GUIDANCE ON EVALUATING UNDER ART. 7 OF REGULATION (EU) No 536/2014, BY THE TERRITORIAL ETHICS COMMITTEES

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1. INTRODUCTION

Each Territorial Ethics Committee ("**TEC**") responsible for evaluating Part II of the application for authorisation for a clinical trial according to the Clinical Trials Regulation (EU) No. 536/2014 (**"Regulation")** must evaluate compliance:

a) The informed consent requirements are laid down in Chapter V.
b) The requirements in Chapter V concern subject protection and informed consent.
c) Article 49 ("*Suitability of individuals involved in the clinical trial*").
d) To the General Data Protection Regulation (**"GDPR**")- General Data Protection Regulation (EU) 2016/679 which repealed Directive 95/46/EC (Art. 94 EU/2016/679);
e) Article 50 ("*Suitability of clinical trial sites"*);
f) Article 76 (Compensation for damages);
g) The applicable rules on collecting, storing, and future using the subject's biological samples.

The meetings with TECs revealed a potential criticality resulting from the need for more homogeneity in the assessment by TECs of the documents in the application dossier. In this regard, it is considered appropriate to recall that TECs have the task and responsibility to examine the whole dossier (protocol and annexes to it, trial contract, informed consent and privacy policy) to make the opinion of the TEC complete and effectively valid throughout the country. The blocking of many studies at the Centers level, downstream of the opinion and the authorisation through CTIS, is one of the factors of competitive disadvantage for Italy compared to other EU countries as the leading testing site.

The following documents have been developed and approved by the National Coordination Centre of the Territorial Ethics Committees for clinical trials on medicinal products for human use and medical devices (**"Coordination Centre")** from models developed at the European level (**"EU Models"):**

a) Curriculum Vitae ("CV") of the Principal Investigator.
b) Declaration of Interests ("**DoI")** by the principal investigator.
c) Site and facilities suitability for each trial.
d) Patient participation and informed consent.
e) Allowances and reimbursements for trial participants.

This "*Guide to Support the Evaluation by the Territorial Ethical Committees n. 536/2014" ("***Guide"**) replaces the

- *"Guide to the evaluation of the Territorial Ethical Committees, of the documents referred to in Art. 7 paragraph 1 of Regulation (EU) n. 536/2014";*
- circulars, from No. 1 to No. 7, adopted in the mandate of the CCNCE appointed by the DM on 25 May 2021

and has the purpose

a) to support the preparation of the documentation relating to Part II of the applications under the Regulation and to facilitate their assessment by the TECs,
b) to regulate the relevant aspects of national legislation that are not governed by the Regulation or by the *Questions and Answers Document - Regulation (EU) 536/2014 (***"Q&A") in the** current version;
c) to collect the most frequent questions from May 2021- May 2024 in a single document.

2. COMPULSORY USE OF THE MODULES PREPARED BY THE COORDINATION CENTRE

The Coordination Centre was established by Law 11 January 2018 No. 3 ("**Law ")** which attributes to the same "functions of coordination, guidance and monitoring of the ethical aspects of clinical trials on medicinal products for human use entrusted to the territorial ethics committees" (Art. 2, paragraph 1).

According to the Law, among the tasks assigned to the Coordination Centre, there is also the task of providing general directives for procedural uniformity on the part of ethical committees (Art. 2, paragraph 3). The Coordination Centre intended, in the elaboration of the forms, to remain as close as possible to the EU Models, and the personalisation of the forms by the TEC would nullify this intention. The modules must also be prepared in the institutional's headed paper.

In detail, the following Models must be used:

1. **EU Models**, in the latest version available (https///health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume10_en), should be used for the following modules:

   a) Curriculum Vitae ("CV"**)** of the Principal Investigator.
   b) Suitability of site and facilities for individual testing.

2. Coordination Centre templates, in the latest version available *(https:/// www.aifa.gov.it/centro-comitatus-ethical coordination),* subject to paragraph 4, shall be used for the following modules:

a) Declaration of Interests ("**DoI").**
b) Patient participation and informed consent.
c) Allowances and reimbursements for trial participants.

EU and CCNCE models are regularly updated. However, suppose evaluations have been undertaken using previous versions of the forms, which were finalised before the publication of the new versions. In that case, TECs shall not again request the preparation of the Models.

