

Draft

11th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials Regulation

Date:

- **Tuesday 11th of June 2019**

Chair :

- [REDACTED], European Commission

Participants:

- EC : [REDACTED]
- EMA : [REDACTED]
[REDACTED]
- AT : [REDACTED]
- BE: [REDACTED]
- DE: [REDACTED]
- SE : [REDACTED]
- Everis : [REDACTED] (partim)
- DK: [REDACTED]

1. Adoption of the agenda

The agenda was adopted.

2. Decision tree for the success of progress on CTIS (EC – EMA)

EMA presented the decision tree proposal that was circulated, including some comments from the European Commission. The decision tree is based on the results of the KPI's, checked against the tolerance criteria that the monitoring subgroup have defined. If all KPI are met, the project can continue unchanged.

However, when Everis should not meet the KPI thresholds, different scenario could arise, depending on the number of KPI's that are not met and how far Everis was from the target. The decision tree is ranging the scenario's from issues with the expectations up unto a complete breakdown of trust.

Most difficult will be the problems of predictability and quality as is it not possible on forehand to define what the course of action will be. It was emphasised that the monitoring of the KPI is an ongoing process, and that the subgroup will continue to monitor the results of the upcoming sprints. This message should also be conveyed to the EMA Management Board.

The monitoring subgroup agreed on the decision tree proposal as discussed during the meeting. It was agreed that the KPI, the tolerance criteria and the decision tree could be presented to the EMA management board. The KPI will be monitored and further refined (if needed) during summer, and will then be discussed at the EMA Management Board of October.

Members are invited to send comments to the decision tree to [REDACTED] before the Coordination Group meeting on Friday 14/06.

3. Results for sprints 5 and 6 (EMA – IT4U)

The outcome of sprints 5 and 6 (i.e. fixed price part) were discussed. Some KPI were generated – although the KPI were not designed for this model. The schedule adherence for sprint 5 was not in line with defined thresholds. However, as a whole, the results for iteration 4 (i.e. sprint 5 + 6 + SAT) were positive. There were no blockers remaining.

4. CTIS project update (EMA- IT4U)

Everis was invited for this part of the meeting and explained the interim update slides. He stressed that a critical phase of the project has started today 11th of June. The [REDACTED] on the safety reporting took some more time than foreseen. A new version of the sandbox will be deployed soon.

5. AOB

It is proposed to start the next meeting of the Monitoring Subgroup with the reporting from Everis, in order to have sufficient time to monitor the progress.