

Member State preparedness

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CTFG Support Clinical Trail Regulation 536/2014 Implementation

CTFG monitors CT implementation / readiness in our Member States (MS) as of agreed key parameter and reports to HMA

- Continuously collect and roundtables since 2015
- CTEG supports with few additional parameters since 2020

Support in implementation:

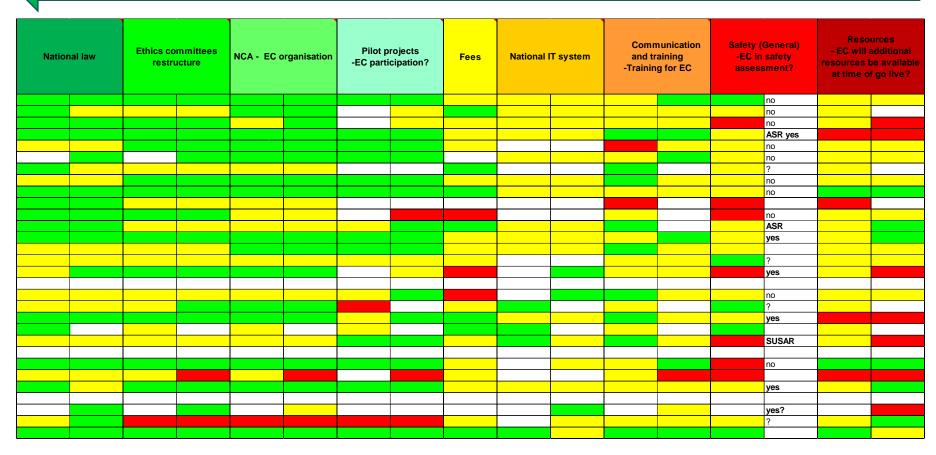
- Procedures on cooperation in assessment, incl. assessment report templates
 - Applications: Voluntary harmonisation procedure (VHP)
 - + Ethics Committees (VHPplus)
 - Surveillance: Safety Reports ASR, SUSARs, others
- Best Practice: Memorandum of understanding
- Training: Curriculum on CTs; assessors NCA/EC
- Exchange on experience in national implementation and cooperation
- Support COM on guidance: recommendations, Question&Answer, IA
- Support CTIS Development

and Medical Devices

National Implementation Status - CTFG/CTEG February 2021

Most progress

Least progress





Current Implementation Status

- National law, NCA/EC organisation and Ehtics committee reorganisation are in 50-60% of MSs on track; while still 2 countries have major hurdles to take
- National pilots or/and VHP are conducted or planned in 2/3 of MSs; in half of these MSs they are running well, different status exist within some MSs
- Fee determination is running behind, more action needed in 60% of MSs



Current Implementation Status (II)

- MSs which plan on national IT development as well as communication and training need more activities in approx 75% of MSs; Both are dependent on CTIS development and application of CTR; different readiness to communication and training within some MSs
- Even improved the last month, still major hurdles are in 30 % of MSs with regard to cooperation in safety; only 20% are on track! In < 1/3 Ethics Committees will participate in this cooperation
- Resources are not on track in most of the MSs, so have to taken care of
 - > MSs have a few month left to get ready ...



Readiness in Cooperation in Safety - CTFG February 2021

(urgent) Safety notification	ASR assessment	SUSAR assessment
cooperation	cooperation	cooperation
cooperation	cooperation	cooperation

- Readiness on safety cooperation improved
- Still majority of MSs need more activity
- Major hurdles exist is some MSs
- Need to get prepared!

Thank you very much for your attention!









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