MINISTÈRE
DES SOLIDARITÉS
ET DE LA SANTÉ

Liberté
Égalité
Fraternité

Clinical trials regulation – Implementation in France

13 May 2022 – EUFEMED

Direction générale
de la santé

French context

- Work to prepare the implementation of 3 EU regulations (MDR, CTR, IVDR) since 2015
- Political priority
  - « Plan santé innovation 2030 » presented by the President of the Republic, June 2021
- Strenghtening of the means of the 39 ECs (CPP)
  - New information system for clinical research (drugs, MD, IVD, other) : developped since 2020, used since 2021
  - Softwares (teleconference, e-signature, translation)
  - Recruitment of administrative staff (service continuity)
  - Compensation of the 2 members preparing the review of the application aligned to that of the experts of the NCA
  - Training to regulation, information systems, national process
  - Support and coordination by the MoH

Preparation specific for CTR implementation

- Adaptation of national regulation
  - ordinance 2016
  - decrees 2016 and 2022
- Pilot phase to simulate the application of CTR with 2 stages
  - Repect of timelines
  - Interaction between NCA (ANSM) and ECs (CPP)
- Adaptation of the operation of Ecs : 20 Ecs with
  - 2 secretaries
  - Two meetings / month & EC ; shorter period between the CTAs submission and their collective review
  - 4 meetings of EC / week

Construction of the french interaction NCA - ECs

- Legal provisions (Ordinance 2016) :
  - ANSM responsible of the evaluation of part I and submission of the french final decision
  - ECs in charge of evaluation of part II
- Organisation drafted by NCA – ECs – MoH – CNRIPH during pilot phase
  - ECs send their questions / evaluation of part I to ANSM (even if no comment)
  - If RFI part I : ECs send their evaluation of the sponsor's answer to ANSM (even if no comment)
  - NCA informs the EC of the taking into account of their questions/evaluation
  - Communication NCA – EC by mail (phone if disagreement or complex issue)
    - ECs formulate their question « ready to paste ». Dedicated template and mail adress.
  - Regular RETEX to elaborate doctrines if needed

Actions of NCA and EC in the CTIS for evaluation of a first submission of a CTA

- NCA :
  - Validation
  - Roles related to the evaluation of part I according to the French role (MSC or RMS)
  - Decision maker
- MoH : attribution of the necessary roles for the CTA to the randomly designed EC
- EC :
  - Roles related to the evaluation of part II
  - Roles related to the view of part I (restricted rights)
  - (decision maker for MS part II)

Contacts for the sponsor during evaluation of a CTA

- When a CTA is submitted in the CTIS, all communication between the sponsor and the national authorities (NCA & EC) are made through the CTIS
- The decision is communicated through the CTIS
- The sponsor does not need to submit a CTA in the national information system, nor to act in the national information system (except for appeals)

After 3 months

- First RETEX
  - Sharing of the access to the CTIS, and of the reception and evaluation of the first CTAs
  - Question regarding the submission of documents facing patients
  - Question regarding the anticipated number of submission of transition CTAs

- No issue reported to the MoH regarding the interaction between NCA & EC during the evaluation of the first CTAs submitted and validated
  - Questions / evaluation on part I transmitted by EC to NCA before D22