16th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials

Regulation

17.09.2019

Audioconference

15.00 – 16.00

Draft minutes of the meeting

Chair: European Commission

Date**:**
- **Tuesday 17th of September**

Chair **:**
- ⬛⬛⬛⬛⬛⬛⬛⬛⬛, European Commission

Participants:
- EC : ⬛⬛⬛⬛⬛⬛⬛⬛
- EMA: ⬛⬛⬛⬛⬛⬛⬛⬛⬛⬛⬛⬛⬛⬛
- AT : ⬛⬛⬛⬛⬛⬛
- BE: ⬛⬛⬛⬛
- DE: ⬛⬛⬛⬛⬛
- Everis : ⬛⬛⬛⬛ (partim)
- DK: ⬛⬛⬛⬛⬛

Actions

- members are invited to give comments to the conclusions document as discussed during the meeting

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1. **Adoption of the agenda**

The agenda was adopted.

2. **Sprint 10 reporting**

Everis presented the results of the KPI for the sprint 10 (and the complete release 10) on the basis of a powerpoint presentation (see annex). The results of sprint 10 were discussed on the basis of slide 5. As for the release results (slide 11-12-13), some detail was given on the individual results for the whole release (sprint $7 – 8 – 9 – 10$) :

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- ⬛⬛⬛⬛⬛⬛⬛⬛⬛

- ████████ items were finalised and ██ bugs were created, resulting in a net result of ██ items
- ████████████ : ████████████
- ████████████
- ████████████ new bugs were identified. However, analysis is still ongoing to pinpoint the origin and root cause

Regression test results were discussed in more detail. Remedial actions have been already put in place, but some additional actions will only be taken in sprint 13 – still almost 2 months away. The importance of these tests was stressed – they are indicative of the quality of development as a whole. The evolution over time was clarified – this was not clear in the slidedeck.

Additional questions on the whole slidedeck can be transferred to Everis (████████████ ████████████ @everis.com)

3. Conclusions from the monitoring period – discussion

A preparatory draft paper was circulated before the meeting as a basis for a discussion on joint conclusions from the Monitoring Sub-group. A reading of this document was performed.

The group agreed on the conclusions chapter. The quality KPIs are crucial parameters for the project and should be improved. A better graphic representation of the results is needed in order to not confuse the reader with the abundance of data.

In the conclusions, a very basic assumption for the audit date is made based on the net items result of release 10. It was emphasised that this is a very basic estimation that does not take into account the complexity of the project. This will be clarified in the text, and a more substantiated calculation will be delivered by EMA end of September.

With regards to the decision tree, there is a consensus that option 2 would be the most appropriate ("Continue with Everis and monitor the improvement plan").   It is clear that there is then a need to prolong the monitoring period. Concrete steps were discussed:

- Increase focus on the functionalities on the basis of the identified business blockers and clusters instead of purely focussing on individual items. It was stressed that this should be seen in a holistic way. In practice, an end-to-end exercise with sponsors and member states should bring more clarity on the exact status of CTIS, getting a view on which bugs are blocking the functionalities. It is expected that such exercise would lower the workload to do before the audit.

- A higher quality of work needs to come from Everis. Both on the issue of bug generation during sprints ("net items") and the regression testing, further corrective action is expected. It was explained that the contract with Everis currently is based on the KPI, and is not very different from the fixed price part. There is a willingness to change the contract in order to incentivise Everis towards a better performanc

There was no consensus on the introduction of a lead PO. It was pointed out that a fast decision process is already in place. However, there is still room for improvement. The need for clear communication and fast decision making was stressed. The need for a lead PO will be further assessed in the upcoming sprint on the basis of concrete interactions.

All members of the subgroup are invited to comment on the draft document by Thursday 19/09 EOB. A new consolidated version will be circulated at the latest on 23/09 as a preparation for the Coordination Group telco on 25/09.