Policlinico S. Orsola Malpighi of Bologna	556	14.4	215	38.7
3	A.O. Universitaria Policlinico Gemelli of Rome	444	11.5	146	32.9
4	A.O. Universitaria Pisana of Pisa	429	11.1	168	39.2
5	A.O. Universitaria S. Martino of Genova	424	11.0	75	17.7
6	A.O. Universitaria Careggi of Firenze	418	10.8	74	17.7
7	IRCCS Policlinico S. Matteo of Pavia	383	9.9	98	25.6
8	A.O. Universitaria S. Giovanni Battista-Molinette of Torino	363	9.4	98	27.0
9	A.O. Universitaria Policlinico of Modena	338	8.7	58	17.2
10	A.O. Universitaria Policlinico Umberto I of Rome	337	8.7	53	15.7
11	A.O. of Padova	314	8.1	49	15.6
12	A.O. Presidio Spedali Civili of Brescia	312	8.1	60	19.2
13	A.O. Universitaria Federico II of Naples	310	8.0	51	16.5
14	A.O. Ospedale Niguarda Ca' Granda of Milan	304	7.9	47	15.5
15	A.O. of Perugia	295	7.6	45	15.3
16	A.O. Universitaria Consorziale Policlinico of Bari	292	7.6	28	9.6
17	A.O. Ospedali Riuniti of Bergamo	265	6.9	49	18.5
18	A.O. Universitaria Senese of Siena	248	6.4	73	29.4
19	IRCCS Istituto Nazionale dei Tumori (INT) of Milan	241	6.2	140	58.1
20	A.O. Universitaria S. Luigi Gonzaga of Orbassano (TO)	234	6.1	60	25.6
21	A.O. Universitaria of Parma	234	6.1	38	16.2
22	IRCCS Istituto Clinico Humanitas of Rozzano (MI)	230	6.0	57	24.8
23	A.O. Universitaria S. Maria della Misericordia of Udine	226	5.9	26	11.5
24	Fondazione PTV Policlinico Tor Vergata of Rome	221	5.7	52	23.5
25	A.O. S. Camillo - Forlanini of Rome	215	5.6	56	26.0
26	A.O. Ospedale S. Gerardo of Monza (MB)	213	5.5	39	18.3
27	A.O. Universitaria Policlinico Giaccone of Palermo	207	5.4	12	5.8
28	IRCCS Ospedale Maggiore Policlinico of Milan	201	5.2	59	29.4



	Centre	CT	% of tot. CT (3,863)	CT coord.	% CT coord./total
29	IRCCS Istituto Europeo di Oncologia (IEO) of Milan	200	5.2	86	43.0
30	A.O. Universitaria Arcispedale S. Anna of Ferrara	195	5.0	20	10.3
31	A.O. Arcispedale S. Maria Nuova of Reggio Emilia	185	4.8	20	10.8
32	A.O. Universitaria Maggiore della Carità of Novara	177	4.6	23	13.0
33	A.O. Ospedale Sacco of Milan	175	4.5	31	17.7
34	Università D'Annunzio of Chieti	175	4.5	58	33.1
35	A.O. Universitaria Ospedali Riuniti - Ospedale Umberto I of Ancona	167	4.3	29	17.4
36	IRCCS Ospedale Casa Sollievo della Sofferenza of S. Giovanni Rotondo (FG)	158	4.1	6	3.8
37	A.O. Universitaria - P.O. Vittorio Emanuele e Ferrarotto of Catania	155	4.0	11	7.1
38	A.O. Universitaria S. Andrea of Rome	153	4.0	23	15.0
39	IRCCS Istituto Nazionale per la Ricerca sul Cancro (IST) of Genoa	151	3.9	32	21.2
40	IRCCS Istituto Regina Elena (IFO) of Rome	150	3.9	32	21.3
41	A.O. Cardarelli of Naples	149	3.9	12	8.1
42	A.O. Ospedale S. Paolo of Milan	143	3.7	18	12.6
43	A.O. Universitaria Policlinico Martino of Messina	137	3.5	3	2.2
44	IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	135	3.5	31	23.0
45	IRCCS Centro di Riferimento Oncologico (CRO) of Aviano (PN)	134	3.5	15	11.2
46	A.O. Universitaria Seconda Università of Naples	132	3.4	19	14.4
47	Università La Sapienza of Rome	124	3.2	20	16.1
48	A.O. Universitaria - P.O. Rodolico of Catania	121	3.1	32	26.4
49	A.O. Bianchi - Melacrino - Morelli of Reggio Calabria	117	3.0	4	3.4
50	IRCCS Fondazione Maugeri - Istituto of Pavia	113	2.9	30	26.5

Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted more than once in the "CT" column.

The column "CT coord." reports the number of clinical trials for which the centre acts as coordinating centre (the sum of this column in the complete table corresponds to the national sample being one coordinating centre per clinical trial).

**Table 45*****Clinical trials per participating centre ordered by region and province***

Total CT: 3,863

Centres: 862

Centre	CT	% on Region	% on Province
Lombardy	2,270		
Province of Milan	1,765	77.8	
IRCCS Fondazione Centro S. Raffaele del Monte Tabor of Milan	565	24.9	32.0
A.O. Ospedale Niguarda Ca' Granda of Milan	304	13.4	17.2
IRCCS Istituto Nazionale dei Tumori (INT) of Milan	241	0.6	13.7
IRCCS Istituto Clinico Humanitas of Rozzano	230	10.1	13.0
IRCCS Ospedale Maggiore Policlinico of Milan	201	8.9	11.4
IRCCS Istituto Europeo di Oncologia (IEO) of Milan	200	8.8	11.3
A.O. Ospedale Sacco of Milan	175	7.7	9.9
A.O. Ospedale S. Paolo of Milan	143	6.3	8.1
IRCCS Cliniche Mangiagalli e Regina Elena of Milan	86	3.8	4.9
IRCCS Fondazione Istituto Neurologico Besta of Milan	72	3.2	4.1
A.O. Ospedale of Legnano	46	2.0	2.6
A.O. Ospedale Fatebenefratelli e Oftalmico of Milan	43	1.9	2.4
A.O. Istituto Ortopedico Pini of Milan	42	1.9	2.4
IRCCS Centro Cardiologico Monzino of Milan	37	1.6	2.1
IRCCS Policlinico S. Donato of S. Donato Milanese	31	1.4	1.8
A.O. Ospedale S. Carlo Borromeo of Milan	30	1.3	1.7
S. Raffaele Turro of Milan	24	1.1	1.4
Ospedale S. Giuseppe Fatebenefratelli of Milan	23	1.0	1.3
IRCCS Multimedica of Sesto S. Giovanni	22	1.0	1.2
IRCCS Istituto Auxologico Italiano - Ospedale S. Luca of Milan	21	0.9	1.2
A.O. Ospedale Salvini of Garbagnate Milanese	18	0.8	1.0
A.O. Città of Sesto S. Giovanni (ICP)	15	0.7	0.8
IRCCS Istituto Ortopedico Galeazzi of Milan	15	0.7	0.8
A.O. Centro Traumatologico Ortopedico (ICP) of Milan	13	0.6	0.7
A.O. Ospedale dei bambini Buzzi (ICP) of Milan	12	0.5	0.7
IRCCS Fondazione Don Gnocchi - Centro S. Maria Nascente of Milan	12	0.5	0.7
A.O. Ospedale Serbelloni of Gorgonzola	11	0.5	0.6



Centre	CT	% on Region	% on Province
A.O. Ospedale Caduti Bollatesi of Bollate	10	0.4	0.6
A.O. Ospedale Casati di Passirana of Rho	10	0.4	0.6
IRCCS Istituto Auxologico Italiano - Ospedale S. Michele of Milan	10	0.4	0.6
A.O. Istituti Clinici di Perfezionamento (ICP) of Milan	9	0.4	0.5
Università of Milan	9	0.4	0.5
A.O. Ospedale Bassini (ICP) of Cinisello Balsamo	7	0.3	0.4
A.O. Ospedale di Circolo of Rho	7	0.3	0.4
A.O. Ospedale di Circolo of Vizzolo Predabissi	7	0.3	0.4
A.O. Ospedale Melloni of Milan	6	0.3	0.3
A.O. Causa Pia Ospitaliera Uboldo of Cernusco sul Naviglio	5	0.2	0.3
A.O. Ospedale of Abbiategrasso	4	0.2	0.2
A.O. Ospedale Fornaroli of Magenta	4	0.2	0.2
ASL Città of Milan	4	0.2	0.2
ASL della Provincia di Milano 2 of Melegnano	4	0.2	0.2
Casa di cura Ambrosiana of Cesano Boscone	2	0.1	0.1
Casa di cura IGEA of Milan	2	0.1	0.1
Centro ambulatoriale del Pio Albergo Trivulzio of Milan	2	0.1	0.1
A.O. Presidio Zappatoni of Cassano d'Adda	1	0.0	0.1
DUAM - Discipline Urologiche-Andrologiche Milanesi of Milan	1	0.0	0.1
Province of Pavia	572	25.2	
IRCCS Policlinico S. Matteo of Pavia	383	16.9	67.0
IRCCS Fondazione Maugeri - Istituto of Pavia	113	5.0	19.8
IRCCS Fondazione Istituto Neurologico Mondino of Pavia	66	2.9	11.5
A.O. Ospedale Arnaboldi of Broni	19	0.8	3.3
Università of Pavia	14	0.6	2.4
A.O. Ospedale Mira of Casorate Primo	12	0.5	2.1
IRCCS Fondazione Maugeri - Istituto of Montescano	6	0.3	1.0
A.O. Ospedale Civile of Vigevano	4	0.2	0.7
A.O. Ospedale Civile of Voghera	4	0.2	0.7
A.O. Nuovo Ospedale unificato of Broni-Stradella	2	0.1	0.3
Casa di cura Beato Matteo of Vigevano	2	0.1	0.3
ASL della Provincia of Pavia	1	0.0	0.2
Province of Brescia	390	17.2	
A.O. Presidio Spedali Civili of Brescia	312	13.7	80.0



Centre	CT	% on Region	% on Province
Istituto Ospedaliero Fondazione Poliambulanza of Brescia	29	1.3	7.4
IRCCS Centro S. Giovanni di Dio Fatebenefratelli of Brescia	17	0.7	4.4
A.O. Ospedale dei bambini Umberto I of Brescia	9	0.4	2.3
Ospedale S. Orsola Fatebenefratelli of Brescia	9	0.4	2.3
A.O. Ospedale of Manerbio	7	0.3	1.8
Istituto Clinico S. Anna of Brescia	7	0.3	1.8
A.O. Presidio of Montichiari	6	0.3	1.5
IRCCS Fondazione Maugeri - Istituto of Lumezzane	5	0.2	1.3
Università of Brescia	5	0.2	1.3
ASL della Provincia of Brescia	4	0.2	1.0
Ospedale Valcamonica of Esine	3	0.1	0.8
A.O. Ospedale Civile of Iseo	2	0.1	0.5
A.O. Ospedale Civile La Memoria of Gavardo	2	0.1	0.5
A.O. Ospedale of Desenzano del Garda	2	0.1	0.5
A.O. Ospedale Mellini of Chiari	2	0.1	0.5
A.O. Ospedale of Leno	1	0.0	0.3
A.O. Presidio of Gardone Val Trompia	1	0.0	0.3
Province of Bergamo	335	14.8	
A.O. Ospedali Riuniti of Bergamo	265	11.7	79.1
A.O. Ospedale di Treviglio-Caravaggio of Treviglio	71	3.1	21.2
A.O. Ospedali Riuniti of Bergamo - Public-private department of immunology of transplants and innovative transplant anti-rejection therapies	13	0.6	3.9
Humanitas Gavazzeni of Bergamo	11	0.5	3.3
A.O. Ospedale Bolognini of Seriate	8	0.4	2.4
A.O. Ospedale Pesenti Fenaroli of Alzano Lombardo	6	0.3	1.8
Policlinico S. Marco of Osio Sotto	6	0.3	1.8
A.O. Ospedale SS. Trinità of Romano di Lombardia	3	0.1	0.9
ASL della Provincia of Bergamo	1	0.0	0.3
Centro ambulatoriale della Clinica Castelli of Bergamo	1	0.0	0.3
Province of Monza and Brianza	254	11.2	
A.O. Ospedale S. Gerardo of Monza	213	9.4	83.9
A.O. Ospedale of Vimercate	22	1.0	8.7
Policlinico di Monza of Monza	15	0.7	5.9
A.O. Ospedale of Desio	7	0.3	2.8
ASL della Provincia of Monza and Brianza	5	0.2	2.0



Centre	CT	% on Region	% on Province
IRCCS Fondazione Maugeri - Istituto of Lissone	2	0.1	0.8
A.O. Ospedale Trabattoni Ronzoni of Seregno	1	0.0	0.4
A.O. Ospedale Vittorio Emanuele III of Carate Brianza	1	0.0	0.4
Province of Varese	228	10.0	
A.O. Ospedale di Circolo e Fondazione Macchi of Varese	111	4.9	48.7
A.O. Ospedale of Busto Arsizio	45	2.0	19.7
A.O. Ospedale S. Antonio Abate of Gallarate	36	1.6	15.8
A.O. Ospedale of Saronno	27	1.2	11.8
A.O. Ospedale Del Ponte of Varese	10	0.4	4.4
IRCCS Fondazione Maugeri - Istituto of Tradate	8	0.4	3.5
Casa di cura S. Maria of Castellanza	7	0.3	3.1
A.O. Ospedale Bellini of Somma Lombardo	6	0.3	2.6
ASL della Provincia of Varese	3	0.1	1.3
Humanitas Mater Domini of Castellanza	2	0.1	0.9
A.O. Ospedale of Cuasso al Monte	1	0.0	0.4
Province of Cremona	112	4.9	
A.O. Istituti Ospitalieri of Cremona	99	4.4	88.4
A.O. Ospedale Maggiore of Crema	14	0.6	12.5
A.O. Ospedale S. Marta of Rivolta d'Adda	1	0.0	0.9
Casa di cura Ancelle della Carità of Cremona	1	0.0	0.9
Province of Lecco	98	4.3	
A.O. Ospedale Manzoni of Lecco	87	3.8	88.8
ASL della Provincia of Lecco	4	0.2	4.1
A.O. Ospedale S. Leopoldo Mandic of Merate	3	0.1	3.1
IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Casatenovo	2	0.1	2.0
IRCCS Medea - Associazione La Nostra Famiglia of Bosisio Parini	2	0.1	2.0
Presidio di riabilitazione Villa Beretta of Costa Masnaga	2	0.1	2.0
Province of Como	93	4.1	
A.O. Ospedale S. Anna of Como	69	3.0	74.2
Ospedale Generale di zona Valduce of Como	19	0.8	20.4
A.O. Ospedale S. Antonio Abate of Cantù	6	0.3	6.5
A.O. Ospedale Villa of Mariano Comense	2	0.1	2.2
Ospedale Sacra Famiglia Fatebenefratelli of Erba	2	0.1	2.2
A.O. Ospedale Erba-Renaldi of Menaggio	1	0.0	1.1



Centre	CT	% on Region	% on Province
ASL della Provincia of Como	1	0.0	1.1
Ospedale Moriggia Pelascini of Gravedona	1	0.0	1.1
Province of Mantova	83	3.7	
A.O. Ospedale Poma of Mantova	79	3.5	95.2
A.O. Ospedale Civile Destra Secchia di Pieve of Coriano	2	0.1	2.4
A.O. Ospedale of Asola	1	0.0	1.2
ASL della Provincia of Mantova	1	0.0	1.2
IRCCS Fondazione Maugeri - Istituto of Castel Goffredo	1	0.0	1.2
Province of Sondrio	50	2.2	
A.O. Ospedale of Sondrio	30	1.3	60.0
A.O. Ospedale Morelli of Sondalo	24	1.1	48.0
A.O. Ospedale of Morbegno	1	0.0	2.0
ASL della Provincia of Sondrio	1	0.0	2.0
Province of Lodi	29	1.3	
A.O. Ospedale Maggiore of Lodi	16	0.7	55.2
A.O. Ospedale of Casalpusterlengo	4	0.2	13.8
A.O. Ospedale of Codogno	4	0.2	13.8
ASL della Provincia of Lodi	4	0.2	13.8
A.O. Ospedale of S. Angelo Lodigiano	1	0.0	3.4
Lazio	1,632		
Province of Rome	1,608	98.5	
A.O. Universitaria Policlinico Gemelli of Rome	444	27.2	27.6
A.O. Universitaria Policlinico Umberto I of Rome	337	20.6	21.0
Fondazione PTV Policlinico Tor Vergata of Rome	221	13.5	13.7
A.O. S. Camillo - Forlanini of Rome	215	13.2	13.4
A.O. Universitaria S. Andrea of Rome	153	9.4	9.5
IRCCS Istituto Regina Elena (IFO) of Rome	150	9.2	9.3
Università La Sapienza of Rome	124	7.6	7.7
IRCCS S. Raffaele Pisana of Rome	89	5.5	5.5
A.O. Universitaria Policlinico Campus Bio-Medico of Rome	82	5.0	5.1
IRCCS Ospedale Pediatrico del Bambino Gesù (OPBG) of Rome	73	4.5	4.5
Università Tor Vergata of Rome	65	4.0	4.0
Ospedale S. Eugenio of Rome	64	3.9	4.0
IRCCS Istituto Nazionale Malattie Infettive Spallanzani of Rome	62	3.8	3.9
Ospedale S. Giovanni Calibita Fatebenefratelli of Rome	51	3.1	3.2



Centre	CT	% on Region	% on Province
A.O. Ospedale S. Filippo Neri of Rome	49	3.0	3.0
A.O. S. Giovanni-Addolorata of Rome	48	2.9	3.0
IRCCS Istituto Dermopatico dell'Immacolata (IDI) of Rome	39	2.4	2.4
IRCCS Fondazione S. Lucia of Rome	24	1.5	1.5
A.O. Universitaria Complesso Integrato Columbus of Rome	23	1.4	1.4
Ospedale Pertini of Rome	22	1.3	1.4
Ospedale Regina Apostolorum of Albano Laziale	22	1.3	1.4
IRCCS Istituto dermatologico S. Gallicano (IFO) of Rome	19	1.2	1.2
Ospedale S. Pietro Fatebenefratelli of Rome	17	1.0	1.1
IRCCS Fondazione Bietti of Rome	16	1.0	1.0
Ospedale S. Giovanni Battista del Sovrano Militare Ordine di Malta of Rome	14	0.9	0.9
AUSL RM/B of Rome	12	0.7	0.7
Ospedale Grassi of Ostia	12	0.7	0.7
AUSL RM/C of Rome	10	0.6	0.6
Policlinico Casilino of Rome	10	0.6	0.6
AUSL RM/E of Rome	7	0.4	0.4
IRCCS Istituti Fisioterapici Ospitalieri (IFO) of Rome	7	0.4	0.4
Ospedale of Albano Laziale	6	0.4	0.4
Ospedale Parodi Delfino of Colferro	6	0.4	0.4
Ospedale S. Giacomo of Rome	6	0.4	0.4
Ospedali Riuniti of Anzio and Nettuno	6	0.4	0.4
AUSL RM/H of Albano Laziale	5	0.3	0.3
Istituto Superiore di Sanità of Rome	5	0.3	0.3
Ospedale Israelitico of Rome	5	0.3	0.3
Ospedale S. Giovanni Evangelista of Tivoli	5	0.3	0.3
AUSL RM/A of Rome	4	0.2	0.2
AUSL RM/G of Tivoli	4	0.2	0.2
IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Rome	4	0.2	0.2
IRCCS Ospedale Pediatrico del Bambino Gesù (OPBG) of Palidoro	4	0.2	0.2
Presidio Territoriale di Prossimità Nuovo Regina Margherita of Rome	4	0.2	0.2
Ospedale Civile S. Paolo of Civitavecchia	3	0.2	0.2



Centre	CT	% on Region	% on Province
Ospedale S. Carlo of Rome	3	0.2	0.2
Ospedale S. Giuseppe of Marino	3	0.2	0.2
Ospedale S. Spirito of Rome	3	0.2	0.2
Policlinico Militare Celio of Rome	3	0.2	0.2
AUSL RM/D of Rome	2	0.1	0.1
Ospedale CTO Alesini of Rome	2	0.1	0.1
Ospedale Madre Giuseppina Vannini of Rome	2	0.1	0.1
AUSL RM/F of Civitavecchia	1	0.1	0.1
Casa di cura S. Valentino of Rome	1	0.1	0.1
Centro Dialisi Diaverum Italia of Ladispoli	1	0.1	0.1
Ospedale Cartoni of Rocca Priora	1	0.1	0.1
Ospedale Civile of Bracciano	1	0.1	0.1
Ospedale Cristo Re of Rome	1	0.1	0.1
Ospedale S. Sebastiano of Frascati	1	0.1	0.1
Province of Latina	55	3.4	
Ospedale S. Maria Goretti of Latina	32	2.0	58.2
Ospedale Fiorini of Terracina	14	0.9	25.5
ICOT - Istituto Chirurgico Ortopedico Traumatologico of Latina	9	0.6	16.4
Ospedale Don Di Liegro of Gaeta	6	0.4	10.9
AUSL of Latina	2	0.1	3.6
Ospedale Regina Elena of Priverno	1	0.1	1.8
Province of Frosinone	43	2.6	
Ospedale Civile SS. Trinità nuova sede of Sora	16	1.0	37.2
S. Raffaele of Cassino	11	0.7	25.6
AUSL of Frosinone	6	0.4	14.0
Ospedale Umberto I of Frosinone	6	0.4	14.0
Ospedale Civile of Ceccano	2	0.1	4.7
Ospedale Civile Del Prete of Pontecorvo	2	0.1	4.7
Province of Viterbo	35	2.1	
Ospedale of Belcolle	27	1.7	77.1
Ospedale of Ronciglione	4	0.2	11.4
AUSL of Viterbo	3	0.2	8.6
Ospedale of Civita Castellana	2	0.1	5.7
Province of Rieti	5	0.3	
Ospedale S. Camillo de Lellis of Rieti	4	0.2	80.0



Centre	CT	% on Region	% on Province
AUSL of Rieti	1	0.1	20.0
Emilia-Romagna	1,474		
Province of Bologna	725	49.2	
A.O. Universitaria Policlinico S. Orsola Malpighi of Bologna	556	37.7	76.7
Ospedale Bellaria of Bologna	54	3.7	7.4
Università di Bologna	51	3.5	7.0
IRCCS Istituto Ortopedico Rizzoli (IOR) of Bologna	39	2.6	5.4
Ospedale Maggiore Pizzardi of Bologna	24	1.6	3.3
AUSL of Bologna	20	1.4	2.8
AUSL of Imola	5	0.3	0.7
Ospedale of Bentivoglio	5	0.3	0.7
Montecatone Rehabilitation Institute of Imola	3	0.2	0.4
Ospedale of Imola	3	0.2	0.4
Ospedale privato Nigrisoli of Bologna	1	0.1	0.1
Province of Modena	431	29.2	
A.O. Universitaria Policlinico of Modena	338	22.9	78.4
Ospedale of Carpi	40	2.7	9.3
Università di Modena	38	2.6	8.8
Nuovo Ospedale S. Agostino - Estense of Modena	17	1.2	3.9
AUSL of Modena	9	0.6	2.1
Nuovo Ospedale of Sassuolo	8	0.5	1.9
Hesperia Hospital Modena of Modena	7	0.5	1.6
Ospedale privato Villa Pineta of Pavullo nel Frignano	4	0.3	0.9
Ospedale of Pavullo nel Frignano	1	0.1	0.2
Province of Parma	293	19.9	
A.O. Universitaria of Parma	234	15.9	79.9
Università di Parma	41	2.8	14.0
Ospedale of Fidenza	18	1.2	6.1
AUSL of Parma	5	0.3	1.7
Ospedale of Borgo Val di Taro	5	0.3	1.7
Province of Ferrara	238	16.1	
A.O. Universitaria Arcispedale S. Anna of Ferrara	195	13.2	81.9
Università di Ferrara	31	2.1	13.0
AUSL of Ferrara	7	0.5	2.9
Ospedale of Cento	4	0.3	1.7



Centre	CT	% on Region	% on Province
Ospedale del Delta of Lagosanto	4	0.3	1.7
Ospedale of Comacchio	1	0.1	0.4
Province of Forlì-Cesena	205	13.9	
Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) of Meldola	104	7.1	50.7
Ospedale Morgagni-Pierantoni of Forlì	47	3.2	22.9
AUSL of Forlì	33	2.2	16.1
Ospedale Bufalini of Cesena	31	2.1	15.1
AUSL of Cesena	8	0.5	3.9
Ospedale of Forlimpopoli	2	0.1	1.0
Ospedale Marconi of Cesenatico	1	0.1	0.5
Province of Reggio Emilia	198	13.4	
A.O. Arcispedale S. Maria Nuova of Reggio Emilia	185	12.6	93.4
AUSL of Reggio Emilia	10	0.7	5.1
Ospedale S. Sebastiano of Correggio	7	0.5	3.5
Ospedale Magati of Scandiano	5	0.3	2.5
Ospedale Civile of Guastalla	3	0.2	1.5
Ospedale S. Anna of Castelnovo ne' Monti	3	0.2	1.5
Ospedale Franchini of Montecchio Emilia	2	0.1	1.0
Province of Ravenna	145	9.8	
Ospedale S. Maria delle Croci of Ravenna	94	6.4	64.8
Ospedale of Faenza	37	2.5	25.5
Ospedale of Lugo	30	2.0	20.7
AUSL of Ravenna	14	0.9	9.7
Villa Maria Cecilia Hospital of Cotignola	10	0.7	6.9
Ospedale privato Domus Nova of Ravenna	4	0.3	2.8
Province of Rimini	111	7.5	
Ospedale of Rimini	87	5.9	78.4
AUSL of Rimini	21	1.4	18.9
Ospedale of Cattolica	12	0.8	10.8
Ospedale of Riccione	2	0.1	1.8
Province of Piacenza	102	6.9	
Ospedale civile of Piacenza	68	4.6	66.7
AUSL of Piacenza	32	2.2	31.4
Ospedale Civile of Fiorenzuola d'Arda	2	0.1	2.0



Centre	CT	% on Region	% on Province
Tuscany	1,309		
Province of Florence	566	43.2	
A.O. Universitaria Careggi of Florence	418	31.9	73.9
Ospedale S. Maria Annunziata of Bagno a Ripoli	47	3.6	8.3
A.O. Universitaria Meyer of Florence	41	3.1	7.2
Università of Florence	24	1.8	4.2
Azienda Sanitaria of Florence	22	1.7	3.9
Ospedale S. Giovanni di Dio Torregalli of Florence	19	1.5	3.4
AUSL 11 of Empoli	7	0.5	1.2
Ospedale S. Giuseppe of Empoli	7	0.5	1.2
Ospedale S. Maria Nuova of Florence	7	0.5	1.2
IRCCS Fondazione Don Gnocchi - Centro S. Maria agli Ulivi of Pozzolatico	3	0.2	0.5
Ospedale degli Infermi of Empoli	2	0.2	0.4
Ospedale del Mugello of Borgo S. Lorenzo	2	0.2	0.4
Ospedale Ponte Nuovo of Florence	2	0.2	0.4
Istituto Ortopedico Toscano of Florence	1	0.1	0.2
Ospedale S. Pietro Igneo of Fucecchio	1	0.1	0.2
Province of Pisa	480	36.7	
A.O. Universitaria Pisana of Pisa	429	32.8	89.4
Università of Pisa	32	2.4	6.7
Fondazione Monasterio - Stabilimento ospedaliero of Pisa	18	1.4	3.8
AUSL 5 of Pisa	8	0.6	1.7
IRCCS Fondazione Stella Maris of Pisa	4	0.3	0.8
Ospedale Lotti of Pontedera	3	0.2	0.6
Ospedale S. Maria Maddalena of Volterra	1	0.1	0.2
Servizio Psichiatrico Diagnosi e Cura of Pisa	1	0.1	0.2
Province of Siena	329	25.1	
A.O. Universitaria Senese of Siena	248	18.9	75.4
Università of Siena	61	4.7	18.5
AUSL 7 of Siena	18	1.4	5.5
Ospedale Valdelsa of Poggibonsi	5	0.4	1.5
Ospedale Amiata Senese of Abbadia S. Salvatore	1	0.1	0.3
Ospedale Valdichiana of Montepulciano	1	0.1	0.3



Centre	CT	% on Region	% on Province
Province of Lucca	134	10.2	
Ospedale Versilia of Camaiore	74	5.7	55.2
Ospedale of Lucca	29	2.2	21.6
AUSL 12 of Viareggio	25	1.9	18.7
AUSL 2 of Lucca	11	0.8	8.2
Ospedale S. Croce of Castelnuovo di Garfagnana	4	0.3	3.0
Ospedale S. Francesco of Barga	1	0.1	0.7
Province of Prato	86	6.6	
Ospedale Misericordia e Dolce of Prato	53	4.0	61.6
AUSL 4 of Prato	34	2.6	39.5
Province of Arezzo	83	6.3	
Ospedale S. Donato of Arezzo	59	4.5	71.1
AUSL 8 of Arezzo	14	1.1	16.9
Ospedale S. Margherita of Cortona	8	0.6	9.6
Ospedale S. Maria alla Gruccia of Montevarchi	7	0.5	8.4
Ospedale of Bibbiena	1	0.1	1.2
Province of Livorno	73	5.6	
Ospedale of Livorno	42	3.2	57.5
AUSL 6 of Livorno	26	2.0	35.6
Ospedale of Cecina	15	1.1	20.5
Ospedale of Piombino	8	0.6	11.0
Province of Grosseto	66	5.0	
Ospedale della Misericordia of Grosseto	58	4.4	87.9
AUSL 9 of Grosseto	8	0.6	12.1
Ospedale S. Andrea of Massa Marittima	1	0.1	1.5
Ospedale S. Giovanni di Dio of Orbetello	1	0.1	1.5
Province of Massa Carrara	40	3.1	
Fondazione Monasterio - Ospedale Pasquinucci of Massa	16	1.2	40.0
AUSL 1 of Massa and Carrara	13	1.0	32.5
Ospedale Civile of Carrara	11	0.8	27.5
Ospedale SS. Giacomo e Cristoforo of Massa	3	0.2	7.5
Ospedale S. Antonio Abate of Fivizzano	2	0.2	5.0
Province of Pistoia	26	2.0	
AUSL 3 of Pistoia	13	1.0	50.0
Spedali Riuniti of Pistoia	11	0.8	42.3



Centre	CT	% on Region	% on Province
Ospedale SS. Cosma e Damiano of Pavia	6	0.5	23.1
Piedmont	988		
Province of Turin	833	84.3	
A.O. Universitaria S. Giovanni Battista-Molinette of Turin	363	36.7	43.6
A.O. Universitaria S. Luigi Gonzaga of Orbassano	234	23.7	28.1
Fondazione del Piemonte per l'Oncologia IRCC of Candiolo	65	6.6	7.8
A.O. Ospedale Mauriziano Umberto I of Turin	55	5.6	6.6
Ospedale Amedeo di Savoia of Turin	41	4.1	4.9
A.O. Ospedale Infantile Regina Margherita of Turin	39	3.9	4.7
A.O. Ospedale Ostetrico Ginecologico S. Anna of Turin	33	3.3	4.0
Ospedale Torino nord Emergenza S. Giovanni Bosco of Turin	30	3.0	3.6
Presidio Sanitario Gradenigo of Turin	28	2.8	3.4
Ospedale Maggiore of Chieri	17	1.7	2.0
ASL TO/2 of Turin	15	1.5	1.8
Università of Turin	15	1.5	1.8
Ospedale Evangelico Valdese of Turin	13	1.3	1.6
Ospedale Civile of Ivrea	12	1.2	1.4
Ospedale Oftalmico of Turin	11	1.1	1.3
A.O. CTO of Turin	9	0.9	1.1
Ospedale S. Croce of Moncalieri	7	0.7	0.8
A.O. Universitaria Ospedale S. Giovanni antica sede of Turin	6	0.6	0.7
Ospedale Civico of Chivasso	6	0.6	0.7
Ospedale Martini of Turin	6	0.6	0.7
A.O. Universitaria Ospedale dermatologico S. Lazzaro of Turin	5	0.5	0.6
Ospedale Maria Vittoria of Turin	5	0.5	0.6
A.O. Maria Adelaide of Turin	4	0.4	0.5
Ospedale Civile Agnelli of Pinerolo	4	0.4	0.5
Ospedale degli Infermi of Rivoli	4	0.4	0.5
ASL TO/3 of Pinerolo	3	0.3	0.4
Ospedale of Ciriè	3	0.3	0.4
A.O. OIRM/S. Anna of Turin	2	0.2	0.2
ASL TO/4 of Ivrea	2	0.2	0.2
ASL TO/5 of Chieri	2	0.2	0.2
A.O. CTO/Maria Adelaide of Turin	1	0.1	0.1
A.O. Universitaria Ospedale S. Vito of Turin	1	0.1	0.1



