AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

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

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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

The CTFG will act as a forum for discussion to agree on common principles, processes, positions, recommendations and guidances to be applied throughout the EMRN, and it will operate to improve harmonisation of the assessment decisions and administrative procedures for clinical trials across the EU/EEA. It will act as a group to discuss and harmonise/coordinate positions, recommendations and guidance on regulatory and scientific aspects of clinical trials throughout their life cycle as well as multinational regulatory/scientific advice on aspects of general interest. This implies interaction with other relevant regulatory bodies, like ethics committees, committees and working parties of European Medicines Agency (EMA), and of the European Commission, as well as with other stakeholders involved in CTs. Adopted guidance documents will be published at the HMA/CTFG website

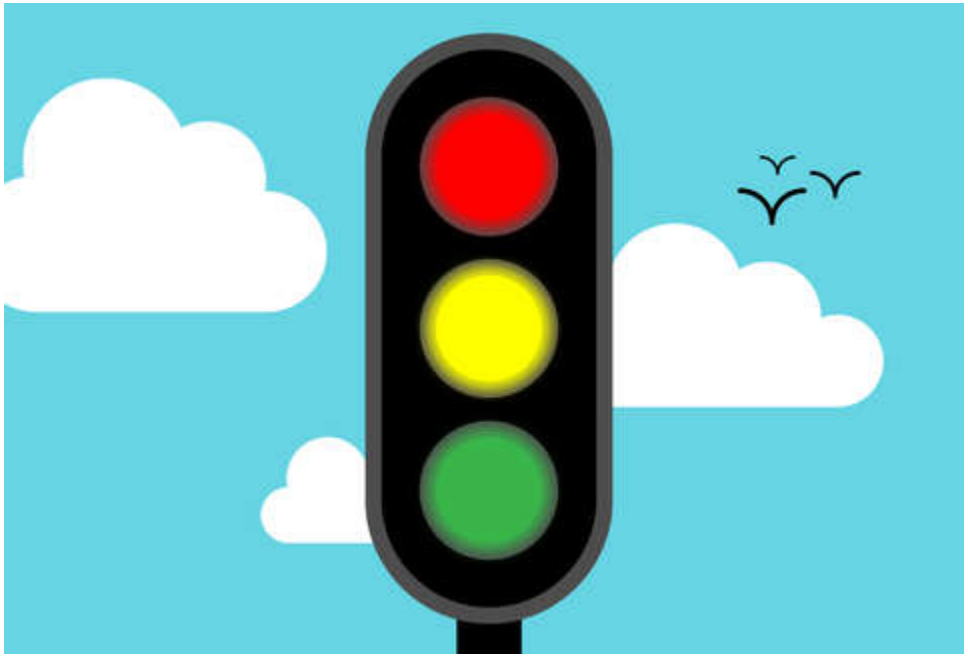
CTFG Activities

- 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

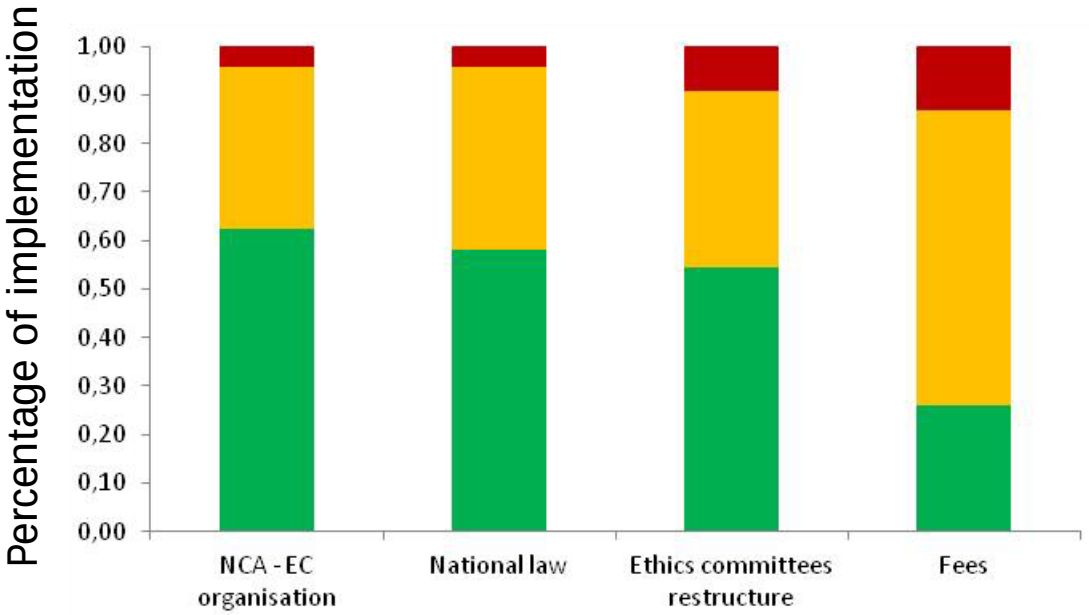
Implementation Status

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. More then 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 almost 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

