AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Status of Implementation in European Member States from CTFG Point of View

Massimiliano Sarra

18/09/2020

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	☐	☐	☐	X optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	☐	☐	☐	X optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

*Massimiliano Sarra, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. I am not receiving any compensation

The Clinical Trials Facilitation and Coordination Group (CTFG)

- Established by the European Heads of Medicines Agencies (HMA) in October 2004.
- To foster a common approach in regulatory requirements relating to clinical trials, across the Community.
- Consist of clinical trials professionals from the EU/EEA Medicines Agencies.

After the publication of the Regulation (EU) No 536/2014 on Clinical Trials (CTR), the CTFG has substantially supported the implementation of the CTR by Member States and the development of the EU portal and EU database, as well as the entire clinical trial IT system (CTIS).

CTFG Mandate: main points

The CTFG

- Acts as a forum for discussion to agree on common principles, processes, positions, recommendations and guidances applicable in EU.
- Operates to improve harmonisation of the assessment decisions and administrative procedures for clinical trials across the EU/EEA.
- Acts as a group to discuss and harmonise/coordinate positions, recommendations and guidance on regulatory and scientific aspects of clinical trials
- Provides multinational regulatory/scientific advice on aspects of general interest.
- Interacts with other relevant regulatory bodies (i.e. ethics committees, the European Commission, European Commission).

CTFG Activities

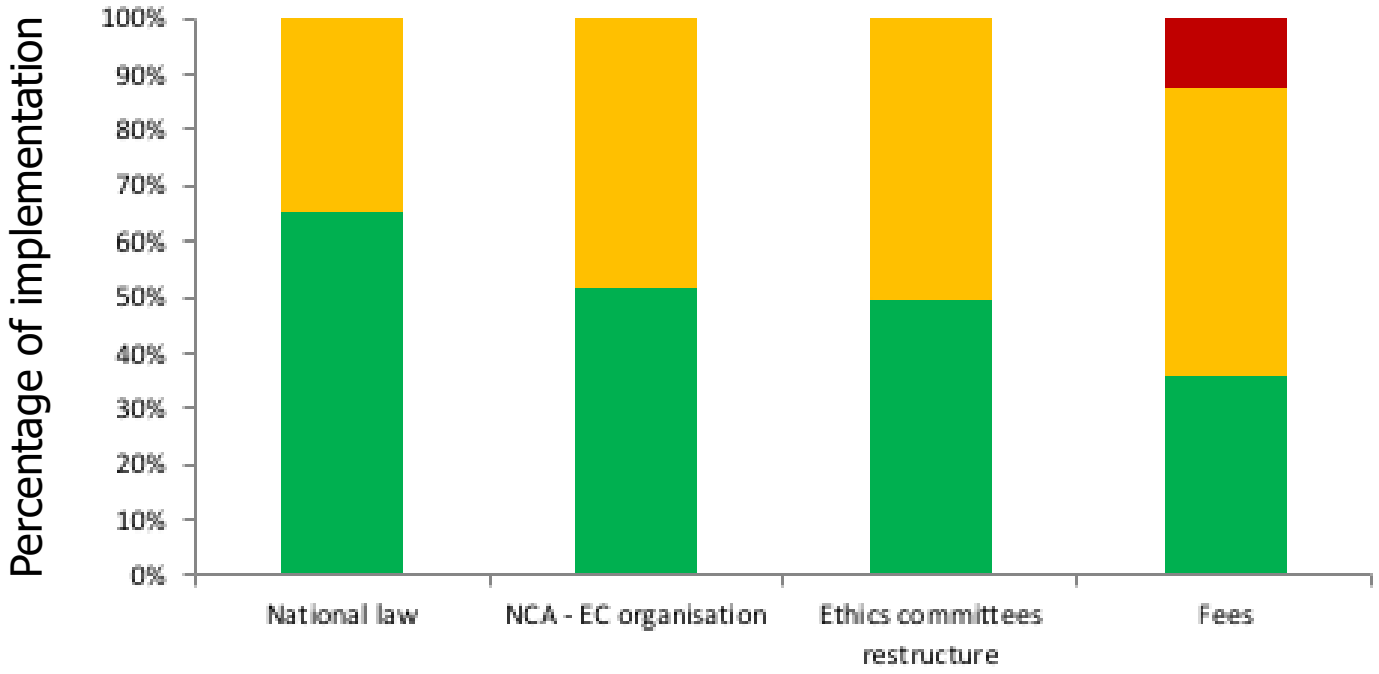
- Sharing Scientific Assessment and Advice
- Risk mitigation and Evolution of clinical trials – horizon scanning
- Safety surveillance
- Harmonise processes and positions
- Training
- Participate in development of information systems
- Communication
- Cooperation with other Working groups
- Collaboration with EMA in the CTIS development
- Production of QnA documents and guidelines in the field of clinical trials