Centre	CT	% on Region	% on Province
Province of Novara	185	18.7	
A.O. Universitaria Maggiore della Carità of Novara	177	17.9	95.7
Clinica S. Gaudenzio of Novara	3	0.3	1.6
IRCCS Fondazione Maugeri - Istituto of Veruno	3	0.3	1.6
Istituto SS. Trinità of Borgomanero	3	0.3	1.6
A.O. Universitaria Ospedale S. Rocco of Galliate	2	0.2	1.1
ASL NO of Novara	1	0.1	0.5
Province of Cuneo	122	12.3	
A.O. S. Croce e Carle of Cuneo	98	9.9	80.3
Ospedale Civico S. Lazzaro of Alba	12	1.2	9.8
ASL CN/1 of Cuneo	7	0.7	5.7
Ospedale Civile of Saluzzo	7	0.7	5.7
Ospedale SS. Annunziata of Savigliano	6	0.6	4.9
ASL CN/2 of Alba	2	0.2	1.6
Ospedale Poveri infermi of Ceva	2	0.2	1.6
Ospedale of Caraglio	1	0.1	0.8
Ospedale Civile of Mondovì	1	0.1	0.8
Province of Alessandria	111	11.2	
A.O. Ospedale Civile SS. Antonio e Biagio of Alessandria	75	7.6	67.6
Ospedale S. Spirito of Casale Monferrato	13	1.3	11.7
Ospedale S. Giacomo of Novi Ligure	11	1.1	9.9
A.O. Ospedale Infantile Arrigo of Alessandria	7	0.7	6.3
ASL AL of Alessandria	6	0.6	5.4
Ospedale SS. Antonio e Margherita of Tortona	4	0.4	3.6
Ospedale Civile of Acqui Terme	1	0.1	0.9
Ospedale S. Antonio of Ovada	1	0.1	0.9
Province of Asti	29	2.9	
Ospedale Cardinale Massaia of Asti	28	2.8	96.6
ASL AT of Asti	1	0.1	3.4
Province of Biella	28	2.8	
Ospedale degli Infermi of Biella	26	2.6	92.9
ASL BI of Biella	2	0.2	7.1
Province of Verbania	15	1.5	
Ospedale Castelli of Verbania	10	1.0	66.7
Ospedale S. Biagio of Domodossola	4	0.4	26.7



Centre	CT	% on Region	% on Province
Ospedale Madonna del popolo of Omegna	1	0.1	6.7
Province of Vercelli	8	0.8	
Ospedale S. Andrea of Vercelli	7	0.7	87.5
Ospedale SS. Pietro e Paolo of Borgosesia	1	0.1	12.5
Veneto	912		
Province of Padova	499	54.7	
A.O. of Padova	314	34.4	62.9
IRCCS Istituto Oncologico Veneto (IOV) of Padova	78	8.6	15.6
Università of Padova	41	4.5	8.2
Ospedale S. Antonio c/o A.O. of Padova	30	3.3	6.0
Ospedale S. Antonio c/o Ospedale Busonera of Padova	12	1.3	2.4
AULSS 16 of Padova	11	1.2	2.2
Istituto Casa di cura Abano Terme of Abano Terme	10	1.1	2.0
P.O. Cosma of Camposampiero	7	0.8	1.4
P.O. of Cittadella	5	0.5	1.0
AULSS 15 Alta Padovana of Cittadella	4	0.4	0.8
P.O. di Piove of Sacco	2	0.2	0.4
Ospedale of Este	1	0.1	0.2
Ospedale Geriatrico of Padova	1	0.1	0.2
Ospedale S. Antonio of Padova	1	0.1	0.2
Province of Verona	280	30.7	
A.O. Universitaria Integrata of Verona - Ospedale Policlinico G.B. Rossi	97	10.6	34.6
A.O. Universitaria Integrata of Verona - Ospedale Civile Maggiore	87	9.5	31.1
Ospedale Sacro Cuore - Don Calabria of Negrar	36	3.9	12.9
Ospedale per acuti Mater Salutis of Legnago	15	1.6	5.4
Ospedale of Valeggio sul Mincio	15	1.6	5.4
AULSS 20 of Verona	14	1.5	5.0
AULSS 21 of Legnago	13	1.4	4.6
Ospedale Orlandi of Bussolengo	13	1.4	4.6
Università of Verona	9	1.0	3.2
AULSS 22 of Bussolengo	8	0.9	2.9
Ospedale Fracastoro of S. Bonifacio	6	0.7	2.1
Ospedale of Isola della Scala	3	0.3	1.1
Ospedale of Caprino Veronese	1	0.1	0.4



Centre	CT	% on Region	% on Province
Province of Vicenza	134	14.7	
Ospedale S. Bortolo of Vicenza	54	5.9	40.3
AULSS 6 of Vicenza	52	5.7	38.8
Casa di cura Villa Margherita of Arcugnano	16	1.8	11.9
Ospedale of Montebelluna Maggiore	6	0.7	4.5
Padiglione Ospedaliero Boldrini of Thiene	6	0.7	4.5
AULSS 4 Alto Vicentino of Thiene	3	0.3	2.2
Ospedale S. Bassiano of Bassano del Grappa	3	0.3	2.2
Ospedale of Valdagno	3	0.3	2.2
AULSS 3 of Bassano del Grappa	2	0.2	1.5
AULSS 5 Ovest Vicentino of Arzignano	2	0.2	1.5
Ospedale of Arzignano	2	0.2	1.5
Padiglione Ospedaliero De Lellis of Schio	2	0.2	1.5
Ospedale Milani of Noventa Vicentina	1	0.1	0.7
Province of Venice	109	12.0	
Ospedale Civile Umberto I of Mestre	24	2.6	22.0
Ospedale SS. Giovanni e Paolo of Venice	24	2.6	22.0
AULSS 13 of Mirano	18	2.0	16.5
AULSS 12 Veneziana of Venice	16	1.8	14.7
Ospedale Calvi of Noale	8	0.9	7.3
Ospedale Civile of Mirano	8	0.9	7.3
IRCCS Ospedale S. Camillo of Venice	4	0.4	3.7
Ospedale dell'Angelo of Mestre	3	0.3	2.8
Ospedale Civile of Dolo	3	0.3	2.8
P.O. of Portogruaro	3	0.3	2.8
AULSS 10 Veneto Orientale of S. Donà di Piave	2	0.2	1.8
AULSS 14 of Chioggia	2	0.2	1.8
P.O. of Chioggia	1	0.1	0.9
Province of Treviso	101	11.1	
Ospedale Ca' Foncello of Treviso	47	5.2	46.5
P.O. of Vittorio Veneto	22	2.4	21.8
Ospedale S. Giacomo Apostolo of Castelfranco Veneto	16	1.8	15.8
AULSS 9 of Treviso	15	1.6	14.9
P.O. of Conegliano	6	0.7	5.9
AULSS 7 of Pieve di Soligo	2	0.2	2.0



Centre	CT	% on Region	% on Province
AULSS 8 of Asolo	2	0.2	2.0
Ospedale Civile S. Valentino of Montebelluna	2	0.2	2.0
IRCCS Medea - Associazione La Nostra Famiglia of Conegliano	1	0.1	1.0
Ospedale di Motta of Livorno	1	0.1	1.0
Province of Belluno	27	3.0	
Ospedale S. Martino of Belluno	17	1.9	63.0
AULSS 2 of Feltre	6	0.7	22.2
AULSS 1 of Belluno	3	0.3	11.1
Ospedale of Pieve di Cadore	1	0.1	3.7
Ospedale S. Maria del Prato of Feltre	1	0.1	3.7
Province of Rovigo	23	2.5	
AULSS 18 of Rovigo	13	1.4	56.5
Ospedale S. Maria della Misericordia of Rovigo	11	1.2	47.8
Ospedale Civile of Adria	1	0.1	4.3
Campania	886		
Province of Naples	764	86.2	
A.O. Universitaria Federico II of Naples	310	35.0	40.6
A.O. Cardarelli of Naples	149	16.8	19.5
IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	135	15.2	17.7
A.O. Universitaria Seconda Università of Naples	132	14.9	17.3
A.O. Monaldi of Naples	55	6.2	7.2
Università Federico II of Naples	49	5.5	6.4
A.O. Cotugno of Naples	24	2.7	3.1
P.O. S. Gennaro of Naples	14	1.6	1.8
Ospedale S. Giovanni di Dio of Frattamaggiore	12	1.4	1.6
P.O. Ospedale S. Giovanni Bosco of Naples	12	1.4	1.6
Ospedale Madonna del Buon Consiglio Fatebenefratelli of Naples	10	1.1	1.3
ASL Napoli 2 Nord of Pozzuoli	9	1.0	1.2
ASL Napoli 3 Sud di Castellammare of Stabia	9	1.0	1.2
Ospedale S. Maria delle Grazie of Pozzuoli	7	0.8	0.9
ASL Napoli 1 Centro	6	0.7	0.8
Seconda Università of Naples	6	0.7	0.8
A.O. Santobono of Naples	5	0.6	0.7
P.O. S. Maria della Pietà of Nola	4	0.5	0.5
P.O. Maresca of Torre del Greco	3	0.3	0.4



Centre	CT	% on Region	% on Province
P.O. Pellegrini of Naples	3	0.3	0.4
P.O. S. Maria della Misericordia of Sorrento	3	0.3	0.4
Ospedale S. Giuliano of Giugliano in Campania	2	0.2	0.3
P.O. Apicella of Pollena Trocchia	2	0.2	0.3
P.O. S. Leonardo di Castellammare of Stabia	2	0.2	0.3
P.O. S. Maria degli Incurabili of Naples	2	0.2	0.3
P.O. Santa Maria di Loreto Mare of Naples	2	0.2	0.3
A.O. Santobono-Pausillipon of Naples	1	0.1	0.1
P.O. Ascalesi of Naples	1	0.1	0.1
P.O. S. Maria della Pietà of Casoria	1	0.1	0.1
P.O. S. Paolo of Naples	1	0.1	0.1
P.O. SS. Annunziata of Naples	1	0.1	0.1
Province of Salerno	123	13.9	
ASL of Salerno	30	3.4	24.4
P.O. Umberto I of Nocera Inferiore	25	2.8	20.3
Ospedale Amico Fucito of Mercato S. Severino	19	2.1	15.4
A.O. Ospedali Riuniti S. Giovanni di Dio e Ruggi d'Aragona of Salerno	17	1.9	13.8
P.O. S. Maria Incoronata dell'Olmo of Cava de' Tirreni	17	1.9	13.8
P.O. Scarlato of Scafati	8	0.9	6.5
P.O. Giovanni da Procida of Salerno	6	0.7	4.9
P.O. Maria SS. Addolorata of Eboli	6	0.7	4.9
P.O. S. Luca of Vallo della Lucania	6	0.7	4.9
P.O. Curto of Polla-S. Arsenio	4	0.5	3.3
P.O. of Agropoli	2	0.2	1.6
P.O. S. Maria della Speranza of Battipaglia	2	0.2	1.6
Casa di cura Cobellis of Vallo della Lucania	1	0.1	0.8
P.O. dell'Immacolata of Sapri	1	0.1	0.8
P.O. S. Francesco d'Assisi of Oliveto Citra	1	0.1	0.8
P.O. Tortora of Pagani	1	0.1	0.8
Province of Avellino	99	11.2	
A.O. S. Giuseppe Moscati of Avellino	91	10.3	91.9
ASL of Avellino	4	0.5	4.0
Casa di cura Montevergine of Mercogliano	2	0.2	2.0
P.O. of Ariano Irpino	2	0.2	2.0



Centre	CT	% on Region	% on Province
P.O. Landolfi of Solofra	2	0.2	2.0
Casa di cura Malzoni - Villa dei Platani of Avellino	1	0.1	1.0
Province of Benevento	78	8.8	
A.O. Rummo of Benevento	61	6.9	78.2
Ospedale Sacro Cuore di Gesù Fatebenefratelli of Benevento	17	1.9	21.8
IRCCS Fondazione Maugeri - Istituto of Telesse Terme	5	0.6	6.4
ASL of Benevento	1	0.1	1.3
Province of Caserta	64	7.2	
A.O. S. Anna e S. Sebastiano of Caserta	48	5.4	75.0
P.O. S. Giuseppe e Melorio of S. Maria Capua Vetere	10	1.1	15.6
P.O. of S. Felice a Cancellio	8	0.9	12.5
ASL of Caserta	3	0.3	4.7
P.O. Moscati of Aversa	2	0.2	3.1
P.O. Palasciano of Capua	2	0.2	3.1
P.O. of Sessa Aurunca	2	0.2	3.1
P.O. of Piedimonte Matese	1	0.1	1.6
Liguria	841		
Province of Genoa	805	95.7	
A.O. Universitaria S. Martino of Genoa	424	50.4	52.7
IRCCS Istituto Nazionale per la Ricerca sul Cancro (IST) of Genoa	151	18.0	18.8
IRCCS Istituto Gaslini of Genoa	98	11.7	12.2
E.O. Ospedali Galliera of Genoa	68	8.1	8.4
Università of Genoa	52	6.2	6.5
Ospedale La Colletta of Arenzano	39	4.6	4.8
Ospedale Villa Scassi of Genoa	23	2.7	2.9
ASL 3 Genovese of Genoa	18	2.1	2.2
Ospedale Padre Micone of Genoa	10	1.2	1.2
ASL 4 Chiavarese of Chiavari	9	1.1	1.1
Ospedale Gallino of Genoa	3	0.4	0.4
Ospedale Civile of Sestri Levante	2	0.2	0.2
Ospedale S. Carlo of Genoa	2	0.2	0.2
Ospedali Riuniti Leonardini e Riboli of Lavagna	1	0.1	0.1
Province of Savona	43	5.1	
A.O. Ospedale S. Corona of Pietra Ligure	29	3.4	67.4
Ospedale S. Paolo of Savona	14	1.7	32.6



Centre	CT	% on Region	% on Province
ASL 2 Savonese of Savona	5	0.6	11.6
Province of La Spezia	27	3.2	
Ospedale S. Bartolomeo of Sarzana	8	1.0	29.6
Ospedale Felettino of La Spezia	7	0.8	25.9
Ospedale S. Andrea of La Spezia	7	0.8	25.9
AUSL 5 Spezzino of La Spezia	3	0.4	11.1
P.O. of La Spezia	2	0.2	7.4
Province of Imperia	20	2.4	
Ospedale of Imperia	7	0.8	35.0
ASL 1 Imperiese of Bussana di Sanremo	6	0.7	30.0
Ospedale of Sanremo	5	0.6	25.0
Ospedale of Bordighera	3	0.4	15.0
Sicily	840		
Provincia of Palermo	427	50.8	
A.O. Universitaria Policlinico Giaccone of Palermo	207	24.6	48.5
A.O. Cervello of Palermo	62	7.4	14.5
Casa di cura La Maddalena of Palermo	52	6.2	12.2
Fondazione Istituto S. Raffaele - Giglio of Cefalù	40	4.8	9.4
A.O. Presidio Civico e Benfratelli of Palermo	30	3.6	7.0
A.O. Villa Sofia of Palermo	21	2.5	4.9
Ospedale Bucerri La Ferla Fatebenefratelli of Palermo	18	2.1	4.2
Università of Palermo	17	2.0	4.0
A.O. Istituto Mediterraneo Trapianti e Terapie ad alta specializzazione (IsMeTT) of Palermo	15	1.8	3.5
A.O. Ospedale Oncologico Ascoli of Palermo	15	1.8	3.5
A.O. Presidio Di Cristina of Palermo	11	1.3	2.6
ASP of Palermo	11	1.3	2.6
CNR - Istituto di Biomedicina e Immunologia Molecolare (IBIM) of Palermo	7	0.8	1.6
A.O. Villa Sofia - C.T.O. of Palermo	3	0.4	0.7
Ospedale Civico of Partinico	3	0.4	0.7
A.O. Civico - Di Cristina - Benfratelli of Palermo	2	0.2	0.5
A.O. Presidio Casa del Sole of Palermo	2	0.2	0.5
Ospedale Cimino of Termini Imerese	1	0.1	0.2
Ospedale Ingrassia of Palermo	1	0.1	0.2



Centre	CT	% on Region	% on Province
Villa Maria Eleonora Hospital of Palermo	1	0.1	0.2
Province of Catania	405	48.2	
A.O. Universitaria - P.O. Vittorio Emanuele e Ferrarotto of Catania	155	18.5	38.3
A.O. Universitaria - P.O. Rodolico of Catania	121	14.4	29.9
A.O. Ospedale Garibaldi-Nesima of Catania	62	7.4	15.3
A.O. per l'emergenza Cannizzaro of Catania	35	4.2	8.6
A.O. Ospedale Ascoli-Tomaselli of Catania	18	2.1	4.4
A.O. Ospedale Garibaldi-Centro of Catania	15	1.8	3.7
Humanitas Centro Catanese di Oncologia of Catania	15	1.8	3.7
ASP of Catania	10	1.2	2.5
A.O. Garibaldi of Catania	8	1.0	2.0
Istituto Oncologico del Mediterraneo of Viagrande	6	0.7	1.5
P.O. S. Marta e S. Venera of Acireale	5	0.6	1.2
A.O. Universitaria - P.O. S. Bambino of Catania	4	0.5	1.0
P.O. S. Giovanni di Dio e S. Isidoro of Giarre	4	0.5	1.0
Casa di cura Morgagni of Catania	2	0.2	0.5
Province of Messina	231	27.5	
A.O. Universitaria Policlinico Martino of Messina	137	16.3	59.3
P.O. S. Vincenzo of Taormina	40	4.8	17.3
A.O. Papardo of Messina	38	4.5	16.5
Università di Messina	19	2.3	8.2
IRCCS Centro neurolesi Bonino Pulejo of Messina	9	1.1	3.9
A.O. Piemonte of Messina	5	0.6	2.2
ASP of Messina	4	0.5	1.7
P.O. Fogliani of Milazzo	3	0.4	1.3
P.O. Barone Romeo of Patti	1	0.1	0.4
P.O. Nuovo Cutroni Zodda of Barcellona Pozzo di Gotto	1	0.1	0.4
Province of Ragusa	30	3.6	
ASP of Ragusa	17	2.0	56.7
A.O. Ospedale Civile Paterno Arezzo of Ragusa	8	1.0	26.7
Ospedale Maggiore of Modica	3	0.4	10.0
Ospedale Guzzardi of Vittoria	2	0.2	6.7
Ospedale Regina Margherita of Comiso	1	0.1	3.3
Province of Enna	13	1.5	
IRCCS Oasi Maria SS. of Troina	7	0.8	53.8



Centre	CT	% on Region	% on Province
ASP of Enna	4	0.5	30.8
Ospedale Basilotta of Nicosia	1	0.1	7.7
Ospedale Ferro-Capra-Branciforte of Leonforte	1	0.1	7.7
Province of Trapani	12	1.4	
A.O. S. Antonio Abate of Erice	7	0.8	58.3
P.O. S. Biagio of Marsala	3	0.4	25.0
ASP of Trapani	1	0.1	8.3
P.O. Ajello of Mazara del Vallo	1	0.1	8.3
Province of Siracusa	11	1.3	
A.O. Ospedale Umberto I of Siracusa	11	1.3	100.0
Province of Agrigento	6	0.7	
A.O. Ospedali Civili Riuniti of Sciacca	3	0.4	50.0
ASP of Agrigento	3	0.4	50.0
Province of Caltanissetta	1	0.1	
A.O. S. Elia of Caltanissetta	1	0.1	100.0
Puglia	648		
Province of Bari	410	63.3	
A.O. Universitaria Consorziata Policlinico of Bari	292	45.1	71.2
IRCCS Ospedale Oncologico of Bari	84	13.0	20.5
Ente ecclesiastico Ospedale Miulli of Acquaviva delle Fonti	19	2.9	4.6
IRCCS Fondazione Maugeri - Istituto of Cassano delle Murge	11	1.7	2.7
ASL BA of Bari	7	1.1	1.7
P.O. Ospedale Di Venere of Carbonara di Bari	4	0.6	1.0
P.O. Ospedale S. Paolo of Bari	4	0.6	1.0
P.O. Ospedale Umberto I of Altamura	4	0.6	1.0
Università of Bari	4	0.6	1.0
A.O. Universitaria Ospedale Pediatrico Giovanni XXIII of Bari	2	0.3	0.5
AUSL BA of Bari	2	0.3	0.5
P.O. Ospedale S. Giacomo of Monopoli	2	0.3	0.5
P.O. Ospedale S. Maria degli Angeli of Putignano	2	0.3	0.5
P.O. Ospedale Civile of Molfetta	1	0.2	0.2
P.O. Ospedale Sarcone of Terlizzi	1	0.2	0.2
Province of Foggia	255	39.4	
IRCCS Ospedale Casa Sollievo della Sofferenza of S. Giovanni Rotondo	158	24.4	62.0



Centre	CT	% on Region	% on Province
A.O. Universitaria Ospedali Riuniti of Foggia	105	16.2	41.2
A.O. Universitaria Ospedali Riuniti of Foggia - Stabilimento Ospedaliero D'Avanzo	2	0.3	0.8
ASL FG of Foggia	2	0.3	0.8
AUSL FG of Foggia	2	0.3	0.8
P.O. Lastaria of Lucera	2	0.3	0.8
P.O. Tatarella of Cerignola	2	0.3	0.8
Stabilimento Ospedaliero of S. Severo	1	0.2	0.4
Province of Lecce	126	19.4	
P.O. Fazzi of Lecce	84	13.0	66.7
Ospedale Cardinale Panico of Tricase	24	3.7	19.0
P.O. Ferrari of Casarano	12	1.9	9.5
ASL LE of Lecce	6	0.9	4.8
Stabilimento Ospedaliero Galateo of S. Cesario di Lecce	5	0.8	4.0
P.O. Veris Delli Ponti of Scorrano	4	0.6	3.2
Casa di cura Città di Lecce Hospital of Lecce	3	0.5	2.4
P.O. Sacro Cuore of Gallipoli	3	0.5	2.4
Stabilimento Ospedaliero Pispico of Poggiardo	2	0.3	1.6
Stabilimento Ospedaliero Tamborino of Maglie	2	0.3	1.6
P.O. S. Caterina Novella of Galatina	1	0.2	0.8
Stabilimento Ospedaliero Romasi of Gagliano del Capo	1	0.2	0.8
Stabilimento Ospedaliero S. Pio da Pietrelcina of Campi Salentina	1	0.2	0.8
Province of Brindisi	86	13.3	
Stabilimento Ospedaliero Di Summa-Perrino of Brindisi	69	10.6	80.2
ASL BR of Brindisi	10	1.5	11.6
Stabilimento Ospedaliero Camberlingo of Francavilla Fontana	5	0.8	5.8
Stabilimento Ospedaliero Melli of S. Pietro Vernotico	4	0.6	4.7
Stabilimento Ospedaliero of Cisternino	2	0.3	2.3
Stabilimento Ospedaliero S. Camillo de Lellis of Mesagne	2	0.3	2.3
Stabilimento Ospedaliero of Ceglie Messapica	1	0.2	1.2
Province of Taranto	42	6.5	
Stabilimento Ospedaliero SS. Annunziata of Taranto	22	3.4	52.4
ASL TA of Taranto	14	2.2	33.3
Stabilimento Ospedaliero of Castellaneta	6	0.9	14.3
Stabilimento Ospedaliero of Manduria	4	0.6	9.5



Centre	CT	% on Region	% on Province
Stabilimento Ospedaliero of Martina Franca	3	0.5	7.1
Stabilimento Ospedaliero of Massafra	3	0.5	7.1
Ospedale S. Giovanni Moscati of Taranto	2	0.3	4.8
Province of Barletta-Andria-Trani	14	2.2	
ASL BAT of Andria	5	0.8	35.7
P.O. Ospedale Bonomo of Andria	3	0.5	21.4
P.O. Ospedale Caduti di tutte le guerre of Canosa di Puglia	3	0.5	21.4
P.O. Ospedale Dimiccoli of Barletta	2	0.3	14.3
P.O. Ospedale S. Nicola Pellegrino of Trani	2	0.3	14.3
P.O. Ospedale Vittorio Emanuele of Bisceglie	1	0.2	7.1
Friuli-Venezia Giulia	531		
Province of Udine	272	51.2	
A.O. Universitaria S. Maria della Misericordia of Udine	226	42.6	83.1
Ospedale S. Antonio of S. Daniele del Friuli	25	4.7	9.2
Università of Udine	20	3.8	7.4
Ospedale Civile of Latisana	6	1.1	2.2
ASS 5 Bassa Friulana of Palmanova Jalmicco	5	0.9	1.8
Ospedale Civile S. Antonio Abate of Tolmezzo	5	0.9	1.8
ASS 4 Medio Friuli of Udine	4	0.8	1.5
Ospedale Civile S. Michele of Gemona del Friuli	2	0.4	0.7
ASS 3 Alto Friuli of Gemona del Friuli	1	0.2	0.4
Istituto di Medicina Fisica e Riabilitazione Gervasutta of Udine	1	0.2	0.4
Ospedale Civile of Palmanova	1	0.2	0.4
Province of Pordenone	190	35.8	
IRCCS Centro di Riferimento Oncologico (CRO) of Aviano	134	25.2	70.5
A.O. S. Maria degli Angeli of Pordenone	66	12.4	34.7
Ospedale S. Maria dei Battuti of S. Vito al Tagliamento	4	0.8	2.1
ASS 6 Friuli Occidentale of Pordenone	1	0.2	0.5
IRCCS Medea - Associazione La Nostra Famiglia of S. Vito al Tagliamento	1	0.2	0.5
Province of Trieste	144	27.1	
A.O. Universitaria Ospedali Riuniti of Trieste	86	16.2	59.7
IRCCS Burlo Garofolo of Trieste	35	6.6	24.3
ASS 1 Triestina of Trieste	15	2.8	10.4
Università of Trieste	10	1.9	6.9



Centre	CT	% on Region	% on Province
Province of Gorizia	7	1.3	
Ospedale of Monfalcone	4	0.8	57.1
ASS 2 Isontina of Gorizia	2	0.4	28.6
Ospedale of Gorizia	2	0.4	28.6
Marche	448		
Province of Ancona	325	72.5	
A.O. Universitaria Ospedali Riuniti - Ospedale Umberto I of Ancona	167	37.3	51.4
A.O. Universitaria Ospedali Riuniti - Ospedale Lancisi of Ancona	64	14.3	19.7
IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Ancona	21	4.7	6.5
A.O. Universitaria Ospedali Riuniti of Ancona	16	3.6	4.9
A.O. Universitaria Ospedali Riuniti - Ospedale Salesi of Ancona	16	3.6	4.9
ASUR - Zona Territoriale 5 of Jesi	16	3.6	4.9
Ospedale Profili of Fabriano	11	2.5	3.4
Università of Ancona	9	2.0	2.8
ASUR - Zona Territoriale 6 of Fabriano	7	1.6	2.2
Ospedale Murri of Jesi	7	1.6	2.2
Ospedali Riuniti of Jesi	4	0.9	1.2
ASUR - Zona Territoriale 7 of Ancona	2	0.4	0.6
Ospedale of Senigallia	2	0.4	0.6
Ospedale SS. Benvenuto e Rocco of Osimo	1	0.2	0.3
Province of Pesaro and Urbino	89	19.9	
A.O. Ospedale S. Salvatore of Pesaro	67	15.0	75.3
Ospedale S. Croce of Fano	23	5.1	25.8
ASUR - Zona Territoriale 3 of Fano	7	1.6	7.9
Ospedale S. Maria della Misericordia of Urbino	4	0.9	4.5
ASUR - Zona Territoriale 1 of Pesaro	2	0.4	2.2
Ospedale Civile of Fossombrone	1	0.2	1.1
Province of Ascoli Piceno	66	14.7	
Ospedale Mazzoni of Ascoli Piceno	40	8.9	60.6
ASUR - Zona Territoriale 13 of Ascoli Piceno	17	3.8	25.8
Ospedale Madonna del Soccorso of S. Benedetto del Tronto	9	2.0	13.6
ASUR - Zona Territoriale 12 of S. Benedetto del Tronto	2	0.4	3.0



Centre	CT	% on Region	% on Province
Province of Macerata	52	11.6	
ASUR - Zona Territoriale 9 of Macerata	28	6.3	53.8
ASUR - Zona Territoriale 8 of Civitanova Marche	11	2.5	21.2
Ospedale of Civitanova Marche	7	1.6	13.5
Ospedale Generale provinciale of Macerata	5	1.1	9.6
Ospedale S. Lucia of Recanati	1	0.2	1.9
Province of Fermo	10	2.2	
ASUR - Zona Territoriale 11 of Fermo	5	1.1	50.0
P.O. Murri of Fermo	4	0.9	40.0
Ospedale Vittorio Emanuele II of Amandola	1	0.2	10.0
Abruzzi	436		
Province of Chieti	265	60.8	
Università D'Annunzio of Chieti	175	40.1	66.0
Ospedale Clinicizzato SS. Annunziata of Chieti	67	15.4	25.3
AUSL of Lanciano-Vasto	17	3.9	6.4
Ospedale Renzetti of Lanciano	13	3.0	4.9
Ospedale S. Pio of Vasto	5	1.1	1.9
AUSL of Chieti	4	0.9	1.5
Ospedale Bernabeo of Ortona	4	0.9	1.5
Ospedale Maria SS. Immacolata of Guardiagrele	2	0.5	0.8
Ospedale Civile of Gissi	1	0.2	0.4
Province of Pescara	113	25.9	
Ospedale Civile dello Spirito Santo of Pescara	79	18.1	69.9
ASL 3 of Pescara	25	5.7	22.1
Ospedale Civile S. Massimo of Penne	7	1.6	6.2
Casa di cura Villa Serena of Città Sant'Angelo	6	1.4	5.3
Province of L'Aquila	88	20.2	
Ospedale Civile S. Salvatore of L'Aquila	56	12.8	63.6
Università of L'Aquila	15	3.4	17.0
Ospedale SS. Filippo e Nicola of Avezzano	9	2.1	10.2
AUSL 4 of L'Aquila	6	1.4	6.8
Ospedale SS. Annunziata of Sulmona	3	0.7	3.4
Ospedale of Castel di Sangro	2	0.5	2.3
AUSL of Avezzano-Sulmona	1	0.2	1.1
Ospedale Rinaldi of Pescara	1	0.2	1.1



Centre	CT	% on Region	% on Province
Province of Teramo	25	5.7	
Ospedale Mazzini of Teramo	17	3.9	68.0
ASL 4 of Teramo	4	0.9	16.0
Ospedale Maria SS. dello Splendore of Giulianova	4	0.9	16.0
Ospedale Civile S. Liberatore of Atri	3	0.7	12.0
Ospedale Val Vibrata of Sant'Omero	2	0.5	8.0
Umbria	426		
Province of Perugia	377	88.5	
A.O. of Perugia	295	69.2	78.2
Università of Perugia	54	12.7	14.3
ASL 2 Umbria of Perugia	11	2.6	2.9
ASL 1 Umbria of Città di Castello	8	1.9	2.1
Ospedale of Gubbio	8	1.9	2.1
Ospedale S. Giovanni Battista of Foligno	6	1.4	1.6
Servizio Psichiatrico Diagnosi e Cura of Perugia	6	1.4	1.6
ASL 3 Umbria of Foligno	5	1.2	1.3
Ospedale of Città di Castello	4	0.9	1.1
Ospedale of Umbertide	3	0.7	0.8
Ospedale of Marsciano	2	0.5	0.5
Ospedale of Città della Pieve	1	0.2	0.3
Ospedale Civile S. Matteo degli Infermi of Spoleto	1	0.2	0.3
Province of Terni	82	19.2	
A.O. S. Maria of Terni	73	17.1	89.0
ASL 4 Umbria of Terni	7	1.6	8.5
Ospedale S. Maria della Stella of Orvieto	2	0.5	2.4
P.O. of Narni	1	0.2	1.2
Sardinia	384		
Province of Cagliari	228	59.4	
A.O. Universitaria Policlinico Monserrato of Cagliari	54	14.1	23.7
Ospedale Businco of Cagliari	50	13.0	21.9
Ospedale Binaghi of Cagliari	30	7.8	13.2
A.O. Brotzu of Cagliari	29	7.6	12.7
A.O. Universitaria Ospedale S. Giovanni di Dio of Cagliari	28	7.3	12.3
ASL of Cagliari	19	4.9	8.3
Università of Cagliari	12	3.1	5.3