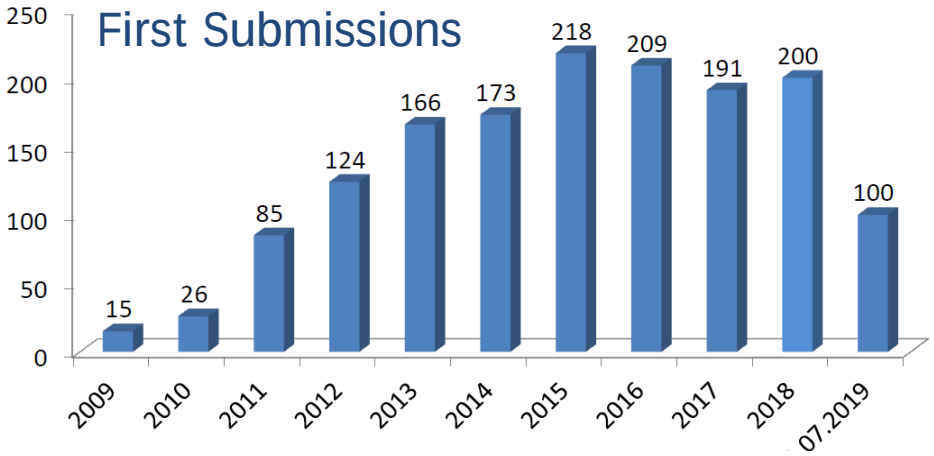
The Voluntary Harmonisation Procedure (VHP)

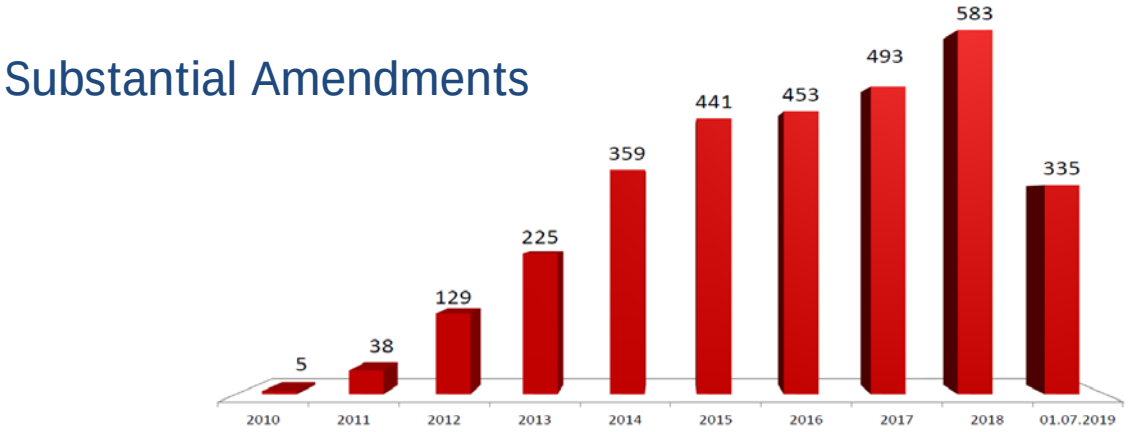
VHP applies to all phase I-IV MN CTs involving 2 or more Member States. It allows the joint assessment of the same documentation provided by the Applicant in a specific timeline, thus leading to the harmonized conclusion on the possibility to approve or reject the CT Application in all the Members States involved.

VHP: Main Characteristics

- Harmonization of the Documents (Protocol, IB, IMPD, risk/benefit) shared by the NCA through the VHP-DB
- A rigid and specific Timeline
- Nomination of a Ref-NCA that leads the assessment and collect the comments of the P-NCA
- Coordinated assessment of the CTA, thus leading to a single harmonized decision among the Member States involved

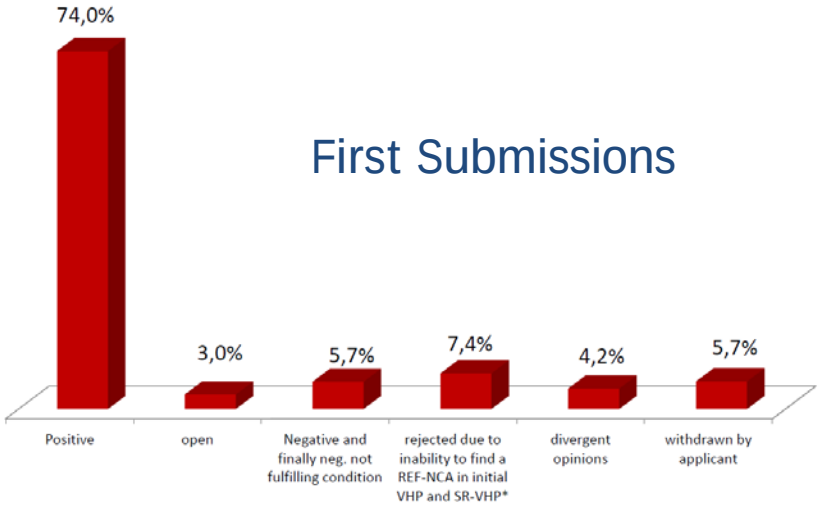
Results of the VHP (2009-01.07.2019)
Nr. of VHP per year



