AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Joint assessment of clinical Trials with EC: The Italian National Pilot Project

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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

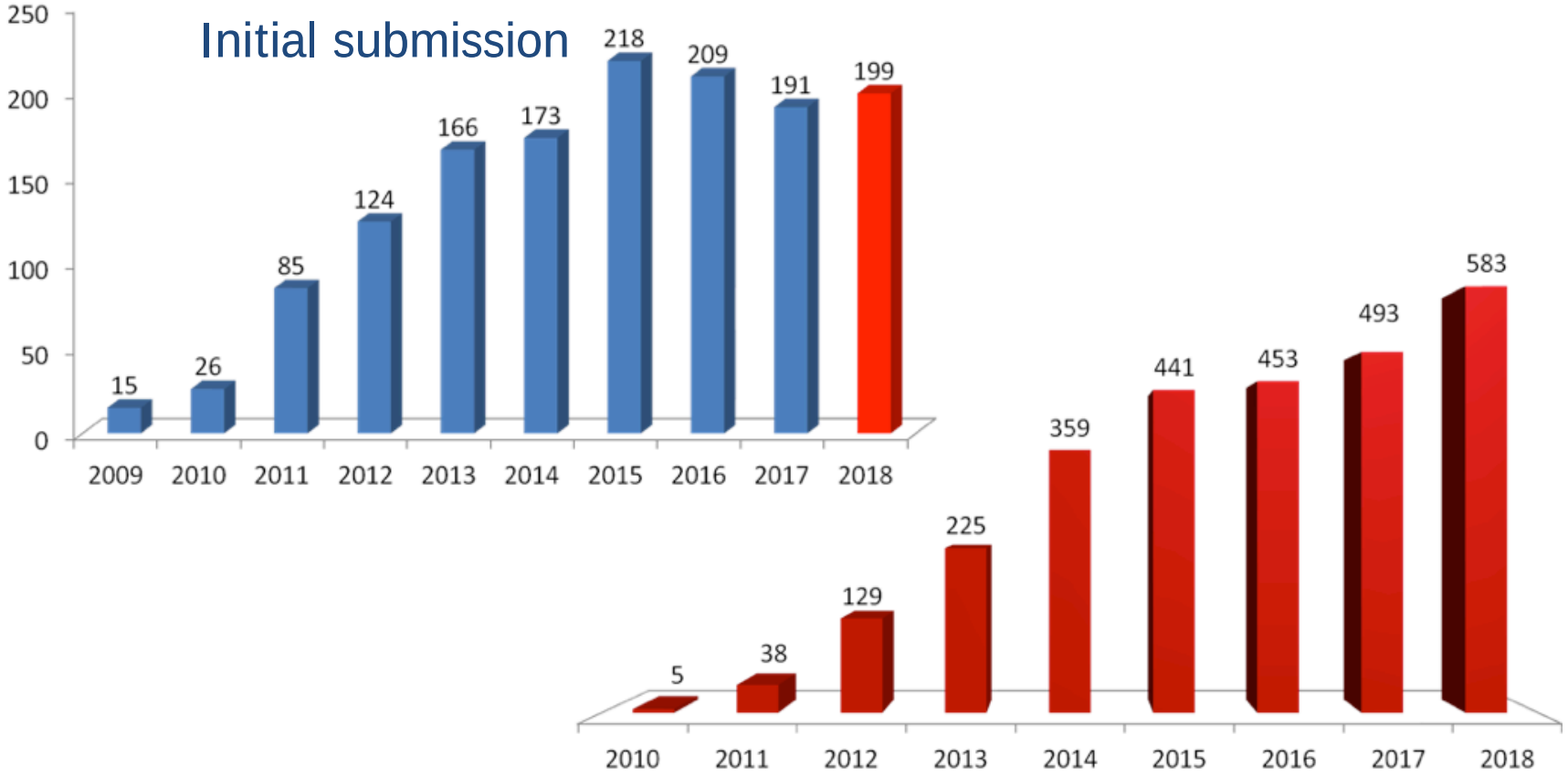
The Voluntary Harmonisation Procedure (VHP)