Centre	CT	% on Region	% on Province
Ospedale Microcitemico of Cagliari	11	2.9	4.8
Ospedale SS. Trinità of Cagliari	8	2.1	3.5
IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Cagliari	2	0.5	0.9
Ospedale Marino of Cagliari	1	0.3	0.4
Province of Sassari	192	50.0	
Ospedale Civile SS. Annunziata of Sassari	82	21.4	42.7
A.O. Universitaria Policlinico of Sassari	48	12.5	25.0
Università of Sassari	47	12.2	24.5
ASL of Sassari	27	7.0	14.1
Ospedale Civile of Alghero	3	0.8	1.6
Ospedale Civile of Thiesi	1	0.3	0.5
Ospedale Civile Vecchio of Sassari	1	0.3	0.5
Province of Olbia-Tempio	20	5.2	
Ospedale S. Giovanni Paolo II of Olbia	13	3.4	65.0
ASL of Olbia	6	1.6	30.0
Ospedale Dettori of Tempio Pausania	1	0.3	5.0
Province of Nuoro	10	2.6	
Ospedale S. Francesco of Nuoro	7	1.8	70.0
Ospedale Zonchello of Nuoro	3	0.8	30.0
Province of Carbonia-Iglesias	8	2.1	
P.O. Sirai of Carbonia	4	1.0	50.0
P.O. S. Barbara of Iglesias	3	0.8	37.5
P.O. Centro Traumatologico Ortopedico of Iglesias	1	0.3	12.5
P.O. F.Ili Crobu of Iglesias	1	0.3	12.5
Province of Medio Campidano	3	0.8	
Ospedale Nostra Signora di Bonaria of S. Gavino Monreale	2	0.5	66.7
ASL of Sanluri	1	0.3	33.3
Province of Ogliastra	1	0.3	
Ospedale Nostra Signora della Mercedes of Lanusei	1	0.3	100.0
Province of Oristano	1	0.3	
ASL of Oristano	1	0.3	100.0
Calabria	267		
Province of Reggio Calabria	126	47.2	
A.O. Bianchi - Melacrino - Morelli of Reggio Calabria	117	43.8	92.9



Centre	CT	% on Region	% on Province
ASP of Reggio Calabria	8	3.0	6.3
Ospedale Civile of Siderno	1	0.4	0.8
Università of Reggio Calabria	1	0.4	0.8
Province of Catanzaro	115	43.1	
A.O. Mater Domini of Catanzaro	59	22.1	51.3
A.O. Ospedale Ciaccio-De Lellis of Catanzaro	31	11.6	27.0
A.O. Ospedale Pugliese of Catanzaro	19	7.1	16.5
ASP of Catanzaro	8	3.0	7.0
A.O. Pugliese-Ciaccio of Catanzaro	6	2.2	5.2
Ospedale of Lamezia Terme	1	0.4	0.9
Province of Cosenza	82	30.7	
A.O. Ospedale Annunziata of Cosenza	44	16.5	53.7
A.O. Ospedale Mariano Santo of Cosenza	13	4.9	15.9
ASP of Cosenza	11	4.1	13.4
P.O. S. Francesco of Paola	5	1.9	6.1
Ospedale Civile Ferrari of Castrovillari	4	1.5	4.9
Ospedali Civile Giannettasio of Rossano	4	1.5	4.9
IRCCS Istituto Nazionale Ricovero e Cura Anziani (INRCA) of Cosenza	2	0.7	2.4
Ospedale Civile Minervini of Mormanno	2	0.7	2.4
Ospedale Generale di zona of Lungro	2	0.7	2.4
A.O. Ospedale S. Barbara of Rogliano	1	0.4	1.2
Centro Diabetologico DEA of Rossano Scalo	1	0.4	1.2
Ospedale Civile of S. Giovanni in Fiore	1	0.4	1.2
Ospedale di S. Marco Argentano	1	0.4	1.2
P.O. Beato Angelo of Aciri	1	0.4	1.2
P.O. of Cetraro	1	0.4	1.2
Province of Vibo Valentia	21	7.9	
P.O. Jazzolino of Vibo Valentia	16	6.0	76.2
P.O. of Tropea	3	1.1	14.3
ASP of Vibo Valentia	1	0.4	4.8
P.O. of Soriano Calabro	1	0.4	4.8
Basilicata	156		
Province of Potenza	141	90.4	
A.O. Ospedale S. Carlo of Potenza	81	51.9	57.4



Centre	CT	% on Region	% on Province
IRCCS Centro di Riferimento Oncologico di Basilicata (CROB) of Rionero in Vulture	71	45.5	50.4
Ospedale Civile Villa d'Agri of Marsicovetere	1	0.6	0.7
Province of Matera	21	13.5	
ASL of Matera	10	6.4	47.6
P.O. of Matera	7	4.5	33.3
P.O. of Policoro	3	1.9	14.3
P.O. of Tinchi	3	1.9	14.3
P.O. of Tricarico	2	1.3	9.5
Molise	134		
Province of Campobasso	77	57.5	
Università Cattolica del Sacro Cuore of Campobasso	35	26.1	45.5
Ospedale Cardarelli of Campobasso	27	20.1	35.1
Centro di ricerca ad alta tecnologia nelle Scienze Bioetiche of Campobasso	11	8.2	14.3
ASREM - Zona Territoriale of Campobasso	5	3.7	6.5
ASREM - Zona Territoriale of Termoli	2	1.5	2.6
Ospedale S. Timoteo of Termoli	1	0.7	1.3
Ospedale Vietri of Larino	1	0.7	1.3
Province of Isernia	65	48.5	
IRCCS Istituto Neurologico Mediterraneo (Neuromed) of Pozzilli	52	38.8	80.0
Ospedale Veneziale of Isernia	13	9.7	20.0
ASREM - Zona Territoriale of Isernia	3	2.2	4.6
ASREM - Zona Territoriale of Agnone	1	0.7	1.5
Trentino-Alto Adige	101		
Province of Bolzano	69	68.3	
Ospedale centrale of Bolzano	34	33.7	49.3
Azienda Sanitaria dell'Alto Adige - Comprensorio Sanitario of Bolzano	30	29.7	43.5
Azienda Sanitaria dell'Alto Adige - Comprensorio Sanitario of Merano	3	3.0	4.3
Azienda Sanitaria dell'Alto Adige - Comprensorio Sanitario of Brunico	1	1.0	1.4
Ospedale aziendale of Bressanone	1	1.0	1.4
Ospedale aziendale of Brunico	1	1.0	1.4



Centre	CT	% on Region	% on Province
Ospedale aziendale Tappeiner of Merano	1	1.0	1.4
Ospedale di base of Vipiteno	1	1.0	1.4
Province of Trento	40	39.6	
P.O. S. Chiara of Trento	30	29.7	75.0
APSS of Trento	11	10.9	27.5
Valle d'Aosta	20		
Province of Aosta	20	100.0	
Ospedale regionale Parini of Aosta	11	55.0	55.0
AUSL della Valle d'Aosta of Aosta	9	45.0	45.0

The sum of clinical trials per region ("CT" column) is higher than the national sample due to the fact that multi-centre trials are carried out in more than one centre and therefore shall be counted more than once.

Likewise, for every region, the sum of clinical trials per province ("CT" column) can be higher than the clinical trials per region and for every province, the sum of clinical trials per centre ("CT" column) can be higher than the clinical trials per province.



Phase I clinical trials

2006-2010

Table 46

Phase I clinical trials per year

CT: 183

Year	CT	%	% of tot. CT per year
2006	19	10.4	2.4
2007	22	12.0	2.8
2008	46	25.1	5.2
2009	43	23.5	5.7
2010	53	29.0	8.0
Total	183	100.0	4.7

Table 47

Phase I clinical trials - First in human per year

CT: 183 of which 51 (27.9%) First in human

Year	CT First in human	% of Phase I CT per year
2006	4	21.1
2007	4	18.2
2008	11	23.9
2009	13	30.2
2010	19	35.9
Total	51	27.9

**Table 48*****Mono-centre and multi-centre Phase I clinical trials per year***

CT: 183

Year	Mono-centre CT		Multi-centre CT		Total	
	CT	%	CT	%	CT	%
2006	2	10.5	17	89.5	19	100.0
2007	4	18.2	18	81.8	22	100.0
2008	6	13.0	40	87.0	46	100.0
2009	9	20.9	34	79.1	43	100.0
2010	7	13.2	46	86.8	53	100.0
Total	28	15.3	155	84.7	183	100.0

Table 49***Multi-centre national and international Phase I clinical trials per year***

Multi-centre CT: 155

Year	National multi-centre CT		International multi-centre CT		Total	
	CT	%	CT	%	CT	%
2006	4	23.5	13	76.5	17	100.0
2007	2	11.1	16	88.9	18	100.0
2008	7	17.5	33	82.5	40	100.0
2009	4	11.8	30	88.2	34	100.0
2010	7	15.2	39	84.8	46	100.0
Total	24	15.5	131	84.5	155	100.0

**Table 50****Phase I clinical trials per typology of Sponsor: profit / no profit**

CT: 183

Typology	CT	%	Sponsors
Profit	145	79.2	58
No profit	38	20.8	25
Public or private Scientific institute for research and care (IRCCS)	16	8.7	7
University hospital, University polyclinic and University	7	3.8	6
Foundation	6	3.3	4
Scientific association	5	2.7	4
Hospital structure *	3	1.6	3
Research institute	1	0.5	1
Total	183	100.0	83

* Hospitals, hospitals under self-administration, assimilated or classified hospitals, private qualified health institutes acting as local health unit, military hospital

Table 51**Phase I clinical trials per year and profit / no profit Sponsors**

CT: 183

Profit Sponsors: 58

No profit Sponsors: 25

Year	Profit		No profit		Total	
	CT	%	CT	%	CT	%
2006	15	79.0	4	21.1	19	100.0
2007	17	77.3	5	22.7	22	100.0
2008	38	82.6	8	17.4	46	100.0
2009	32	74.4	11	25.6	43	100.0
2010	43	81.1	10	18.9	53	100.0
Total	145	79.2	38	20.8	183	100.0

**Table 52*****Phase I clinical trials per therapeutic area***

CT: 183

Therapeutic area	CT	%	cum. %
Oncology	117	63.9	63.9
Haematology	25	13.7	77.6
Immunology and infectious diseases	12	6.6	84.2
Gastroenterology	6	3.3	87.4
Endocrinology	3	1.6	89.1
Neurology	3	1.6	90.7
Musculo-skeletal system diseases	3	1.6	92.3
Cardiology/Vascular diseases	2	1.1	93.4
Respiratory system diseases	2	1.1	94.5
Nephrology/Urology	2	1.1	95.6
Ophthalmology	2	1.1	96.7
Rheumatology	2	1.1	97.8
Pharmacology/Toxicology	1	0.6	98.4
Psychiatry/Psychology	1	0.6	98.9
Otolaryngology	1	0.6	99.5
Gynaecology and obstetrics	1	0.6	100.0
Total	183	100.0	

**Table 53*****Phase I clinical trials per typology of participating centre***

CT: 183

Typology	CT	% of Phase I CT (183)	Centre involved
Public or private Scientific institute for research and care (IRCCS)	122	66.7	23
University hospital, University polyclinic and University	110	60.1	38
Hospital structure *	70	38.3	77
Local health unit	12	6.6	8
Private centre **	4	2.2	4
Research institute	2	1.1	1

* Hospitals, hospitals under self-administration, assimilated or classified hospitals, private qualified health institutes acting as local health unit, military hospital

** Recognised suitable for running clinical trials of drugs

Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted in more than one typology of centre.



Objectives of the clinical trials

2006-2010

Table 54

Clinical trials per objective

Total CT: 3,863

Objective	CT	% of tot. CT (3,863)
Efficacy	3,408	88.2
Safety	3,276	84.8
Therapy	1,469	38.0
Pharmacokinetic	1,025	26.5
Pharmacodynamic	537	13.9
Dose response studies	473	12.2
Pharmacogenetic	422	10.9
Pharmacogenomic	313	8.1
Prophylaxis	261	6.8
Pharmaco-economic	235	6.1
Diagnosis	122	3.2
Bioequivalence	63	1.6
Other	341	8.8



Table 55

Clinical trials per objective and phase (% of total CT per phase)

Total CT: 3,863

Objective	Phase I		Phase II		Phase III		Phase IV		Bioeq / Biod	
	CT	% of Phase I CT (183)	CT	% of Phase II CT (1,467)	CT	% of Phase III CT (1,679)	CT	% of Phase IV CT (489)	CT	% of Bioeq/ Biod CT (45)
Efficacy	132	72.1	1,325	90.3	1,567	93.3	384	78.5	0	0.0
Safety	175	95.6	1,286	87.7	1,485	88.4	320	65.4	10	22.2
Therapy	33	18.0	494	33.7	626	37.3	307	62.8	9	20.0
Pharmacokinetic	126	68.9	423	28.8	426	25.4	31	6.3	19	42.2
Pharmacodynamic	65	35.5	248	16.9	201	12.0	20	4.1	3	6.7
Dose response studies	69	37.7	237	16.2	137	8.2	28	5.7	2	4.4
Pharmacogenetic	36	19.7	153	10.4	209	12.4	22	4.5	2	4.4
Pharmacogenomic	22	12.0	130	8.9	151	9.0	10	2.0	0	0.0
Prophylaxis	4	2.2	82	5.6	128	7.6	47	9.6	0	0.0
Pharmaco-economic	2	1.1	42	2.9	169	10.1	22	4.5	0	0.0
Diagnosis	1	0.5	43	2.9	34	2.0	42	8.6	2	4.4
Bioequivalence	4	2.2	6	0.4	10	0.6	6	1.2	37	82.2
Other	35	19.1	116	7.9	152	9.1	37	7.6	1	2.2

**Table 56*****Mono-centre and multi-centre clinical trials per objective***

Total CT: 3,863 of which 794 (20.5%) mono-centre and 3,069 (79.5%) multi-centre CT

Objective	Mono-centre CT		Multi-centre CT		Total	
	CT	%	CT	%	CT	%
Efficacy	596	17.5	2,812	82.5	3,408	100.0
Safety	496	15.1	2,780	84.9	3,276	100.0
Therapy	323	22.0	1,146	78.0	1,469	100.0
Pharmacokinetic	73	7.1	952	92.9	1,025	100.0
Pharmacodynamic	30	5.6	507	94.4	537	100.0
Dose response studies	49	10.4	424	89.6	473	100.0
Pharmacogenetic	18	4.3	404	95.7	422	100.0
Pharmacogenomic	6	1.9	307	98.1	313	100.0
Prophylaxis	63	24.1	198	75.9	261	100.0
Pharmaco-economic	6	2.6	229	97.4	235	100.0
Diagnosis	56	45.9	66	54.1	122	100.0
Bioequivalence	45	71.4	18	28.6	63	100.0
Other	36	10.6	305	89.4	341	100.0

**Table 57*****National and international multi-centre clinical trials per objective***

Multi-centre CT: 3,069 of which 846 (27.6%) national and 2,223 (72.4%) international CT

Objective	National multi-centre CT		International multi-centre CT		Total	
	CT	%	CT	%	CT	%
Efficacy	734	26.1	2,078	73.9	2,812	100.0
Safety	642	23.1	2,138	76.9	2,780	100.0
Therapy	429	37.4	717	62.6	1,146	100.0
Pharmacokinetic	72	7.6	880	92.4	952	100.0
Pharmacodynamic	32	6.3	475	93.7	507	100.0
Dose response studies	58	13.7	366	86.3	424	100.0
Pharmacogenetic	35	8.7	369	91.3	404	100.0
Pharmacogenomic	20	6.5	287	93.5	307	100.0
Prophylaxis	36	15.7	193	84.3	229	100.0
Pharmaco-economic	81	40.9	117	59.1	198	100.0
Diagnosis	21	31.8	45	68.2	66	100.0
Bioequivalence	5	27.8	13	72.2	18	100.0
Other	56	18.4	249	81.6	305	100.0

**Table 58*****Clinical trials per objective and profit / no profit Sponsor***

Total CT: 3,863 of which 2,383 (61.7%) profit and 1,480 (38.3%) no profit

Profit Sponsors: 347

No profit Sponsors: 216

Objective	Profit		No profit		Total	
	CT	%	CT	%	CT	%
Efficacy	2,163	63.5	1,244	36.5	3,408	100.0
Safety	2,265	69.1	1,011	30.9	3,276	100.0
Therapy	725	49.4	744	50.6	1,469	100.0
Pharmacokinetic	918	89.6	107	10.4	1,025	100.0
Pharmacodynamic	484	90.1	53	9.9	573	100.0
Dose response studies	382	80.8	103	21.8	473	100.0
Pharmacogenetic	372	88.2	50	11.8	422	100.0
Pharmacogenomic	285	91.1	28	8.9	313	100.0
Prophylaxis	135	51.7	126	48.3	261	100.0
Pharmaco-economic	194	82.6	41	17.4	235	100.0
Diagnosis	42	34.4	80	65.6	122	100.0
Bioequivalence	50	79.4	13	20.6	63	100.0
Other	260	76.2	81	23.8	341	100.0



Table 59

Clinical trials per objective and therapeutic area

Total CT: 3,863

Objective	Oncology		Cardiology/ Vascular diseases		Neurology		Immunology and infectious diseases		Haematology		Other therapeutic areas		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
Efficacy	1,035	30.4	316	9.3	303	8.9	250	7.3	241	7.1	1,263	37.1	3,408	100.0
Safety	1,003	30.6	295	9.0	314	9.6	276	8.4	236	7.2	1,152	35.2	3,276	100.0
Therapy	452	30.8	134	9.1	127	8.6	97	6.6	116	7.9	543	37.0	1,469	100.0
Pharmacokinetic	373	36.4	72	7.0	89	8.7	106	10.3	71	6.9	314	30.6	1,025	100.0
Pharmacodynamic	196	36.5	52	9.7	39	7.3	44	8.2	27	5.0	179	33.3	537	100.0
Dose response studies	120	25.4	41	8.7	54	11.4	30	6.3	32	6.8	196	41.4	473	100.0
Pharmacogenetic	191	45.3	27	6.4	47	11.1	29	6.9	19	4.5	109	25.8	422	100.0
Pharmacogenomic	164	52.4	14	4.5	32	10.2	17	5.4	14	4.5	72	23.0	313	100.0
Prophylaxis	31	11.9	49	18.8	9	3.4	51	19.5	22	8.4	99	37.9	261	100.0
Pharmaco-economic	49	20.9	30	12.8	29	12.3	19	8.1	10	4.3	98	41.7	235	100.0
Diagnosis	39	32.0	13	10.7	12	9.8	4	3.3	10	8.2	44	36.1	122	100.0
Bioequivalence	4	6.3	13	20.6	4	6.3	3	4.8	1	1.6	38	60.3	63	100.0
Other	139	40.8	17	5.0	29	8.5	41	12.0	16	4.7	99	29.0	341	100.0



Clinical trials with orphan drugs and on rare diseases

2006-2010

Table 60

Clinical trials with orphan drugs per year

CT: 268

Year	CT	%	% of tot. CT per year
2006	41	15.3	5.3
2007	39	14.6	4.9
2008	60	22.4	6.8
2009	62	23.1	8.2
2010	66	24.6	10.0
Total	268	100.0	6.9

Table 61

Clinical trials with orphan drugs per year and phase

CT: 268

Year	Phase I		Phase II		Phase III		Phase IV		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%
2006	1	2.4	13	31.7	24	58.5	3	7.3	41	100.0
2007	1	2.6	18	46.2	20	51.5	0	0.0	39	100.0
2008	3	5.0	23	38.3	32	53.3	2	3.3	60	100.0
2009	7	11.3	23	37.1	30	48.4	2	3.2	62	100.0
2010	8	12.1	23	34.9	32	48.5	3	4.6	66	100.0
Total	20	7.5	100	37.3	138	51.5	10	3.7	268	100.0

**Table 62*****Mono-centre and multi-centre clinical trials with orphan drugs per year***

CT: 268

Year	Mono-centre CT		Multi-centre CT		Total	
	CT	%	CT	%	CT	%
2006	1	2.4	40	97.6	41	100.0
2007	2	5.1	37	94.9	39	100.0
2008	1	1.7	59	98.3	60	100.0
2009	4	6.5	58	93.6	62	100.0
2010	2	3.0	64	97.0	66	100.0
Total	10	3.7	258	96.3	268	100.0

Table 63***National and international multi-centre clinical trials with orphan drugs per year***

Multi-centre CT: 258

Year	National multi-centre CT		International multi-centre CT		Total	
	CT	%	CT	%	CT	%
2006	8	20.0	32	80.0	40	100.0
2007	5	13.5	32	86.5	37	100.0
2008	11	18.6	48	81.4	59	100.0
2009	3	5.2	55	94.8	58	100.0
2010	6	9.4	58	90.6	64	100.0
Total	33	12.8	225	87.2	258	100.0

**Table 64*****Clinical trials with orphan drugs per typology of Sponsor: profit / no profit***

CT: 268

Typology	CT	%	Sponsors
Profit	218	81.3	95
No profit	50	18.7	33
Foundation	14	5.2	5
University hospital, University polyclinic and University	12	4.5	10
Scientific association	10	3.7	7
Public or private Scientific institute for research and care (IRCCS)	9	3.4	6
Hospital structure *	3	1.1	3
Local health unit	1	0.4	1
Research institute	1	0.4	1
Total	268	100.0	128

* Hospitals, hospitals under self-administration, assimilated or classified hospitals, private qualified health institutes acting as local health unit, military hospital

Table 65***Clinical trials with orphan drugs per year and profit / no profit Sponsor***

CT: 268

Profit Sponsors: 95

No profit Sponsors: 33

Year	Profit		No profit		Total	
	CT	%	CT	%	CT	%
2006	33	80.5	8	19.5	41	100.0
2007	30	76.9	9	23.1	39	100.0
2008	45	75.0	15	25.0	60	100.0
2009	52	83.9	10	16.1	62	100.0
2010	58	87.9	8	12.1	66	100.0
Total	218	81.3	50	18.7	268	100.0

**Table 66*****Clinical trials with orphan drugs per therapeutic area***

CT: 268

Therapeutic area	CT	%	cum. %
Oncology	109	40.7	40.7
Haematology	51	19.0	59.7
Neurology	19	7.1	66.8
Cardiology/Vascular diseases	18	6.7	73.5
Respiratory system diseases	12	4.5	78.0
Rheumatology	10	3.7	81.7
Endocrinology	9	3.4	85.1
Paediatrics/Neonatology	9	3.4	88.4
Ophthalmology	7	2.6	91.0
Immunology and infectious diseases	7	2.6	93.7
Gastroenterology	5	1.9	95.5
Musculo-skeletal system diseases	4	1.5	97.0
Dermatology/Plastic surgery	4	1.5	98.5
Nephrology/Urology	3	1.1	99.6
Gynaecology and obstetrics	1	0.4	100.0
Total	268	100.0	

**Table 67*****Clinical trials with orphan drugs per typology of participating centre***

CT: 268

Typology	CT	% of CT on orphan drugs (268)	Centres involved
University hospital, University polyclinic and University Hospital structure *	225	84.0	58
Public or private Scientific institute for research and care (IRCCS)	180	67.2	129
Local health unit	178	66.4	30
Private centre **	41	15.3	33
Research institute	12	4.5	7
	2	0.7	2

* Hospitals, hospitals under self-administration, assimilated or classified hospitals, private qualified health institutes acting as local health, military hospital

** Recognised suitable for running clinical trials of drugs

Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted in more than one typology of centre.



Clinical trials on rare diseases

Table 68

Clinical trials on rare diseases per therapeutic area

CT: 503

Therapeutic area	CT	%	cum. %
Oncology	175	34.8	34.8
Haematology	104	20.7	55.5
Neurology	58	11.5	67.0
Cardiology/Vascular diseases	29	5.8	72.8
Respiratory system diseases	23	4.6	77.3
Endocrinology	20	4.0	81.3
Rheumatology	18	3.6	84.9
Paediatrics/Neonatology	15	3.0	87.9
Immunology and infectious diseases	14	2.8	90.7
Nephrology/Urology	14	2.8	93.4
Ophthalmology	9	1.8	95.2
Musculo-skeletal system diseases	8	1.6	96.8
Gastroenterology	7	1.4	98.2
Dermatology/Plastic surgery	4	0.8	99.0
Psychiatry/Psychology	2	0.4	99.4
Traumatology and emergency medicine	1	0.2	99.6
Genito urinary system	1	0.2	99.8
Gynaecology and obstetrics	1	0.2	100.0
Total	503	100.0	



Substantial amendments to clinical trials

2009-2010

Table 69

Substantial amendments per year of clinical trial's single opinion issuing

Total SA: 4,638

Total CT amended: 1,793

Year of CT	SA	CT amended
2000	11	3
2001	7	2
2002	16	7
2003	55	24
2004	57	25
2005	210	86
2006	350	162
2007	776	306
2008	1,488	476
2009	1,277	470
2010	391	232
Total	4,638	1,793

Table 70

Substantial amendments per phase

Total SA: 4,638

Total CT amended: 1,793

CT Phase	SA	%	CT amended	Average SA per CT
Phase III	2,675	57.7	966	2.8
Phase II	1,412	30.4	583	2.4
Phase I	282	6.1	111	2.5
Phase IV	267	5.8	131	2.0
Bioeq / Biod	2	0.0	2	1.0
Total	4,638	100.0	1,793	2.6

**Table 71*****Substantial amendments per authorisation procedure***

Total SA: 4,638

Total CT amended: 1,793

Authorisation procedure	SA	%	CT amended	Average SA per CT
Evaluation of every EC	2,496	53.8	1,324	1.9
Evaluation of every EC and ISS	147	3.2	79	1.9
Evaluation of every EC and AIFA	5	0.1	3	1.7
Evaluation of the coordinating EC	709	15.3	514	1.4
Evaluation of the coordinating EC and ISS	78	1.7	52	1.5
Evaluation of the coordinating EC and AIFA	3	0.1	3	1.0
Notification	507	10.9	425	1.2
Evaluation of a satellite EC for changing of the PI *	693	14.9	407	1.7
Total	4,638	100.0		

* Principal Investigator

There may be more than one amendment on the same clinical trial involving different authorisation procedures.

**Table 72*****Substantial amendments per typology***

Total SA: 4,638

Total CT amended: 1,793

Typology	SA	%	CT amended	Average SA per CT
Modifications to CTA form / protocol /other documents or urgent safety measures	3,719	80.2	1,656	2.2
Change of investigator in a satellite centre	693	14.9	407	1.7
Change of coordinating investigator	119	2.6	116	1.0
Temporary suspension of the trial	74	1.6	71	1.0
Re-start-up of the trial	33	0.7	30	1.1
Total	4,638	100.0		

There may be more than one amendment on the same clinical trial involving different typologies.



**Analysis on the following substantial amendment typology:
“Modifications to CTA form / protocol / other documents
or urgent safety measures”**

Table 72 a**Details per typology**

SA: 3,719

CT amended: 1,656

Typology - Details	SA	%	CT amended	Average SA per CT
Documents attached to the CTA	2,719	73.1	1,362	2.0
Information about the CTA form	2,395	64.4	1,356	1.8
Protocol	1,890	50.8	1,286	1.5
Other documents or information	921	24.8	674	1.4
Urgent safety measures	187	5.0	149	1.3

Table 72 b**Details per typology and profit / no profit Sponsor**

SA: 3,719

CT amended: 1,656

Typology - Details	Profit		No profit		Total	
	SA	%	SA	%	SA	%
Documents attached to the CTA	2,417	88.9	302	11.1	2,719	100.0
Information about the CTA form	2,056	85.8	339	14.2	2,395	100.0
Protocol	1,513	80.1	377	19.9	1,890	100.0
Other documents or information	810	87.9	111	12.1	921	100.0
Urgent safety measures	159	85.0	28	15.0	187	100.0

In both tables, the same amendment may involve different typologies and therefore shall be counted more than once.

**Table 72 c*****Details per reason***

SA: 3,719

CT amended: 1,656

Reason	SA	%	CT amended	Average SA per CT
Safety, rights, well-being or integrity of participants in the clinical trial	1,234	33.2	770	1.6
Modifications to the clinical trial carrying out or management	1,050	28.2	722	1.5
Modifications to the quality of the investigational medicinal product (IMP)	551	14.8	409	1.3
Interpretation of documents concerning scientific/value of the clinical trial	481	12.9	406	1.2
Transfer of main tasks concerning the clinical trial	183	4.9	168	1.1
Substitution of Sponsor, legal representative, applicant	161	4.3	149	1.1

The same amendment may involve different reasons and therefore shall be counted more than once.

**Table 72 d*****Details per reason and profit / no profit Sponsor***

SA: 3,719

CT amended: 1,656

Reason	Profit		No profit		Total	
	SA	%	SA	%	SA	%
Safety, rights, well-being or integrity of participants in the clinical trial	1,095	88.7	139	11.3	1,234	100.0
Modifications to the clinical trial carrying out or management	994	94.7	56	5.3	1,050	100.0
Modifications to the quality of the investigational medicinal product (IMP)	532	96.6	19	3.4	551	100.0
Interpretation of documents concerning scientific/value of the clinical trial	324	67.4	157	32.6	481	100.0
Transfer of main tasks concerning the clinical trial	174	95.1	9	4.9	183	100.0
Substitution of Sponsor, legal representative, applicant	141	87.6	20	12.4	161	100.0

The same amendment may involve different reasons and therefore shall be counted more than once.

**Table 73*****Substantial amendments per therapeutic area***

Total SA: 4,638

Total CT amended: 1,793

Therapeutic area of CT	SA	%	CT amended	Average SA per CT
Oncology	1,761	38.0	644	2.7
Cardiology/Vascular diseases	493	10.6	162	3.0
Haematology	392	8.5	158	2.5
Neurology	371	8.0	142	2.6
Immunology and infectious diseases	331	7.1	134	2.5
Endocrinology	236	5.1	90	2.6
Gastroenterology	190	4.1	79	2.4
Rheumatology	184	4.0	68	2.7
Nephrology/Urology	155	3.3	64	2.4
Respiratory system diseases	126	2.7	60	2.1
Ophthalmology	91	2.0	37	2.5
Musculo-skeletal system diseases	64	1.4	31	2.1
Psychiatry/Psychology	56	1.2	23	2.4
Dermatology/Plastic surgery	47	1.0	22	2.1
Paediatrics/Neonatology	39	0.8	22	1.8
Genito urinary system	33	0.7	14	2.4
Anaesthesiology	22	0.5	16	1.4
Gynaecology and obstetrics	22	0.5	15	1.5
Traumatology and emergency medicine	18	0.4	8	2.3
Otolaryngology	5	0.1	2	2.5
Pharmacology/Toxicology	1	0.0	1	1.0
Oral and maxillofacial surgery	1	0.0	1	1.0
Total	4,638	100.0	1,793	2.6

**Table 74*****Substantial amendments per typology of Sponsor: profit / no profit***

Total SA: 4,638

Total CT amended: 1,793

Typology	SA	%	CT amended	Average SA per CT	Sponsors
Profit	3,930	84.7	1,399	2.8	213
No Profit	708	15.3	394	1.8	117
Public or private Scientific institute for research and care (IRCCS)	169	3.6	101	1.7	18
Scientific association	160	3.4	74	2.2	24
University hospital, University polyclinic and University	133	2.9	96	1.4	28
Foundation	123	2.7	48	2.6	12
Hospital structure *	74	1.6	48	1.5	20
Local health unit	22	0.5	12	1.8	8
Research institute	22	0.5	13	1.7	5
Government body	5	0.1	2	2.5	2
Total	4,638	100.0	1,793	2.6	330

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

**Table 75*****Substantial amendments per profit Sponsor***

SA: 3,930

CT amended: 1,399

The first 29 profit Sponsors out of 213 (13.6%) represent 79.1% of the substantial amendments

	Profit sponsor	SA	%	cum. %	CT amended	Average SA per CT
1	Novartis	452	11.5	11.5	147	3.1
2	Pfizer	384	9.8	21.3	106	3.6
3	Roche	294	7.5	28.8	100	2.9
4	Bristol Myers Squibb	269	6.8	35.6	65	4.1
5	GlaxoSmithKline	155	3.9	39.5	64	2.4
6	Amgen	145	3.7	43.2	42	3.5
7	Bayer	126	3.2	46.4	40	3.2
8	Lilly	124	3.2	49.6	51	2.4
9	AstraZeneca	123	3.1	52.7	36	3.4
10	Boehringer Ingelheim	114	2.9	55.6	45	2.5
11	Sanofi-Aventis	106	2.7	58.3	43	2.5
12	Schering Plough	87	2.2	60.5	23	3.8
13	Janssen-Cilag	77	2.0	62.5	32	2.4
14	Merck Sharp & Dohme	72	1.8	64.3	26	2.8
15	Gruppo Merck	64	1.6	66.0	28	2.3
16	Celgene	60	1.5	67.5	17	3.5
17	Gruppo Abbott	60	1.5	69.0	17	3.5
18	MSD Italia	52	1.3	70.3	15	3.5
19	Novo Nordisk	52	1.3	71.7	16	3.3
20	Eisai	45	1.1	72.8	15	3.0
21	UCB Pharma	43	1.1	73.9	15	2.9
22	Actelion Pharmaceuticals	30	0.8	74.7	13	2.3
23	Gruppo Daiichi Sankyo	28	0.7	75.4	6	4.7
24	Takeda	27	0.7	76.1	9	3.0
25	Astellas	27	0.7	76.7	12	2.3
26	Gruppo Menarini	26	0.7	77.4	11	2.4
27	Lundbeck	24	0.6	78.0	7	3.4
28	Pierre Fabre	22	0.6	78.6	11	2.0
29	Servier	22	0.6	79.1	16	1.4

The data regarding Sponsors, their names and clinical trials associated to them, take into consideration any registered office's variation, merger, acquisition and/or incorporation.

