Drafting group for IT business requirement for safety cooperation

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Mandate (I)

Legal Basis : Implementing Regulation Article 11

Objectives :

"The drafting group will **discuss**, describe and **agree the business requirements** that will ***drive*** the creation of **new, or modification of existing IT systems** to support the coordination of safety assessments of clinical trial."

"…the first objective of the drafting group will be to **determine the holistic IT requirements and agree** on the business **requirements for the functionalities to be available at the time of the go-live** to comply with the Implementing Regulation by 31st January 2022 **with pragmatic IT solutions** and to a **development plan to further improve the IT support**."

"…the second objective will be to carry out the evaluation and based on the findings determine and agree on a proposal with the business **requirements** needed for **further implementation post go-live**"

Mandate (II)

Governance

- The business requirements and the proposed solutions will be circulated to
  - the CT/CTIS business groups ***for information***
  - the **CTR coordination group for adoption**

Membership

- Nominated members of the Clinical Trials Facilitation and Coordination Group (**CTFG**) safety subgroup and relevant **EC and EMA colleagues; Cochaired** by EMA and CTFG

- Provide **business** input to **support the Best Practice on cooperation in safety surveillance** in CTs and defining **essential priority functionalities needed for go live and post go live**

Meetings since end of June 2021, ongoing

Milestones

Go Live Functionalities:

- **SUSAR : EVDAS** report templates
- **ASR** use of existing submission and assessment **module in CTIS**
- **Repository** : to store tables and documents relevant for **cooperation in safety**
- **saMS selection** ‚workaround'
- **Communication** to sponsor and between MSs via **adHoc workflow** in CTIS
  (additional communication tool for MSs will be functional mailbox, especially in the beginning)

➢ Overall, there will be the need to work in different systems

Go Live Functionalities

➢ SMS (Substance Management System) process in place in xEVMPD for unequivocal registration and validation of active substances: relevant for registration of Active Substances in CTIS and for the reporting… of SUSARs/ASRs in CTIS and EVCTM

➢ Overall,
- so far high level functionalities defined
- ongoing work to specify detailed requirements and implementation in Q4 to support cooperation at go live…

Post go live Functionalities to be specified further and reviewed with experiences.