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

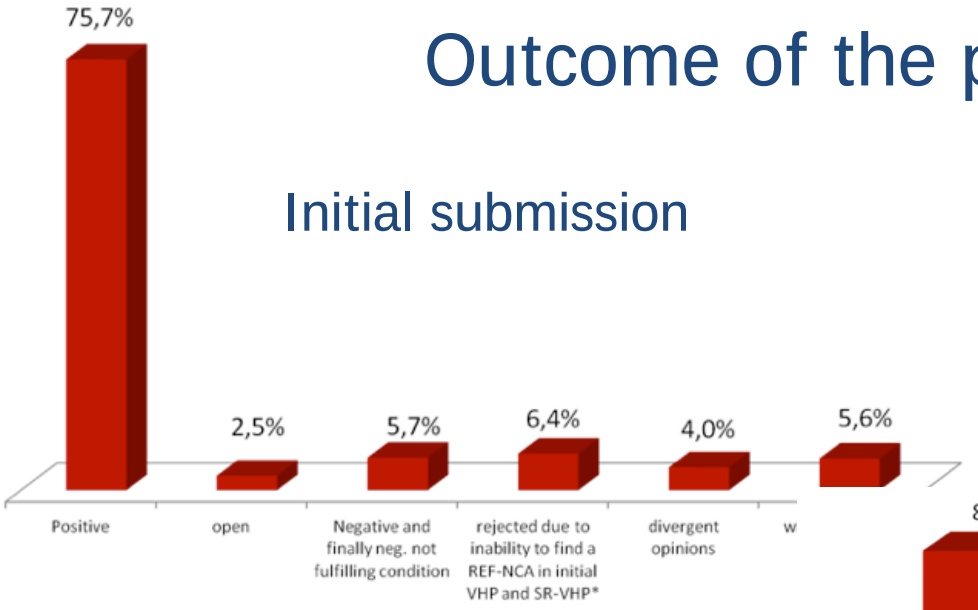
- Harmonization of the Documents (Protocol, IB, IMPD, risk/benefit) shared by the NCA through the VHP-DB
- A rigid and specific Timeline
- Nomination of a Ref-NCA that leads the assessment and collect the comments of the P-NCA
- Coordinated assessment of the CTA, thus leading to a single harmonized decision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