**Table 76*****Substantial amendments per no profit Sponsor***

SA: 708

CT amended: 394

The first 34 no profit Sponsors out of 117 (29.1%) represent 72.6% of the substantial amendments

	No profit Sponsor	SA	%	cum. %	CT amended	Average SA per CT
1	GIMEMA - Gruppo Italiano Malattie EMatologiche dell'Adulto (Rome)	58	8.2	8.2	18	3.2
2	IRCCS Fondazione Centro S. Raffaele del Monte Tabor of Milan	45	6.4	14.5	23	2.0
3	Consorzio Oncotech (Naples)	39	5.5	20.1	7	5.6
4	Istituto di Ricerche Farmacologiche Mario Negri (Milan)	36	5.1	25.1	16	2.3
5	IRCCS Istituto Europeo di Oncologia (IEO) of Milan	36	5.1	30.2	18	2.0
6	Fondazione Neoplasie Sangue (Turin)	34	4.8	35.0	14	2.4
7	A.O. Universitaria Policlinico S. Orsola Malpighi of Bologna	20	2.8	37.9	16	1.3
8	A.O. Universitaria Policlinico Gemelli of Rome	17	2.4	40.3	15	1.1
9	AIEOP - Associazione Italiana Ematologia Oncologia Pediatrica (Bologna)	13	1.8	42.1	5	2.6
10	IRCCS Istituto Clinico Humanitas of Rozzano (MI)	13	1.8	43.9	8	1.6
11	GOIRC - Gruppo Oncologico Italiano di Ricerca Clinica (Parma)	12	1.7	45.6	7	1.7
12	IRCCS Policlinico S. Matteo of Pavia	12	1.7	47.3	1	1.2
13	A.O. Ospedali Riuniti of Bergamo	11	1.6	48.9	6	1.8
14	Istituto Superiore di Sanità of Rome	11	1.6	50.4	6	1.8
15	IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	11	1.6	52.0	7	1.6
16	Università Federico II of Naples	10	1.4	53.4	5	2.0
17	A.O. Presidio Spedali Civili of Brescia	10	1.4	54.8	7	1.4



	No profit Sponsor	SA	%	cum. %	CT amended	Average SA per CT
18	Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan	9	1.3	56.1	3	3.0
19	GISCAD - Gruppo Italiano per lo Studio sui Carcinomi Apparato Digerente (Arluno, MI)	9	1.3	57.3	4	2.3
20	A.O. Universitaria Policlinico of Modena	9	1.3	58.6	6	1.5
21	A.O. Universitaria Pisana of Pisa	9	1.3	59.9	8	1.1
22	AUSL 1 of Massa and Carrara	8	1.1	61.0	3	2.7
23	A.O. of Padova	8	1.1	62.1	4	2.0
24	Università of Perugia	8	1.1	63.3	5	1.6
25	IRCCS Istituto Gaslini of Genoa	8	1.1	64.4	6	1.3
26	A.O. Universitaria Senese of Siena	7	1.0	65.4	4	1.8
27	E.O. Ospedali Galliera of Genoa	7	1.0	66.4	4	1.8
28	IIL - Intergruppo Italiano Linfomi (Alessandria)	7	1.0	67.4	5	1.4
29	IRCCS Istituto Nazionale dei Tumori (INT) of Milan	7	1.0	68.4	5	1.4
30	A.O. Universitaria Arcispedale S. Anna of Ferrara	6	0.8	69.2	1	6.0
31	OPDC - Otsuka Pharmaceutical Development & Commercialization (USA)	6	0.8	70.1	3	2.0
32	A.O. Universitaria Integrata of Verona	6	0.8	70.9	4	1.5
33	A.O. Universitaria of Parma	6	0.8	71.8	4	1.5
34	EORTC - European Organisation for Research and Treatment of Cancer (Belgium)	6	0.8	72.6	4	1.5

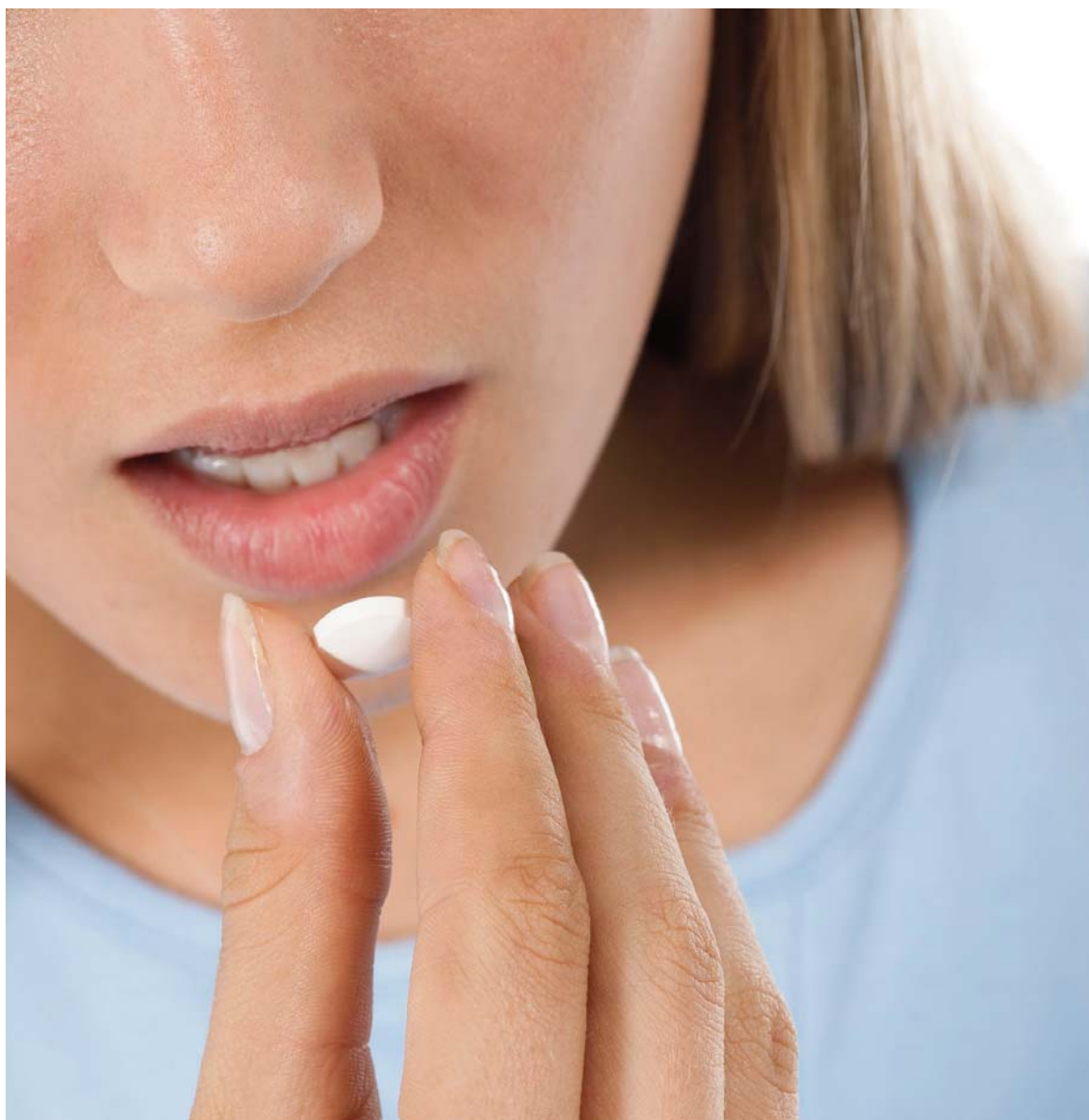
The data regarding Sponsors, their names and clinical trials associated to them, take into consideration any registered office's variation, merger, acquisition and/or incorporation.



Analysis

Clinical trials on female population





■ Summary of main results 2006-2010

Gender pharmacology is under close scrutiny these days, especially that aimed at women. Given the huge amount of data collected, even OsSC could not avoid back out of performing a specific analysis on clinical trials dedicated to the female population.

In the five-year period 2006-2010, there were 314 clinical trials carried out specifically in the female population in Italy, with over 64% of these concentrating on oncology.

It is worth underlining that there is a substantial

balance between the studies sponsored by pharmaceutical companies and no profit organisations. The majority of studies analysed efficacy and safety.

Moreover, there were 52 studies aimed at pregnant women, while 47 focussed on breastfeeding ones. The therapeutic area most analysed in this case was neurology.

The most involved regions in these trials were Lombardy, Emilia-Romagna, Lazio and Tuscany, in line with other clinical trials.

These numbers show a progressive increase in attention to gender pharmacology, which should hold some positive surprises for us in the future.



Clinical trials exclusively involving women

(Clinical trials involving both genders are not included in this analysis)

Table 77

Clinical trials exclusively involving women per year and phase

CT: 314

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq/Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	5	6.2	37	45.7	33	40.7	6	7.4	0	0.0	81	100.0
2007	1	1.4	35	49.3	29	40.8	6	8.5	0	0.0	71	100.0
2008	2	3.6	27	48.2	21	37.5	6	10.7	0	0.0	56	100.0
2009	2	3.1	28	43.8	25	39.1	9	14.1	0	0.0	64	100.0
2010	2	4.8	19	45.2	15	35.7	6	14.3	0	0.0	42	100.0
Total	12	3.8	146	46.5	123	39.2	33	10.5	0	0.0	314	100.0

Table 78

Clinical trials exclusively involving women per forecast age group

CT: 314

Age group	CT	%
Adults (from 19 to 64 years of age)	306	97.5
OAPs (65+ years of age)	229	72.9
Minors (from 13 to 18 years of age)	3	1.0
Children (up to 12 years of age)	2	0.6

Enrolled subjects could fall into more than one age group; therefore the same trial may be counted more than once.

**Table 79*****Clinical trials exclusively involving women per therapeutic area***

CT: 314

Therapeutic area	CT	%	cum. %
Oncology	203	64.6	64.6
Gynaecology and obstetrics	44	14.0	78.7
Musculo-skeletal system diseases	15	4.8	83.4
Anaesthesiology	13	4.1	87.6
Endocrinology	11	3.5	91.1
Rheumatology	5	1.6	92.7
Genito urinary system	5	1.6	94.3
Nephrology/Urology	4	1.3	95.5
Neurology	3	1.0	96.5
Haematology	2	0.6	97.1
Gastroenterology	2	0.6	97.8
Immunology and infectious diseases	2	0.6	98.4
Paediatrics/Neonatology	2	0.6	99.0
Dermatology/Plastic surgery	1	0.3	99.4
Respiratory system diseases	1	0.3	99.7
Psychiatry/Psychology	1	0.3	100.0
Total	314	100.0	

**Table 80***Clinical trials exclusively involving women per therapeutic area and phase*

CT: 314

Therapeutic area	CT					
	Phase I	Phase II	Phase III	Phase IV	Bioeq/Biod	Total
Oncology	10	125	66	2	0	203
Gynaecology and obstetrics	1	6	27	10	0	44
Musculo-skeletal system diseases	0	1	12	2	0	15
Anaesthesiology	0	0	7	6	0	13
Endocrinology	0	2	3	6	0	11
Rheumatology	0	1	2	2	0	5
Genito urinary system	0	2	2	1	0	5
Nephrology/Urology	0	2	1	1	0	4
Neurology	0	2	1	0	0	3
Haematology	1	0	1	0	0	2
Gastroenterology	0	1	1	0	0	2
Immunology and infectious diseases	0	2	0	0	0	2
Paediatrics/Neonatology	0	0	0	2	0	2
Dermatology/Plastic surgery	0	0	0	1	0	1
Respiratory system diseases	0	1	0	0	0	1
Psychiatry/Psychology	0	1	0	0	0	1
Total	12	146	123	33	0	314

**Table 81**

***Clinical trials exclusively involving women per therapeutic classification -
ATC up to 5th level***

CT: 314 of which 312 (99.4%) with ATC 2nd level and 232 (73.9%) with ATC 5th level
of at least one test drug specified

Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
L	Antineoplastic and immunomodulating agents	190	5.3	62.1	31.6	1.0	100.0
L01	Antineoplastic agents	165	6.1	63.0	29.7	1.2	100.0
L01XC03	Trastuzumab	31	6.5	67.7	22.6	3.2	100.0
L01BC06	Capecitabine	24	0.0	83.3	12.5	4.2	100.0
L01DB01	Doxorubicin	22	4.5	77.3	18.2	0.0	100.0
L01CA04	Vinorelbine	19	0.0	89.5	5.3	5.2	100.0
L01XC07	Bevacizumab	19	0.0	52.6	47.4	0.0	100.0
L01CD01	Paclitaxel	18	11.1	66.7	22.2	0.0	100.0
L01CD02	Docetaxel	15	6.7	73.3	20.0	0.0	100.0
L01AA01	Ciclofosfamide	14	0.0	92.9	7.1	0.0	100.0
L01XA02	Carboplatin	12	0.0	83.3	16.7	0.0	100.0
L01XE07	Lapatinib	11	9.1	63.6	27.3	0.0	100.0
L01XA01	Cisplatino	10	0.0	80.0	20.0	0.0	100.0
L01DB03	Epirubicin	8	12.5	87.5	0.0	0.0	100.0
L01BC05	Gemcitabine	7	0.0	85.7	14.3	0.0	100.0
L01BC02	Fluorouracile	5	0.0	100.0	0.0	0.0	100.0
L01CX01	Trabectedin	5	0.0	60.0	40.0	0.0	100.0
L01XE10	Everolimus	4	0.0	25.0	75.0	0.0	100.0
L01DC04	Ixabepilone	3	33.3	33.3	33.3	0.0	100.0
L01XX17	Topotecan	3	0.0	100.0	0.0	0.0	100.0
L01BA04	Pemetrexed	2	0.0	100.0	0.0	0.0	100.0
L01XE05	Sorafenib	2	0.0	100.0	0.0	0.0	100.0
L01AX03	Temozolomide	1	0.0	100.0	0.0	0.0	100.0
L01DC03	Mitomycin	1	0.0	100.0	0.0	0.0	100.0
L01XA03	Oxaliplatin	1	0.0	100.0	0.0	0.0	100.0
L01XC06	Cetuximab	1	0.0	100.0	0.0	0.0	100.0
L01XE03	Erlotinib	1	0.0	100.0	0.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
L01XE04	Sunitinib	1	0.0	100.0	0.0	0.0	100.0
L01XE06	Dasatinib	1	100.0	0.0	0.0	0.0	100.0
L01XX19	Irinotecan	1	0.0	0.0	100.0	0.0	100.0
L02	Endocrine therapy	25	0.0	56.0	44.0	0.0	100.0
L02BG04	Letrozole	10	0.0	60.0	40.0	0.0	100.0
L02BA03	Fulvestrant	6	0.0	83.3	16.7	0.0	100.0
L02AE04	Triptorelin	3	0.0	100.0	0.0	0.0	100.0
L02BG06	Exemestane	3	0.0	66.7	33.3	0.0	100.0
L02BA01	Tamoxifen	2	0.0	0.0	100.0	0.0	100.0
L02AE02	Leuprorelin	1	0.0	100.0	0.0	0.0	100.0
L02AE03	Goserelin	1	0.0	0.0	100.0	0.0	100.0
L02BB03	Bicalutamide	1	0.0	0.0	100.0	0.0	100.0
L02BG03	Anastrozole	1	0.0	0.0	100.0	0.0	100.0
L03	Immunostimulants	6	0.0	50.0	50.0	0.0	100.0
L03AA02	Filgrastim	1	0.0	0.0	100.0	0.0	100.0
L03AA13	Pegfilgrastim	1	0.0	100.0	0.0	0.0	100.0
L03AB10	Peginterferone alfa-2b	1	0.0	100.0	0.0	0.0	100.0
L04	Immunosuppressants	5	0.0	100.0	0.0	0.0	100.0
L04AA18	Everolimus	1	0.0	100.0	0.0	0.0	100.0
G	Genito urinary system and sex hormones	35	0.0	22.9	45.7	31.4	100.0
G03	Sex hormones and modulators of the genital system	26	0.0	15.4	53.8	30.8	100.0
G03AA12	Drospirenone and estrogen	3	0.0	0.0	66.7	33.3	100.0
G03CA03	Estradiol	3	0.0	0.0	33.3	66.7	100.0
G03DA04	Progesterone	2	0.0	0.0	50.0	50.0	100.0
G03GA05	Follitropin alfa	2	0.0	50.0	0.0	50.0	100.0
G03AA07	Levonorgestrel and estrogen	1	0.0	100.0	0.0	0.0	100.0
G03AA09	Desogestrel and estrogen	1	0.0	0.0	0.0	100.0	100.0
G03AA10	Gestodene and estrogen	1	0.0	0.0	100.0	0.0	100.0
G03BA03	Testosterone	1	0.0	0.0	100.0	0.0	100.0
G03CA01	Ethinylestradiol	1	0.0	0.0	0.0	100.0	100.0
G03DA02	Medroxyprogesterone	1	0.0	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
G03DA03	Hydroxyprogesterone	1	0.0	100.0	0.0	0.0	100.0
G03DB04	Nomegestrol	1	0.0	0.0	100.0	0.0	100.0
G03FA12	Medroxyprogesterone and estrogen	1	0.0	0.0	0.0	100.0	100.0
G03FB05	Norethisterone and estrogen	1	0.0	0.0	0.0	100.0	100.0
G03GA30	Combinations	1	0.0	0.0	100.0	0.0	100.0
G03XC01	Raloxifene	1	0.0	0.0	0.0	100.0	100.0
G04	Urologicals	6	0.0	50.0	33.3	16.7	100.0
G04BD08	Solifenacin	1	0.0	0.0	0.0	100.0	100.0
G04BX13	Dimethyl sulfoxide	1	0.0	0.0	100.0	0.0	100.0
G04CB02	Dutasteride	1	0.0	0.0	100.0	0.0	100.0
G02	Other gynaecologicals	4	0.0	25.0	25.0	50.0	100.0
G02AB01	Methylethergometrine	2	0.0	0.0	50.0	50.0	100.0
G02BA03	Plastic IUD with progestogen	1	0.0	100.0	0.0	0.0	100.0
A	Alimentary tract and metabolism	18	0.0	33.3	55.6	11.1	100.0
A10	Drugs used in diabetes	9	0.0	44.4	55.6	0.0	100.0
A10BA02	Metformin	9	0.0	44.4	55.6	0.0	100.0
A10BH01	Sitagliptin	1	0.0	100.0	0.0	0.0	100.0
A11	Vitamins	4	0.0	25.0	50.0	25.0	100.0
A11AA03	Multivitamins and other minerals, including combination	1	0.0	0.0	0.0	100.0	100.0
A11CC05	Colecalciferol	2	0.0	50.0	50.0	0.0	100.0
A02	Drugs for acid related disorders	1	0.0	0.0	100.0	0.0	100.0
A02BB01	Misoprostol	1	0.0	0.0	100.0	0.0	100.0
A04	Antiemetics and antinauseants	1	0.0	0.0	100.0	0.0	100.0
A04AD12	Aprepitant	1	0.0	0.0	100.0	0.0	100.0
A05	Bile and liver therapy	1	0.0	0.0	100.0	0.0	100.0
A05AA02	Ursodeoxycholic acid	1	0.0	0.0	100.0	0.0	100.0
A07	Antidiarrheals, intestinal antiinflammatory/ antiinfective agents	1	0.0	100.0	0.0	0.0	100.0
A07AA11	Rifaximin	1	0.0	100.0	0.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
A16	Other alimentary tract and metabolism products	1	0.0	0.0	0.0	100.0	100.0
A16AB05	Laronidase	1	0.0	0.0	0.0	100.0	100.0
M	Musculo-skeletal system	18	0.0	22.2	72.2	5.6	100.0
M05	Drugs for treatment of bone diseases	14	0.0	7.1	85.8	7.1	100.0
M05BA02	Clodronic acid	1	0.0	0.0	100.0	0.0	100.0
M05BA04	Alendronic acid	1	0.0	0.0	0.0	100.0	100.0
M05BA08	Zoledronic acid	3	0.0	33.3	66.7	0.0	100.0
M05BX03	Strontium ranelate	2	0.0	0.0	100.0	0.0	100.0
M05BX04	Denosumab	2	0.0	0.0	100.0	0.0	100.0
M01	Antiinflammatory and antirheumatic products	2	0.0	50.0	50.0	0.0	100.0
M01AE01	Ibuprofen	1	0.0	0.0	100.0	0.0	100.0
M03	Muscle relaxants	1	0.0	100.0	0.0	0.0	100.0
M03AX01	Botulinum toxin	1	0.0	100.0	0.0	0.0	100.0
M09	Other drugs for disorders of the musculo-skeletal system	1	0.0	100.0	0.0	0.0	100.0
N	Nervous system	16	0.0	12.5	50.0	37.5	100.0
N01	Anesthetics	12	0.0	0.0	50.0	50.0	100.0
N01AB07	Desflurane	1	0.0	0.0	0.0	100.0	100.0
N01AH03	Sufentanil	5	0.0	0.0	0.0	100.0	100.0
N01AH06	Remifentanil	1	0.0	0.0	100.0	0.0	100.0
N01AX03	Ketamine	3	0.0	0.0	100.0	0.0	100.0
N01BB09	Ropivacaine	4	0.0	0.0	75.0	25.0	100.0
N01BB10	Levobupivacaine	3	0.0	0.0	0.0	100.0	100.0
N02	Analgesics	2	0.0	50.0	50.0	0.0	100.0
N02AE01	Buprenorphine	1	0.0	0.0	100.0	0.0	100.0
N06	Psychoanaleptics	2	0.0	50.0	50.0	0.0	100.0
N06AB05	Paroxetine	1	0.0	100.0	0.0	0.0	100.0
V	Various	11	0.0	45.5	36.4	18.1	100.0
V09	Diagnostic radiopharmaceuticals	4	0.0	100.0	0.0	0.0	100.0
V03	All other therapeutic products	3	0.0	0.0	66.7	33.3	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
V06	General nutrients	2	0.0	0.0	50.0	50.0	100.0
V08	Contrast media	2	0.0	50.0	50.0	0.0	100.0
V08CA08	Gadobenic acid	1	0.0	0.0	100.0	0.0	100.0
V08CA11	Gadofosveset	1	0.0	100.0	0.0	0.0	100.0
B	Blood and blood forming organs	9	11.1	0.0	55.6	33.3	100.0
B01	Antithrombotic agents	5	0.0	0.0	60.0	40.0	100.0
B01AB04	Dalteparin	1	0.0	0.0	100.0	0.0	100.0
B01AB05	Enoxaparin	2	0.0	0.0	100.0	0.0	100.0
B01AB06	Nadroparin	1	0.0	0.0	100.0	0.0	100.0
B01AC06	Acetylsalicylic acid	1	0.0	0.0	0.0	100.0	100.0
B03	Antianemic preparations	3	33.3	0.0	66.7	0.0	100.0
B03AA07	Ferrous sulfate	1	0.0	0.0	100.0	0.0	100.0
B03BB01	Folic acid	1	0.0	0.0	100.0	0.0	100.0
B05	Blood substitutes and perfusion solutions	1	0.0	0.0	0.0	100.0	100.0
B05BB01	Electrolytes	1	0.0	0.0	0.0	100.0	100.0
H	Systemic hormonal preparations, excluding sex hormones and insulins	8	0.0	0.0	62.5	37.5	100.0
H05	Calcium homeostasis	6	0.0	0.0	50.0	50.0	100.0
H05AA02	Teriparatide	2	0.0	0.0	50.0	50.0	100.0
H05AA03	Parathyroid hormone	3	0.0	0.0	33.3	66.7	100.0
H05BA01	Calcitonin (salmon synthetic)	1	0.0	0.0	100.0	0.0	100.0
H01	Pituitary and hypothalamic hormones and analogues	2	0.0	0.0	100.0	0.0	100.0
H01BB02	Oxitocin	1	0.0	0.0	100.0	0.0	100.0
J	General antiinfectives for systemic use	7	14.3	28.6	42.8	14.3	100.0
J01	Antibacterials for systemic use	3	33.3	0.0	33.3	33.3	100.0
J01DB04	Cefazolin	1	0.0	0.0	100.0	0.0	100.0
J01MA17	Prulifloxacin	2	50.0	0.0	0.0	50.0	100.0
J07	Vaccines	2	0.0	0.0	100.0	0.0	100.0
J05	Antivirals for systemic use	1	0.0	100.0	0.0	0.0	100.0
J05AB04	Ribavirin	1	0.0	100.0	0.0	0.0	100.0



Therapeutic classification ATC up to 5 th level		CT (Phase I-II-III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
J06	Immune sera and immunoglobulins	1	0.0	100.0	0.0	0.0	100.0
J06BB09	Cytomegalovirus immunoglobulin	1	0.0	100.0	0.0	0.0	100.0
C	Cardiovascular system	2	0.0	0.0	50.0	50.0	100.0
C08	Calcium channel blockers	1	0.0	0.0	100.0	0.0	100.0
C08CA05	Nifedipine	1	0.0	0.0	100.0	0.0	100.0
C10	Lipid modifying agents	1	0.0	0.0	0.0	100.0	100.0
C10AA05	Atorvastatin	1	0.0	0.0	0.0	100.0	100.0
D	Dermatologicals	2	0.0	50.0	0.0	50.0	100.0
D02	Emollients and protectives	1	0.0	100.0	0.0	0.0	100.0
D11	Other dermatological preparations	1	0.0	0.0	0.0	100.0	100.0
D11AX16	Eflornithine	1	0.0	0.0	0.0	100.0	100.0

The same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

**Table 82*****Clinical trials exclusively involving women per participating centre's region***

CT: 314

Region	CT	% of CT (314)	Centres involved	Average CT per centre	CT coord.	% CT coord./total
Lombardy	174	55.4	56	7	76	43.7
Emilia-Romagna	130	41.4	33	9	53	40.8
Lazio	121	38.5	36	6	45	37.2
Tuscany	87	27.7	25	5	28	32.2
Campania	79	25.2	21	6	26	32.9
Piedmont	77	24.5	32	5	17	22.1
Veneto	69	22.0	43	3	7	10.1
Sicily	69	22.0	22	5	8	11.6
Puglia	64	20.4	15	7	5	7.8
Liguria	63	20.1	15	5	22	34.9
Friuli-Venezia Giulia	58	18.5	10	8	9	15.5
Sardinia	41	13.1	11	5	5	12.2
Marche	39	12.4	20	3	1	2.6
Umbria	39	12.4	8	6	5	12.8
Molise	30	9.6	6	6	4	13.3
Abruzzi	29	9.2	12	4	3	10.3
Trentino-Alto Adige	18	5.7	5	4	0	0.0
Basilicata	18	5.7	2	10	0	0.0
Calabria	16	5.1	9	2	0	0.0
Valle d'Aosta	1	0.3	1	1	0	0.0

Multi-centre clinical trials are carried out in more than one centre and therefore the same study shall be counted in more than one region in the "CT" column.

In the "Centres involved" column the number of centres participating in clinical trials is reported for each region. In this case each centre is counted only once, even if it is participating in more than one trial.

The number reported in the "Average CT per centre" column represents the average number of clinical trials each centre is carrying out per region. This number is calculated summing the studies performed in each centre, divided by the number of centres involved.

The "CT coord." column reports the number of clinical trials whose coordinating centre is in the region (the sum of this column corresponds to the national sample being one coordinating centre per clinical trial).

**Table 83*****Clinical trials exclusively involving women per typology of Sponsor: profit / no profit***

CT: 314

Typology	CT	%	Sponsors
Profit	160	51.0	53
No profit	154	49.0	55
University hospital, University polyclinic and University	59	18.8	17
Public or private Scientific institute for research and care (IRCCS)	45	14.3	11
Scientific association	19	6.1	6
Hospital structure *	19	6.1	13
Local health unit	7	2.2	6
Foundation	4	1.3	1
Government body	1	0.3	1
Total	314	100.0	108

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

Table 84***Clinical trials exclusively involving women per objective***

CT: 314

Objective	CT	% of CT (314)
Efficacy	280	89.2
Safety	254	80.9
Therapy	114	36.3
Pharmacokinetic	57	18.2
Dose response studies	30	9.6
Pharmacogenetic	38	12.1
Pharmacodynamic	31	9.9
Prophylaxis	25	8.0
Pharmacogenomic	21	6.7
Pharmaco-economic	9	2.9
Diagnosis	5	1.6
Bioequivalence	4	1.3
Other	21	6.7



Clinical trials involving pregnant women

*(Clinical trials involving women only
and those involving both genders are included in this analysis)*

Table 85

*Clinical trials involving pregnant women
per year and phase*

CT: 52

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq/Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	0	0.0	3	27.3	7	63.6	1	9.1	0	0.0	11	100.0
2007	0	0.0	3	27.3	5	45.5	3	27.3	0	0.0	11	100.0
2008	0	0.0	3	23.1	9	69.2	1	7.7	0	0.0	13	100.0
2009	0	0.0	0	0.0	1	20.0	4	80.0	0	0.0	5	100.0
2010	0	0.0	2	16.7	4	33.3	6	50.0	0	0.0	12	100.0
Total	0	0.0	11	21.2	26	50.0	15	28.8	0	0.0	52	100.0

Table 86

*Clinical trials involving pregnant women
per forecast age group*

CT: 52

Age group	CT	%
Adults (from 19 to 64 years of age)	52	100.0
OAPs (65+ years of age)	21	40.4
Minors (from 13 to 18 years of age)	3	5.8
Children (up to 12 years of age)	3	5.8

Enrolled subjects could fall into more than one age group; therefore the same trial may be counted more than once.