3. USE OF THE PORTALS

Art. 6 paragraph 3 of the DM 30 January 2023 obligates **TECs to download from CTIS/OsSC** the documentation necessary for their assessments and subsequent opinions. The TEC can, therefore, not require sponsors to upload documentation to other portals.

On the other hand, uploading to the Centre's portal to negotiate contracts, budgets, etc., is a matter noted in the relations between the Promoter and the Centre itself that, unlike the TEC, has no access to CTIS or OsSC. The use of platforms or portals is how each Centre, instead of transmitting via pec or email, within its own technical and administrative organisation, acquires from its contractual counterparts (sponsor and CRO, who have it) the necessary information for the negotiation and conclusion of the experimental contracts, the development of the relative budget and the elaboration of every other site-specific act that allows the start of the experimentation or study.

4. SIGNATURE OF DOCUMENTS

When referring to the following paragraphs, please find a summary of the procedures to be adopted for the documents covered by this Guide:

i. **Documents signed by the Sponsor:** all documents signed by the Sponsor do not require a signature, as they are automatically replaced by the electronic submission of the trial in CTIS (see protocol, synopsis, etc.).
ii. **Principal investigator's curriculum vitae**: see paragraph 6.
iii. **Declaration of interest:** see paragraph 7.
iv. **Site suitability:** please refer to paragraph 8.

5. ACCELERATED ASSESSMENTS AGREED AT THE EUROPEAN LEVEL FOR PUBLIC HEALTH EMERGENCIES (EU REGULATION 2022/123, ART. 15.2.B)

Only in accelerated assessments agreed at the European level for public health emergencies (EU Regulation 2022/123, Art. 15.2.b), can the following be done:

- The EU Models can also be used for DoI, informed consent and Indemnities and expenses for participants in the trial;
- documentation may be provided in English;
- **before the start of the trial,** the following additional documentation shall be acquired by the TECs:

  i. Informed consent is also in the Italian version.
  ii. The conflict-of-interest model of the principal investigator in the format approved by the Coordination Centre. This model is in addition to the one prepared according to the EU Models. This model is necessary to complete the assessments referred to in Art. 6 of D. Lgs. 52/2019 and subsequent modifications and integrations.

6. CURRICULUM VITAE ("CV") PRINCIPAL EXPERIMENTER (AND OTHER EXPERIMENTERS)

The suitability of all principal investigators shall be verified as part of the evaluation of Part II, as defined in Articles 7 and 49 and Annex I, Section M, Paragraphs 64 and 65 of the Regulation. Therefore, the qualifications of the principal investigators should be described in a curriculum vitae prepared in the format annexed to paragraph two.

In CTIS, only the curriculum of the principal investigator should be uploaded.

The CV must show:

i. Any work experience relevant to the study being evaluated. Particular attention should be paid to rare disease trials for which the investigator should include specific clinical expertise in the rare disease being tested in the CV.
ii. Any training experience relevant to the study being evaluated. The investigator shall include compulsory training. Particular attention should be paid to trials relating to rare diseases for which the investigator should take care to include in the CV the specific training experience in the rare disease being tested.

The Curriculum must be updated to the latest relevant information available. The inclusion in CTIS of the Curriculum by the Sponsor is equivalent to an implicit attestation of conformity of the document inserted to the original that the Sponsor has received from the principal investigator.

The CV template includes fields with all the information required in Annex I, Section M, Paragraph 65 of the Regulation. The principal investigators shall prepare the model for the applicable parts and be part of the application file. Each principal investigator shall indicate all relevant experiences irrespective of their role.

The CV shall assess **the suitability of the principal investigator for each test** site[1].

It is recalled that other persons involved in the conduct of the clinical trial, including other investigators, must also have the appropriate competencies to carry out their task (EU Regulation No 536/2014, Article 49 and, Annex I, Section N, Paragraph 67); this aspect is indicated in the declaration of suitability of the site, to the *point where it is asked to* "specify the human resources available at the site and their skills concerning the study proposed". Therefore, all participating investigators, principals and non-core, must draw up and keep their curriculum vitae up to date, under the same format attached hereto, so that their qualifications can continuously be assessed at the beginning or during the trial. The updating of the CV by all investigators is necessary to allow the Principal Investigator to keep up to date the list of qualified persons to whom to delegate significant tasks related to the study (DM 15 July 1997, Annex 1, p.to 1.34 and 4.1.5).