Results of the VHP (2009-2018)
Nr. of VHP per year

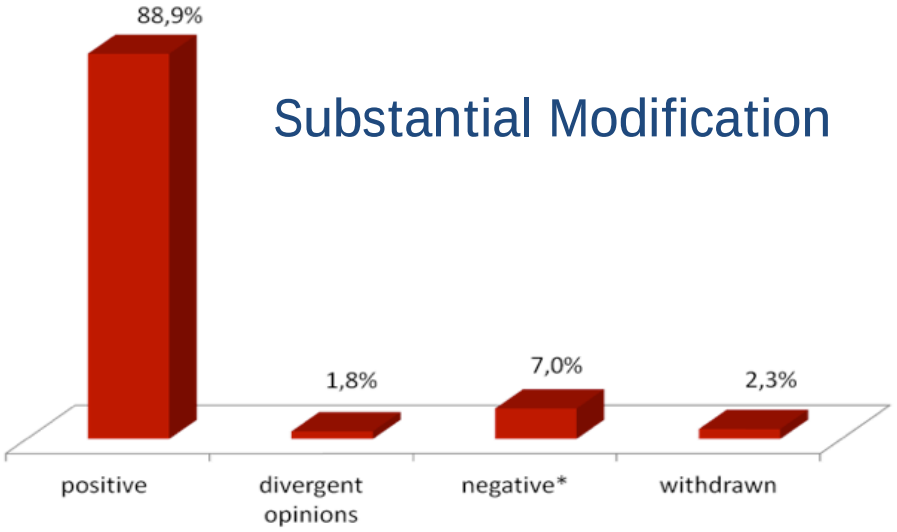


Results of the VHP (2009-2018)
Outcome of the procedures

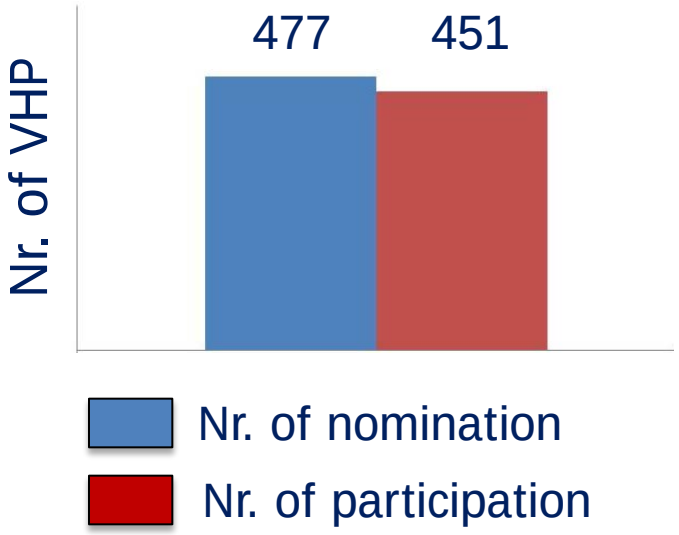
Initial submission



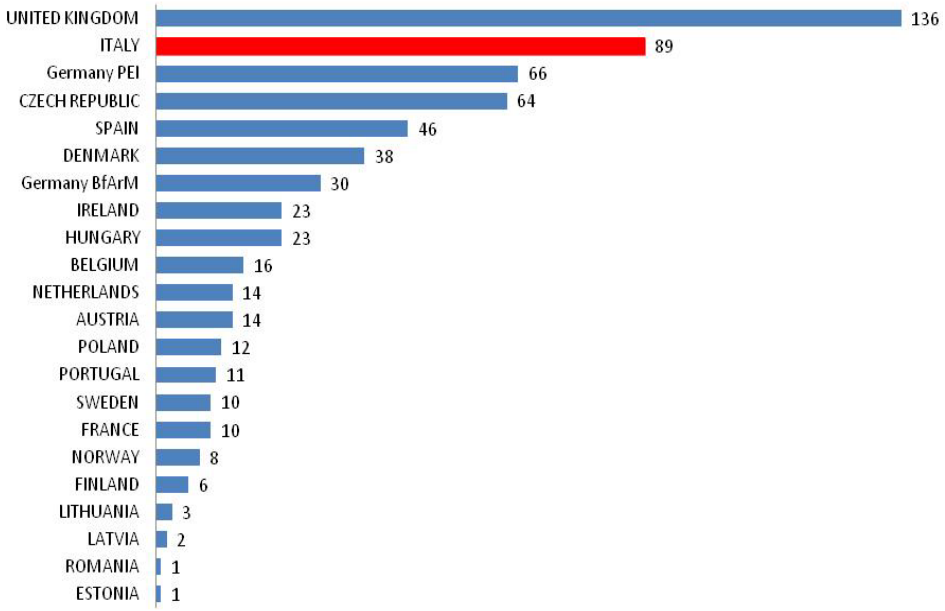
Substantial Modification



Involvement of Italy in VHP procedures (Cumulative data 2015-2018)