**Table 87**

***Clinical trials involving pregnant women
per therapeutic area***

CT: 52

Therapeutic area	CT	%	cum. %
Gynaecology and obstetrics	13	25.0	25.0
Anaesthesiology	8	15.4	40.4
Oncology	6	11.5	51.9
Immunology and infectious diseases	4	7.7	59.6
Neurology	4	7.7	67.3
Dermatology/Plastic surgery	3	5.8	73.1
Gastroenterology	3	5.8	78.8
Cardiology/Vascular diseases	2	3.8	82.7
Paediatrics/Neonatology	2	3.8	86.5
Traumatology and emergency medicine	2	3.8	90.4
Haematology	1	1.9	92.3
Pharmacology/Toxicology	1	1.9	94.2
Musculo-skeletal system diseases	1	1.9	96.2
Ophthalmology	1	1.9	98.1
Rheumatology	1	1.9	100.0
Total	52	100.0	

**Table 88**

***Clinical trials involving pregnant women
per therapeutic area and phase***

CT: 52

Therapeutic area	CT					
	Phase I	Phase II	Phase III	Phase IV	Bioeq/Biod	Total
Gynaecology and obstetrics	0	0	10	3	0	13
Anaesthesiology	0	0	4	4	0	8
Oncology	0	5	1	0	0	6
Immunology and infectious diseases	0	3	1	0	0	4
Neurology	0	0	2	2	0	4
Dermatology/Plastic surgery	0	1	2	0	0	3
Gastroenterology	0	0	2	1	0	3
Cardiology/Vascular diseases	0	0	1	1	0	2
Paediatrics/Neonatology	0	1	0	1	0	2
Traumatology and emergency medicine	0	0	1	1	0	2
Haematology	0	0	1	0	0	1
Pharmacology/Toxicology	0	0	0	1	0	1
Musculo-skeletal system diseases	0	0	0	1	0	1
Ophthalmology	0	1	0	0	0	1
Rheumatology	0	0	1	0	0	1
Total	0	11	26	15	0	52

**Table 89**

***Clinical trials involving pregnant women
per therapeutic classification – ATC up to 2nd level***

CT: 52 of which 51 (98.1%)

with ATC 2nd level of at least one test drug specified

Therapeutic classification ATC up to 2 nd level		CT (Phase II-III-IV)	%			
			Phase II	Phase III	Phase IV	Total
A	Alimentary tract and metabolism	9	0.0	66.7	33.3	100.0
A09	Digestives, including enzymes	2	0.0	50.0	50.0	100.0
A10	Drugs used in diabetes	2	0.0	100.0	0.0	100.0
A02	Drugs for acid related disorders	1	0.0	100.0	0.0	100.0
A03	Drugs for functional gastrointestinal disorders	1	0.0	0.0	100.0	100.0
A05	Bile and liver therapy	1	0.0	100.0	0.0	100.0
A11	Vitamins	1	0.0	100.0	0.0	100.0
A16	Other alimentary tract and metabolism products	1	0.0	0.0	100.0	100.0
N	Nervous system	9	0.0	44.4	55.6	100.0
N01	Anesthetics	7	0.0	57.1	42.9	100.0
N04	Anti-Parkinson drugs	1	0.0	0.0	100.0	100.0
N07	Other nervous system drugs	1	0.0	0.0	100.0	100.0
B	Blood and blood forming organs	8	0.0	50.0	50.0	100.0
B01	Antithrombotic agents	5	0.0	40.0	60.0	100.0
B05	Blood substitutes and perfusion solutions	2	0.0	50.0	50.0	100.0
B03	Antianemic preparations	1	0.0	100.0	0.0	100.0
G	Genito urinary system and sex hormones	5	0.0	80.0	20.0	100.0
G03	Sex hormones and modulators of the genital system	4	0.0	75.0	25.0	100.0
G02	Other gynaecologicals	1	0.0	100.0	0.0	100.0
L	Antineoplastic and immunomodulating agents	5	60.0	20.0	20.0	100.0
L01	Antineoplastic agents	3	100.0	0.0	0.0	100.0
L03	Immunostimulants	2	0.0	50.0	50.0	100.0
V	Various	5	60.0	20.0	20.0	100.0
V03	All other therapeutic products	2	50.0	0.0	50.0	100.0



Therapeutic classification ATC up to 2 nd level		CT (Phase II-III-IV)	%			
			Phase II	Phase III	Phase IV	Total
V04	Diagnostic agents	1	100.0	0.0	0.0	100.0
V06	General nutrients	1	0.0	100.0	0.0	100.0
V09	Diagnostic radiopharmaceuticals	1	100.0	0.0	0.0	100.0
J	General antiinfectives for systemic use	4	75.0	25.0	0.0	100.0
J05	Antivirals for systemic use	3	66.7	33.3	0.0	100.0
J06	Immune sera and immunoglobulins	1	100.0	0.0	0.0	100.0
M	Musculo-skeletal system	4	25.0	50.0	25.0	100.0
M01	Antiinflammatory and antirheumatic products	1	0.0	0.0	100.0	100.0
M03	Muscle relaxants	1	0.0	100.0	0.0	100.0
M04	Antigout preparations	1	100.0	0.0	0.0	100.0
M05	Drugs for treatment of bone diseases	1	0.0	100.0	0.0	100.0
D	Dermatologicals	3	33.3	66.7	0.0	100.0
D06	Antibiotics and chemotherapeutics for dermatological use	1	0.0	100.0	0.0	100.0
D07	Corticosteroids, dermatological preparations	1	0.0	100.0	0.0	100.0
D08	Antiseptics and disinfectants	1	100.0	0.0	0.0	100.0
C	Cardiovascular system	2	0.0	100.0	0.0	100.0
C01	Cardiac therapy	1	0.0	100.0	0.0	100.0
C08	Calcium channel blockers	1	0.0	100.0	0.0	100.0
H	Systemic hormonal preparations, excluding sex hormones and insulins	1	0.0	100.0	0.0	100.0
H01	Pituitary and hypothalamic hormones and analogues	1	0.0	100.0	0.0	100.0
R	Respiratory system	1	0.0	0.0	100.0	100.0
R05	Cough and cold preparations	1	0.0	0.0	100.0	100.0

The total number of ATC 1st level clinical trials ("CT" column) is higher than the number indicated in the subtitle because the same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

Likewise, regarding each therapeutic classification, the total number of ATC 2nd level clinical trials ("CT" column) can be higher than the ATC 1st level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

**Table 90**

***Clinical trials involving pregnant women
per typology of Sponsor: profit / no profit***

CT: 52

Typology	CT	%	Sponsors
No profit	40	76.9	25
University hospital, University polyclinic and University	20	38.5	8
Hospital structure *	9	17.3	8
Public or private Scientific institute for research and care (IRCCS)	6	11.5	4
Local health unit	3	5.8	3
Scientific association	1	1.9	1
Foundation	1	1.9	1
Profit	12	23.1	10
Total	52	100.0	35

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

Table 91

***Clinical trials involving pregnant women
per objective***

CT: 52

Objective	CT	% of CT (52)
Efficacy	45	86.5
Safety	35	67.3
Therapy	16	30.8
Prophylaxis	12	23.1
Pharmacokinetic	7	13.5
Pharmacodynamic	5	9.6
Dose response studies	5	9.6
Pharmacogenetic	3	5.8
Diagnosis	2	3.8
Bioequivalence	1	1.9
Pharmacogenomic	1	1.9
Other	3	5.8



Clinical trials involving breastfeeding women

*(Clinical trials involving women only
and those involving both genders are included in this analysis)*

Table 92

*Clinical trials involving breastfeeding women
per year and phase*

CT: 47

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq/Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	0	0.0	2	20.0	7	70.0	1	10.0	0	0.0	10	100.0
2007	0	0.0	4	44.4	4	44.4	1	11.1	0	0.0	9	100.0
2008	0	0.0	5	41.7	6	50.0	1	8.3	0	0.0	12	100.0
2009	0	0.0	0	0.0	4	50.0	4	50.0	0	0.0	8	100.0
2010	0	0.0	1	12.5	1	12.5	6	75.0	0	0.0	8	100.0
Total	0	0.0	12	25.5	22	46.8	13	27.7	0	0.0	47	100.0

Table 93

*Clinical trials involving breastfeeding women
per forecast age group*

CT: 47

Age group	CT	%
Adults (from 19 to 64 years of age)	46	97.9
OAPs (65+ years of age)	35	74.5
Minors (from 13 to 18 years of age)	4	8.5
Children (up to 12 years of age)	3	6.4

Enrolled subjects could fall into more than one age group; therefore the same trial may be counted more than once.

**Table 94**

***Clinical trials involving breastfeeding women
per therapeutic area***

CT: 47

Therapeutic area	CT	%	cum. %
Neurology	9	19.1	19.1
Oncology	7	14.9	34.0
Cardiology/Vascular diseases	6	12.8	46.8
Anaesthesiology	3	6.4	53.2
Dermatology/Plastic surgery	3	6.4	59.6
Gastroenterology	3	6.4	66.0
Immunology and infectious diseases	3	6.4	72.3
Paediatrics/Neonatology	3	6.4	78.7
Gynaecology and obstetrics	2	4.3	83.0
Ophthalmology	2	4.3	87.2
Traumatology and emergency medicine	2	4.3	91.5
Haematology	1	2.1	93.6
Pharmacology/Toxicology	1	2.1	95.7
Musculo-skeletal system diseases	1	2.1	97.9
Rheumatology	1	2.1	100.0
Total	47	100.0	

**Table 95**

***Clinical trials involving breastfeeding women
per therapeutic area and phase***

CT: 47

Therapeutic area	CT					
	Phase I	Phase II	Phase III	Phase IV	Bioeq/Biod	Total
Neurology	0	0	7	2	0	9
Oncology	0	6	1	0	0	7
Cardiology/Vascular diseases	0	1	4	1	0	6
Anaesthesiology	0	1	0	2	0	3
Dermatology/Plastic surgery	0	1	1	1	0	3
Gastroenterology	0	1	1	1	0	3
Immunology and infectious diseases	0	1	2	0	0	3
Pediatrics/Neonatology	0	0	1	2	0	3
Gynaecology and obstetrics	0	0	1	1	0	2
Ophthalmology	0	1	1	0	0	2
Traumatology and emergency medicine	0	0	1	1	0	2
Haematology	0	0	1	0	0	1
Pharmacology/Toxicology	0	0	0	1	0	1
Musculo-skeletal system diseases	0	0	0	1	0	1
Rheumatology	0	0	1	0	0	1
Total	0	12	22	13	0	47

**Table 96**

***Clinical trials involving breastfeeding women
per therapeutic classification – ATC up to 2nd level***

CT: 47 of which 46 (97.9%)

with ATC 2nd level of at least one test drug specified

Therapeutic classification ATC up to 2 nd level		CT (Phase II-III-IV)	%			
			Phase II	Phase III	Phase IV	Total
B	Blood and blood forming organs	9	22.2	55.6	22.2	100.0
B01	Antithrombotic agents	5	40.0	40.0	20.0	100.0
B05	Blood substitutes and perfusion solutions	2	0.0	50.0	50.0	100.0
B02	Antihemorrhagics	1	0.0	100.0	0.0	100.0
B03	Antianemic preparations	1	0.0	100.0	0.0	100.0
A	Alimentary tract and metabolism	8	12.5	37.5	50.0	100.0
A09	Digestives, including enzymes	2	0.0	50.0	50.0	100.0
A10	Drugs used in diabetes	2	50.0	50.0	0.0	100.0
A11	Vitamins	2	0.0	50.0	50.0	100.0
A03	Drugs for functional gastrointestinal disorders	1	0.0	0.0	100.0	100.0
A16	Other alimentary tract and metabolism products	1	0.0	0.0	100.0	100.0
L	Antineoplastic and immunomodulating agents	6	66.7	16.7	16.6	100.0
L01	Antineoplastic agents	4	100.0	0.0	0.0	100.0
L03	Immunostimulants	2	0.0	50.0	50.0	100.0
C	Cardiovascular system	4	0.0	100.0	0.0	100.0
C01	Cardiac therapy	2	0.0	100.0	0.0	100.0
C07	Beta blocking agents	1	0.0	100.0	0.0	100.0
C08	Calcium channel blockers	1	0.0	100.0	0.0	100.0
C09	Agents acting on the renin-angiotensin system	1	0.0	100.0	0.0	100.0
C10	Lipid modifying agents	1	0.0	100.0	0.0	100.0
N	Nervous system	4	0.0	50.0	50.0	100.0
N04	Anti-Parkinson drugs	3	0.0	66.7	33.3	100.0
N07	Other nervous system drugs	1	0.0	0.0	100.0	100.0



Therapeutic classification ATC up to 2 nd level		CT (Phase II-III-IV)	%			
			Phase II	Phase III	Phase IV	Total
V	Various	4	75.0	0.0	25.0	100.0
V03	All other therapeutic products	2	50.0	0.0	50.0	100.0
V04	Diagnostic agents	1	100.0	0.0	0.0	100.0
V09	Diagnostic radiopharmaceuticals	1	100.0	0.0	0.0	100.0
J	General antiinfectives for systemic use	3	33.3	66.7	0.0	100.0
J05	Antivirals for systemic use	2	50.0	50.0	0.0	100.0
J06	Immune sera and immunoglobulins	1	0.0	100.0	0.0	100.0
M	Musculo-skeletal system	3	0.0	66.7	33.3	100.0
M01	Antiinflammatory and antirheumatic products	1	0.0	0.0	100.0	100.0
M03	Muscle relaxants	1	0.0	100.0	0.0	100.0
M05	Drugs for treatment of bone diseases	1	0.0	100.0	0.0	100.0
D	Dermatologicals	2	50.0	50.0	0.0	100.0
D07	Corticosteroids, dermatological preparations	1	0.0	100.0	0.0	100.0
D08	Antiseptics and disinfectants	1	100.0	0.0	0.0	100.0
P	Antiparasitic products, insecticides and repellents	2	0.0	50.0	50.0	100.0
P02	Anthelmintics	1	0.0	100.0	0.0	100.0
P03	Ectoparasiticides, including scabicides, insecticides and repellents	1	0.0	0.0	100.0	100.0
R	Respiratory system	2	0.0	0.0	100.0	100.0
R05	Cough and cold preparations	2	0.0	0.0	100.0	100.0
G	Genito urinary system and sex hormones	1	0.0	0.0	100.0	100.0
G02	Other gynaecologicals	1	0.0	0.0	100.0	100.0
H	Systemic hormonal preparations, excluding sex hormones and insulins	1	0.0	100.0	0.0	100.0
H01	Pituitary and hypothalamic hormones and analogues	1	0.0	100.0	0.0	100.0
S	Sensory organs	1	0.0	100.0	0.0	100.0
S01	Ophthalmologicals	1	0.0	100.0	0.0	100.0

**Note Table 96**

The total number of ATC 1st level clinical trials ("CT" column) is higher than the number indicated in the subtitle because the same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

Likewise, regarding each therapeutic classification, the total number of ATC 2nd level clinical trials ("CT" column) can be higher than the ATC 1st level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

Table 97

***Clinical trials involving breastfeeding women
per typology of Sponsor: profit / no profit***

CT: 47

Typology	CT	%	Sponsors
No profit	33	70.2	29
University hospital, University polyclinic and University	16	34.0	13
Public or private Scientific institute for research and care (IRCCS)	5	10.6	4
Hospital structure *	5	10.6	5
Local health unit	3	6.4	3
Scientific association	2	4.3	2
Foundation	1	2.1	1
Research institute	1	2.1	1
Profit	14	29.8	12
Total	47	100.0	41

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

**Table 98**

***Clinical trials involving breastfeeding women
per objective***
CT: 47

Objective	CT	% of CT (47)
Efficacy	40	85.1
Safety	35	74.5
Therapy	18	38.3
Prophylaxis	8	17.0
Dose response studies	7	14.9
Diagnosis	4	8.5
Pharmacokinetic	4	8.5
Pharmacodynamic	3	6.4
Pharmacogenetic	3	6.4
Bioequivalence	2	4.3
Pharmacogenomic	1	2.1
Other	3	6.4

Analysis

*Clinical trials involving patients
incapable of validly submitting their consent*





■ Summary of main results 2006-2010

Pursuant to the European directive 2001/20, the legislative decree 211 of 2003 clearly stipulates the possibility to perform clinical trials on subjects incapable of validly submitting their consent.

In this analysis, clinical trials exclusively on paediatric patients and minors (i.e. the age group between 0 and 18 years of age) have not been taken into consideration following a verification of patients. Regarding these studies, the patient's parents should give the informed consent.

In the population of adults incapable of validly submitting their consent, this can be given by

their legal representative, administrator or appointed guardian.

There were 216 clinical trials held in the 2006-2010 period on this cluster of patients; the focus was on neurological studies (49 studies of which 35 in phase III), oncology (25 studies of which 11 in phase II and 11 in phase III), haematology (24 studies of which 10 in phase II and 10 in phase III) and then immunology and infectious diseases (22 studies).

Pharmaceutical companies account for 67.1% of the clinical trials, while 32.9% had a no profit Sponsor. In these typologies of studies, the objectives were always efficacy and safety (in both cases, 190 out of 216 studies).

**Table 99**

*Clinical trials involving patients incapable of validly submitting their consent
per year and phase*

CT: 216

Year	Phase I		Phase II		Phase III		Phase IV		Bioeq/Biod		Total	
	CT	%	CT	%	CT	%	CT	%	CT	%	CT	%
2006	2	5.7	15	42.9	17	48.6	1	2.9	0	0.0	35	100.0
2007	0	0.0	15	35.7	21	50.0	6	14.3	0	0.0	42	100.0
2008	0	0.0	13	26.5	32	65.3	4	8.2	0	0.0	49	100.0
2009	3	5.4	16	28.6	28	50.0	9	16.1	0	0.0	56	100.0
2010	1	2.9	12	35.3	16	47.1	5	14.7	0	0.0	34	100.0
Total	6	2.8	71	32.9	114	52.8	25	11.6	0	0.0	216	100.0

Table 100

*Clinical trials involving patients incapable of validly submitting their consent
per forecast age group*

CT: 216

Age group	CT	%
Adults (from 19 to 64 years of age)	197	91,2
OAPs (65+ years of age)	154	71,3
Minors (from 13 to 18 years of age)	75	34,7
Children (up to 12 years of age)	47	21,8

Enrolled subjects could fall into more than one age group; therefore the same trial may be counted more than once.

**Table 101**

***Clinical trials involving patients incapable of validly submitting their consent
per therapeutic area***

CT: 216

Therapeutic area	CT	%	cum. %
Neurology	49	22.7	22.7
Oncology	25	11.6	34.3
Haematology	24	11.1	45.4
Immunology and infectious diseases	22	10.2	55.6
Paediatrics/Neonatology	19	8.8	64.4
Cardiology/Vascular diseases	15	6.9	71.3
Traumatology and emergency medicine	10	4.6	75.9
Respiratory system diseases	9	4.2	80.1
Anaesthesiology	8	3.7	83.8
Endocrinology	7	3.2	87.0
Ophthalmology	7	3.2	90.3
Psychiatry/Psychology	6	2.8	93.1
Rheumatology	6	2.8	95.8
Gastroenterology	3	1.4	97.2
Nephrology/Urology	3	1.4	98.6
Gynaecology and obstetrics	1	0.5	99.1
Musculo-skeletal system diseases	1	0.5	99.5
Oral and maxillofacial surgery	1	0.5	100.0
Total	216	100.0	

**Table 102**

***Clinical trials involving patients incapable of validly submitting their consent
per therapeutic classification – ATC up to 2nd level***

CT: 216

with ATC 2nd level of at least one test drug specified

Therapeutic classification ATC up to 2 nd level	CT (Phase I-II- III-IV)	%				
		Phase I	Phase II	Phase III	Phase IV	Total
N Nervous system	51	0.0	17.6	66.7	15.7	100.0
N07 Other nervous system drugs	16	0.0	31.3	56.3	12.5	100.0
N06 Psychoanaleptics	15	0.0	6.7	86.7	6.7	100.0
N03 Antiepileptics	10	0.0	10.0	90.0	0.0	100.0
N05 Psycholeptics	6	0.0	16.7	33.3	50.0	100.0
N01 Anesthetics	3	0.0	33.3	33.3	33.3	100.0
N02 Analgesics	1	0.0	0.0	0.0	100.0	100.0
L Antineoplastic and immunomodulating agents	46	8.7	50.0	39.1	2.2	100.0
L01 Antineoplastic agents	28	14.3	50.0	35.7	0.0	100.0
L04 Immunosuppressants	12	0.0	50.0	50.0	0.0	100.0
L03 Immunostimulants	6	0.0	50.0	33.3	16.7	100.0
B Blood and blood forming organs	27	3.7	25.9	59.3	11.1	100.0
B01 Antithrombotic agents	13	0.0	38.5	61.5	0.0	100.0
B02 Antihemorrhagics	8	12.5	12.5	50.0	25.0	100.0
B05 Blood substitutes and perfusion solutions	6	0.0	16.7	66.7	16.7	100.0
J General antiinfectives for systemic use	24	0.0	37.5	58.3	4.2	100.0
J02 Antimycotics for systemic use	8	0.0	37.5	62.5	0.0	100.0
J05 Antivirals for systemic use	7	0.0	71.4	28.6	0.0	100.0
J06 Immune sera and immunoglobulins	4	0.0	25.0	75.0	0.0	100.0
J01 Antibacterials for systemic use	3	0.0	0.0	66.7	33.3	100.0
J04 Antimycobacterials	1	0.0	0.0	100.0	0.0	100.0
J07 Vaccines	1	0.0	0.0	100.0	0.0	100.0
A Alimentary tract and metabolism	17	0.0	35.3	58.8	5.9	100.0
A10 Drugs used in diabetes	4	0.0	25.0	75.0	0.0	100.0
A16 Other alimentary tract and metabolism products	4	0.0	25.0	75.0	0.0	100.0
A02 Drugs for acid related disorders	2	0.0	100.0	0.0	0.0	100.0



Therapeutic classification ATC up to 2 nd level	CT (Phase I-II- III-IV)	%				
		Phase I	Phase II	Phase III	Phase IV	Total
A07 Antidiarrheals, intestinal antiinflammatory/ antiinfective agents	2	0.0	0.0	50.0	50.0	100.0
A09 Digestives, including enzymes	2	0.0	100.0	0.0	0.0	100.0
A01 Stomatological preparations	1	0.0	0.0	100.0	0.0	100.0
A04 Antiemetics and antinauseants	1	0.0	0.0	100.0	0.0	100.0
A11 Vitamins	1	0.0	0.0	100.0	0.0	100.0
C Cardiovascular system	14	0.0	35.7	28.6	35.7	100.0
C01 Cardiac therapy	3	0.0	0.0	0.0	100.0	100.0
C07 Beta blocking agents	3	0.0	33.3	33.3	33.3	100.0
C09 Agents acting on the renin-angiotensin system	3	0.0	0.0	100.0	0.0	100.0
C10 Lipid modifying agents	3	0.0	66.7	0.0	33.3	100.0
C02 Antihypertensives	2	0.0	50.0	50.0	0.0	100.0
C04 Peripheral vasodilators	1	0.0	100.0	0.0	0.0	100.0
C08 Calcium channel blockers	1	0.0	0.0	100.0	0.0	100.0
R Respiratory system	12	0.0	41.7	50.0	8.3	100.0
R07 Other respiratory system products	5	0.0	60.0	40.0	0.0	100.0
R03 Drugs for obstructive airway diseases	4	0.0	25.0	50.0	25.0	100.0
R01 Nasal preparations	1	0.0	100.0	0.0	0.0	100.0
R05 Cough and cold preparations	1	0.0	0.0	100.0	0.0	100.0
R06 Antihistamines for systemic use	1	0.0	0.0	100.0	0.0	100.0
M Musculo-skeletal system	10	0.0	20.0	50.0	30.0	100.0
M01 Antiinflammatory and antirheumatic products	5	0.0	40.0	20.0	40.0	100.0
M09 Other drugs for disorders of the musculo-skeletal system	4	0.0	0.0	100.0	0.0	100.0
M03 Muscle relaxants	1	0.0	0.0	0.0	100.0	100.0
V Various	8	0.0	37.5	50.0	12.5	100.0
V03 All other therapeutic products	7	0.0	28.6	57.1	14.3	100.0
V01 Allergens	1	0.0	100.0	0.0	0.0	100.0
S Sensory organs	5	20.0	40.0	40.0	0.0	100.0
S01 Ophthalmologicals	5	20.0	40.0	40.0	0.0	100.0



Therapeutic classification ATC up to 2 nd level		CT (Phase I-II- III-IV)	%				
			Phase I	Phase II	Phase III	Phase IV	Total
G	Genito-urinary system and sex hormones	3	0.0	0.0	66.7	33.3	100.0
G03	Sex hormones and modulators of the genital system	3	0.0	0.0	66.7	33.3	100.0
H	Systemic hormonal preparations, excluding sex hormones and insulins	2	0.0	0.0	50.0	50.0	100.0
H02	Corticosteroids for systemic use	2	0.0	0.0	50.0	50.0	100.0
D	Dermatologicals	1	0.0	100.0	0.0	0.0	100.0
D07	Corticosteroids, dermatological preparations	1	0.0	100.0	0.0	0.0	100.0

The total number of ATC 1st level clinical trials ("CT" column) is higher than the number indicated in the subtitle because the same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

Likewise, regarding each therapeutic classification, the total number of ATC 2nd level clinical trials ("CT" column) can be higher than the ATC 1st level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

**Table 103**

***Clinical trials involving patients incapable of validly submitting their consent
per typology of Sponsor: profit / no profit***

CT: 216

Typology	CT	%	Sponsors
Profit	145	67.1	60
No profit	71	32.9	44
University hospital, University polyclinics and University	31	14.4	14
Hospital structure *	13	6.0	10
Public or private Scientific institute for research and care (IRCCS)	13	6.0	6
Local health unit	5	2.3	5
Scientific association	4	1.9	4
Foundation	4	1.9	4
Research institute	1	0.5	1
Total	216	100.0	104

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

**Table 104**

Clinical trials involving patients incapable of validly submitting their consent per objective

CT: 216

Objective	CT	% of CT (216)
Efficacy	190	88.0
Safety	190	88.0
Therapy	81	37.5
Pharmacokinetic	72	33.3
Dose response studies	42	19.4
Pharmacodynamic	40	18.5
Pharmacogenetic	24	11.1
Pharmaco-economic	21	9.7
Pharmacogenomic	20	9.3
Prophylaxis	13	6.0
Diagnosis	5	2.3
Bioequivalence	1	0.5
Other	25	11.6

Observational studies





■ Summary of main results 1st March – 31st December 2010

The guidelines issued by the Italian Medicines Agency in 2008, foresaw the creation of a Registry on Observational Studies (RSO). We are now able to present this data publicly, in line with the OsSC's common practices concerning transparency and coordination.

Firstly, these are some definitions to assist the comprehension of the following tables.

Regarding start-up date, the completion of all administrative/authorisation procedures (EC's opinion, signature of agreements, etc.) is considered, and therefore when the centre can officially be considered ready to perform the study.

Likewise, the conclusion of the study is when the last enrolled patient has been examined, where applicable; in the event there is no direct contact with the patients, the conclusion is the date defined by the protocol.

Studies under evaluation are those awaiting the opinion from the coordinating Ethics committee. While those under revision are studies that have a suspended evaluation (by the coordinating Ethics committee).

116 studies in the period 1st March to 31st December were registered and sent to the central database. The following analysis is focussed on 90 studies (of the 26 excluded, 24 were under evaluation, 1 had a negative single opinion and 1 was under revision).

There were 52 prospective studies (57.8%), 36 retrospective and 11 transversal. 97.8% of studies were carried out in public health structures; in 58 cases the Sponsor coincided with the Applicant, 36.2% of cases had a commercial Sponsor and 63.8% were performed by no profit organizations.

The most studied areas were neurology (20% of all cases), oncology (15.6%) and haematology (14.4%).

Table 105

Studies per status

Total studies: 116

Status	Studies	%
Approved by the coordinating EC	31	26.7
Notified	30	25.9
Open	29	25.0
Under evaluation	24	20.7
With negative single opinion	1	0.9
Under revision	1	0.9
Concluded	0	0.0
Total	116	100.0



**The following tables take into consideration only these studies:
approved by the coordinating EC – notified – open – concluded**

Table 106**Studies per typology**

Studies: 90

Typology	Studies	%
Prospective studies	52	57.8
Retrospective studies	36	40.0
Transversal studies	11	12.2

Each study could fall into more than one typology and therefore be counted more than once.

Table 107**Studies per structures where they are performed**

Studies: 90

Structures	Studies	%
Public health structures	88	97.8
Private health structures	9	10.0
Specialist physicians	1	1.1
GPs and/or pediatricians	0	0.0

Each study can be performed in more than one structure and therefore be counted more than once.

Table 108**Studies per design**

Studies: 90

Design	Studies	%
Cohort	62	68.9
Transversal	14	15.6
Case-control	5	5.6
Other	9	10.0
Total	90	100.0

**Table 109*****Studies per typology of applicant***

Studies: 90

Applicants: 73

Typology	Studies	%	Applicants
Applicant coinciding with Sponsor	58	64.5	46
Applicant not coinciding with Sponsor	32	35.5	27
Total	90	100.0	73

Table 110***Studies per typology of applicant coinciding with Sponsor: profit / no profit***

Studies: 58

Applicants: 46

Typology	Studies	%	Applicants
Profit	21	36.2	16
No profit	37	63.8	30
Public or private Scientific institute for research and care (IRCCS)	12	20.7	9
University hospital, University polyclinic and University	11	19.0	9
Foundations	4	6.9	2
Local health unit	3	5.2	3
Scientific associations	3	5.2	3
Hospital structure *	3	5.2	3
Research institute	1	1.7	1
Total	58	100.0	46

* Hospitals, hospitals under self administration, assimilated or classified hospitals, privates qualified health institutes acting as local health unit, military hospital

**Table 111*****Studies per typology of applicant not coinciding with Sponsor***

Studies: 32

Applicants: 27

Typology	Studies	%	Applicants
CRO	19	59.4	11
Other *	13	40.6	16
Total	32	100.0	27

* for example, Italian affiliate (applicant) with foreign headquarter (Sponsor)

Table 112***Studies per source of finance***

Studies: 90

Source of finance	Studies	%
Source coinciding with Sponsor	56	62.2
Source not coinciding with Sponsor	34	37.8
Pharmaceutical company	22	24.4
Foundation or charity	1	1.1
AIFA (calls for independent research)	4	4.4
MIUR *	0	0.0
ISS	0	0.0
CNR **	0	0.0
Other	7	7.8
Total	90	100.0

* Ministry of Education, University and Research

** National Research Council

Table 113***Studies per scope***

Studies: 90

Scope	Studies	%
Descriptive	63	70.0
Mixed	16	17.8
Analytical (etiological)	11	12.2
Total	90	100.0

**Table 114*****Studies per primary objective***

Studies: 90

Primary objective	Studies	%
Efficacy in clinical practice (effectiveness)	41	45.6
Safety	30	33.3
Use of drug	23	25.6
Appropriateness	11	12.2
Pharmaco-economic	9	10.0
Other	24	26.7

Each study could have more than one objective and therefore be counted more than once.

Table 115***Studies per aim***

Studies: 90

Aim	Studies	%
Knowledge gathering	77	85.6
PASS (Post Authorization Safety Study)	8	8.9
Other	5	5.6
Total	90	100.0

**Table 116*****Studies per therapeutic area***

Studies: 90

Therapeutic area	Studies	%
Neurology	18	20.0
Oncology	14	15.6
Haematology	13	14.4
Anaesthesiology	6	6.7
Cardiology/Vascular diseases	6	6.7
Endocrinology	4	4.4
Immunology and infectious diseases	4	4.4
Psychiatry/Psychology	4	4.4
Rheumatology	4	4.4
Dermatology/Plastic surgery	3	3.3
Gynaecology and obstetrics	3	3.3
Nephrology/Urology	3	3.3
Pharmacology/Toxicology	2	2.2
Musculo-skeletal system diseases	2	2.2
Respiratory system diseases	1	1.1
Ophthalmology	1	1.1
Paediatrics/Neonatology	1	1.1
Genito urinary system	1	1.1
Total	90	100.0

**Table 117*****Studies per therapeutic classification – ATC up to 2nd level***

Studies: 90

Therapeutic classification ATC up to 2 nd level	Studies	% of ATC 1 st level	% of studies with ATC spec. (90)
L Antineoplastic and immunomodulating agents	32		35.6
L01 Antineoplastic agents	21	65.6	23.3
L04 Immunosuppressants	11	34.4	12.2
L03 Immunostimulants	4	12.5	4.4
L02 Endocrine therapy	2	6.3	2.2
N Nervous system	19		21.1
N05 Psycholeptics	5	26.3	5.6
N06 Psychoanaleptics	5	26.3	5.6
N02 Analgesics	3	15.8	3.3
N04 Anti-Parkinson drugs	3	15.8	3.3
N01 Anesthetics	2	10.5	2.2
N03 Antiepileptics	2	10.5	2.2
N07 Other nervous system drugs	2	10.5	2.2
H Systemic hormonal preparations, excluding sex hormones and insulins	11		12.2
H02 Corticosteroids for systemic use	5	45.5	5.6
H05 Calcium homeostasis	3	27.3	3.3
H01 Pituitary and hypothalamic hormones and analogues	2	18.2	2.2
H03 Thyroid therapy	1	9.1	1.1
B Blood and blood forming organs	10		11.1
B01 Antithrombotic agents	6	60.0	6.7
B02 Antihemorrhagics	3	30.0	3.3
B03 Antianemic preparations	1	10.0	1.1
V Various	8		8.9
V03 All other therapeutic products	4	50.0	4.4
V08 Contrast media	4	50.0	4.4
J General antiinfectives for systemic use	7		7.8
J01 Antibacterials for systemic use	4	57.1	4.4
J02 Antimycotics for systemic use	1	14.3	1.1
J04 Antimycobacterials	1	14.3	1.1



Therapeutic classification ATC up to 2 nd level		Studies	% of ATC 1 st level	% of studies with ATC spec. (90)
J05	Antivirals for systemic use	1	14.3	1.1
J07	Vaccines	1	14.3	1.1
C	Cardiovascular system	6		6.7
C01	Cardiac therapy	3	50.0	3.3
C09	Agents acting on the renin-angiotensin system	3	50.0	3.3
C10	Lipid modifying agents	2	33.3	2.2
C02	Antihypertensives	1	16.7	1.1
C03	Diuretics	1	16.7	1.1
C07	Beta blocking agents	1	16.7	1.1
C08	Calcium channel blockers	1	16.7	1.1
M	Musculo-skeletal system	6		6.7
M03	Muscle relaxants	3	50.0	3.3
M01	Antiinflammatory and antirheumatic products	2	33.3	2.2
M05	Drugs for treatment of bone diseases	1	16.7	1.1
A	Alimentary tract and metabolism	4		4.4
A10	Drugs used in diabetes	3	75.0	3.3
A07	Antidiarrheals, intestinal antiinflammatory/ antiinfective agents	1	25.0	1.1
G	Genito urinary system and sex hormones	2		2.2
G03	Sex hormones and modulators of the genital system	2	100.0	2.2
R	Respiratory system	1		1.1
R03	Drugs for obstructive airway diseases	1	100.0	1.1
R05	Cough and cold preparations	1	100.0	1.1
R06	Antihistamines for systemic use	1	100.0	1.1
R07	Other respiratory system products	1	100.0	1.1
S	Sensory organs	1		1.1
S01	Ophthalmologicals	1	100.0	1.1

The total number of ATC 1st level clinical trials ("CT" column) is higher than the number indicated in the subtitle because the same clinical trial may involve more than one test drug and therefore shall be counted in more than one ATC classification.

Likewise, regarding each therapeutic classification, the total number of ATC 2nd level clinical trials ("CT" column) can be higher than the ATC 1st level clinical trial number given that the same clinical trial may involve more than one test drug and therefore shall be counted more than once.

