

*Draft*

## **10th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials Regulation**

Date:

- Wednesday 29<sup>th</sup> May 2019

Chair :

- [REDACTED], European Commission

Participants:

- EC : [REDACTED]
- EMA : [REDACTED]
- AT : [REDACTED]
- BE: [REDACTED]
- DE: [REDACTED]
- SE : [REDACTED]

### **1. Adoption of the agenda**

The agenda was adopted.

### **2. Presentation of [REDACTED] - European Commission**

[REDACTED] is new in the EU Commission – B4 team and his main focus will be the follow-up of the different governance bodies that are put in place for the CTIS. This ranges from participating to the meetings of the CTIS expert group over the meetings of the CTR coordination group and monitoring subgroup.

### **3. Indicators/metrics to enable measuring the success rate of progress**

A discussion was held on the basis of the document that was circulated. This is an update of the document that was also table on the 15th of May. The basis of the document was the agreed list of Key Performance Indicators. The aim of the discussion is now to define the level of tolerance that is accepted on each of the 8 indicators. The values are for internal use only and are therefore not to communicated to Everis. They should be followed up after each sprint.

Specific comments per KPI:

- Schedule adherence : thresholds accepted as mentioned in the document
- Sprint content adherence: concerns were voiced on the lack of detail with regards to complex issues. It was stressed that the number of items with high, middle and low complexity will be reported for each sprint. The values are maintained.
- Readiness for release: thresholds are accepted for release 1, but will be higher for future sprints as the experience of the team will grow
- Net issues per sprint: for sprint 7, the value "19" is withheld. For future sprints, the value will have to be calculated on the basis of the (non-technical) items in each sprint
- User satisfaction: the mean value should be used. It is propose to test the questionnaire after sprint 7 in order to collect comments.
- Regression test metrics: thresholds as mentioned in the document were accepted
- Test coverage metrics: thresholds as mentioned in the document were accepted
- Security testing metrics: thresholds as mentioned in the document were accepted, but will have to be reassessed after sprint 7

The expectations as mentioned in the document were agreed.

#### 4. CTIS project update

Due to time constraints, Everis was not asked to join. [REDACTED] gave a short update. Monitoring group members are asked to take a look to the presentation that was circulated pre-meeting and formulate questions in writing to EMA ([REDACTED] – [REDACTED] – [REDACTED] – [REDACTED]).

#### 5. AOB

Now that the KPIs and the success criteria have been finalised, both can be taken to the management board. Next step is then the development of a decision tree, to tackle the different scenarios that could arise at the time of evaluation of the concrete results of the KPI. This evaluation is planned for the EMA Management Board in October, after discussion in the Monitoring Group and Coordination Group. EMA will circulate a draft proposal.

Ideally, the decision tree could already be discussed at EMA Management Board on the 12<sup>th</sup> of June. COM will investigate the possibilities of switching the dates of the Monitoring Group (planned on the 11<sup>th</sup> of June) and the Coordination Group (planned on the 14<sup>th</sup>).

*POST-MEETING: due to agenda constraints, it was not possible to switch the dates. The decision tree will be discussed at the Monitoring Group on the 11<sup>th</sup> of June.*