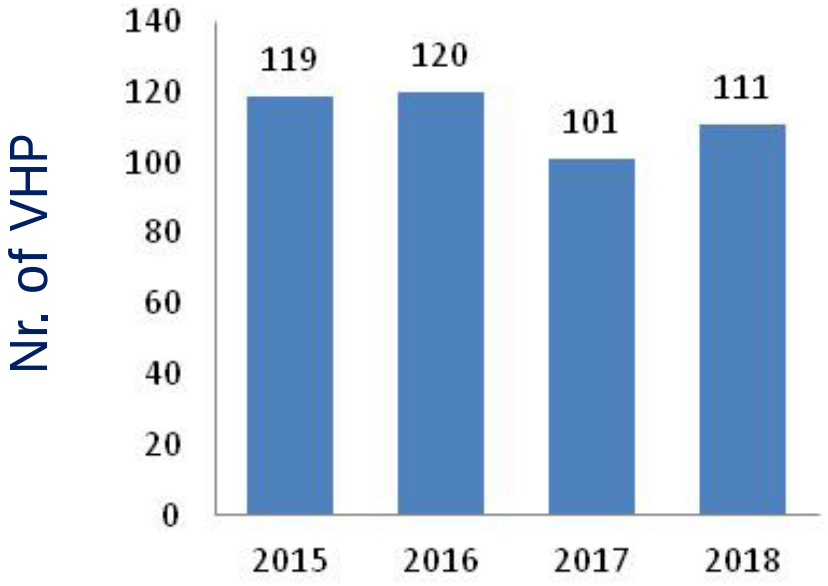
Nr. di VHP come Ref-NCA

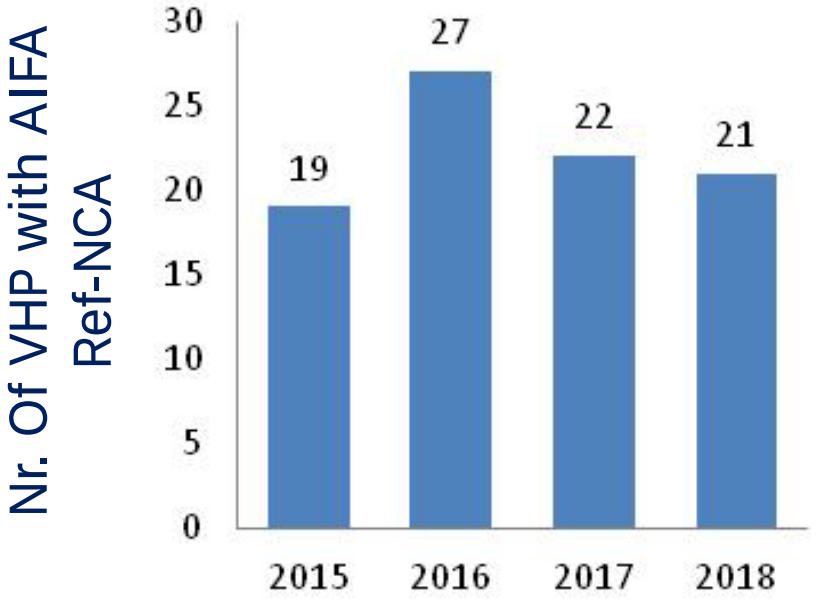


Source: HMA website

Involvement of Italy in VHP procedures (01.2015-09.2018)

