Draft

5th Meeting of the monitoring sub-group of the Coordination Group

EU Clinical Trials Regulation

Date:

- **Wednesday 20th March 19**

Chair :

- ▮▮▮▮▮▮▮▮ , European Commission

Participants:

- EC : ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
- EMA : ▮▮
- AT : ▮▮▮▮▮▮▮▮▮▮ ;
- BE: ▮▮▮▮▮▮
- DE: ▮▮▮ ;
- DK: ▮▮▮▮▮▮▮▮▮▮▮
- SE : ▮▮▮▮▮▮▮

Adoption of the previous minutes

Comments to the minutes should be sent directly by email to ▮▮▮▮▮▮▮ .

Presentations

1. **IT4U delivery**
- The development of the sprint 5 is progressing as expected and are on track with the baseline plan, even if some activities are slightly behind schedule there are not affecting the key milestones.
- The main activity of the feature management backlog team during the last period was to setup the new delivery model and supporting the backlog consolidation task force

Interactive session for sprint 5

has been moved to end of April. Champions will check the sprint 5 new functions and bug fixes during this interactive session.

Regression test cycle

- ▮▮ **new bugs have been found** during the test cycle (▮▮ already identified in previous test cycles)
- EMA is analysing if the bugs are duplicates , bug already exist but not in backlog, and if there are bugs specific for the safety reporting)
- These bugs will be addressed in the new iterative model

- Performance test is not finalised yet.

Sandbox : important to have as a tool to test the end to end business scenario , will be available at the end of March

2. New delivery model

A quick presentation of the new delivery model has been given by ░░░░.

The planning of the UAT depends on the decision taken by the champions of the number of sprints needed to arrive to a suitable version. ░░░░ explained that this is not the task of the coordination group to decide on the prioritisation and sprint content.

- o There is still some questions regarding the prioritisation.
- o EMA explained that a subset of the backlog (+- 650 issues) have been sent to the champions for review/analyse
- o Champions must review the list and determine for each issue if they must be fixed for the UAT (business value = 3) , after UAT (business value = 2) or after go live (business value = 1).
- o 1/3 (around 145 issue) of the list has already been reviewed by the champions. They explained that this 145 issues needs to be checked again to verify if there are not duplicates or if they are not obsolete
  - ▪ Still not clear for EC what will happened now with these 145 items and if EMA can feed the sprint 1
- o Champion asked some more clarity on the process of prioritisation
- o EC request that during the next monitoring group a clear and short presentation of the backlog consolidation progress is given.
- o The availability and workload of the champions has been raised

Progress status update on the pre UAT 0.7 bug fixing: The group acknowledged the progress in fixing the bugs but it is important to close them completely. Very few bugs are closed. Is the status 'closed' indicate that the bug is really fixed ? EMA : After each sprint a clarification session with the champions will be done to check if they are closed or not.

3. Review metrics

The group agrees with the current monitoring of the CTIS so far. EC asked to add one slide on the progress for the consolidation of the backlog and prioritisation to feed the first sprint.