Implementation Status

The CTFG periodic monitoring of the national implementation status in preparation of the CT Regulation 536/2014 by a heat/traffic light table focus on 9 key activities and is attached in Annex I.

- NCA - EC organisation
- Ethics committees restructure
- National law
- Fees
- National IT system
- Communication and training
- Pilot projects
- Safety
- Resources

National Implementation of the New Regulation



- Progressing well, on target following the national implementation plan
- Some progress, more activity needed
- Little progress, major hurdles remain

Communication/Training and Pilot Projects

NCAs are particularly active in providing information and training on topics related to the new regulation. Nearly 90% of the MS are currently active or are willing to start training to the other regulatory bodies, in particular to the Ethics Committees (EC).

In line with this more than 90% of the MS have started or are willing to start a pilot project aimed at testing the national system functionalities in the context of the new regulation. Most of this project are aimed at involving the EC in the coordinated assessment of CTA submitted via national procedure or VHP.

List of MS who are carrying on a pilot project including participation in VHP

https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2019_09_CTFG_EUMS_national_pilot_projects_intro_VHP-plus.pdf

Coordinated assessment AIFA and EC: The Pilot Project

The VHP experience

Due to the lack of coordination between AIFA and ECs, currently requests for evaluation of clinical trials that are submitted via VHP in Italy undergo a serious delay in the national phase, since the rapid granting of AIFA authorization does not match the evaluation of the EC that follows a different timing.

Coordinated assessment AIFA and EC: Main charecteristics of t0eh pilot project

•The Sponsor and the Coordinating Ethics Committee (CEC) voluntarily agree to participate in the coordinated assessment process.

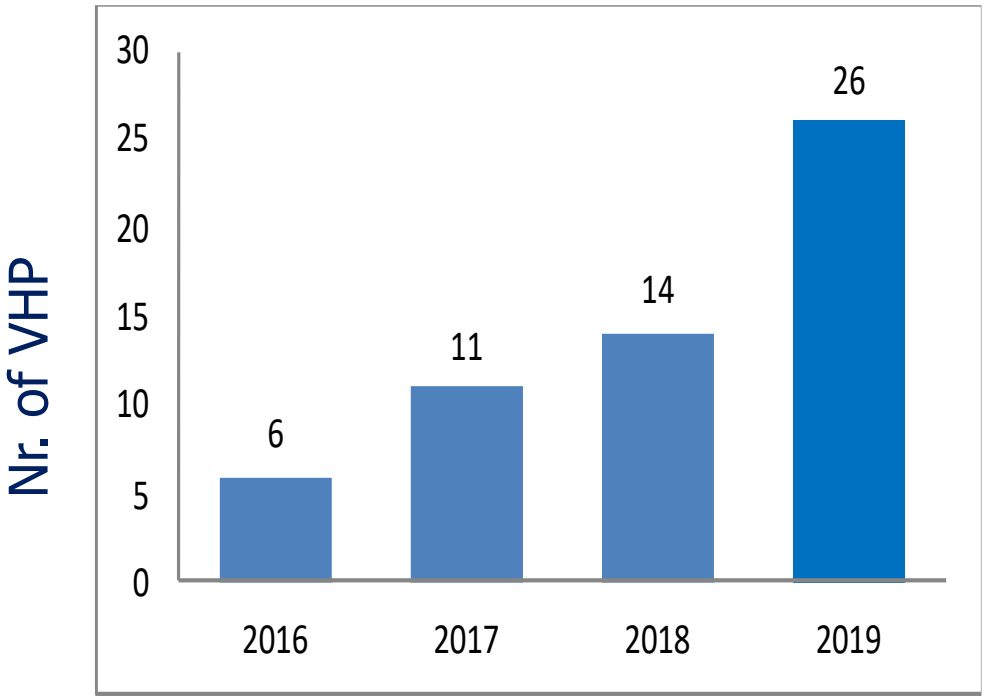
•AIFA acts as a mediator between Sponsors and CEC. The CEC adheres to the procedure and agrees to comply with the VHP timelines.