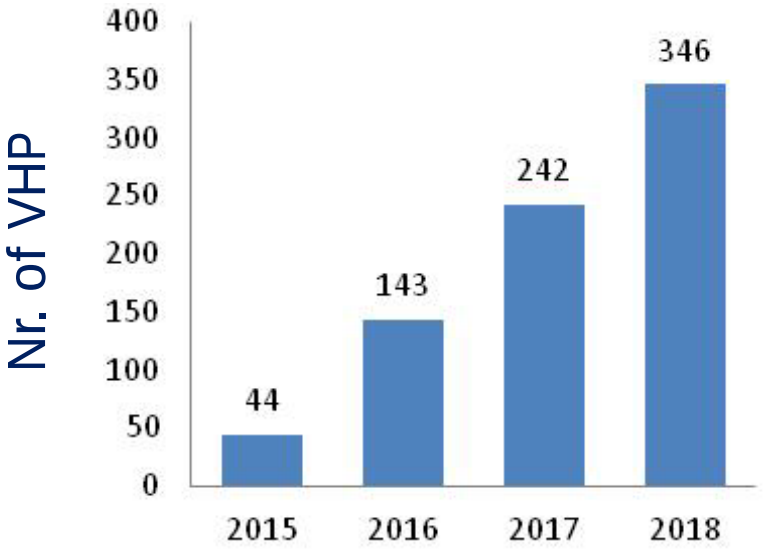
Initial submissions involving Italy

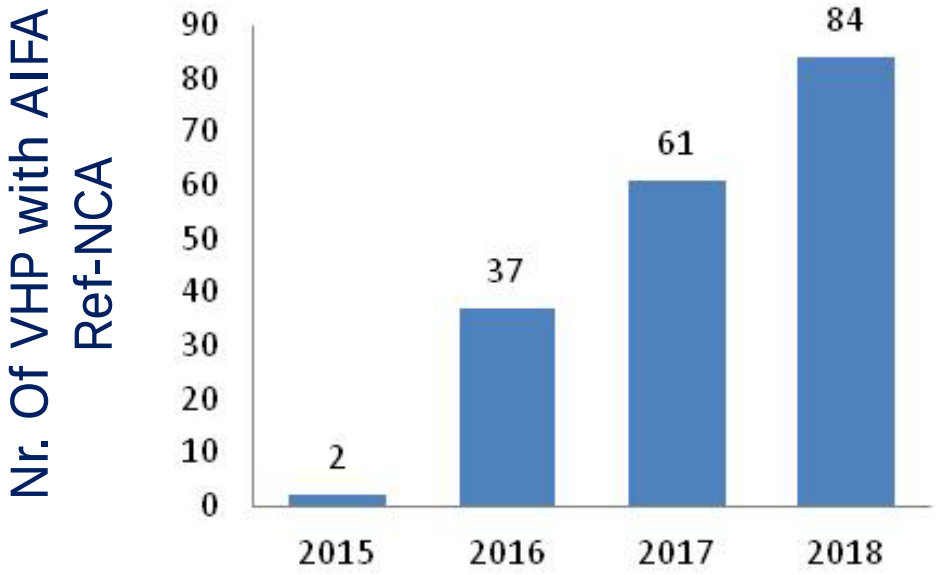




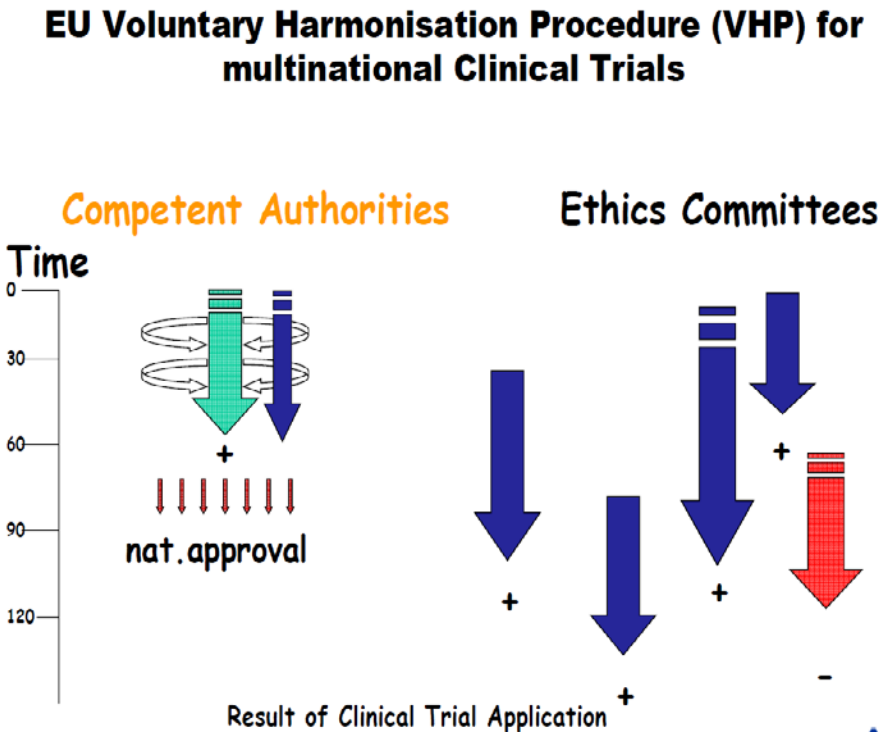
Involvement of Italy in VHP procedures (01.2015-09.2018)

Substantial Amendments involving Italy





Involvment of Ethics committes in VHP: VHP Plus



VHP-plus is a VHP involving Ethics Committees in the assessment of benefit/risk, IB and protocol in some Member States

Ethics committees in Italy

Currently in Italy there are about 100 different ethics committees distributed in different regions according to the number of inhabitants.

