Draft

13th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials Regulation

Date:

- **Wednesday, 17th of July, 2019**

Chair :

- , European Commission

Participants:

- EC :
- EMA : ,
- Everis :
- AT :
- DE:
- DK:
- SE :

1. Adoption of the agenda

The agenda was adopted.

2. Sprint 7 reporting – IT4U

Everis explained the results for the KPI reporting – please refer to the powerpoint presentation (2019_07-17 CTIS update Monitoring sub-group_ v1 9 - see annex). Slides 4, 5 and 6 were discussed in detail. It was emphasised before the meeting that the EMA tresholds mentionned in the slides are not to be confused with the tresholds set up by the Monitoring Subgroup. The EMA tresholds were communicated to Everis .

Discussion in detail:

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- : the KPI that was agreed is presented in bold. The result shows that out of the items that were in the sprint scope, were delivered. items were started but not completed, and items were re-opened before the FAT (factory acceptance testing – own Everis testing). In order to create more clarity, Everis was asked to provide an overview (see annex) that summarises the evolution of the number of items in the sprint.

- The KPI result would therefore be [redacted] (i.e [redacted]). After the next step (SAT – site acceptance testing at the EMA enviroment), 8 items were reopened, leading to [redacted] items being delivered for business validation. [redacted] items were closed after validation by business.

- [redacted]

- [redacted]: next to the [redacted] items that [redacted] the SAT (see above), there were [redacted] bugs created. These break down in [redacted] bugs. This leads to a net number of items of [redacted]

As planned, a more complete set of KPI (including metrics on regression testing, test automation, security testing and user satisfaction) will be available for the next sprint.

Everis recognises that the result is below expectations, and has already proposed some corrective measures (see also slide 7). Examples are increased sanity checks to identify dependencies and improve the accuracy of estimates. For future sprints, reserve capacity will be foreseen to tackle carry-over items.

3. Fixed price part : remaining items & results of regression testing

The 3 remaining items of the fixed price part will be delivered during sprint 8. The regression issues have been added to the list of items for which a business value needs to be assigned.

4. Release 2 planning

The timeline for the adoption of the release 2 planning was briefly discussed on the basis of slide 10. Product Owners have been working on business blockers (i.e. key functionalities for which no appropriate alternative way of working in the Clinical Trial Information System could satisfactorily solve the needs of a typical user). These business blockers should be prioritized in the different workstreams. The plan for release 2 will be adopted by the CTIS expert group on the 1st of August.

5. Internal discussion on results and thresholds

After Everis stepped out of the meeting, the KPI results were briefly discussed. In general, the results are disappointing. The number of (net) items delivered is rather low, especially when compared to the size of the backlog. This implies that the time to deliver the auditable release would be longer than anticipated. Positive point is that the all items that passed the SAT also passed business validation.

The impact of the corrective actions will (in part) be visible in the sprint 8 reporting. Combined with the extra numbers, this will give a better picture.

6. AOB

- The new program manager, [redacted], presented himself

- The survey that will be used to measure the user satisfaction is still under discussion. COM asked to finalise the survey in order to have a fixed set of questions to measure user satisfaction. The final version will be circulated to the Monitoring Sub-group for information.