•If the deadlines are not met during the procedure, the CEC can not conclude the assessment process which will be finalized only during the national phase.

•The conclusion of each phase of the VHP will be shared with the Sponsor through specific communication.

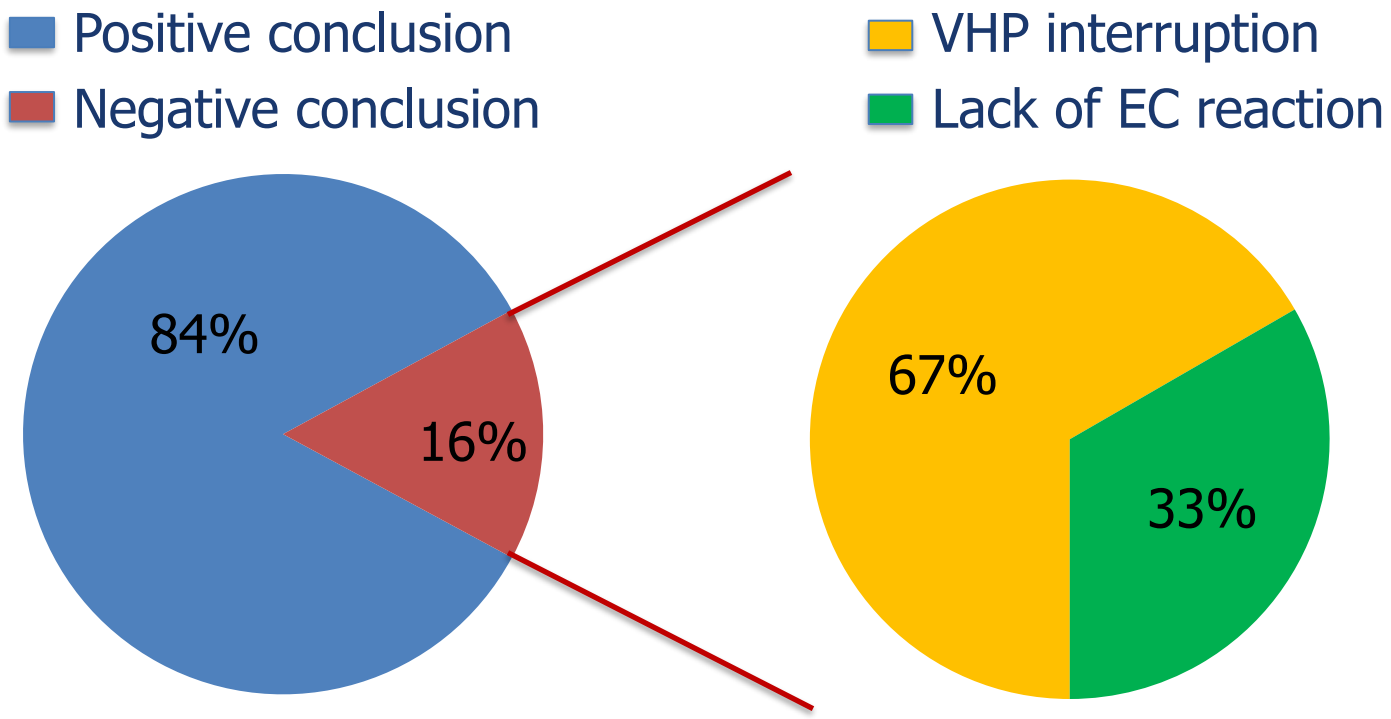
Application of VHP with request of participation to the pilot projects