NB. The number of EC will be reduced to 40 with the implementation of the national law

Authorization of CTA in Italy

AIFA

- IMPD
- IB
- Protocol

Coordinator EC

- IMPD
- IB
- Protocol
- ICF
- Administrative documents

Collaborators EC

- ICF
- Administrative documents
- “Local feasibility”

- Different conclusions
- Different timelines
- Delay in the start of the CT

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: The Pilot Project

The pilot project

Objective:

- Harmonization of the assessment, decisions and timelines

Endpoints:

- Provide a complete national authorization according to the VHP timelines
- Assess the feasibility of the national system in view of the implementation of the regulation 536/2014.
- Practice with new approach to the joint assessment of the Part 1.

Coordinated assessment AIFA and EC: Main charecteristics of the 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.

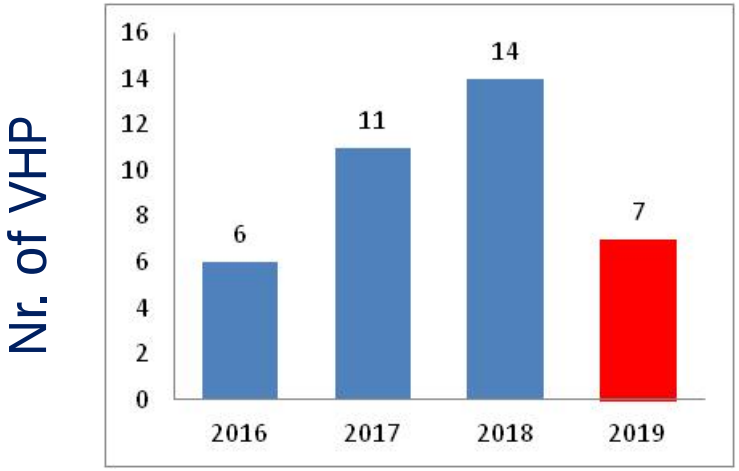
•If the deadlines are not met during the procedure, the CEC can not conclude the assessment process which will be finalized only during the national phase.

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

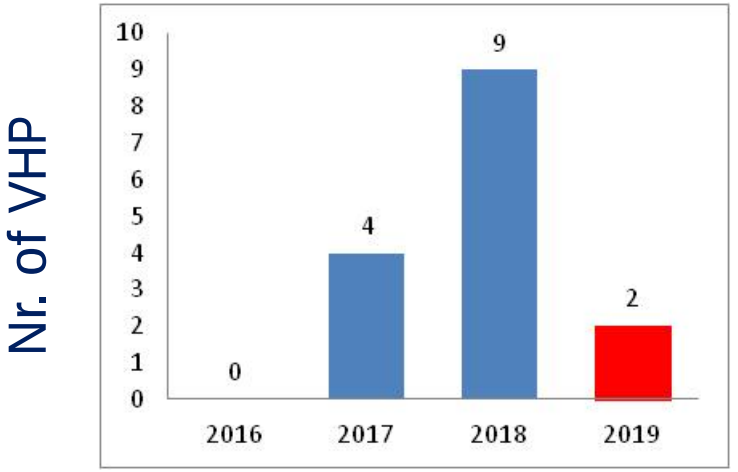
Application of VHP with request of participation to the pilot projects

The project started in may 2016 and so far the joint assessmnet AIFA/CE has been requested for 38 initial submissions and 15 substantial amendments distributed in the years as follows:

