

Draft

12th meeting of the monitoring sub-group of the Coordination Group on the EU clinical trials Regulation

Date:

- Monday 24th of June 2019

Chair :

- [REDACTED], European Commission

Participants:

- EC : [REDACTED]
- EMA : [REDACTED]
[REDACTED]
- AT : [REDACTED]
- DE: [REDACTED]
- SE : [REDACTED]
- Everis : [REDACTED])
- DK: [REDACTED]

1. Adoption of the agenda

The agenda was adopted.

2. CTIS project update (EMA- IT4U)

Everis explained the update slides. A lot of activity took place in the last couple of weeks.

- The safety reporting module will be accepted on 2/7/2019
- Concerning the fixing of 52 pre-UAT bugs : 49 were closed. 1 bug is to be resolved in sprint 7 of the new delivery model. 2 bugs are linked to technical issues with the liferay platform – the latter will be taken up in the monitoring subgroup meeting on the 17th of July
- [REDACTED] saw approximately [REDACTED] items identified. Out of them, [REDACTED] were unknown from [REDACTED]. Additionally, [REDACTED] out of [REDACTED] test case were blocked due to an issue related to [REDACTED]. This point will be taken up again during the telco on 17/7
- Sprint 7 is on track – the scope for sprint 8 was approved

In the weeks to come, the plan for release 2 will be finalised. PO's stress that they need a complete overview of the backlog in order to set priorities. Furthermore, clarity is needed on the open tickets

in Jira compared to Confluence. The release plan is high-level, but it is assumed that release 1 is fully delivered, and that the 120 to 160 items in release 2 will have a high impact on business (and be part of the auditable release).

The Commission emphasised that scheduling issues should be tabled immediately, in order to anticipate on possible delays.

3. Planning for the MSG meetings during summer, reporting dates and content

The MSG meetings will take place every 3 weeks and will follow the sprints. The KPI's for the sprint will be transferred a couple of days before the teleconference. In light of the holiday period, alternates can be nominated to the Commission to receive the documentation and invitations for the telco.

It was also proposed to plan a Coordination Group meeting on the 25th of September, in order to bridge the limited time between the delivery of the Release 1 results and the EMA Management Board (4/10).

4. AOB

A new program manager, [REDACTED], took up his role and will be present at the Sevilla meeting