**Table 118****Studies per therapeutic classification – ATC 5th level**Studies: 90 of which 55 (61.1%) with ATC 5th level of at least one test drug specified**L – Antineoplastic and immunomodulating agents**Studies: 32 of which 25 (78.1%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (25)
L01XC02	Rituximab	6	24.0
L04AA23	Natalizumab	4	16.0
L01AA01	Ciclofosfamide	3	12.0
L04AX04	Lenalidomide	3	12.0
L01BC02	Fluorouracil	2	8.0
L01CA02	Vincristine	2	8.0
L01DB01	Doxorubicin	2	8.0
L01XC04	Alemtuzumab	2	8.0
L03AA02	Filgrastim	2	8.0
L04AB01	Etanercept	2	8.0
L04AB04	Adalimumab	2	8.0
L01AA02	Clorambucil	1	4.0
L01AA06	Ifosfamide	1	4.0
L01AA09	Bendamustine	1	4.0
L01BB04	Cladribine	1	4.0
L01BB05	Fludarabine	1	4.0
L01BB06	Clofarabine	1	4.0
L01BC05	Gemcitabine	1	4.0
L01BC06	Capecitabine	1	4.0
L01CA04	Vinorelbine	1	4.0
L01XC03	Trastuzumab	1	4.0
L01XC07	Bevacizumab	1	4.0
L01XC10	Ofatumumab	1	4.0
L01XD03	Methyl aminolevulinate	1	4.0
L01XE01	Imatinib	1	4.0
L01XE04	Sunitinib	1	4.0
L01XX08	Pentostatin	1	4.0
L01XX23	Mitotane	1	4.0
L02BA01	Tamoxifen	1	4.0
L03AA10	Lenograstim	1	4.0
L03AA13	Pegfilgrastim	1	4.0
L03AB07	Interferon beta-1a	1	4.0
L04AA24	Abatacept	1	4.0
L04AB02	Infliximab	1	4.0
L04AC03	Anakinra	1	4.0

**N – Nervous system**Studies: 19 of which 9 (47.4%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (9)
N05AH03	Olanzapine	2	22.2
N05AH04	Quetiapine	2	22.2
N05AN01	Lithium	2	22.2
N06DA02	Donepezil	2	22.2
N06DA03	Rivastigmine	2	22.2
N06DA04	Galantamine	2	22.2
N02BG08	Ziconotide	1	11.1
N03AX14	Levetiracetam	1	11.1
N04BA02	Levodopa and decarboxylase inhibitor	1	11.1
N05AD01	Haloperidol	1	11.1
N05AX08	Risperidone	1	11.1
N05BA06	Lorazepam	1	11.1
N05BA08	Bromazepam	1	11.1
N05BA12	Alprazolam	1	11.1
N06AB03	Fluoxetine	1	11.1
N06AB04	Citalopram	1	11.1
N06AB05	Paroxetine	1	11.1
N06AB06	Sertraline	1	11.1
N06AB10	Escitalopram	1	11.1
N06DX01	Memantine	1	11.1

J – General anti-infectives for systemic useStudies: 7 of which 3 (42.9%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (3)
J01CR02	Amoxicillin and enzyme inhibitor	2	66.7
J01CA04	Amoxicillin	1	33.3
J01CR05	Piperacillin and enzyme inhibitor	1	33.3
J01DB04	Cefazolin	1	33.3
J01DD04	Ceftriaxone	1	33.3
J01DE01	Cefepime	1	33.3
J01DF01	Aztreonam	1	33.3
J01DH02	Meropenem	1	33.3



Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (3)
J01DH03	Ertapenem	1	33.3
J01GB01	Tobramycin	1	33.3
J01GB03	Gentamicin	1	33.3
J01GB06	Amikacin	1	33.3
J01MA02	Ciprofloxacin	1	33.3
J01MA12	Levofloxacin	1	33.3
J01MA14	Moxifloxacin	1	33.3
J01XA01	Vancomycin	1	33.3
J01XB01	Colistin	1	33.3
J01XX08	Linezolid	1	33.3
J01XX09	Daptomycin	1	33.3
J02AX05	Micafungin	1	33.3
J04AB02	Rifampicin	1	33.3

C – Cardiovascular system

Studies: 6 of which 1 (16.7%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (1)
C09BA04	Perindopril and diuretics	1	100.0

V – Various

Studies: 8 of which 4 (50.0%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (4)
V03AC01	Deferoxamine	1	25.0
V03AC03	Deferasirox	1	25.0
V03AN01	Oxygen	1	25.0
V08CA03	Gadodiamide	1	25.0
V08CA08	Gadobenic acid	1	25.0
V08CA09	Gadobutrol	1	25.0



H – Systemic hormonal preparations, excluding sex hormones and insulins

Studies: 11 of which 9 (81.8%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (9)
H02AB07	Prednisone	3	33,3
H01CB03	Lanreotide	1	11,1
H02AB02	Dexamethasone	1	11,1
H02AB06	Prednisolone	1	11,1
H03AA01	Levothyroxine sodium	1	11,1
H05AA02	Teriparatide	1	11,1
H05AA03	Parathyroid hormone	1	11,1
H05BX01	Cinacalcet	1	11,1

B – Blood and blood forming organs

Studies: 10 of which 4 (40.0%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (4)
B02BD02	Coagulation factor VIII	1	25,0
B02BD03	Factor VIII inhibitor bypassing activity	1	25,0
B02BD08	Eptacog alfa (activated)	1	25,0
B03XA01	Erythropoietin	1	25,0

A – Alimentary tract and metabolism

Studies: 4 of which 1 (25.0%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (1)
A10BB09	Gliclazide	1	100,0

**M – Musculo-skeletal system**

Studies: 6 of which 3 (50.0%) with ATC 5th level specified of at least one test drug specified

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (3)
M03AX01	Botulinum toxin	2	66,7
M03BX09	Eperisone	1	33,3

S – Sensory organs

Studies: 1

Therapeutic classification ATC 5 th level		Studies	% of studies with ATC spec. (1)
S01LA04	Ranibizumab	1	100,0

**Table 119****Studies per coordinating centre**

Studies: 90

	Coordinating centre	Studies	%
1	A.O. Universitaria Pisana of Pisa	4	4.4
2	A.O. of Perugia	3	3.3
3	A.O. Universitaria Policlinico Gemelli of Rome	3	3.3
4	A.O. Universitaria Policlinico Umberto I of Rome	3	3.3
5	IRCCS Fondazione Centro S. Raffaele del Monte Tabor of Milan	3	3.3
6	IRCCS Ospedale Maggiore Policlinico of Milan	3	3.3
7	Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) of Meldola (FC)	3	3.3
8	A.O. Ospedale Niguarda Ca' Granda of Milan	2	2.2
9	A.O. Universitaria Careggi of Florence	2	2.2
10	A.O. Universitaria Federico II of Naples	2	2.2
11	A.O. Universitaria Integrata of Verona - Ospedale Policlinico G.B. Rossi	2	2.2
12	A.O. Universitaria Policlinico of Modena	2	2.2
13	A.O. Universitaria S. Luigi Gonzaga of Orbassano (TO)	2	2.2
14	A.O. Universitaria S. Martino of Genoa	2	2.2
15	IRCCS Istituto Europeo di Oncologia (IEO) of Milan	2	2.2
16	IRCCS Ospedale Pediatrico del Bambino Gesù (OPBG) of Rome	2	2.2
17	IRCCS Policlinico S. Matteo of Pavia	2	2.2
18	Ospedale Civile S. Salvatore of L'Aquila	2	2.2
19	Università La Sapienza of Rome	2	2.2
20	A.O. Ospedale dei bambini Buzzi (ICP) of Milan	1	1.1
21	A.O. Ospedale Fatebenefratelli e Oftalmico of Milan	1	1.1
22	A.O. Ospedale S. Antonio Abate of Gallarate (VA)	1	1.1
23	A.O. Ospedale S. Gerardo of Monza (MB)	1	1.1
24	A.O. Ospedale S. Paolo of Milan	1	1.1
25	A.O. Ospedale Sacco of Milan	1	1.1
26	A.O. Presidio Spedali Civili of Brescia	1	1.1
27	A.O. S. Camillo - Forlanini of Rome	1	1.1
28	A.O. Universitaria - P.O. Rodolico of Catania	1	1.1
29	A.O. Universitaria - P.O. Vittorio Emanuele e Ferrarotto of Catania	1	1.1
30	A.O. Universitaria Arcispedale S. Anna of Ferrara	1	1.1



	Coordinating centre	Studies	%
31	A.O. Universitaria Maggiore della Carità of Novara	1	1.1
32	A.O. Universitaria Ospedali Riuniti - Ospedale Lancisi of Ancona	1	1.1
33	A.O. Universitaria Policlinico Campus Bio-Medico of Rome	1	1.1
34	A.O. Universitaria Policlinico Giaccone of Palermo	1	1.1
35	A.O. Universitaria Policlinico S. Orsola Malpighi of Bologna	1	1.1
36	A.O. Universitaria S. Andrea of Rome	1	1.1
37	A.O. Universitaria S. Giovanni Battista-Molinette of Turin	1	1.1
38	ASL 3 Genovese of Genoa	1	1.1
39	ASL Città of Milan	1	1.1
40	ASL della Provincia of Como	1	1.1
41	AULSS 9 of Treviso	1	1.1
42	AUSL of Modena	1	1.1
43	AUSL of Rimini	1	1.1
44	AUSL RM/E of Rome	1	1.1
45	Fondazione Monasterio - Stabilimento ospedaliero of Pisa	1	1.1
46	IRCCS Centro di Riferimento Oncologico (CRO) of Aviano (PN)	1	1.1
47	IRCCS Centro di Riferimento Oncologico of Basilicata (CROB) of Rionero in Vulture (PZ)	1	1.1
48	IRCCS Fondazione Istituto Neurologico Besta of Milan	1	1.1
49	IRCCS Fondazione Istituto Neurologico Mondino of Pavia	1	1.1
50	IRCCS Fondazione S. Lucia of Rome	1	1.1
51	IRCCS Istituto Auxologico Italiano - Ospedale S. Luca of Milan	1	1.1
52	IRCCS Istituto Clinico Humanitas of Rozzano (MI)	1	1.1
53	IRCCS Istituto Dermopatico dell'Immacolata (IDI) of Rome	1	1.1
54	IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	1	1.1
55	IRCCS Istituto Neurologico Mediterraneo (Neuromed) of Pozzilli (IS)	1	1.1
56	IRCCS Istituto Ortopedico Galeazzi of Milan	1	1.1
57	IRCCS Ospedale Pediatrico del Bambino Gesù (OPBG) of S. Marinella (RM)	1	1.1
58	IRCCS Ospedale S. Camillo of Venice	1	1.1
59	Ospedale centrale of Bolzano	1	1.1
60	Ospedale of Carpi (MO)	1	1.1
61	Università of L'Aquila	1	1.1
62	Università of Bologna	1	1.1
63	Università of Siena	1	1.1
	Total	90	100.0

Ethics committees





■ Summary of main results 2007-2010

The following pages contain an overview of the Ethics committees in Italy, and an analysis of their work with specific attention to the number of evaluations given and within which timeframe, for the period 2007-2010. All data derive from information entered in the OsSC.

Following the reorganisation of the health system in some Italian regions, the phenomenon of aggregation of Ethics committees spread in 2010, with the consequent decrease in numbers to a still high 245 (254 in 2009 and 269 in 2008). This is still far from what is happening in other European countries; indeed, our national average is approximately 1 EC per 250,000 inhabitants, while other EU countries have one EC for every 500,000. Lombardy is still the region with the highest number of Ethics committees, followed by Lazio, Sicily and Campania.

It is worth noting that the activity of these bodies is concentrated in only 66.1%. In fact, of the 245 Ethics committees in Italy, only 162 gave a single

opinion as a coordinator between 2007 and 2010. Of this subgroup, 19 gave at least one evaluation per month (48 in the four-year period). Regarding the acceptance/refusal of the single opinion, 241 satellite Ethics committees (3 of which are no longer operative) expressed their opinion: of these, 116 gave their opinion with an average evaluation time of one a month.

Data concerning the quantity of opinions given by Ethics committees is given in this section, together with the number of average days for this decision. Time is indeed a fundamental parameter to evaluate the work of these bodies on an international scale, and Italian legislation sets a clear timeframe for the completion of these evaluations.

National average times for issuing the single opinion is decreasing: the number has dropped from an average 45 days in 2007, to 36 in 2008, 26 in 2009 and 21 in 2010. An opposite trend has been experienced in the average times for issuing the acceptance/refusal of the single opinion, which was higher in 2010 than in previous years, and exceeding the foreseen times according to Italian regulations.

**Table 120*****Ethics committees per region and inhabitants***

Total EC: 245

Region	EC	%	Inhabitants on 31/12/2010*	Inhabitants/ EC
Lombardy	61	24.9	9,917,714	162,585
Lazio	34	13.9	5,728,688	168,491
Sicily	21	8.6	5,051,075	240,527
Campania	19	7.8	5,834,056	307,056
Puglia	13	5.3	4,091,259	314,712
Tuscany	13	5.3	3,749,813	288,447
Sardinia	11	4.5	1,675,411	152,310
Veneto	11	4.5	4,937,854	448,896
Calabria	10	4.1	2,011,395	201,140
Emilia-Romagna	9	3.7	4,432,418	492,491
Liguria	9	3.7	1,616,788	179,643
Friuli-Venezia Giulia	8	3.3	1,235,808	154,476
Piedmont	7	2.9	4,457,335	636,762
Abruzzi	4	1.6	1,342,366	335,592
Basilicata	4	1.6	587,517	146,879
Marche	4	1.6	1,565,335	391,334
Trentino-Alto Adige	3	1.2	1,037,114	345,705
Molise	2	0.8	319,780	159,890
Umbria	1	0.4	906,486	906,486
Valle d'Aosta	1	0.4	128,230	128,230
Total	245	100.0	60,626,442	247,455

* Source Istat – National Institute of Statistics

Chart I

Ethics committees per region

Total EC: 245



more than 240,000 inhabitants / EC
less than 240,000 inhabitants / EC

Each region illustrates its number of Ethics committees

**Table 121****Members of Ethics committees per professional qualification**

Total EC: 245

Average number of members per EC: 15

(non-mandatory members are indicated in italics)

Professional qualification	Members	%
Clinician	766	21.6
Representative of the voluntary association for assistance	281	7.9
Pharmacist *	273	7.7
Bioethics expert	259	7.3
Pharmacologist	252	7.1
Health Director (ex officio)	249	7.0
Representative for paramedics	247	7.0
Biostatistician	244	6.9
General practitioner	237	6.7
Expert of legal and insurance matters	228	6.4
Forensic pathologist	130	3.7
Paediatrician	85	2.4
Scientific Director (ex officio)	41	1.2
<i>Theologist / Religious officer</i>	28	0.8
<i>Psychologist</i>	19	0.5
<i>Biologist</i>	9	0.3
<i>Epidemiologist</i>	9	0.3
<i>Philosopher</i>	8	0.2
<i>Administrative staff</i>	8	0.2
<i>Veterinarian</i>	7	0.2
<i>Psychiatrist / Neuropsychiatrist</i>	6	0.2
<i>Sociologist</i>	5	0.1
<i>Chemist</i>	3	0.1
Director of regional Health Department	2	0.1
<i>Statistician</i>	1	0.0
<i>Other</i>	147	4.1
Total	3,544	100.0

* includes the pharmacist (ex officio) of the Institution's Pharmaceutical Department, where the clinical trial takes place, the pharmacist of the regional Health Service and the pharmacist (different from the mandatory member)



Analysis on time necessary to issue the single opinion and the acceptance/refusal of the single opinion

CT evaluated in the period 2007-2010:

3,176 of which 668 mono-centre and 2,508 multi-centre CT

In the following analyses regarding the time necessary to issue the single opinion and the acceptance/refusal of the single opinion, all cases where the date of reception of the application by the EC is equal to the date of the EC's meeting (days=0) and cases where the timeframe is greater than one year (days>365) have been excluded.

Table 122

Single opinion per outcome and year

SO granted: 3,176

Outcome	2007	2008	2009	2010	Total
Favourable SO	795	878	752	660	3,085
Unfavourable SO	20	16	25	30	91
Total	815	894	777	690	3,176

Table 123

Average time to issue the single opinion per year

SO granted: 3,176 of which 2,957 (93.1%) with a timeframe between 1 and 365 days

The time to issue the SO is calculated as being the difference between the EC's reception of the application and the date where the EC expressed its decision. In the event of a suspended decision, the date of reception of integrative information instead of the application (838 cases out of 3,176) is considered.

Average time to issue the SO (days)	2007		2008		2009		2010		Total	
	Avg.	Min-Max	Avg.	Min-Max	Avg.	Min-Max	Avg.	Min-Max	Avg.	Min-Max
SO issuing	45	1-344	36	1-300	26	1-337	21	1-246	33	1-344
for multi-centre CT	42	1-344	35	1-300	26	1-244	20	1-246	31	1-344
for mono-centre CT	54	1-296	43	1-243	25	1-337	26	1-182	38	1-337

**Table 124****Acceptance/refusal of the single opinion per outcome and year**

Multi-centre CT with acceptance/refusal of SO in at least one satellite centre: 2,519

Outcome	2007	2008	2009	2010	Total
Acceptance of SO	4,338	5,032	4,456	3,761	17,587
Refusal of SO	205	246	239	181	871
Total	4,543	5,278	4,695	3,942	18,458

Table 125**Median times to issue the acceptance/refusal of the single opinion per year**

Acceptance/refusal of SO: 18,458 of which 16,175 (87.6%) with a timeframe between 1 and 365 days

The time to issue the acceptance/refusal of the SO is calculated as being the difference between the day the EC expressed its final decision and:

- the date of reception of the application by the EC's satellite centre, if the SO issuing has occurred prior to the receipt of the application;
- the date of the SO issuing, if this has occurred after the date of reception of the application by the EC's satellite centre.

To these numbers, 7 days have been subtracted for the evaluation of the application.

Median time to issue the acceptance/refusal of the SO (days)	2007		2008		2009		2010		Total	
	Median	Min-Max	Median	Min-Max	Median	Min-Max	Median	Min-Max	Median	Min-Max
Acceptance / refusal of the SO	35	1-365	32	1-365	35	1-364	40	1-365	35	1-365

As a synthetic indicator of times to issue the acceptance/refusal of the single opinion by the Ethics committees in these years, this year's Report has opted for the use of a median time for acceptance/refusal of the SO, in order to obtain a more stable number, less influenced by various anomalies.

**Table 126*****Ethics committees' activity per region***

Total EC: 245

Evaluations issued: 21,634 of which 3,176 (14.7%) SO
and 18,458 (85.46%) acceptances/refusals of the SO

Region	CT evaluated	Evaluations issued			EC
		Total	SO	Acceptances/ refusals of SO	
Abruzzi	347	437	58	379	4
Basilicata	139	165	9	156	4
Calabria	235	337	8	329	10
Campania	807	1,297	112	1,185	19
Emilia-Romagna	1,311	2,353	406	1,947	9
Friuli-Venezia Giulia	482	602	57	545	8
Lazio	1,457	2,581	432	2,149	34
Liguria	712	892	150	742	9
Lombardy	2,050	4,698	974	3,724	61
Marche	400	526	48	478	4
Molise	82	97	11	86	2
Piedmont	868	1,434	192	1,242	7
Puglia	583	1,001	54	947	13
Sardinia	316	409	27	382	11
Sicily	763	1,196	67	1,129	21
Tuscany	1,171	1,811	385	1,426	13
Trentino-Alto Adige	104	114	5	109	3
Umbria	364	427	56	371	1
Valle d'Aosta	19	20	0	20	1
Veneto	852	1,237	125	1,112	11
Total		21,634	3,176	18,458	245

Multi-centre clinical trials are evaluated by more than one EC and therefore the same study shall be counted in more than one region in the column "CT evaluated".

The columns relating to the "Evaluations issued" expresses per region the number of opinions given by the EC (SO and acceptances/refusals of SO). In the case of multi-centre CT, the same study shall be counted more than once due to the fact that it can be evaluated by different ECs in the same region or in different regions.



Table 127

Single opinions and average times to issue the opinion per Ethics committee and year

Total EC: 245 of which 162 (66.1%) have issued at least 1 SO

The first 19 EC of 162 (11.7%) represent 53.0% of the SO issued

The time to issue the SO is calculated as being the difference between the EC's reception of the application and the date where the EC expressed its decision. In the event of a suspended decision, the date of reception of integrative information instead of the application (838 cases out of 3,176) is considered.

The analysis of average times can be influenced by suspended evaluations, even recurring suspension of the same CT prior to the issuing of the final decision. In these cases, if the date of reception of the integrating documentation is unknown, the calculation is based on the date of reception of the initial application.

Ethics committee	2007		2008		2009		2010		Total		
	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	%	cum. %	Avg. time (days)
1 CE dell'IRCCS Fondazione S. Raffaele del Monte Tabor of Milan	54	50	52	36	41	13	49	11	196	6.2	30
2 CE dell'A.O. Universitaria Policlinico S. Orsola-Malpighi of Bologna	56	46	51	63	37	46	28	12	172	5.4	45
3 CE dell'A.O. Universitaria Pisana of Pisa	46	83	44	44	35	8	40	14	165	5.2	40
4 CE dell'Università Cattolica del Sacro Cuore Policlinico Universitario Gemelli of Rome	28	29	43	28	33	16	15	15	119	3.7	23
5 CE dell'IRCCS Fondazione Istituto Nazionale Tumori (INT) of Milan	21	47	31	29	33	33	24	24	109	3.4	35
6 CE dell'IRCCS Fondazione Policlinico S. Matteo of Pavia	25	22	28	21	13	22	17	14	83	2.6	20
7 CE dell'A.O. Universitaria S. Giovanni Battista of Turin	31	26	25	33	18	23	8	13	82	2.6	27
8 CE dell'A.O. Universitaria Senese of Siena	23	24	20	18	18	13	20	11	81	2.6	17



	Ethics committee	2007		2008		2009		2010		Totale			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
9	CE della Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan	20	76	15	48	23	50	20	33	78	2.5	34.2	52
10	CE of the Province of Modena	18	84	13	75	25	31	19	24	75	2.4	36.5	51
11	CE dell'A.O. Universitaria Careggi of Florence	14	64	20	48	18	51	19	16	71	2.2	38.8	44
12	CE dell'IRCCS Istituto Europeo di Oncologia (IEO) of Milan	18	25	21	27	14	17	15	20	68	2.1	40.9	23
13	CE dell'A.O. Universitaria S. Martino of Genoa	23	27	13	70	14	30	16	19	66	2.1	43.0	34
14	CE dell'Azienda Policlinico Umberto I of Rome	13	48	21	34	14	47	11	54	59	1.9	44.8	44
15	CE delle Aziende Sanitarie dell'Umbria of Perugia	13	48	18	56	13	13	12	26	56	1.8	46.6	44
16	CE dell'A.O. Spedali Civili of Brescia	19	9	10	21	16	13	8	12	53	1.7	48.3	14
17	CE dell'A.O. Universitaria S. Luigi Gonzaga of Orbassano (TO)	11	28	16	18	10	19	15	13	52	1.6	49.9	19
18	CE della Fondazione PTV Policlinico Tor Vergata of Rome	13	36	18	27	13	37	7	44	51	1.6	51.5	34
19	CE dell'A.O. Universitaria Integrata of Verona	11	52	13	34	7	20	17	16	48	1.5	53.0	30
20	CE Carlo Romano dell'Università Federico II of Naples	6	35	15	36	16	29	10	63	47	1.5	54.5	39



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
21	CE of the Province of Parma	6	19	12	25	16	17	13	8	47	1.5	56.0	17
22	CE dell'A.O. S. Camillo-Forlanini of Rome	14	22	12	24	8	12	13	13	47	1.5	57.5	18
23	CE dell'Università D'Annunzio e della ASL Lanciano-Vasto-Chieti of Chieti	12	20	17	23	12	19	5	69	46	1.4	58.9	27
24	CE dell'A.O. of Padua	12	68	12	42	8	17	12	20	44	1.4	60.3	40
25	CE dell'A.O. Ospedale Niguarda Ca' Granda of Milan	12	36	11	34	11	28	8	5	42	1.3	61.6	28
26	CE dell'IRCCS Istituto Clinico Humanitas of Rozzano (MI)	5	33	6	17	14	19	15	16	40	1.3	62.9	19
27	CE di Area Vasta Romagna e Istituto Scientifico Romagnolo Tumori (IRST) of Meldola (FC)	7	49	14	37	9	39	8	42	38	1.2	64.1	41
28	CE dell'A.O. S. Gerardo of Monza (MB)	7	12	12	15	8	16	10	21	37	1.2	65.2	17
29	CE dell'IRCCS Istituto Gaslini of Genoa	8	42	12	25	10	15	6	23	36	1.1	66.4	26
30	CE dell'A.O. Universitaria Policlinico Vittorio Emanuele of Catania	10	27	12	23	6	11	7	15	35	1.1	67.5	20
31	CE dell'A.O. Ospedali Riuniti of Bergamo	11	49	10	27	6	36	6	30	33	1.0	68.5	36
32	CE dell'A.O. Universitaria Ospedali Riuniti Umberto I-Lancisi-Salesi of Ancona	7	78	6	36	8	9	9	23	30	0.9	69.5	35
33	CE dell'IRCCS Fondazione Maugeri of Pavia	6	29	8	18	11	25	5	23	30	0.9	70.4	24
34	CE dell'A.O. Sacco of Milan	12	50	5	33	6	19	5	27	28	0.9	71.3	37
35	CE dell'IRCCS Istituto Neurologico Besta of Milan	6	17	9	22	11	16	1	2	27	0.9	72.1	18
36	CE dell'A.O. Policlinico Consorziale of Bari	7	96	8	31	8	18	3	99	26	0.8	73.0	52
37	CE dell'A.O. S. Andrea of Rome	2	19	8	23	5	14	9	17	24	0.8	73.7	19



	Ethics committee	2007		2008		2009		2010		Totale			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
38	CE dell'A.O. Universitaria Maggiore della Carità of Novara	2	48	2	20	9	33	11	16	24	0.8	74.5	25
39	CE dell'IRCCS Istituti Fisioterapici Ospitalieri (IFO) of Rome	6	48	8	44	6	34	4	16	24	0.8	75.2	38
40	CE dell'IRCCS Istituto Nazionale per la Ricerca sul Cancro of Genoa	10	19	6	19	4	23	4	22	24	0.8	76.0	20
41	CE dell'IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	0	-	5	44	13	35	4	32	22	0.7	76.7	37
42	CE della AUSL of Bologna	5	132	4	39	9	27	3	1	21	0.7	77.3	52
43	CE dell'A.O. Ospedale of Lecco	7	66	10	35	4	26	0	-	21	0.7	78.0	44
44	CE dell'A.O. Universitaria S. Maria della Misericordia of Udine	3	76	11	27	5	72	2	21	21	0.7	78.7	44
45	CE of the Province of Ferrara	10	47	4	50	2	29	3	13	19	0.6	79.3	41
46	CE dell'A.O. Universitaria della Seconda Università of Naples	3	74	3	71	7	31	6	24	19	0.6	79.8	44
47	CE della ASL of the Province of Milan 2 of Melegnano	4	17	11	45	2	21	1	37	18	0.6	80.4	35
48	CE of the Province of Reggio Emilia	7	83	6	24	3	25	2	30	18	0.6	81.0	47
49	CE dell'Università Campus Bio-Medico of Rome	0	-	5	25	8	32	5	64	18	0.6	81.5	40
50	CE dell'IRCCS Istituti Ortopedici Rizzoli (IOR) of Bologna	3	18	6	25	1	99	6	20	16	0.5	82.1	27
51	CE dell'IRCCS Istituto S. Raffaele Pisana of Rome	6	20	3	17	3	-	4	24	16	0.5	82.6	20
52	CE dell'A.O. S. Paolo of Milan	3	22	5	29	4	62	3	18	15	0.5	83.0	35
53	CE dell'A.O. Universitaria Policlinico Giaccone dell'Università of Palermo	3	21	4	24	5	29	3	19	15	0.5	83.5	24



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
54	CE dell'A.O. OIRM/S. Anna of Turin	5	70	3	39	1	116	5	31	14	0.4	83.9	53
55	CE dell'IRCCS Centro di Riferimento Oncologico (CRO) of Aviano (PN)	2	19	4	31	5	30	3	44	14	0.4	84.4	31
56	CE dell'IRCCS Istituto Burlo Garofolo of Trieste	1	14	8	15	4	24	1	14	14	0.4	84.8	17
57	CE della ASL 3 Genovese of Genoa	8	36	2	35	1	6	2	17	13	0.4	85.2	30
58	CE dell'A.O. Universitaria Meyer of Florence	3	29	1	37	2	19	7	13	13	0.4	85.6	21
59	CE dell'IRCCS Ospedale Pediatrico Bambino Gesù of Rome	2	7	3	30	4	13	4	12	13	0.4	86.1	16
60	CE della AUSL 12 of Viareggio (LU)	4	61	0	--	4	12	3	10	11	0.3	86.4	31
61	CE dell'IRCCS Istituto Dermopatico dell'Immacolata (IDI) e Ospedale S. Carlo of Rome	3	45	4	34	3	31	1	7	11	0.3	86.7	33
62	CE della ASL of the Province of Bergamo	3	44	2	68	5	32	0	-	10	0.3	87.1	43
63	CE della ASL of Sassari	2	27	2	103	4	13	2	36	10	0.3	87.4	38
64	CE della AUSL 6 of Livorno	2	105	4	69	2	6	2	32	10	0.3	87.7	56
65	CE dell'A.O. Ospedale di Circolo e Fondazione Macchi of Varese	4	44	2	28	4	29	0	--	10	0.3	88.0	35
66	CE dell'IRCCS Fondazione Istituto Neurologico Mondino of Pavia	8	26	0	--	0	-	2	17	10	0.3	88.3	24
67	CE dell'IRCCS Istituto Nazionale Malattie Infettive Spallanzani of Rome	0	--	4	27	3	12	3	23	10	0.3	88.6	22
68	CE dell'IRCCS Istituto Neurologico Mediterraneo Neuromed of Pozzilli (IS)	2	35	3	37	4	21	1	50	10	0.3	88.9	31
69	CE dell'IRCCS Ospedale Oncologico of Bari	3	34	1	27	3	31	3	24	10	0.3	89.3	30
70	CE dell'A.O. Cardarelli of Naples	3	37	4	46	1	61	1	5	9	0.3	89.5	40
71	CE dell'A.O. S. Giuseppe Moscati of Avellino	2	10	3	23	3	33	1	23	9	0.3	89.8	23



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
72	CE dell'A.O. Universitaria di Cagliari	0	-	2	25	2	29	5	18	9	0.3	90.1	22
73	CE della AUSL RM/A of Rome	2	70	2	106	2	6	2	14	8	0.3	90.4	49
74	CE of the Province of Verona	2	18	4	75	2	45	0	-	8	0.3	90.6	53
75	CE of the Province of Vicenza	0	-	3	82	2	55	3	12	8	0.3	90.9	49
76	CE dell'A.O. S. Salvatore di Pesaro	2	28	2	23	2	16	2	29	8	0.3	91.1	24
77	CE dell'Azienda Sanitaria di Firenze	5	47	0	-	0	-	3	5	8	0.3	91.4	35
78	CE dell'E.O. Ospedali Galliera di Genova	1	6	2	29	1	25	4	44	8	0.3	91.6	33
79	CE della ASL 1 Avezzano Sulmona-L'Aquila	1	22	2	54	2	10	2	14	7	0.2	91.8	28
80	CE della ASL di Cagliari	2	62	2	27	1	28	2	4	7	0.2	92.1	25
81	CE della ASL di Milano	3	53	3	21	0	-	1	11	7	0.2	92.3	33
82	CE della ASUR - Azienda Sanitaria Unica Regionale delle Marche di Ancona	1	19	2	28	1	12	3	1	7	0.2	92.5	13
83	CE della AUSL 4 of Prato	1	98	2	33	1	25	3	10	7	0.2	92.7	31
84	CE della AUSL 8 of Arezzo	1	66	1	18	4	12	1	9	7	0.2	92.9	20
85	CE dell'A.O. Istituti Ospitalieri di Cremona	3	42	1	15	2	20	1	15	7	0.2	93.2	28
86	CE dell'A.O. Ospedale S. Carlo di Potenza	1	16	3	7	2	50	1	80	7	0.2	93.4	31
87	CE dell'A.O. S. Croce e Carle di Cuneo	3	27	1	8	1	3	2	5	7	0.2	93.6	14
88	CE dell'A.O. SS. Antonio e Biagio e Arrigo di Alessandria	1	27	2	20	2	19	2	-	7	0.2	93.8	21
89	CE dell'IRCCS Fondazione S. Lucia of Rome	1	18	2	8	2	8	2	24	7	0.2	94.0	14
90	CE della ASL TO/2 of Torino	3	54	2	32	1	12	0	-	6	0.2	94.2	39
91	CE della AUSL RM/B of Rome	4	21	2	4	0	-	0	-	6	0.2	94.4	15
92	CE of the Province of Treviso	3	93	1	191	0	-	2	14	6	0.2	94.6	83
93	CE dell'A.O. Istituti Clinici di Perfezionamento (ICP) of Milan	0	-	2	127	4	19	0	-	6	0.2	94.8	55
94	CE dell'A.O. Fatebenefratelli e Oftalmico of Milan	2	17	3	43	0	-	0	-	5	0.2	95.0	33