Studies

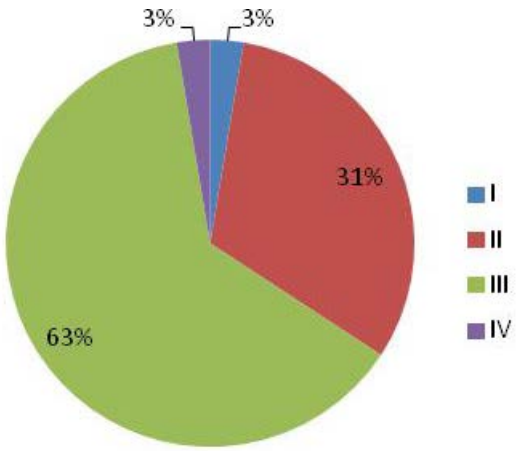


Substantial Amendment

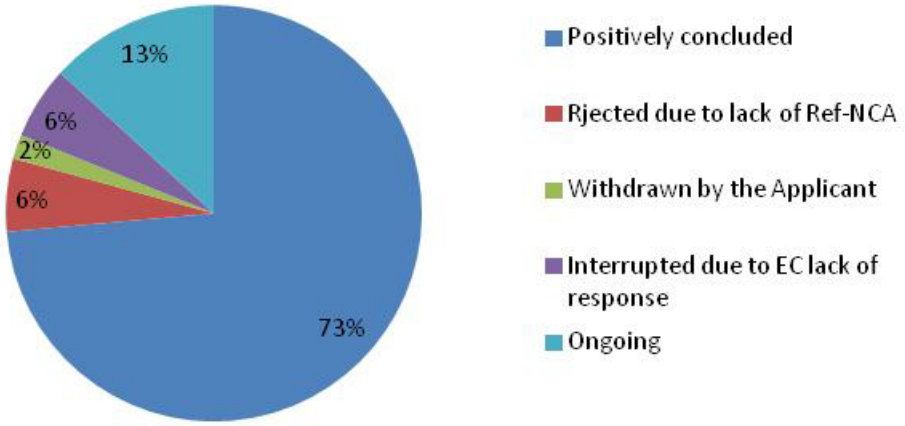


Preliminary Results of the pilot project

Distribution of Application on teh basis of the trial phase

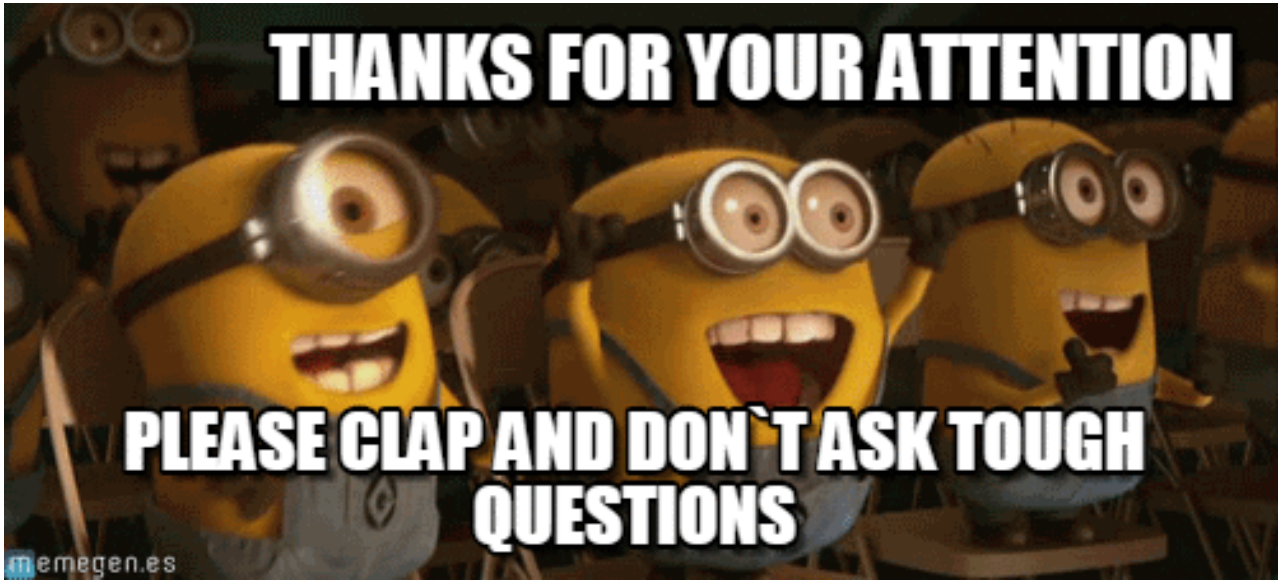


Outcome of the procedure assessed through the pilot project



Brief summary of the experience

1. Issues coming from the EC mainly on clinical part
2. Positive feedback from the interaction with ECs
3. The assessment approach
4. The concept of Grounds for Non Acceptance (GNA)
5. How to correctly formulate a GNA
6. The definition of conditions
7. The assessment of a substantial amendment in VHP
8. Positive feedback from the industries



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