

15th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials

Regulation

28.08.2019

Audioconference

15.00 – 16.00

Draft minutes of the meeting

Chair: European Commission

Date:

- **Wednesday 28 August 2019**

Chair :

- [redacted], European Commission

Participants:

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

Actions

- intermediate reporting to be continued for sprint 10
- Everis to provide additional data on the regression tests
- members of the monitoring sub-group to provide proposed conclusions of the monitoring period to the Commission

1. Adoption of the agenda

The agenda was adopted.

2. Sprint 9 reporting

Everis presented the results of the KPI for the sprint 9 on the basis of a powerpoint presentation (see annex)

- [redacted]

- [redacted] (due to [redacted] new major bugs)
- [redacted] This result [redacted]. This issue is further investigated – Everis will provide additional information, more specifically on the regression tests in the FAT environment and possible cause of the performance issue (action point).

[redacted].
The intermediate reporting after FAT and SAT will be maintained (action point).

Everis has taken corrective actions, but some of them might have an impact only after the delivery of the current release. [redacted]. Therefore, some remedial actions will not be visible in the results from release 10. However, intermediate results of the first sprint from release 11 (sprint 11) will be known at the end of September.

Everis has also put in place an internal audit in order to identify new improvement actions – the results of this audit will be available for the next monitoring sub-group meeting.

With regards to sprint 10, a number of items [redacted] were excluded from the scope, implying that they will not be further developed in the current release. On the other hand, some items that were supposed to be in sprint 10 were already developed and covered in the business validation for sprint 9.

3. Internal discussion on results and thresholds

The results of the KPI were compared with the thresholds that were defined by the Monitoring sub-group – see the table below.

	1. Schedule adherence for critical activities	2. Sprint content adherence	3. Readiness for Release 1 scope	
	% actual/ planned duration (1)	% of items resolved/ items in scope	% of readiness	
Tasks				
Sprint 7				
Sprint 8				
Sprint 9				

[redacted] The intermediate monitoring will be maintained in order to get quick feedback on the (intermediate) result for sprint 10.

4. Preparation of the conclusions from the monitoring period

As the monitoring period comes to an end mid-September, conclusions need to be drafted on the next steps for the CTIS period, and this on the basis of the results of the fixed price part and the release done under the new delivery model.

All members of the monitoring sub-group are invited to share their (preliminary) conclusions in order to formulate a document summarizing the outcome of the monitoring period to share with the Coordination Group (25/09/2019) and subsequently with the EMA Management Board (4/10/2019). Feedback can be sent to the Commission, who will draft a draft proposal to be tabled at the next monitoring sub-group on the 17th of September.

5. Upcoming meetings

- 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