

Info session : Clinical Trial Regulation

Count down has started : Go live 31 Jan 2022

Are we ready ?

23 th September 2021

Greet Musch

1: General State of play at EU level : NCA (CTFG 09/2021)

| Ethics committees restructure | National law | NCA - EC organisation | Pilot projects | National IT system | Communication and training | Fees | Resources | Safety (General) |
|-------------------------------|--------------|-----------------------|----------------|--------------------|----------------------------|------|-----------|------------------|
| | | | | | | | | |
| | | | | NA | | | | |
| | | | N/A | NA | | NA | | |
| | | | N/A | NA | | | | |
| | | | VHP plus | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | NA | | | | | |
| | | | NA | | | | | |
| | | | | | | | | |
| | | | | NA | | | | |
| NA | N/A | | | | | NA | | |
| | | | N/A | NA | | | | |
| | | | | | | | | |
| | | | | NA | | | | |
| | | | NA | | | | | |
| | | | | | | | | |
| | | | N/A | NA | | | | |
| | | | N/A | | | | | |
| | | | | NA | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | NA | | | | |
| | | | N/A | NA | | | | |
| NA | | | N/A | NA | | | | |
| | | | | | | | | |
| | | | N/A | NA | | | | |
| | | | N/A | NA | | | | |

1: General State of play at EU level : Ethics committees

| NCA - EC organisation | Ethics committees restructure | National law | National IT system | Ethics committee in safety assessment | Do ethics committees participate to pilots (if any) ? | training for EC | Will additional resources be available at the moment of go-live ? |
|------------------------|--|--|--|---------------------------------------|--|--|---|
| | | adoption launched | depending on API | no | national | EMA master trainer program | dependent on fee regulation |
| | | | depending on API | no | | will be foreseen (October/November) using the tools provided by EMA | yes |
| | | | N/A | | | | |
| some progress | one EC | yes | N/A | no | | ? | additional |
| in progress | | | depending on API | ASR yes, SUSAR no | yes, through VHP+ | ? | |
| ? | ? | | API dependent | yes | | training is ongoing , master training | EC: ok |
| | | | api dependent | no | yes, through VHP+ | VHP+ | progress |
| practical coordination | some progress has been made for NCA/EC cooperation | Draft legislation with Parliament for adoption | API dependent - expected by March 2022 | no | Not at the moment, not possible until national law is implemented. Plans to conduct either national or VHP+ pilot in Q3-Q4 of 2021 | whatever is available through EMA/CTFG | probably no |
| | patient organisation representative was added | | | not foreseen | planned pilot in VHP+ | CTIS master training+CTR training | |
| | | (fees) | API dependent | ASR yes, SUSAR no | pilot and national VHP+ | | limited resources esp. for coordinated safety assesemnt |
| | | parliamentary review | N/A | no | started Q4/2020-Q1 2021 | green/yellow -- ongoing | green/yellow-EC yellow for safety review |



2 : Main concerns at MS level

➤ Training :

- Optimising the workprocesses : preparing the use of CTIS in an efficient way once the CTR goes live
- CTIS : Master trainers plan to have access to the sandbox end of October

➤ Resources

➤ Safety assessment and surveillance and sufficient IT support for implementing act on safety coöperation



3: Best Practice guidance

- Assessment report : template and principles of coördination Reference Member State and Member State Concerned
- Harmonisation principles on
 - Validation
 - Conditions
 - Request for Information
 - Appeal procedures
 -



Next steps - CTIS



- *Focus:*
 - *Ensure quality and stability of CTIS for successful go-live*
 - *Deliver essential technical support for safety monitoring*
 - *Change management and communication – we all need to get ready*
- *Get ready:*
 - *Define functions and processes embedding CTIS*
 - ***Nominate the Member State Administrators***
 - ***Define the form of MS organisations (NCA/IECs)***
 - ***Choose the people to work with CTIS, train the people who implement the processes***
- *Countdown has started:*
 - *Go Live 31 January 2022*

Contact

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des produits de santé – AFMPS**

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A large, stylized graphic of a human eye in the background. The eye is composed of a light blue iris with a white pupil, and a grey eyelid. The eye is looking directly forward.

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notre préoccupation**

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