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
95	CE dell'A.O. Universitaria Ospedali Riuniti of Foggia	0	-	2	20	3	11	0	-	5	0.2	95.1	15
96	CE dell'IRCCS Istituto Auxologico Italiano of Milan	0	-	4	28	0	-	1	11	5	0.2	95.3	24
97	CE dell'IRCCS Ospedale della Sofferenza of S. Giovanni Rotondo (FG)	3	49	1	6	0	-	1	9	5	0.2	95.4	32
98	CE della AUSL 1 of Massa and Carrara	0	-	1	-	3	8	0	-	4	0.1	95.6	8
99	CE della AUSL 9 of Grosseto	0	-	4	56	0	-	0	-	4	0.1	95.7	56
100	CE della AUSL of Pescara	1	38	1	204	2	64	0	-	4	0.1	95.8	92
101	CE of the Province of Padua	0	-	1	133	1	6	2	13	4	0.1	95.9	51
102	CE dell'A.O. Bianchi-Melacrino-Morelli of Reggio Calabria	0	-	1	44	0	-	3	16	4	0.1	96.1	23
103	CE dell'A.O. Monaldi of Naples	1	-	3	117	0	-	0	-	4	0.1	96.2	117
104	CE dell'A.O. S. Filippo Neri of Rome	2	85	0	-	1	21	1	17	4	0.1	96.3	52
105	CE dell'A.O. Universitaria Ospedali Riuniti of Trieste	1	55	0	-	3	16	0	-	4	0.1	96.4	26
106	CE dell'APSS of Trento	0	-	1	158	0	-	3	34	4	0.1	96.6	65
107	CE dell'IRCCS Centro Cardiologico Monzino of Milan	2	11	1	27	0	-	1	18	4	0.1	96.7	17
108	CE dell'IRCCS Istituto Oncologico Veneto (IOV) of Padua	3	60	0	-	1	13	0	-	4	0.1	96.8	49
109	CE della ASL 2 Savonese of Savona	0	-	2	75	0	-	1	28	3	0.1	96.9	59
110	CE della ASL BR of Brindisi	0	-	1	29	1	9	1	39	3	0.1	97.0	26
111	CE della ASL LE of Lecce	1	13	2	1	0	-	0	-	3	0.1	97.1	5
112	CE della ASP of Palermo	2	47	1	7	0	-	0	-	3	0.1	97.2	33
113	CE della AUSL 2 of Lucca	0	-	0	-	1	28	2	14	3	0.1	97.3	18
114	CE della AUSL of Latina	1	66	1	50	0	-	1	37	3	0.1	97.4	51



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
115	CE della AUSL RM/C of Rome	1	-	1	7	0	-	1	6	3	0.1	97.5	7
116	CE della Fondazione Istituto S. Raffaele-Giglio of Cefalù (PA)	2	9	0	-	0	-	1	7	3	0.1	97.6	8
117	CE dell'A.O. Ospedale Civile of Legnano (MI)	1	51	1	29	1	1	0	-	3	0.1	97.7	27
118	CE dell'A.O. Poma of Mantova	0	-	0	-	0	-	3	33	3	0.1	97.8	33
119	CE dell'A.O. S. Antonio Abate of Gallarate (VA)	0	-	0	-	1	12	2	11	3	0.1	97.9	12
120	CE dell'A.O. S. Maria degli Angeli of Pordenone	0	-	1	61	2	15	0	-	3	0.1	98.0	38
121	CE dell'A.O. Treviglio-Caravaggio of Treviglio (BG)	0	-	0	-	2	20	1	56	3	0.1	98.0	32
122	CE dell'A.O. Universitaria Mater Domini of Catanzaro	1	37	2	28	0	-	0	-	3	0.1	98.1	31
123	CE dell'IRCCS Istituto Nazionale Riposo e Cura Anziani (INRCA) of Ancona	0	-	1	11	1	30	1	14	3	0.1	98.2	18
124	CE dell'Istituto Mediterraneo Trapianti e Terapie ad alta specializzazione (IsMeT) of Palermo	0	-	0	-	1	124	2	23	3	0.1	98.3	57
125	CE dell'Ospedale S. Giovanni Calibita Fatebenefratelli Isola Tiberina of Rome	2	27	0	-	1	84	0	-	3	0.1	98.4	46
126	CE dell'Università of Pavia	1	5	2	5	0	-	0	-	3	0.1	98.5	5
127	CE degli Ospedali Fatebenefratelli S. Giuseppe of Milan e Sacra Famiglia of Erba (CO)	0	-	1	28	0	-	1	17	2	0.1	98.6	23
128	CE della ASL of the Province of Brescia	0	-	0	-	2	24	0	-	2	0.1	98.6	24
129	CE of the Province of Venice	1	-	1	66	0	-	0	-	2	0.1	98.7	66
130	CE dell'A.O. Istituto Ortopedico Pini of Milan	0	-	0	-	1	1	1	7	2	0.1	98.8	4
131	CE dell'A.O. Ospedale di Circolo of Busto Arsizio (VA)	1	79	0	-	0	-	1	8	2	0.1	98.8	44



	Ethics committee	2007		2008		2009		2010		Total			
		SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	Avg. time (days)	SO	%	cum. %	Avg. time (days)
132	CE dell'A.O. Ospedali Riuniti Villa Sofia - Cervello of Palermo	0	-	0	-	1	63	1	58	2	0.1	98.9	61
133	CE dell'A.O. S. Anna of Como	1	62	0	-	0	-	1	7	2	0.1	99.0	35
134	CE dell'A.O. Universitaria Policlinico Martino of Messina	1	74	0	-	0	-	1	104	2	0.1	99.0	89
135	CE dell'ARNAS Garibaldi of Catania	1	-	1	53	0	-	0	-	2	0.1	99.1	53
136	CE dell'IRCCS Centro di Riferimento Oncologico di Basilicata (CROB) of Rionero in Vulture (PZ)	0	-	2	39	0	-	0	-	2	0.1	99.1	39
137	CE dell'Istituto Superiore di Sanità (ISS) of Rome	1	21	1	12	0	-	0	-	2	0.1	99.2	17
138	CE della ASL 4 of Teramo	1	29	0	-	0	-	0	-	1	0.0	99.2	29
139	CE della ASL BA of Bari	0	-	0	-	1	14	0	-	1	0.0	99.3	14
140	CE della ASL of Salerno	0	-	1	16	0	-	0	-	1	0.0	99.3	16
141	CE della ASL FG of Foggia	0	-	1	41	0	-	0	-	1	0.0	99.3	41
142	CE della ASL Napoli 2 nord of Pozzuoli (NA)	1	7	0	-	0	-	0	-	1	0.0	99.4	7
143	CE della ASREM of Campobasso	0	-	0	-	0	-	1	17	1	0.0	99.4	17
144	CE della AUSL 3 of Pistoia	0	-	0	-	1	7	0	-	1	0.0	99.4	7
145	CE della AUSL of Frosinone	0	-	1	24	0	-	0	-	1	0.0	99.5	24
146	CE della AUSL of Viterbo	0	-	0	-	0	-	1	15	1	0.0	99.5	15
147	CE dell'A.O. Brotzu of Cagliari	0	-	0	-	0	-	1	18	1	0.0	99.5	18
148	CE dell'A.O. Civico e Benfratelli - Di Cristina-Ascoli of Palermo	1	148	0	-	0	-	0	-	1	0.0	99.6	148
149	CE dell'A.O. of the Province of Pavia	0	-	0	-	1	6	0	-	1	0.0	99.6	6
150	CE dell'A.O. of Cosenza	0	-	0	-	0	-	1	83	1	0.0	99.6	83
151	CE dell'A.O. Ospedale S. Carlo Borromeo of Milan	0	-	0	-	0	-	1	-	1	0.0	99.7	-



	Ethics committee	2007			2008			2009			2010			Total			
		SO	Avg. time (days)		SO	Avg. time (days)		SO	Avg. time (days)		SO	Avg. time (days)		SO	%	cum. %	Avg. time (days)
152	CE dell'A.O. per l'emergenza Cannizzaro of Catania	0	-	-	0	-	-	1	8	-	0	-	-	1	0.0	99.7	8
153	CE dell'A.O. Salvini of Garbagnate Milanese (MI)	0	-	-	0	-	-	1	97	-	0	-	-	1	0.0	99.7	97
154	CE dell'ASP - Comprensorio Sanitario of Bolzano	0	-	-	0	-	-	0	-	-	1	14	1	1	0.0	99.7	14
155	CE dell'ASS 1 Triestina of Trieste	0	-	-	0	-	-	1	88	-	0	-	-	1	0.0	99.8	88
156	CE delle Istituzioni Ospedaliere Cattoliche (CEIOC) of Brescia	1	15	-	0	-	-	0	-	-	0	-	-	1	0.0	99.8	15
157	CE dell'IRCCS Fondazione Don Carlo Gnocchi of Milan	0	-	-	0	-	-	0	-	-	1	27	1	1	0.0	99.8	27
158	CE dell'IRCCS Gruppo Multimedica of Sesto S. Giovanni (MI)	0	-	-	0	-	-	1	3	-	0	-	-	1	0.0	99.9	3
159	CE dell'IRCCS Ospedale S. Camillo of Venice	0	-	-	0	-	-	0	-	-	1	13	1	1	0.0	99.9	13
160	CE dell'Ospedale Israelitico of Rome	1	10	-	0	-	-	0	-	-	0	-	-	1	0.0	99.9	10
161	CE dell'Ospedale Regina Apostolorum of Albano Laziale (RM)	0	-	-	0	-	-	1	140	-	0	-	-	1	0.0	99.9	140
162	CE dell'Ospedale Valduce of Como	1	93	-	0	-	-	0	-	-	0	-	-	1	0.0	100.0	93

Table 128

Acceptance/refusal of the single opinion and median times to issue the opinion per Ethics committee and year

Total EC: 245 of which 238 (97.1%) have given at least one acceptance/refusal of the SO

The first 116 EC out of 238 (48.7%) represent 86.3% of the total acceptances/refusals issued

(the table includes 3 Ethics committees that gave evaluations in 2007 but are no longer operative)

The time to issue the acceptance/refusal of the SO is calculated as being the difference between the day the EC expressed its final decision and:

- the date of reception of the application by the EC's satellite centre, if the SO issuing has occurred prior to the receipt of the application;
- the date of the SO issuing if this has occurred after the date of reception of the application by the EC's satellite centre.

	Ethics committee	2007		2008		2009		2010		Total		
		Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	%	cum. %
1	CE di Area Vasta Romagna e Istituto Scientifico Romagnolo Tumori (IRST) of Meldola (FC)	100	30	106	45	116	43	99	60	421	2.3	2.3
2	CE dell'A.O. Universitaria S. Martino of Genoa	109	93	95	114	101	80	69	43	374	2.0	4.3
3	CE delle Aziende Sanitarie dell'Umbria of Perugia	79	37	114	49	91	42	87	43	371	2.0	6.3
4	CE dell'Azienda Policlinico Umberto I of Rome	95	30	89	31	93	50	85	57	362	2.0	8.3
5	CE dell'A.O. Universitaria Careggi of Florence	98	40	87	57	85	49	79	52	349	1.9	10.2
6	CE of the Province of Modena	87	61	93	75	89	50	74	65	343	1.9	12.0
7	CE dell'A.O. Universitaria Policlinico S. Orsola-Malpighi of Bologna	106	20	81	22	99	43	57	53	343	1.9	13.9
8	CE dell'A.O. Universitaria Policlinico S. Maria della Misericordia of Bologna	100	20	81	22	99	43	57	53	343	1.9	15.8



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	%	cum. %	Median time (days)
8	CE dell'Università Cattolica del Sacro Cuore - Policlinico Universitario Gemelli of Rome	75	15	100	14	67	10	81	70	323	1.7	15.6	15
9	CE dell'A.O. Universitaria S. Giovanni Battista of Turin	84	14	89	13	71	17	62	56	306	1.7	17.3	18
10	CE dell'A.O. of Padua	83	42	88	44	71	46	54	42	296	1.6	18.9	45
11	CE dell'IRCCS Fondazione S. Raffaele del Monte Tabor of Milan	60	16	84	23	69	24	76	29	289	1.6	20.5	24
12	CE dell'A.O. Universitaria Pisana of Pisa	80	60	72	45	68	37	67	36	287	1.6	22.0	45
13	CE dell'IRCCS Fondazione Policlinico S. Matteo of Pavia	71	21	66	23	66	34	67	30	270	1.5	23.5	26
14	CE Carlo Romano dell'Università Federico II of Naples	67	68	72	36	75	42	54	60	268	1.5	24.9	50
15	CE dell'A.O. Policlinico Consorziale of Bari	67	37	82	28	62	16	46	57	257	1.4	26.3	28
16	CE dell'A.O. Spedali Civili of Brescia	60	18	74	15	64	15	52	8	250	1.4	27.7	15
17	CE dell'A.O. Ospedale Niguarda Ca' Granda of Milan	58	38	63	37	72	22	56	14	249	1.3	29.0	27
18	CE dell'A.O. Universitaria S. Maria della Misericordia of Udine	45	18	77	56	81	60	45	75	248	1.3	30.4	56
19	CE dell'A.O. Universitaria S. Luigi Gonzaga of Orbassano (TO)	57	10	61	25	56	29	57	13	231	1.3	31.6	18
20	CE of the Province of Parma	47	20	69	14	61	8	49	7	226	1.2	32.8	12



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	%	cum. %	Median time (days)	
21	CE of the Province of Reggio Emilia	56	41	71	41	46	52	47	56	220	1.2	34.0	46
22	CE dell'A.O. Universitaria Policlinico-Vittorio Emanuele of Catania	44	30	50	39	65	29	60	28	219	1.2	35.2	32
23	CE dell'A.O. Universitaria Senese of Siena	56	25	59	23	59	18	42	12	216	1.2	36.4	19
24	CE dell'A.O. Universitaria Ospedali Riuniti Umberto I-Lancisi-Salesi of Ancona	56	31	53	57	62	37	42	70	213	1.2	37.6	41
25	CE dell'A.O. Universitaria Policlinico Giaccone dell'Università of Palermo	59	32	41	30	58	31	41	42	199	1.1	38.6	32
26	CE dell'A.O. Universitaria Maggiore della Carità of Novara	38	28	51	31	66	34	38	31	193	1.0	39.7	32
27	CE of the Province of Ferrara	54	42	44	38	50	43	42	45	190	1.0	40.7	43
28	CE della Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan	53	63	38	41	56	34	42	37	189	1.0	41.7	43
29	CE dell'A.O. Ospedali Riuniti of Bergamo	43	45	52	46	45	46	49	36	189	1.0	42.8	45
30	CE della Fondazione PTV Policlinico Tor Vergata of Rome	42	47	49	44	46	55	46	47	183	1.0	43.7	49
31	CE dell'Università D'Annunzio e della ASL Lanciano-Vasto-Chieti of Chieti	43	22	64	32	48	33	27	127	182	1.0	44.7	36
32	CE dell'A.O. S. Gerardo of Monza (MB)	40	22	52	20	37	21	40	23	169	0.9	45.6	21
33	CE della ASUR - Azienda Sanitaria Unica Regionale delle Marche of Ancona	45	46	49	35	41	23	31	34	166	0.9	46.5	31
34	CE della ASL of Sassari	40	42	57	28	38	24	27	36	162	0.9	47.4	29



	Ethics committee	2007		2008		2009		2010		Total		
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %
35	CE dell'A.O. Universitaria Integrata of Verona	46	57	41	44	36	30	35	22	158	0.9	48.3
36	CE dell'A.O. Sacco of Milan	56	54	43	51	29	106	26	104	154	0.8	49.1
37	CE dell'A.O. Cardarelli of Naples	33	76	41	73	44	49	27	49	145	0.8	49.9
38	CE dell'IRCCS Istituti Fisioterapici Ospitalieri (IFO) of Rome	44	48	44	47	17	68	38	86	143	0.8	50.7
39	CE dell'A.O. S. Camillo-Forlanini of Rome	37	50	52	36	29	92	23	56	141	0.8	51.4
40	CE dell'A.O. Universitaria Policlinico Martino of Messina	45	98	38	72	38	126	20	105	141	0.8	52.2
41	CE dell'IRCCS Ospedale Casa Sollievo della Sofferenza of S. Giovanni Rotondo (FG)	43	67	30	42	34	24	33	39	140	0.8	53.0
42	CE dell'A.O. OIRM/S. Anna of Turin	32	50	32	71	48	44	26	77	138	0.7	53.7
43	CE della ASL LE of Lecce	4	107	37	218	47	166	48	71	136	0.7	54.4
44	CE dell'A.O. S. Andrea of Rome	26	30	42	42	32	25	35	28	135	0.7	55.2
45	CE dell'A.O. Universitaria della Seconda Università of Naples	34	73	37	41	30	100	34	55	135	0.7	55.9
46	CE della ASL TO/2 of Turin	38	36	41	41	27	39	27	42	133	0.7	56.6
47	CE dell'A.O. SS. Antonio e Biagio e Arrigo of Alessandria	33	25	30	25	31	26	35	57	129	0.7	57.3
48	CE della ASL of Salerno	17	42	49	23	30	30	30	18	126	0.7	58.0
49	CE dell'A.O. Ospedale di Circolo e Fondazione Macchi of Varese	27	54	46	56	29	49	24	73	126	0.7	58.7
50	CE of the Province of Venice	36	31	23	76	29	190	35	71	123	0.7	59.4
												78



	Ethics committee	2007			2008			2009			2010			Total			
		Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	%	cum. %	Median time (days)
51	CE of the Province of Vicenza	27	84	37	34	37	45	37	45	21	47	122	0.7	122	0.7	60.0	42
52	CE dell'A.O. S. Croce e Carle of Cuneo	33	22	33	23	23	29	23	29	23	30	112	0.6	112	0.6	60.6	24
53	CE of the Province of Treviso	15	48	43	55	33	110	33	110	20	94	111	0.6	111	0.6	61.2	64
54	CE dell'IRCCS Istituto Nazionale Tumori Fondazione Pascale of Naples	20	41	24	38	32	34	32	34	33	28	109	0.6	109	0.6	61.8	30
55	CE dell'IRCCS Centro di Riferimento Oncologico (CRO) of Aviano (PN)	13	43	32	31	40	34	40	34	22	41	107	0.6	107	0.6	62.4	35
56	CE of the Province of Verona	18	85	33	89	31	77	31	77	24	89	106	0.6	106	0.6	63.0	88
57	CE dell'A.O. S. Paolo of Milan	34	56	33	26	22	24	22	24	17	23	106	0.6	106	0.6	63.5	28
58	CE dell'IRCCS Fondazione Istituto Nazionale Tumori (INT) of Milan	19	20	30	26	26	27	26	27	28	26	103	0.6	103	0.6	64.1	26
59	CE dell'IRCCS Fondazione Maugeri of Pavia	29	26	36	14	21	14	21	14	17	17	103	0.6	103	0.6	64.7	17
60	CE dell'IRCCS Istituto Clinico Humanitas of Rozzano (MI)	10	21	21	49	38	24	38	24	33	22	102	0.6	102	0.6	65.2	25
61	CE della AUSL of Bologna	21	57	24	82	33	41	33	41	23	32	101	0.5	101	0.5	65.8	43
62	CE della AUSL of Pescara	17	140	29	100	33	89	33	89	21	58	100	0.5	100	0.5	66.3	84
63	CE dell'A.O. Bianchi-Melacrino-Morelli of Reggio Calabria	21	30	26	26	26	13	26	13	27	27	100	0.5	100	0.5	66.8	25
64	CE dell'A.O. Universitaria Ospedali Riuniti of Foggia	16	32	27	32	27	36	27	36	30	64	100	0.5	100	0.5	67.4	35



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
65	CE dell'IRCCS Istituto Europeo di Oncologia (IEO) of Milan	23	35	23	22	26	24	28	22	100	0.5	67.9	26
66	CE della ASL of Cagliari	26	50	24	55	21	80	26	125	97	0.5	68.5	63
67	CE dell'ARNAS Garibaldi of Catania	31	33	27	39	16	21	22	44	96	0.5	69.0	33
68	CE dell'IRCCS Istituto Nazionale per la Ricerca sul Cancro of Genoa	19	14	34	17	22	16	19	24	94	0.5	69.5	17
69	CE dell'Azienda Sanitaria of Florence	25	38	34	22	18	28	15	35	92	0.5	70.0	29
70	CE dell'A.O. Universitaria Ospedali Riuniti of Trieste	15	121	34	97	22	83	18	113	89	0.5	70.5	101
71	CE della ASL BR of Brindisi	29	36	22	11	19	15	18	22	88	0.5	70.9	22
72	CE della AUSL of Piacenza	22	55	26	36	15	15	22	42	85	0.5	71.4	37
73	CE dell'IRCCS Istituto Nazionale Malattie Infettive Spallanzani of Rome	36	18	18	16	20	43	9	48	83	0.4	71.8	26
74	CE dell'IRCCS Istituto Oncologico Veneto (IOV) of Padua	9	20	22	74	28	54	24	54	83	0.4	72.3	54
75	CE dell'A.O. Istituti Ospitalieri of Cremona	19	43	22	24	25	21	15	27	81	0.4	72.7	24
76	CE della ASP of Palermo	22	60	26	47	24	76	6	170	78	0.4	73.2	60
77	CE dell'A.O. Poma of Mantova	24	64	26	56	17	49	10	41	77	0.4	73.6	56
78	CE della AUSL 12 of Viareggio (LU)	14	28	24	23	22	15	15	14	75	0.4	74.0	21
79	CE della AUSL 8 of Arezzo	11	33	18	15	24	23	20	15	73	0.4	74.4	17
80	CE dell'A.O. Ospedali Riuniti Villa Sofia - Cervello of Palermo	25	58	16	44	16	26	16	28	73	0.4	74.8	36



	Ethics committee	2007			2008			2009			2010			Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)		
81	CE dell'A.O. S. Salvatore of Pesaro	22	37	29	20	14	38	8	32	73	0.4	75.2	27				
82	CE dell'A.O. S. Giuseppe Moscati of Avellino	12	43	27	31	17	41	16	52	72	0.4	75.6	41				
83	CE della ASL 3 Genovese of Genoa	18	28	17	29	12	27	22	44	69	0.4	75.9	33				
84	CE della AUSL 4 of Prato	15	62	20	34	17	32	17	18	69	0.4	76.3	32				
85	CE dell'A.O. S. Anna of Como	11	38	21	16	18	21	18	14	68	0.4	76.7	20				
86	CE della AUSL 6 of Livorno	27	49	22	80	11	50	7	83	67	0.4	77.0	55				
87	CE dell'A.O. Ospedale S. Carlo of Potenza	15	30	18	156	21	113	13	101	67	0.4	77.4	108				
88	CE della ASL 1 Avezzano-Sulmona-L'Aquila	23	40	25	30	11	39	7	22	66	0.4	77.8	36				
89	CE dell'A.O. Treviglio-Caravaggio of Treviglio (BG)	20	60	22	30	14	57	9	50	65	0.4	78.1	47				
90	CE della AUSL RM/C of Rome	8	26	21	36	22	90	13	80	64	0.3	78.5	72				
91	CE dell'ASP - Comprensorio Sanitario of Bolzano	13	38	25	40	15	74	11	42	64	0.3	78.8	52				
92	CE dell'A.O. Ospedale di Circolo of Busto Arsizio (VA)	22	66	15	59	11	59	15	51	63	0.3	79.1	59				
93	CE dell'IRCCS Centro di Riferimento Oncologico of Basilicata (CROB) of Rionero in Vulture (PZ)	14	26	12	22	17	32	20	45	63	0.3	79.5	29				
94	CE dell'Università Campus Bio-Medico of Rome	13	41	17	56	20	60	13	63	63	0.3	79.8	56				
95	CE della AUSL of Latina	10	61	23	57	17	69	12	51	62	0.3	80.2	57				
96	CE della AUSL 9 of Grosseto	16	42	20	33	14	6	10	13	60	0.3	80.5	30				



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
97	CE della ASL of the Province of Milan 2 of Melegnano	19	21	25	26	11	30	4	47	59	0.3	80.8	24
98	CE dell'IRCCS Istituto S. Raffaele Pisana of Rome	16	38	19	24	10	31	14	25	59	0.3	81.1	27
99	CE dell'IRCCS Ospedale Pediatrico Bambino Gesù of Rome	12	23	10	15	14	42	22	12	58	0.3	81.4	15
100	CE dell'A.O. Ospedale of Lecco	15	37	15	42	14	36	13	45	57	0.3	81.8	39
101	CE dell'A.O. Ospedale Civile of Legnano (MI)	16	57	15	54	16	155	9	142	56	0.3	82.1	85
102	CE della Provincia Religiosa di S. Pietro Fatebenefratelli of Rome	13	17	19	34	10	46	13	51	55	0.3	82.4	39
103	CE dell'A.O. della Valtellina e della Valchiavenna of Sondrio	10	20	17	49	18	51	10	45	55	0.3	82.7	46
104	CE dell'IRCCS Ospedale Oncologico of Bari	12	74	16	20	13	28	14	19	55	0.3	83.0	23
105	CE dell'A.O. Pugliese-Ciaccio of Catanzaro	20	24	16	27	9	27	8	14	53	0.3	83.2	26
106	CE dell'A.O. Rummo of Benevento	15	55	14	63	15	83	9	49	53	0.3	83.5	57
107	CE dell'A.O. Universitaria of Cagliari	10	100	12	64	17	110	14	102	53	0.3	83.8	97
108	CE dell'E.O. Ospedali Galliera of Genoa	16	36	13	37	16	55	8	81	53	0.3	84.1	47
109	CE della ASL TA of Taranto	4	43	24	81	15	49	9	49	52	0.3	84.4	65
110	CE della ASP of Messina	14	163	22	112	6	90	10	86	52	0.3	84.7	101
111	CE della ASREM of Campobasso	10	65	22	32	14	44	5	28	51	0.3	84.9	40
112	CE dell'A.O. Civico e Benfratelli-Di Cristina-Ascoli of Palermo	24	56	15	56	11	61	1	24	51	0.3	85.2	56



	Ethics committee	2007			2008			2009			2010			Total			
		Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	%	cum. %	Median time (days)	
113	CE dell'A.O. S. Maria degli Angeli of Pordenone	18	17	16	24	14	49	3	53	51	0.3	85.5	31				
114	CE della ASL NA/1 of Naples	10	175	16	116	6	145	18	96	50	0.3	85.8	106				
115	CE dell'A.O. Monaldi of Naples	9	100	11	38	14	54	15	65	49	0.3	86.0	55				
116	CE dell'A.O. S. Giovanni-Addolorata of Rome	12	65	13	44	13	50	11	31	49	0.3	86.3	50				
117	CE dell'A.O. of Cosenza	9	12	15	7	15	26	8	67	47	0.3	86.5	18				
118	CE della ASL 2 Savonese of Savona	13	32	18	28	8	40	7	24	46	0.2	86.8	29				
119	CE della AUSL RM/B of Rome	13	43	8	50	17	70	8	44	46	0.2	87.0	50				
120	CE della ASP of Cosenza	9	170	3	-	8	147	25	194	45	0.2	87.3	182				
121	CE of the Province of Padua	8	99	18	53	10	126	9	71	45	0.2	87.5	89				
122	CE dell'A.O. Universitaria Mater Domini of Catanzaro	26	62	9	54	2	27	8	111	45	0.2	87.8	60				
123	CE dell'IRCCS Istituto Gaslini of Genoa	12	19	8	34	18	31	7	53	45	0.2	88.0	28				
124	CE dell'A.O. of Desio and Vimercate (MB)	11	102	22	43	4	163	7	120	44	0.2	88.3	80				
125	CE dell'Ospedale S. Giovanni Calibita Fatebenefratelli Isola Tiberina of Rome	9	45	13	14	10	69	12	45	44	0.2	88.5	38				
126	CE dell'A.O. Salvini of Garbagnate Milanese (MI)	10	50	12	51	12	63	9	37	43	0.2	88.7	49				
127	CE dell'APSS of Trento	10	25	14	18	13	42	5	94	42	0.2	89.0	31				
128	CE della AUSL 1 of Massa and Carrara	5	89	9	30	11	27	16	49	41	0.2	89.2	38				
129	CE della AUSL of Frosinone	8	54	12	24	12	31	9	57	41	0.2	89.4	35				
130	CE dell'A.O. Ospedale S. Carlo Borromeo of Milan	15	89	8	33	16	168	2	44	41	0.2	89.6	98				
131	CE dell'A.O. S. Anna e S. Sebastiano of Caserta	14	27	16	35	6	40	4	122	40	0.2	89.8	38				



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
132	CE dell'IRCCS Fondazione Istituto Neurologico Mondino of Pavia	13	32	11	32	7	30	8	25	39	0.2	90.1	32
133	CE della AUSL 2 of Lucca	9	69	13	29	7	37	9	26	38	0.2	90.3	29
134	CE della Fondazione Istituto S. Raffaele-Giglio of Cefalù (PA)	9	29	6	9	6	13	17	18	38	0.2	90.5	16
135	CE dell'A.O. Fatebenefratelli e Oftalmico of Milan	3	91	8	61	15	54	10	29	36	0.2	90.7	47
136	CE dell'A.O. of the Province of Pavia	8	43	12	13	8	17	7	7	35	0.2	90.8	15
137	CE dell'A.O. Istituto Ortopedico Pini of Milan	11	34	5	25	11	19	8	14	35	0.2	91.0	19
138	CE dell'A.O. Ospedali Riuniti Papardo - Piemonte of Messina	7	67	11	33	7	27	10	88	35	0.2	91.2	48
139	CE dell'A.O. S. Filippo Neri of Rome	8	15	8	13	8	17	11	19	35	0.2	91.4	15
140	CE dell'IRCCS Istituto Neurologico Besta of Milan	7	21	12	22	10	26	6	69	35	0.2	91.6	22
141	CE dell'IRCCS Istituto Neurologico Mediterraneo Neuromed of Pozzilli (IS)	9	60	13	32	6	33	7	40	35	0.2	91.8	35
142	CE della ASL of the Province of Brescia	8	174	5	61	13	42	8	40	34	0.2	92.0	57
143	CE della ASP of Catania	9	63	8	54	11	35	6	73	34	0.2	92.2	55
144	CE of the Province of Belluno	13	54	9	63	2	47	10	37	34	0.2	92.4	54
145	CE dell'A.O. S. Antonio Abate of Gallarate (VA)	6	39	12	20	9	24	6	82	33	0.2	92.5	26
146	CE della ASL BA of Bari	3	182	12	64	13	137	4	135	32	0.2	92.7	134
147	CE dell'A.O. per l'emergenza Cannizzaro of Catania	10	43	8	49	9	54	5	54	32	0.2	92.9	50
148	CE della ASL 4 of Teramo	7	30	8	70	12	138	4	30	31	0.2	93.0	93
149	CE della ASL of Milan	10	39	13	58	5	35	3	129	31	0.2	93.2	48
150	CE della AUSL of Viterbo	3	162	11	113	12	92	5	20	31	0.2	93.4	83



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
151	CE of the Province of Rovigo	8	119	7	120	12	50	4	109	31	0.2	93.5	77
152	CE della ASL Napoli 2 nord of Pozzuoli (NA)	10	47	10	75	8	58	2	11	30	0.2	93.7	58
153	CE dell'A.O. of Melegnano (MI)	13	49	6	60	7	90	4	95	30	0.2	93.9	63
154	CE dell'A.O. Universitaria Meyer of Florence	5	27	5	26	9	28	11	21	30	0.2	94.0	25
155	CE della ASP of Ragusa	11	161	5	14	9	17	4	57	29	0.2	94.2	33
156	CE della AUSL 3 of Pistoia	4	26	16	33	6	52	3	22	29	0.2	94.3	33
157	CE dell'A.O. Brotzu of Cagliari	11	106	3	54	7	110	8	47	29	0.2	94.5	92
158	CE della AUSL 5 Spezzino of La Spezia	8	38	9	45	7	55	4	109	28	0.2	94.7	45
159	CE dell'A.O. Cardinale Panico of Tricase (LE)	6	10	8	28	5	37	8	86	27	0.1	94.8	45
160	CE della ASL of Matera	4	35	17	45	5	16	0	-	26	0.1	94.9	23
161	CE dell'A.O. Istituti Clinici di Perfezionamento (ICP) of Milan	4	17	3	27	10	71	9	41	26	0.1	95.1	38
162	CE dell'IRCCS Istituto Nazionale Riposo e Cura Anziani (INRCA) of Ancona	3	203	11	95	5	50	7	38	26	0.1	95.2	81
163	CE della ASL of Caserta	4	31	13	41	6	55	2	80	25	0.1	95.4	41
164	CE dell'IRCCS Centro Cardiologico Monzino of Milan	2	43	11	28	3	23	9	24	25	0.1	95.5	28
165	CE della ASL Napoli 3 sud of Brusciano (NA)	4	44	7	33	7	48	5	1	23	0.1	95.6	39
166	CE dell'A.O. Cotugno of Naples	2	5	12	26	8	15	1	29	23	0.1	95.7	26
167	CE dell'A.O. of the Province of Lodi	4	35	12	55	4	79	3	81	23	0.1	95.9	45
168	CE delle Istituzioni Ospedaliere Cattoliche (CEIOC) of Brescia	11	35	4	29	2	33	6	36	23	0.1	96.0	35
169	CE dell'IRCCS Gruppo Multimedica of Sesto S. Giovanni (MI)	2	158	6	53	5	125	10	18	23	0.1	96.1	53
170	CE dell'IRCCS Istituto Burlo Garofolo of Trieste	9	139	2	47	5	19	7	21	23	0.1	96.2	38
171	CE dell'IRCCS Istituto Dermatologico dell'Immacolata (IDI) e Osp. S. Carlo of Rome	10	33	5	40	1	57	7	32	23	0.1	96.4	33



