

14th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials

Regulation

07.08.2019

Audioconference

15.30 – 16.30

Draft minutes of the meeting

Chair: European Commission

Date:

- **Wednesday 7 August 2019**

Chair :

- [redacted], European Commission

Participants:

- EC : [redacted]
- EMA : [redacted],
- AT : [redacted]
- BE: [redacted]
- DE: [redacted]
- SE : [redacted]
- Everis : [redacted]
- DK: [redacted];

Actions

- Agreement to extend the sprint duration from 3 weeks to 4 weeks as of the sprint 11 (next release)
- EC to draft an e-mail to ask intermediate results of the sprint 9 and 10

1. Adoption of the agenda

The agenda was adopted.

2. CTIS project update (EMA- IT4U)

Everis presented the results of the KPI for the sprint 8:

- [redacted] sprint 8
- [redacted] (due to [redacted] new major bugs)
- [redacted] [redacted]

The results are [redacted]

Main root cause: items with effort longer than 1 sprint, complexity, inaccurate technical and functional information.

Actions planned

■ additional developers and ■ consultants to reinforce the production capacity. Nevertheless, the benefits of those measures will only be seen in 2 or 3 sprints. Everis team will work on the sprint 10 earlier than expected. One participant highlighted the difficulty for Everis to deliver complex items.

Commission stressed that the results presented are not those expected and the KPI of the sprints 7 and 8 are far from being fulfilled. It is crucial to have corrective actions and find solutions for the sprint 9 and 10.

Everis asked to have more time to deliver the items in each sprint and is particularly committed to improve the net item per sprint which decreases over time.

The group supported the extension of the sprint from 3 to 4 weeks as of the sprint 11 (next release). While the participants recognized the importance to deliver the project, extending to 4 weeks will have a negative impact on the overall timing of the CTR unless more items are introduced in each sprint. To date, the size of the sprint 11 is not defined.

Moreover, this change can improve the timeline adherence but not the quality.

The group asked if the results of the sprint 11 will be known by the time of the EMA management board. Intermediate results of the sprint 11 will be known at the end of September.

3. Internal discussion on results and thresholds – all, without IT4U – 15'

The results of the KPI were examined by the group. The results presented by IT4U are not those expected and the KPI of the sprints 7 and 8 are far from being fulfilled. Despite corrective actions introduced by IT4U early July, it is very likely that the KPI of the sprint 9 and 10 will not be fulfilled either.

The group agreed to send an e-mail to Everis asking to provide intermediate results of the sprint 9 and 10 after SAT, FAT and business validation. EC to draft the e-mail.

The objective is twofold: - sending a signal to the contractor that the current situation is not acceptable and does not meet our expectations and – strengthening the oversight and management of the project by IT4U which is both crucial and urgent.

4. User surveys on performance of the supplier and interaction with the PO's – 10'

Not discussed

5. Upcoming meetings

- 28/08/2019 – 15:00 Monitoring sub-group (sprint 9 results)
- 17/09/2019 – 15:00 Monitoring sub-group (sprint 10 results)
- 25/09/2019 – 9:00 CTR Coordination group meeting (results of release 1)
- 04/10/2019 EMA Management Board