7. DECLARATION OF INTERESTS OF THE PRINCIPAL INVESTIGATOR (AND OTHER INVESTIGATORS)

The TEC must assess the suitability of the principal investigator and verify whether conditions exist, such as economic interests, spousal relationships, cohabitation or kinship and institutional affiliations, that could affect its impartiality according to the Regulation and the legislation in force in Italy.

The principal investigator's DoI model shall be included in the application file, submitted for evaluation to the TEC, and uploaded to CTIS. The DoI model developed by the CCNCE contains fields that include all the information required in Annex I, Section M, Paragraph 66 of the Regulation and D. Lgs. 52/2019 and subsequent modifications and integrations, art. 6.

The inclusion in CTIS of the DoI is equivalent to an implicit attestation of conformity of the document inserted to the original that the Sponsor has received from the principal investigator. The DoI of the principal investigator must be updated through CTIS, also moments after the beginning of the study,

[1] Principal investigator' means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site.

if new conflicts of interest occur (D. Lgs. 52/2019 and subsequent modifications and integrations, art. 6). See Q&A for the type of amendment.

Regarding the modalities of compilation of Table 1. A " **Role/charge held at the/I Promoter/s of the** trial and in general with the pharmaceutical industry about a particular product/product group" the following is specified: the PI must indicate the relationship/activity with the Promoter of the study for which it compiles the declaration or with the Promoters of studies that test products like the one being tested.

By way of example:

i. Suppose the IP does not play any role/position with the Promoter of the trial for which it makes the declaration and is PI of studies testing products like the one being tested. In that case, the relevant activity will be indicated in Table 1. A.
ii. If the IP does not play any role/position with the Promoter of the trial for which it compiles the declaration and is PI of studies testing products NOT like the one being tested, no relevant activity carried out will be indicated in Table 1. A.

It is necessary to ensure the independence and transparency of the trials to ensure that, for each experimental site, the investigators do not have financial or personal interests that could affect their impartiality[2]. As head of the test group, the Principal Investigator shall keep an up-to-date list of suitably qualified persons to whom he has delegated significant tasks relating to the study (DM 15 July 1997, Annex 1, no 1.34 and 4.1.5).

As head of the experimental team, the Principal Investigator is responsible for preparing and updating the list of qualified persons to whom he has delegated significant tasks relating to the study (DM 15 July 1997, Annex 1, p.to 1.34 and 4.1.5). Therefore, the Principal Experimenter should collect the DoI of each experimenter and verify that i) the DoI of all investigators is always up to date, ii) there are no conflicts of interest in place, and where present, must provide as required by law.

[2] "Art.6 no 4 del D.lgs. 14/05/2019, n. 52 "Without prejudice to any other relevant legal provisions, the investigator shall, to ensure the independence and impartiality of the clinical trial, declare his financial interests in advance to the clinical trial facility, the spouse or the partner or the relative within the second grade of the proposed study, as well as dependency, advice or collaboration relationships, for any reason, with the sponsor, at any stage of the study to be formed. The Ethics Committee shall assess this statement and the absence of any shareholding in the capital of the pharmaceutical company holding the drug under study, the investigator, the spouse, or the partner, to safeguard the independence and impartiality of the clinical trial, including at times after the start of the study if new conflicts of interest arise".".

8. SUITABILITY OF THE SITE AND FACILITIES FOR THE INDIVIDUAL TRIAL

The Regulation, art. 50, Annex I, Section N, Paragraph 67, provides that "*SUITABILITY OF THE FACILITIES (INFORMATION PER MEMBER STATE CONCERNED) 67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted."* The D.Lgs. 14/05/2019, n. 52 and subsequent modifications, integrations and implementing acts define the authorisation procedures for the conduct of clinical trials. By current legislation, each experimental site must be authorised and suitable for each trial (c.d. site-specific suitability).

The site-specific suitability of facilities shall be considered in the context of the assessment of Part II, as defined in Article 7 of the Regulation. Concerning the personnel assessment, it is recalled that the template should be completed in such a way as to show that all personnel involved in conducting a clinical trial are qualified in terms of education, training and experience to carry out its tasks concerning the specific trial subject to approval.