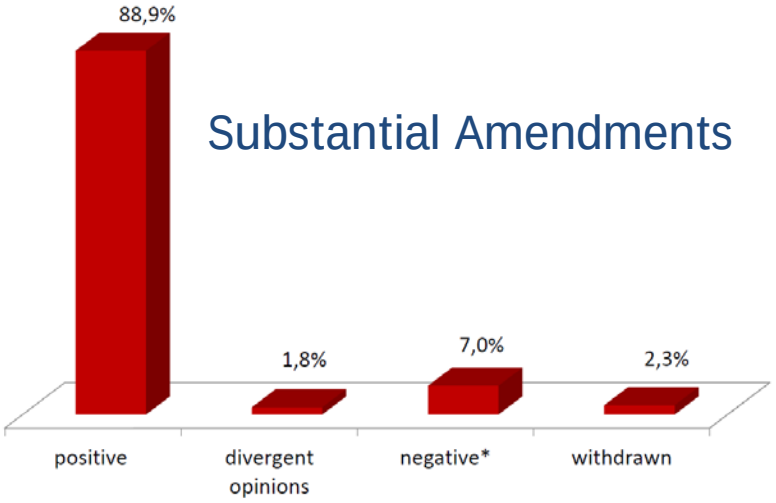


Results of the VHP (2009-01.07.2019) Outcome of the procedures

First Submissions



Substantial Amendments



National IT System

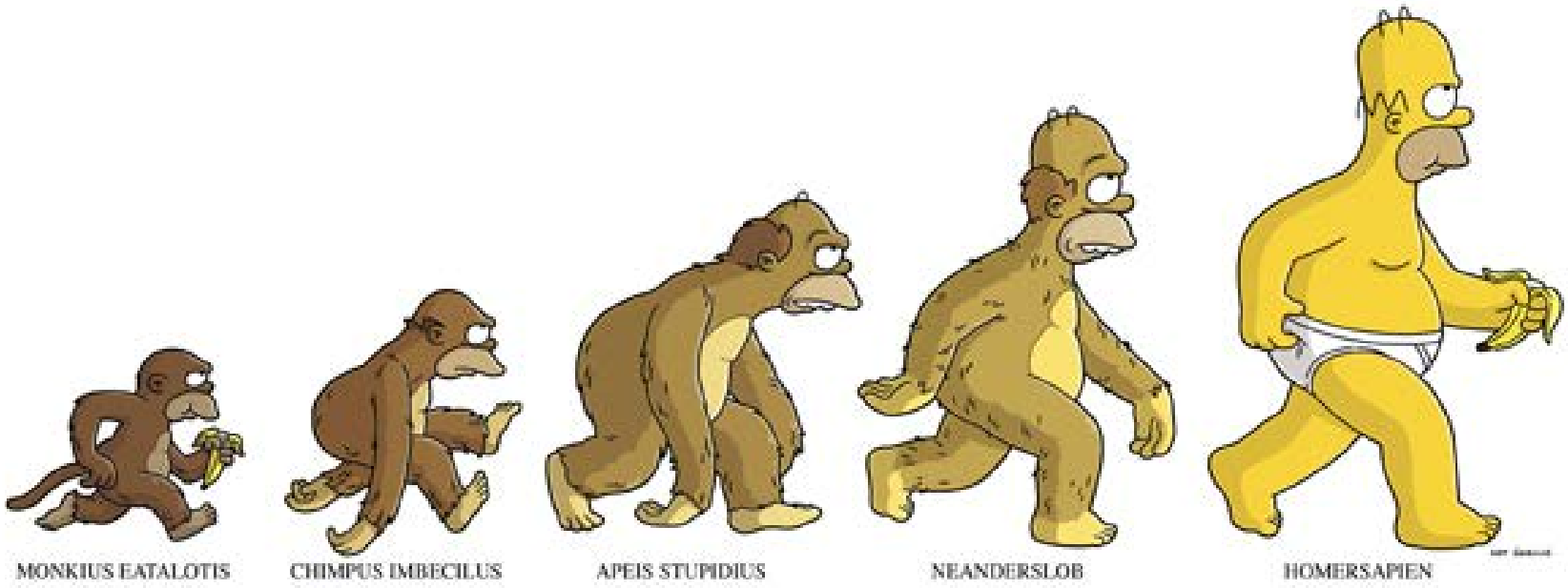
According to the articles 80-84 EMA should provide, handle and update the informatic systems in collaboration with MS and the European Commission

Most of the NCAs plans to have their national IT system. So far only a couple of MS have their own IT system active, however almost 80% of the MS are actively working to develop an IT system. 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



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