	Ethics committee	2007		2008		2009		2010		Total		
		Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	Median time (days)	Acc./Ref. SO	%	cum. %
172	CE della ASL of the Province of Monza and Brianza (MB)	4	25	11	85	2	64	5	38	22	0.1	96.5
173	CE della ASL of the Province of Bergamo	3	21	7	24	4	34	7	49	21	0.1	96.6
174	CE della AUSL RM/A of Rome	5	42	7	36	2	12	7	44	21	0.1	96.7
175	CE della AUSL RM/H of Albano Laziale	3	56	5	32	8	65	5	32	21	0.1	96.8
176	CE dell'Ospedale Generale Regionale Miulli of Acquaviva delle Fonti (BA)	6	42	4	62	6	37	5	124	21	0.1	96.9
177	CE degli Ospedali Fatebenefratelli S. Giuseppe of Milan e Sacra Famiglia of Erba (CO)	3	22	7	23	7	25	3	33	20	0.1	97.1
178	CE della ASL 1 Imperiese of Bussana of Sanremo (IM)	5	27	7	95	2	63	6	132	20	0.1	97.2
179	CE della ASL BAT of Andria (BT)	0	-	13	73	6	104	1	156	20	0.1	97.3
180	CE della ASL of Olbia	1	82	8	33	7	52	4	94	20	0.1	97.4
181	CE della AUSL della Valle d'Aosta of Aosta	2	33	8	43	5	36	5	102	20	0.1	97.5
182	CE dell'Ospedale Regina Apostolorum of Albano Laziale (RM)	5	48	6	35	3	27	6	18	20	0.1	97.6
183	CE della ASL FG of Foggia	11	60	8	28	0	-	0	-	19	0.1	97.7
184	CE dell'IRCCS Istituto Auxologico Italiano of Milan	5	18	9	28	2	22	3	4	19	0.1	97.8
185	CE dell'Ospedale Valduce of Como	5	50	5	85	5	31	4	55	19	0.1	97.9
186	CE dell'IRCCS Istituti Ortopedici Rizzoli (IOR) of Bologna	6	30	4	34	2	59	6	50	18	0.1	98.0
187	CE della ASL 8 of Vibo Valentia	5	33	7	18	3	34	2	28	17	0.1	98.1
188	CE dell'A.O. Bolognini of Seriate (BG)	4	18	2	59	6	34	5	23	17	0.1	98.2
189	CE della ASL of Avellino	3	246	6	113	3	92	3	206	15	0.1	98.3
190	CE della AUSL RM/D of Rome	5	80	7	73	2	90	1	41	15	0.1	98.3
191	CE della AUSL RM/G of Tivoli	0	-	1	62	7	192	7	42	15	0.1	98.4



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
192	CE della AUSL RM/E of Rome	3	193	4	95	6	59	1	331	14	0.1	98.5	92
193	CE della ASL 4 Chiavarese of Chiavari (GE)	3	231	5	84	5	47	0	–	13	0.1	98.6	57
194	CE dell'A.O. Ospedali Riuniti S. Giovanni di Dio e Ruggi d'Aragona of Salerno	3	14	4	97	4	54	2	153	13	0.1	98.6	66
195	CE dell'ASS 1 Triestina of Trieste	4	113	4	52	4	14	1	33	13	0.1	98.7	37
196	CE dell'A.O. of Desenzano del Garda (BS)	4	44	3	28	5	18	0	–	12	0.1	98.8	29
197	CE dell'Associazione Cavalieri di Malta (ACISMOM) of Rome	3	10	4	55	5	9	0	–	12	0.1	98.8	11
198	CE dell'IRCCS Fondazione Don Carlo Gnocchi of Milan	0	–	6	63	4	54	2	95	12	0.1	98.9	61
199	CE della ASL of the Province of Varese	2	11	4	40	4	40	1	47	11	0.1	99.0	40
200	CE della ASP of Siracusa	3	8	5	21	2	9	1	224	11	0.1	99.0	11
201	CE dell'A.O. Ospedale Maggiore of Crema (CR)	4	29	3	26	2	39	2	148	11	0.1	99.1	32
202	CE della ASP of Reggio Calabria	4	127	4	62	0	–	2	57	10	0.1	99.1	62
203	CE dell'IRCCS Fondazione S. Lucia of Rome	4	18	3	8	1	–	2	28	10	0.1	99.2	18
204	CE della ASL of Nuoro	2	63	3	36	2	24	2	85	9	0.0	99.2	40
205	CE della ASP of Catanzaro	0	–	5	75	4	40	0	–	9	0.0	99.3	62
206	CE dell'ASS 2 Isontina of Gorizia	2	99	3	58	2	18	2	27	9	0.0	99.3	48
207	CE dell'IRCCS Centro Neurolesi Borino-Pulejo of Messina	2	31	1	36	3	62	3	21	9	0.0	99.4	38
208	CE dell'A.O. Santobono-Pausilipon of Naples	1	56	0	–	4	27	3	251	8	0.0	99.4	41
209	CE dell'Istituto Mediterraneo Trapianti e Terapie ad alta specializzazione (IsMeTT) of Palermo	0	–	3	75	3	7	2	145	8	0.0	99.5	62
210	CE della ASL of Carbonia	0	–	4	58	2	19	1	62	7	0.0	99.5	45
211	CE della ASP of Enna	1	12	4	223	2	56	0	–	7	0.0	99.6	164
212	CE della ASP of Trapani	3	9	2	151	2	142	0	–	7	0.0	99.6	104
213	CE della AUSL of Rieti	4	30	1	48	0	–	2	49	7	0.0	99.6	30



	Ethics committee	2007		2008		2009		2010		Total		
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %
214	CE della ASP of Agrigento	0	-	5	62	0	-	0	-	5	0.0	99.7
215	CE della AUSL RM/F of Civitavecchia	0	-	1	42	4	50	0	-	5	0.0	99.7
216	CE dell'A.O. Mellini of Chiari (BS)	2	22	1	28	1	11	1	177	5	0.0	99.7
217	CE dell'Ospedale Israelitico of Rome	3	7	1	26	1	49	0	-	5	0.0	99.7
218	CE dell'ASS 6 Friuli Occidentale of Pordenone	2	15	0	-	2	42	0	-	4	0.0	99.8
219	CE dell'IRCCS Associazione Oasi Maria SS. of Troina (EN)	1	23	2	15	1	18	0	-	4	0.0	99.8
220	CE del Policlinico Militare Celio of Rome	3	29	0	-	0	-	0	-	3	0.0	99.8
221	CE della ASL of the Province of Como	1	14	2	29	0	-	0	-	3	0.0	99.8
222	CE della ASL of Sanluri (VS)	1	40	1	111	1	180	0	-	3	0.0	99.8
223	CE della ASL di Vallecambonica-Sebino of Breno (BS)	1	103	1	71	1	35	0	-	3	0.0	99.8
224	CE dell'ASP - Comprensorio Sanitario of Merano (BZ)	0	-	2	41	0	-	1	58	3	0.0	99.9
225	CE dell'IRCCS Istituto Medea-Associazione La Nostra Famiglia of Bosisio Parini (LC)	0	-	1	114	2	56	0	-	3	0.0	99.9
226	CE dell'IRCCS Ospedale S. Camillo of Venice	0	-	0	-	0	-	3	35	3	0.0	99.9
227	CE dell'Università of Pavia	1	13	2	25	0	-	0	-	3	0.0	99.9
228	CE della ASP of Crotone	2	43	0	-	0	-	0	-	2	0.0	99.9
229	CE dell'Università of Milan *	2	-	0	-	0	-	0	-	2	0.0	99.9
230	CE della ASL 9 of Locri (RC)	0	-	1	-	0	-	0	-	1	0.0	99.9
231	CE della ASL BN/1 of Benevento	0	-	1	38	0	-	0	-	1	0.0	99.9
232	CE della ASL of the Province of Cremona	1	-	0	-	0	-	0	-	1	0.0	99.9
233	CE della ASL of the Province of Lodi	1	34	0	-	0	-	0	-	1	0.0	99.9
234	CE della ASL of the Province of Mantova	0	-	0	-	1	43	0	-	1	0.0	99.9
235	CE della ASL of the Province of Milan 1 di Magenta *	1	-	0	-	0	-	0	-	1	0.0	99.9
												0



	Ethics committee	2007		2008		2009		2010		Total			
		Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	Median time (days)	Acc./ Ref. SO	%	cum. %	Median time (days)
236	CE della ASL of the Province of Pavia	0	-	0	-	1	-	0	-	1	0.0	99.9	-
237	CE della ASL of Lanusei (OG)	0	-	1	-	0	-	0	-	1	0.0	99.9	-
238	CE della ASL of Oristano	0	-	1	85	0	-	0	-	1	0.0	99.9	85
239	CE della ASP of Caltanissetta	1	6	0	-	0	-	0	-	1	0.0	99.9	6
240	CE della ASS 5 of Palmanova (UD) *	1	204	0	-	0	-	0	-	1	0.0	99.9	0
241	CE dell'Istituto Superiore di Sanità (ISS) of Rome	1	15	0	-	0	-	0	-	1	0.0	100.0	15

* Ethics committees no longer operative

Appendix 1

Legislation





List of relative legislation regarding clinical trials of drugs as at 31st December 2010

Ministerial decree 14th July 2009

O.J. n. 213 of 14th September 2009

Minimum requirements for insurance contracts for patients participating in clinical trials of drugs.

AIFA Specification of 23rd December 2008

O.J. n. 3 of 5th January 2009

Self-certification of minimum requirements for the Contract Research Organisations (CRO) for clinical trials of drugs according to article 7, commas 5 & 6 and article 8 of the ministerial decree of 31st March 2008.

Ministerial decree 7th November 2008

O.J. n. 80 of 6th April 2009

Modifications and integrations to the decrees of 19th March 1998, referring to "Recognition of centre's suitability for clinical trials of drugs"; 8th May 2003 regarding "Therapeutic use of drugs undergoing clinical trials", and 12th May 2006 concerning "Minimum requirements for the Ethics committees' structure, organization and functioning for clinical trials of drugs".

Ministerial decree 31st March 2008

O.J. n. 279 of 28th November 2008

Definition of the minimum requirements for CRO involved in clinical trials of drugs.

Errata to AIFA Specification of 20th March 2008

O.J. n. 82 of 7th April 2008

Communication regarding the specification of 20th March 2008 of the Italian Medicines Agency, concerning "Guidelines for the classification and carrying out of observational studies on drugs".

AIFA Specification of 20th March 2008

O.J. n. 76 of 31st March 2008

Guidelines for the classification and carrying out of observational studies on drugs.

Ministerial decree 21st December 2007

O.S. n. 51 to the

O.J. n. 53 of 3rd March 2008

Directions for submitting the request for authorisation of a clinical trial on a medicinal product for human use to the Competent Authority, for communicating substantial amendments, for declaring the end of the trial and for the request of an opinion to the Ethics Committee.

Government decree n. 200 of 6th November 2007

O.S. n. 228/L to the

O.J. n. 261 of 9th November 2007

Transposition of Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

Ministerial decree 12th May 2006

O.J. n. 194 of 22nd August 2006

Minimum requirements to set up, organise and run an Ethics committee for clinical trials of drugs.

Ministerial decree 17th December 2004

O.J. n. 43 of 22nd February 2005

Prescriptions and conditions of a general nature referring to the conduct of clinical trials of medicines with special reference to those designed to enhance clinical practice as an integral part of health and medical care.

**Government decree n. 211 of 24th June 2003**

*O.S. n. 130/L to the
O.J. n. 184 of 9th August 2003*

Transposition of Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical use.

Ministerial decree 8th May 2003

O.J. n. 173 of 28th July 2003

Therapeutic use of drugs undergoing clinical trials.

CIRC. n. 6 of 2nd September 2002

O.J. n. 214 of 12th September 2002

Activities of Ethics committees pursuant to ministerial decree of 18th March 1998.

**Decree of the I.S.S. President
26th April 2002**

O.J. n. 105 of 7th May 2002

Verification of composition and harmlessness of new drugs prior to clinical trials on humans. Identification of documentation to be submitted to ISS pursuant to article 4, comma 2 of the President of the Republic's Decree n. 439 of 21st September 2001.

**Presidential Decree n. 439
of 21st September 2001**

O.J. n. 294 of 19th December 2001

Simplified regulations for verification and control procedures on new systems and protocols for clinical trials.

Ministerial decree 30th May 2001

O.J. n. 216 of 17th September 2001

Inspections on the due following of regulations concerning good manufacturing and good clinical practices.

Ministerial decree 10th May 2001

O.J. n. 139 of 18th June 2001

Controlled clinical trials in general practice and paediatrics.

Ministerial decree 28th December 2000

O.J. n. 4 of 5th January 2001

Measures aimed at minimising the risk of infecting humans, by drugs, with agents that cause bovine spongiform encephalopathy (mad cow).

Decree 25th May 2000

O.J. n. 133 of 9th June 2000

Computerised sending of data concerning clinical trials of drugs.

Ministerial decree 23rd November 1999

O.J. n. 21 of 27th January 2000

Composition and determination of the national Ethics committee's function for clinical trials of drugs, pursuant to legislative decree n. 229 of 19th June 1999.

CIRC. n. 16 of 12th October 1999

O.J. n. 255 of 29th October 1999

Irregularities in the authorisation process and in the conduct of clinical trials of drugs.

Ministerial decree 13th May 1999

O.J. n. 174 of 27th July 1999

Integration to the ministerial decree of 18th March 1998 concerning "Means for exemption of verifications for drugs used in clinical trials" and to the ministerial decree of 19th March 1998 concerning "Recognition of centre's suitability for clinical trials of drugs".

CIRC. n. 6 of 8th April 1999

O.J. n. 90 of 19th April 1999

Clarifications on the ministerial decrees of 18th and 19th March 1998 published in the Official Journal n. 123 of 28th May 1998.

**Ministerial decree 20th January 1999***O.J. n. 31 of 8th February 1999*

Measures regarding marketing and clinical trials of drugs containing materials derived from cows.

Ministerial decree 7th October 1998*O.J. n. 274 of 23rd November 1998*

Integrations to the attachment to ministerial decree of 19th March 1998 concerning "Recognition of centre's suitability for clinical trials on drugs".

Ministerial decree 15th September 1998*O.J. n. 222 of 23rd September 1998*

Integration to the ministerial decree of 18th March 1998 concerning "Means for exemption of verifications on drugs used in clinical trials".

Ministerial decree 19th March 1998*O.J. n. 122 of 28th May 1998*

Recognition of centre's suitability for clinical trials on drugs.

Ministerial decree 18th March 1998*O.J. n. 122 of 28th May 1998*

Means for exemption of verifications on drugs used in clinical trials.

Ministerial decree 22nd December 1997*O.J. n. 33 of 10th February 1998*

Residual tariffs pursuant to ministerial decree of 19th July 1993 concerning the compensation for the Ministry of Health, ISS and Institute for Safety at Work for the services given by these institutes.

Ministerial decree 15th July 1997*O.S. n. 162 to the**O.J. n. 191 of 18th August 1997*

Implementation of EU guidelines for good clinical practice in carrying out clinical trials of drugs (*the attachments thereto substitute the attachments to Ministerial decree of 27th April 1992*).

Presidential Decree 14th January 1997*O.S. n. 37 to the**O.J. n. 42 of 20th February 1997*

Approval of the act of establishment and coordination of the regions and autonomous provinces of Trento and Bolzano regarding structural, technological and organisational minimum requirements for carrying out public health activities in public and private centres.

Ministerial decree 4th December 1990*O.J. n. 297 of 21st December 1990*

Modifications to Ministerial decree 23rd June 1981 concerning the rules of scientific information on drugs.

The entire list of documents concerning legislation in force is available online at the PRC website
(Clinical Research on Drugs Portal in Italy)
<http://ricerca-clinica.agenziafarmaco.it/it/node/3>

Appendix 2

Glossary





Glossary

Active substance or active ingredient

The pharmacologically active component in a drug, responsible for the desired effect of the drug itself.

Adverse event

Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

Adverse reaction

Any damaging or undesired reaction to a drug during the clinical trial, regardless of the dose administered.

AIFA calls for independent research

These are aimed at public or no profit health structures. Research is financed by AIFA using a part of the 5% fund of promotional costs borne by pharmaceutical companies, as foreseen by the AIFA by-laws (L. 326/2003).

The areas of research in the calls are as follows:

- studies on orphan drugs and rare diseases (not foreseen in the 2008 and 2009 calls);
- comparisons between therapeutic strategies for high impact problems relating to public health and the public health system;
- studies on the safety of drugs, and evaluations of training and information to improve the impact of appropriate use.

ATC

Anatomic, Therapeutic, Chemical Classification
Alpha-numerical classification system according to the World Health Organisation (WHO) standard. This system divides drugs into 14 groups main "Anatomical" (1st level) with two sub-groups "Therapeutic" (2nd and 3rd levels).

The ATC classification includes two further sub-groups "Chemical/therapeutic" and "Chemical" for a total of five hierarchical levels following this scheme:

1st Level – Main Anatomical Group (distinguished by the letters: A, B, C, D, G, H, J, L, M, N, P, R, S, or V)

2nd Level – Main Therapeutic Group (distinguished by a double-digit number)

3rd Level – Sub-group Pharmacological Therapeutic (distinguished by a letter of the alphabet)

4th Level - Sub-group Chemical Pharmacological Therapeutic (distinguished by a letter of the alphabet)

5th Level - Sub-group Chemical (distinguished by a double-digit number, specific to each chemical substance).

Example of diazepam's classification (ATC = N05BA01):

N	Nervous system
_ 05	Psycholeptics
_ B	Anxiolytics
_ A	Benzodiazepine derivatives
_ 01	Diazepam

Biotechnological active ingredient

An active ingredient responsible for the drug's expected effect produced by biotechnology.

Biotechnology

The use of biological organisms, systems or processes for producing medicines.

Chemical active ingredient

A chemical active ingredient in a drug.

Clinical trial (or clinical study)

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, me-



tabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. This definition includes clinical trials conducted at a single centre (mono-centre) or a number of centres (multi-centre), only in Italy or also in other member states of the European Union.

Clinical trial of bioequivalence and bioavailability

This is a study to evaluate the percentage of drug administered that reaches the systemic circulation (bioavailability) and the equivalence of other formulations (bioequivalence).

Clinical trial protocol

The document that describes the rationale, objectives, methods and procedures for the correct conduct of a clinical trial.

Comparator medicinal product

A drug that can be commercialised or a placebo, used as a comparator in a clinical trial with a controlled design.

Competent Authority

The director general or legal representative of public health structures or similar where clinical trials are carried out (legislative decree n. 211 of 2003); the general manager of the local health unit in the private structure with authorisation to perform clinical trials pursuant to ongoing legislation.

The Italian Medicines Agency is the competent authority for authorisations regarding clinical trials on products for somatic cell therapy, gene therapy and drugs containing genetically modified organisms. The ISS is the competent authority for new drugs, pursuant to the President of the Republic's Decree n. 439 of 21st September 2001, and all Phase I clinical trials.

Controlled clinical trial

A controlled clinical trial is one where the drug is tested with a control group. The control group can

be administered with a placebo, a product whose efficacy is known, a surgical procedure or a different dosage of the same drug.

Coordinating centre of the clinical trial

Centre identified by the Sponsor where the Italian coordinator for the clinical trial carries out his/her work.

CRO

Contract Research Organization

A company, institution or organisation (commercial, academic or other) with whom the Sponsor has stipulated a contract to entrust a part or its entire responsibilities regarding the clinical trial (drafting of protocol, selection of centres and investigators, choice and use of a monitor, elaboration of reports, statistical analysis, preparation of documentation to submit to the supervisory authority, etc.) as foreseen by the Good Clinical Practices, notwithstanding the responsibilities of the Sponsor relating to the clinical trial itself.

Cross over

Comparison between two or more treatments in which the participants in the clinical trial, following a certain period of time established by the protocol, switch from one treatment to an alternative one.

CTA

Clinical Trial Application

Application for authorisation to perform a clinical trial (Ministerial Decree 21st December 2007).

CTA form

Form to apply for the authorisation to perform a clinical trial or for the opinion of the Ethics committee.

Dose-response

The dose-response relationship shows the variations of the effect of the drug, following a period of administration. This relation is applicable to individuals and populations.

**Double blind**

Clinical trial in which both the investigator and the subject involved in the study (healthy volunteer or patient) are not aware of the treatment received.

Efficacy

Measurement that indicates whether the drug has given the desired result.

EMA

European Medicines Agency

E-submission

Computerised procedure for sending with a digital signature the documentation regarding the application (CTA), authorisation of the competent authority and opinion of the Ethics committee for monitoring the clinical trial.

Ethics committee

An independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent. The EC can be set up in one or more public health structure or similar, in a private IRCCS or in the office of the regional administration for these matters. The Ethics committee is also responsible for:

- carrying out the revision and expressing a favourable/unfavourable opinion regarding the clinical trial's protocol;
- evaluating proposed substantial amendments and giving its favourable/unfavourable opinion;
- verifying the suitability of the investigator(s), the centres, methods and materials used to obtain and document the informed consent of the clinical trial's participants.
- periodically evaluate approved clinical trials.

EU

European Union.

EudraCT

European Union Drug Regulatory Authorities Clinical Trials database

A database set up on 1st May 2004 at EMA pursuant to the Directive 2001/20/EC, which collects all the data for every clinical trial on drugs involving at least one clinical centre in the European Union.

This is a confidential registry and it is accessible to the competent authorities of member States, and EMA European Commission.

EudraCT code

Unique identification number of every clinical trial in the European database EudraCT, assigned free of charge, and to be requested via computer through the site <https://eudract.ema.europa.eu>.

Extractive medicinal product

A medical product obtained by extraction. This can include biological/biotechnological products, human blood or plasma derivatives, extracts from animals, bacterial extracts and toxins or other extracted vegetable or similar active ingredients.

GCP

Good Clinical Practice

An international standard of ethics and scientific quality to plan, carry out, register, and report clinical studies on humans.

Adhering to these GCP standards publicly guarantees not only the rights, safety and wellbeing of the enrolled subjects in line with the principles established in the Declaration of Helsinki, but it also guarantees the reliability of the data concerning the clinical trial.

Gene therapy medicinal product

A product for transferring a gene to a human for



its expression in vivo for protective purposes, diagnostic or therapeutic.

GMO

A Genetically Modified Organism (GMO) or a Genetically Engineered Organism (GEO) is an organism whose genes have been modified using genetic engineering.

Healthy volunteer

A subject in good health enrolled in a clinical trial.

Herbal medicinal product

A medicinal product using a vegetable or preparation of a vegetable active ingredient.

Homeopathic medicinal product

A drug obtained from homeopathic substances or preparations or similar, in accordance with the production process outlined in the European Pharmacopoeia or, in its absence, official Pharmacopoeia used in EU member States; a homeopathic drug may contain more than one substance.

Immunological medicinal product

Drug used to produce an immunological response (vaccines, toxins, sera or allergens).

IMP

Investigational Medicinal Product

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

Informed consent

Decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after be-

ing duly informed of its nature, significance, implications and risks and appropriately documented by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative or by an authority, individual or organisation in accordance with the relevant legislation. If the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in current legislation.

Interventional clinical trial

Clinical trial where a subject is previously assigned to a specific therapeutic strategy based on the clinical protocol.

Investigator

A doctor or dentist qualified for investigations, who is responsible for the conduct of the clinical trial at a given centre. If a trial is conducted by a team of individuals at a trial centre, the investigator is the leader responsible for the team and may be called the "principal investigator".

ISS

Istituto Superiore di Sanità

The main technical-scientific body of the National Health System. This is a public body uniting the functions of research and consultancy, training and control to protect public health.

No profit sponsor

Structure, body or public institution or similar or foundation or moral institution or no profit research and/or health institute or public or private Scientific Institutes for Research and Care (IRCCS) or employee of the aforesaid structures who carries out the role of Sponsor within his/her institutional duties.

Non-interventional clinical trial or observational study

A study where the medicinal product(s) is (are) prescribed in accordance with the terms of the



marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study.

No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Objective of the trial

Definition per category of the clinical trial objective (efficacy, safety, pharmacokinetics, pharmacogenetics, etc.).

Open clinical trial

A clinical trial where both the investigators and the enrolled subjects are aware of the treatment administered.

Orphan drug

Potentially useful product for treating a rare disease whose profits would not justify research and development costs. EMA establishes which drugs are orphan drugs.

OsSC

Osservatorio nazionale sulla Sperimentazione Clinica dei medicinali.

National Monitoring Centre on Clinical Trials of Drugs.

Database that collects information concerning clinical trials held in Italy since 2000.

Parallel groups

A clinical trial where two or more treatments are evaluated simultaneously in distinct groups of patients.

Pharmacodynamics

Studies the effects a drug has on a living body.

Pharmaco-economics

Studies the costs and the effects the use of a particular drug would have on the national health service comparing one therapy to other available ones.

Pharmacogenetics

Studies the genetic factors that produce different responses to the same drug.

Pharmacogenomics

Studies the genetic variations that affect the responses to a drug.

Pharmacokinetics

Studies what a living body does to a drug.

Phase I clinical trial

The first moment of clinical development of a new active ingredient that includes the first administration of this product in humans.

Phase I trials involve a small number of subjects (up to 30 persons) frequently healthy volunteers but also patients.

They usually do not have a therapeutic objective given that they are preliminary studies on the safety and tolerability of an experimental drug. Phase I also includes pharmacokinetics studies and may also include pharmacodynamics.

Phase I - First in human clinical trial

Administration of the drug for the first time in humans during a phase I clinical trial.

Phase II clinical trial

A pilot therapeutic study whose objective is to demonstrate the activity and evaluate the short-term safety of an active ingredient in patients suffering from a disease or with a clinical condition that the active ingredient was developed for.

The study is carried out on a limited number of patients (between 100 and 300) and it is often in an advanced stage with a comparative control group



(e.g. control with placebo). This phase also has the objective of determining an appropriate level of dosage and/or therapeutic schemes and (if possible) the dose/response relationship in order to plan more extensive therapeutic studies.

Phase III clinical trial

This is a study on a larger group of patients (usually several hundred and sometimes several thousand) – and possibly diversified – to compare the effects of the new treatment against a placebo or a standard treatment used in clinical practice.

The trend and characteristics of the most frequent adverse reactions need to be investigated and the experimental medicines characteristics need to be examined (clinically revealed interaction with other drugs, responses to particular factors such as age, etc.).

Phase III clinical trials are usually randomised and double blind, and are carried out in numerous centres and in different countries simultaneously.

Phase IV clinical trial

A study on a commercialised drug (post-marketing) to evaluate its therapeutic value and/or damaging effects (pharmacovigilance), in a normal prescription context.

PI

Principal Investigator.

Placebo

A control substance that does not contain an active ingredient, known to have no effects (fake treatment). This is administered to persons taking part in some clinical trials.

Plasma derived medicinal product

Drug produced from blood or plasma.

Private centre

Private health structure recognised for health assistance and/or suitable for running clinical trials,

by the local health unit for one or more specialist branches of health assistance.

Profit sponsor

Industry or pharmaceutical company or profit private company (excluding private IRCCS).

Protocol code

Unique identification number of a protocol assigned by the Sponsor.

Radiopharmaceutical medicinal product

A radioactive drug made of radionuclides for diagnostic or therapeutic purposes.

Randomised

A clinical trial where subjects are randomly assigned to one of the treatment group.

Rare disease

A disease that affects a very limited number of patients. The European limit is a disease that affect 5 persons every 10,000 (European definition based on the indications of "European Community Programme of Action for Rare Diseases 1999-2003").

RSO

Registro Studi Osservazionali.

Registry of all observational studies on drugs carried out in Italy, set up according to specific guidelines set out by AIFA with its specification on 20th March 2008

(<http://osservazionali.agenziafarmaco.it/>).

Safety

Tolerance profile of a drug, defined by its adverse effects.

Satellite or collaborating centre

Centre that participates in a multi-centre clinical trial where the coordinator does not operate.



Single blind

Clinical trial where subjects (healthy volunteers or patients) in the trial do not know which treatment they are taking, while investigators are aware of this.

Single Opinion

The opinion on a multi-centre clinical trial expressed by the Ethics committee of the Italian structure where the clinical trial's coordinator performs the trial.

Somatic cell therapy medicinal product

Use of live somatic cells from the patient him/herself, foreign (from another human being) or xenogenic (from animals), whose biological characteristics have been substantially modified as a result of their manipulation to obtain a therapeutic, diagnostic or protective effect.

Source of financing or material support to the clinical trial

Any (public or private) organisation or pharmaceutical company that provides economic financing or material support for the carrying out of the clinical trial.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

Sponsor's legal representative

Person, company, institution or organisation authorised to act on behalf of the Sponsor in a clinical trial. This body must be registered in the EU or EC (article 20, legislative decree n. 291 of 2006).

Structure

Synonym of health centre.

Subject

An individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control. The subject may be a healthy volunteer or a patient.

Subject incapable of giving their consent

A subject to be enrolled in a clinical trial who is incapable of personally giving his/her consent (e.g. minors or subjects with mental illnesses).

Substantial amendment to the protocol

An amendment that affects the safety of the subjects in the clinical trial or modifies the interpretation of the scientific support documentation for the clinical trial, or an amendment that significantly modify the way the clinical trial is carried out.

Appendice 3

Training





Workshops and Training Courses for clinical trials on drugs organised by the Italian Medicines Agency

2010

16-17th March, Rome

“Meeting on the carrying out of no profit studies financed by AIFA”.

2009

6-8th July, Rome

“Course on Clinical Trials”.
In collaboration with Ga²len – EAACI Summer School.

22, 23, 29 and 30th April, Rome

“National Monitoring Centre on clinical trials of drugs (OsSC) – Powers and functions for Ethics Committees”

12, 13, 19, 20, 26 and 27th February, Bologna

“National Monitoring Centre on clinical trials of drugs (OsSC) – Powers and functions for Ethics Committees”

2008

3rd June, Rome

“CTA - Clinical Trial Application – Ministerial Decree 21st December 2007”.
For Ethics Committees Pharmacologists.

13-16th May, Rome

“CTA - Clinical Trial Application – Ministerial Decree 21st December 2007”.
For no profit Sponsors, pharmaceutical company Sponsors and Clinical Research Organisations (CRO).

17-20th March, Rome

“CTA - Clinical Trial Application – Ministerial Decree 21st December 2007”.
For Ethics Committees.

2007

16-18th April, Rome

“Course for promoting GCP and to improve the quality of clinical trials not for commercial purposes”.

22-24th January, Rome

“Course for promoting GCP and to improve the quality of clinical trials not for commercial purposes”.

2006

4-6th December, Rome

“Course for promoting GCP and to improve the quality of clinical trials not for commercial purposes”.

20-22nd November, Rome

“Course for promoting GCP and to improve the quality of clinical trials not for commercial purposes”.

8th February, Rome

National Conference - “Clinical Research and Innovation in the pharmaceutical sector”.
Inside SANIT – Convention of Health Services .

2004

9th July, Rome

“Ethics Committees and observational research: theory and practice”.
In collaboration with Italian Company of Medical Statistics and Clinical Epidemiology.

2003

28th November, Rome

“Innovation - Research - Pharmacovigilance: three challenges for the European Union”.



8-9th October, Rome

"The new version of the National Monitoring Centre on clinical trials of drugs".

10th June, Rome

"The new version of the National Monitoring Centre on clinical trials of drugs".

8th April, Rome

"Insurance and contractual aspects in clinical trials".

18th March, Rome

"Biostatistical competences in local Ethics Committees".

In collaboration with the ISS and Italian Company of Medical Statistics and Clinical Epidemiology.

2002

7-9th May, Rome

"Role and function of Ethics Committees for clinical trials of drugs".

11-12th March, Rome

"Role and function of Local Health Units, GPs and Paediatricians in Clinical Trials".

2001

28th June, Rome

"National Monitoring Centre on Clinical Trials - 2nd round table on OsSC transparency".

14-15th June, Rome

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

30th May, Genoa

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

21st May, Rome

"National Monitoring Centre on Clinical Trials - 1st round table on OsSC transparency".

11th April, Cagliari

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

10th April, Acireale

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

2nd March, Rome

"Ethics, drugs and medicine - National Conference of Ethics Committees".

In collaboration with the National Committee for Bioethics.

19-23rd February - 28th February, Rome

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

2000

18th December, Bari

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

5th December, Naples

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

4th December, Rome

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.

29-30th November, Bologna

"National Monitoring Centre on Clinical Trials".
In collaboration with Cineca.



22-24th November, Bologna

“National Monitoring Centre on Clinical Trials”.
In collaboration with Cineca.

20th October, Rome

“2nd Italian Workshop on GCP Inspections in EU Member States”.

17-19th October, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

3-5th July, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

15th June, Rome

“1st Italian Workshop on GCP Inspections in EU Member States”.

12-14th June, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

3-5th May, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

12-14th April, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

1999

12-14th July, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

30 June - 2nd July, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

14-16th June, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

17-19th May, Rome

“Role and function of Ethics Committees for clinical trials of drugs”.

For a list of new programmed meetings and documentation relating to Workshops and Training Courses previously held, please visit the OsSC website
<http://oss-sper-clin.agenziafarmaco.it/formazione.htm>

Printed in October 2011
Print: Tecnocarta80 srl
Typesetting: Palombi & Lanci srl
Graphic Design: Paola Valentini, **COHIBA**design