The site-specific fitness template includes fields with all the information required in Annex I, Section N, Paragraph 67 of the Rules. Where the required information for this template is provided elsewhere in the application dossier, it is sufficient to refer to the document rather than repeat it.

The model must be signed by the Legal Representative of the experimental site or by a delegate of the experimental site with the necessary powers. Any delegation to the signature must be made in writing with a date before the template's signature and must not be uploaded to CTIS. The template must be digitally signed with a PADES signature or equivalent and entered CTIS.

Concerning the method of filling in the form, the following is specified:

i. On the first page of the form, there is the field "identification number of the centre": this field is not mandatory for Italy.
ii. If updates are made to points directly indicated in the module/ indirectly recalled by the same on an amendment to the protocol, which determines changes in the assessment of the site's suitability, the latter must be updated.

9. PATIENT PARTICIPATION AND INFORMED CONSENT

The adequacy of how subjects participate in the study and how to obtain informed consent should be considered i) in the evaluation of Part II, as provided for in Article 7 of the Regulation and ii) according to current legislation and according to the indications of the Coordination Centre "Guidelines for the collection of informed consent to participation in clinical trials" available at the following link: https://www.aifa.gov.it/centro-coordinamento-comitati-etici). Using the Informed Consent forms published by the CCNCE is not mandatory, and the Guidelines call for compliance with the fundamental requirements of informed consent. Informed consent can be signed digitally in compliance with current legislation.

Based on questions received, the following points are made:

- **Competitive Inclusion:** Experimenters must inform the patient of the three competitive types of inclusion and the consequences that it determines. Therefore, the information and informed consent given to the patient in multicenter competitive inclusion trials should clearly state that the patient is agreeing to be included in a competitive trial and therefore may not be included, even if you have already given your consent, if the maximum number of patients that can be included has been reached.
- **Reimbursement of expenses and compensatory allowances:** The informed consent of all trials must contain, clearly and understandably, all information relating to any reimbursement of costs and compensatory allowances provided for participation in the study.
- **Therapeutic Continuity:** The Informed Consent shall specify the information related to the therapeutic continuity referred to in paragraph 12 of this Guide.

10. REIMBURSEMENT OF EXPENSES AND ALLOWANCES FOR TRIAL PARTICIPANTS

Decree 21/12/2007 ("How to submit the request for authorisation to the competent authority, for the communication of substantial amendments and the declaration of conclusion of the clinical trial and the request for an opinion to the ethics committee") is still in force. However, the provisions of point 6.1.2.8 of the D.M, 21 December 2007 cannot be considered applicable under the Regulation, according to which (i) "any compensation for loss of earnings is only possible for healthy volunteers participating in the trial", (ii) any reimbursement of expenses must be limited to those "costs incurred by patients to go to the testing centre, ... only if the clinical trial is carried out in highly specialised centres (present only in some Regions), ... determining the need for long journeys by patients", and the same for more (iii) are considered foreseeable only in cases where this "involves particular or rare diseases".

However, the general principle remains that "the possibility of financial cover for "living" expenses incurred and documented by the patients involved in the study can be considered". This implies that the "Initial Application Dossier" (Annex 1 to the Regulation) should specifically include "information on financial transactions and allowances paid to subjects and the investigator/site for participation in the clinical trial" (paragraph P. point 70).

According to the Regulation, therefore, can be recognised:

i. **The Compensatory Allowance**, the compensation for loss of earnings and the reimbursement of expenses incurred for participation in the study (e.g. costs for accommodation, food, transport, etc.), can be recognised to the subjects included in the categories referred to in art. 31-34 of the Regulation. The Compensatory Allowance (i.e. reimbursement of expenses and loss of earnings) can also be recognised for accompanying patients who cannot travel alone. It is understood that the contract between the Promoter and the Experimental Centre ("Centre"), in addition to regulating the possibility of recognition of the Compensatory Allowance, must lay down both the criteria for access and the procedures for granting and documenting expenditure incurred.

ii. **The Expenses Refund**, which unlike the Compensatory Allowance does not include the possibility of reimbursing the loss of earnings resulting from participation in the study, may also be recognised under the conditions laid down in the Protocol and the Contract to categories other than incapacitated persons, minors, and pregnant women. Reimbursement of expenses may also be granted for accompanying patients who cannot travel alone. It is understood that the contract between the Promoter and the Centre, in addition to regulating the possibility of recognition of the reimbursement of expenses, must provide both the access criteria and the modalities of payment.

