

Meeting of the monitoring sub-group of the Coordination Group

EU Clinical Trials Regulation

Date:

- Thursday 2nd May 2019

Chair :

- [REDACTED], European Commission

Participants:

- EC : [REDACTED] s
- EMA : [REDACTED]
[REDACTED] ;
- Everis : [REDACTED]
- AT : [REDACTED] ;
- BE: [REDACTED]
- DE: [REDACTED]
- DK: [REDACTED]
- SE : [REDACTED]

Adoption of the previous minutes

Comments to the minutes should be sent directly by email to [REDACTED].

CTIS project update by Everis

- Sprint 5 is finished and sprint 6 is going well
- There is still a delay in Development:
 - Development end scheduled for May 6 instead of May 2
 - 21 items have been closed by the CT Champions out of the 52
 - The "3rd batch bug fixing validation" scheduled for 2/5 will take place on May 7
- Note: Sprint does not end with the development phase:
 - 3 meetings are still planned during the month of May in order to validate the work done by Everis
 - PO's should validate the bugs fixed by Everis during the next 3 calls "Pre-UAT7 bug fixing / Validation 3/5".
- Crucial moments:
 - The demo of iteration 4 on May 23rd
 - [REDACTED] scheduled for June 7
- Comments:
 - [REDACTED] s particularly important as it covers all functionalities for the entire cycle

- Question:
 - Does this [REDACTED] check all the features developed so far for the entire platform?
- Conclusion
 - The development is going well, with a few days delay
 - Sprint 6 is globally on Track
 - It would be useful to have more information on other testing criteria related to Safety or Penetration

Discussion on KPI's

Meaning and use of KPI's

1st KPI: [REDACTED]

- Question:
 - Is it necessary to limit the number of items in each sprint?:
 - Should Everis' effort or work be limited to the number of items in each sprint?
 - Could Everis' team fix bugs that are not necessarily expected in this sprint, once their work is done?
 - *Sprint should be by regular items and back up items distinguished.*
 - *Resolve is not closed, often additional bugs are raised by SAT and especially by business*
 - *Additional KPI covering the preparation work like Backlog Grooming, Analysis & Design*
 - *Amount started in backlog and are now... would be useful too, also these activities started in March with new supplier.*
- Answer:
 - Each Sprint has a scope that is pre-set with PO's
 - Flexibility:
 - Everis could stop solving some bugs to focus on others depending on the evolution of the sprint
 - It is necessary to keep a certain flexibility in order to ensure a good efficiency of the team
 - Some bugs can be more complex than expected
 - The objective is of course to solve 100% of the items in the sprint.

2nd and 3rd KPI's: [REDACTED]

New/reopened bugs drug SAT or business validation

- Comments of Everis:
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- Remarks:
 - Others «items or issues" could appear and not necessarily bugs
 - There is a need to change the terminology of what is being measured
- Question:
 - Is this process done automatically?
 - What is the level of automation?

- Penetration could also be assessed
- Answer
 - [REDACTED]
- Conclusion
 - These 2 performance indicators could also be discussed with the Project Owners who are in the front line

4th KPI: [REDACTED]

- Comment of Everis:
 - [REDACTED]
 - [REDACTED]
- Relevant questions:
 - [REDACTED]
 - [REDACTED]
 - Closed items for POs should also be closed for all end users
- Observation:
 - It would be advisable to have a UAT before the Audit:
 - This UAT would really validate the readiness before the Audit
 - There should therefore be a time period between the end of the quality resolution, UAT and Audit.

5th [REDACTED]

- Comment of Everis:
 - [REDACTED]
 - [REDACTED]
- Remark:
 - The added value would also be:
 - To show duplicated items that are eliminated
 - To get a more global vision:
 - not only at each sprint but for the project as a whole
 - It would be very valuable to be able to benefit from a broader vision
 - The measure of Backlog management is of interest not only for service provider but also for Experts and PO's
- Proposal by [REDACTED]:
 - Possibly add a new KPI that better reflects the work of POs in backlog management

6th KPI [REDACTED]

- Comment
 - [REDACTED]
 - [REDACTED]
 - This KPI is not the subject of any further comments

7th KPI [REDACTED]

- Comment by Everis:
 - This soft indicator is not focused on testing
 - [REDACTED]
 - [REDACTED]
- Remarks:
 - [REDACTED]

- The essential aspect of this indicator is to measure interactions
 - It would be interesting to have a Baseline:
 - Be able to compare users' perceptions now, and in 6 months
- [REDACTED] argues that there should be more other testing tools focused on penetration and safety

Debate in the absence of Everis

- Need to assess the performance of the service provider as accurately as possible:
 - What are the real criteria for success?
 - What can we expect as a "success" at the end of the 6 months?
 - What is the acceptable level of tolerance: 85%, 100%?
 - For each KPI what would make sense for all participants after 6 months?
- Conclusion
 - [REDACTED] suggested that participants send their comments and proposals:
 - The feedback & questions will be addressed to [REDACTED] and the whole group by next Wednesday