



Federal Institute  
for Drugs  
and Medical Devices

# Member State preparedness

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Clinical Trial Facilitation and Coordination Group  
CTFG

# CTFG Support Clinical Trial 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

# National Implementation Status

## - CTFG/CTEG February 2021



National law		Ethics committees restructure		NCA - EC organisation		Pilot projects -EC participation?		Fees	National IT system		Communication and training -Training for EC		Safety (General) -EC in safety assessment?		Resources - EC will additional resources be available at time of go live?	
													no			
													no			
													no			
													ASR yes			
													no			
													no			
													?			
													no			
													no			
													no			
													no			
													ASR			
													yes			
													?			
													yes			
													no			
													?			
													yes			
													SUSAR			
													no			
													yes			
													yes?			
													?			

# 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 cooperation	ASR assessment cooperation	SUSAR assessment cooperation
Yellow	Yellow	Yellow
Green	Yellow	Yellow
White	White	White
Red	Red	Red
Yellow	Green	Yellow
Yellow	Yellow	Green
Green	Yellow	Green
Yellow	Yellow	Green
Yellow	Red	Red
Yellow	Yellow	White
Yellow	Yellow	Yellow
Green	Yellow	Red
Yellow	Green	Yellow
Green	Green	Red
Yellow	Yellow	Yellow
Yellow	Yellow	Red
White	White	White
Red	Yellow	White
Green	Green	Green
White	White	White
Red	Yellow	Red
Yellow	Yellow	Yellow
Red	Red	Red
Yellow	Red	Red
White	White	White
Yellow	Yellow	Yellow
White	White	White
White	White	White

- Readiness on safety cooperation improved
- Still majority of MSs **need more activity**
- Major hurdles exist in some MSs

➤ *Need to get prepared!*

# Thank you very much for your attention!



## Contact

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