Meeting of the monitoring sub-group of the Coordination Group
EU Clinical Trials Regulation

Date:
- Thursday 2nd May 2019

Chair:
- [Name], European Commission

Participants:
- EC: [Name]
- EMA: [Name]
- Everis: [Name]
- AT: [Name]
- BE: [Name]
- DE: [Name]
- DK: [Name]
- SE: [Name]

Adoption of the previous minutes
Comments to the minutes should be sent directly by email to [Name].

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
  - [Name] scheduled for June 7
- Comments:
  - [Name] is particularly important as it covers all functionalities for the entire cycle
• Question:
  o Does this check all the features developed so far for the entire platform?

• Conclusion
  o The development is going well, with a few days delay
  o Sprint 6 is globally on Track
  o 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: 

• Question:
  o 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:
  o Each Sprint has a scope that is pre-set with PO’s
  o 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: 

New/reopened bugs drug SAT or business validation

• Comments of Everis:
• Remarks:
  o Others «items or issues” could appear and not necessarily bugs
  o There is a need to change the terminology of what is being measured

• Question:
  o Is this process done automatically?
    • What is the level of automation?
Penetration could also be assessed

**Answer**

- ...

**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:**

- ...

**Relevant questions:**

- 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 KPI: [Redacted]

**Comment of Everis:**

- ...

**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**

- ...

**This KPI is not the subject of any further comments**

7th KPI: [Redacted]

**Comment by Everis:**

- This soft indicator is not focused on testing

**Remarks:**

- ...
- 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
- 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
  - suggested that participants send their comments and proposals:
    - The feedback & questions will be addressed to and the whole group by next Wednesday