The material provision of expense reimbursements and Compensatory Allowances may be carried out, instead of by staff employed by each experimental Centre, by specialised organisations ("Service Provider") entrusted with carrying out this activity by the stipulation, written form of specific contracts. It must, however, be ensured that the provision of services by the Service Provider does not in any way prejudice the fundamental principle prohibiting direct economic relations between patients and sponsors and investigators and, in general, the independence and autonomy of patients and experimenters. The following shall constitute a minimum guarantee for this purpose:

1) adequate verification by the Centre, before the conclusion of the contract, aimed at obtaining information on the activity and experience of the Service Provider - in particular, if proposed by the promoter, and on its independence;

2) the conclusion, in writing, of a contract between the Centre and the Service Provider, including:

i. The payment of the Service Provider by the Centre, as consideration for the performance of specific services related to the management of refunds, with provisions to be provided by the promoter.
ii. The declaration of the Service Provider, under its responsibility, not to receive any other consideration by the promoter or third parties for the same reason.
iii. The contractual obligation, assumed directly by the Service Provider in respect of the Centre (with explicit and exclusive assumption of any liability in this regard), not to communicate, transmit or disclose in any way the personal data or other identifying elements of the patients and others entitled to the Reimbursement of expenses or compensation to the promoter profit (cf. art. 1, paragraph 1, letter r, D. lgs. 200/2007) of the trial.
iv. The appointment of the Service Provider as data controller by the Centre is so that it has direct responsibility in the case of a data breach.

Finally, it should be noted that

a) The provision of compensatory allowances (subject to Articles 31 to 34 of the Regulation):

- must cover only loss of earnings and expenses, which can be effectively documented by patients and any accompanying persons when going to the testing Centre;
- must not be related to costs already borne by the National Health Service, or the patient would have had to pay for treating his pathology;
- shall not be used, directly or indirectly, to compensate for or unduly affect the violation of the rights and security of the participants.

b) Payment of expenses:

- must be limited to actual costs incurred by the patients and any accompanying persons who travel to the testing Centre;
- must not be related to costs already borne by the National Health Service or that the patient would have had to pay for the treatment of his pathology;
- may not be used, directly or indirectly, to compensate for violating the rights and security of the participants and to affect them unduly.

11. CLINICAL TRIALS REGULATION (EU) 536/2014 AND GENERAL DATA PROTECTION REGULATION (EU) 2016/679

Regulation 536/2014 provides a single assessment of the application and an opinion by the competent TEC, with value for the entire national territory. The evaluation of the TEC is the parameter of the adequacy and adherence of the protocol, all its constituent elements, and privacy legislation. As stated in the CTIS portal (Section 'Forms and MSC'), the application must be accompanied, in Part I, a "Statement of compliance with Regulation (EU) 2016/679 (GDPR)" and, in Part II, a verification of the "Compliance with national requirements on data protection". Following the opinion of the TEC and the authorisation of the trial by the Competent Authority, the Centre and promoter are the parties to the contract (site-specific) of the trial and is their autonomous faculty (and liability) accept or not as assessed and authorised.

12. CONTRACTS FOR CLINICAL TRIALS ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

The Coordination Centre has adopted the following draft Contract- type:

1. Contract for the conduct of clinical trials on medicinal products.
2. Contract for the conduct of the independent clinical trial on medicinal products.
3. Contract for the conduct of clinical investigation on EC unmarked medical device.
4. The contract is for conducting a clinical investigation on a CE-marked medical device used outside its intended use.

These draft Contract- types, under and for Art. 2 of the Law, constitute minimum content that must be respected with the possibility of supplementing it where such additions do not conflict with the minimum content.

Adopting the draft Contract types must not lead to stiffening of the TEC/Sponsor; therefore, integrations are acceptable and do not conflict with the minimum contents of the draft Contract types. The latter shall be subject to negotiation by the parties and shall not, as a rule, be the subject of questions to the CCNCE.