The project started in may 2016 and at the end of 2019 the joint assessmnet has been requested for nearly 60 clinical trial applications submiited via VHP distributed in the years as follows:



Results of the pilot project (2016-2019)

Outcome of the procedure assessed through the pilot project



National IT System

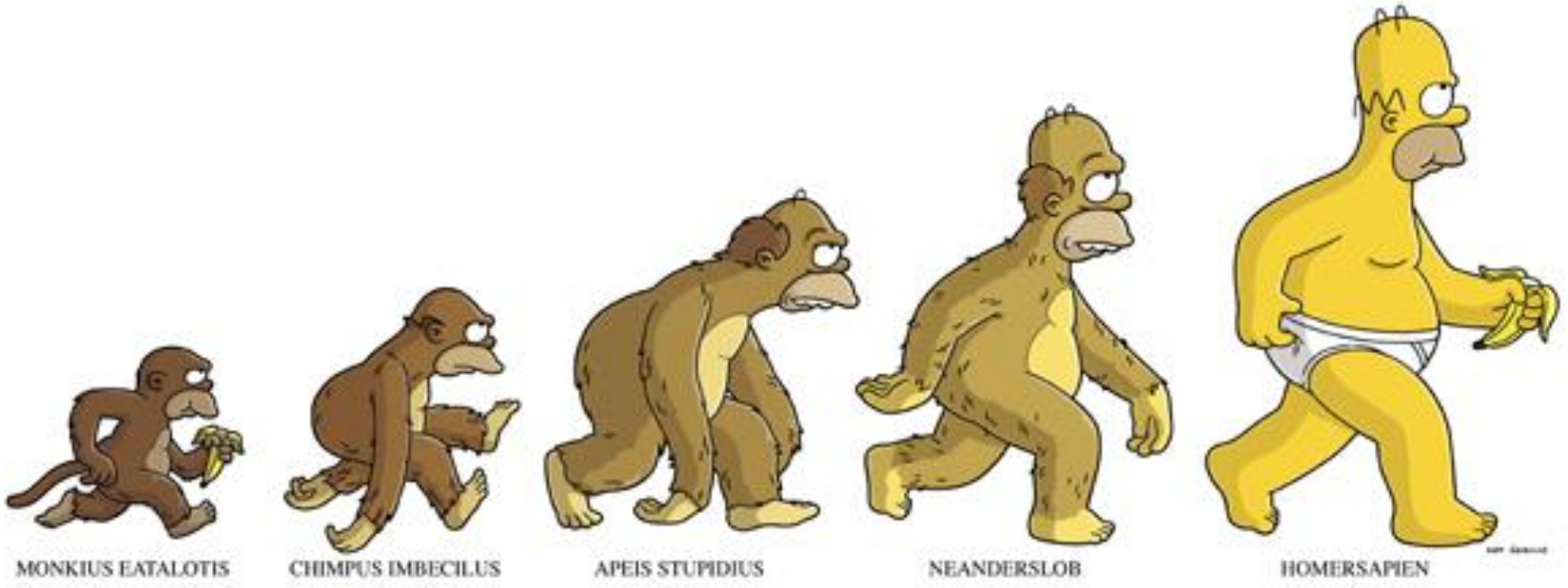
According to the articles 80-84 EMA should provide, handle and update the informatic systems in collaboration with MS and the European Commission

Only part of the NCAs plan to have their national IT system. So far only few MS have their own IT system active, however all the MS who plan to have their own IT system are actively working in the development. The CTFG is collaborating with the EMA to set up specific requirements that every national IT system should have to allow a connection with the CTIS.

Safety and Resources

Implementation of the New regulation requirements to comply with the assessment of the safely issues involving clinical trials and the implementation of the national resources in view of the changes introduced by the new regulation are still a major hurdles for at least 20% of the MS. Even if most of the MS are implementing actions aimed at managing the safety issues in a coordinated view, the status of the progresses is generally considered behind the expectations. The same applies to the recruitment of new resources by the NCA.

Conclusions



2001/20/CE

536/2014

Massimiliano Sarra, PhD
Pre-authorization Dept.
Italian Medicine Agency (AIFA)
m.sarra@aifa.gov.it
Tel. +39 06.59784075

www.aifa.gov.it