Draft Contract- types may only be modified exceptionally and residual without the prior approval of the CCNCE. However, the changes, in addition to having to be reported in the contract ("point I" of the premises of the model), must be reported to the CCNCE together with the reasons of an exceptional nature that have determined the need to conclude a contract that deviates from the minimum content

set out in the Schemes adopted by the CCNCE. Reporting is necessary for monitoring and evaluating future adjustments to the Schedules.

In response to some questions received, the Coordination Centre states:

i. **Parties to the Contract**: The Promoter of the Trial may delegate, using a written contract, part or all of its tasks to a natural person or to a Company (e.g. CRO also delegated to the conclusion of the Contract). If the Promoter is established outside the European Union, under art. 74 of the European Regulation must have conferred a mandate with representation to a natural or legal person established in the European Union as its legal representative. However, this delegation does not change the Promoter's Liability (Art. 71 of the Regulation). Therefore, the situations, rights, and obligations related to the role of the Promoter, even if formally delegated to natural or legal persons different from the same, will continue to refer to the Promoter itself, which will be the ultimate responsibility. A copy of the Mandate, with representation and subsequent changes, must be entered in the Trial Master file.

ii. **Principle of therapeutic continuity**: The principle of therapeutic continuity specifies the following. The principle of therapeutic continuity does not appear as an obligation in a specific decree or regulation. Still, it is an integral part of the GMPs, since the Helsinki Declaration, on which the GMPs are based, states in Article *34: "**Post- Trials Provisions** In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process".* Competence and responsibility for assessing a clinical benefit lies with the Principal Investigator. Instruments to ensure this therapeutic continuity may include ad hoc studies (e.g. expanded access or open-label extension) reserved for the population participating in the trial or programs of compassionate use or other regulatory solutions. In the patient's best interests, information on how to ensure therapeutic continuity shall be contained in the information and the informed consent model relating to the experimental protocol and communicated to the participants when signing the informed consent. Where such information is unavailable, clarifications should be requested from the sponsor during the clinical trial evaluation to verify any conditions related to the clinical design that may render such continuity incompatible with the trial design in question and the related data integrity. Any reasons that determine an unavailability of the promoter to ensure therapeutic continuity must be specified in writing by the Promoter to the Institution and be evaluated by the Ethics Committee. Information on whether the Promoter is willing to ensure post-trial access to the drug referred to above, with the related reasons, should be made clear to participants in the

trial in the informed consent documents that, in the event of reasons arising, they should be updated.

iii. **Regulatory Law and the Competent Court**: The CCNCE believes it leaves the parties the freedom of choice but recommends reference to the Promoter's headquarters, especially in the case of multicentric international contexts. When there are hundreds of centres worldwide, the contractual regulations for the trials (and the settlement of possible disputes) must be able to standardise beyond local borders and particularities. The Coordination Centre considers that identifying the regulatory law and the promoter's forum may, in such cases, encourage the location of critical clinical trials in Italy.

13. ACRONIMS

Coordination Centre = National Coordination Centre of the Territorial Ethics Committees for clinical trials on medicinal products for human use and medical devices

CTIS = Clinical Trial Information System

CTR = Clinical Trial Regulation

CV = Curriculum Vitae

DoI = Declaration of Interest

EU-CTEG = EU Clinical Trials Expert Group

EU Models = Forms drawn up at the European level

GDPR = General Data Protection Regulation

Q&A = Questions and Answers Document – Regulation (EU) 536/2014

Regulation = Regulation (EU) No 536/2014

TEC = Territorial Ethical Committees

The Chair of the Coordination Centre
(Carlo M. Petrini)

Firmato digitalmente da
Carlo Maria Petrini
CN = Carlo Maria Petrini
C = IT

Members of the Coordination Centre

Carlo Maria Petrini (Chairman)

Gianni Tognoni (Vice Chair)

Giovanni Barosi

Paolo Bruzzi

Mario Guerrieri

Tommasina Iorno

Agostino Migone De Amicis

Maria Luisa Moro

Renzo Pegoraro

Maria Platter

Patrizia Popoli

Giuseppe Remuzzi

Angelo Ricci

Franco Rossi

Antonella Eliana Sorgente