

Thursday 7 March 2019

Draft

4th Meeting of the monitoring sub-group of the Coordination Group

EU Clinical Trials Regulation

Date:

- **Wednesday 6 march 19**
 - Audioconference 3.30 -5 pm (Brussels time)

Chair :

- [REDACTED], European Commission

Participants:

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

Minutes of the meeting

Introduction

- [REDACTED] congratulates the agency for contract signature
 - This signature puts the project in a different perspective:
 - it allows for monitoring from now on

Adoption of the agenda

- It is agreed that comments on the draft of the previous minutes will be sent in writing
 - Agency will make the comments and provide answers

Project update by EMA

- Contract signed with the service provider constitutes a whole for the deliverable
 - Contract is divided into 2 parts:
 - the fixed-price part
 - the "New Delivery model".
- The short-term priority is to fix the 52 bugs in the fixed price contract:
 - they will have to be fixed within the next two months, between March and May 2019
- In the medium term 41 bugs will be fixed:

- As part of the New Delivery model according to the priorities defined with the champions
- Release 0.9 is proceeding as planned
 - Delivery is expected to close by the end of May 2019
- The consolidation of the back log is progressing very satisfactorily with the UAT champions.
- The next step is now to generate more details on the iterative part :
 - This process should start next week

Discussion

- Participants would like more information on the prioritization of these few hundred bugs
 - What feasibility for a realistic planning to fix these bugs?
 - The clock is ticking : 6 months from now
- Is it possible to organize a UAT at the end of May to check if the system is working properly?
 - What is planned: a demo or a test?
- Participants want to have metrics that can be used to evaluate IT4U's performance
- EMA answer:
 - A demo is planned but no testing
 - Prioritisation has yet to go forward:
 - Champions will decide on the basis of criteria in line with business values
 - A business value will be allocated to each item
 - The list is systematically implemented in Jira
 - Meetings with champions are held weekly
 - This process will be completed by June 19
 - It will be possible to determine the N of sprints required before the UAT
 - This process makes it possible to establish a list of items to be analysed according to 3 essential criteria related to business value:
 - Bugs or items to fix:
 - Before the audit
 - Before the GO LIVE
 - After the GO live

Preliminary Conclusion:

- **Sand box**
 - It would be useful to have a Sand box at the end of May so that champions can test and familiarize themselves with the features.
- **Preparation of the Management Board**
 - A priori EMA wishes to present the Big Picture to the MB as well as the metrics defined in the contract
 - [redacted] and [redacted] asked to present a precise planning & timeline:

Presentation of IT4U

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- Sprint 5 and 6 is going according to plan :
 - There's just a little delay for sprint 4
- Manual testing is complete:
 - there is no major deviation
- R0.9 does not record any BCM, which is quite reassuring
- Sprint 5 of R 0.7 includes 35 of the 52 bugs:

- 17 bugs have already been fixed
- The cycle is scheduled to end on March 13

Discussion

- IT4U:
 - There is no UAT planned at the end of R0.9
 - From now on, the process will be simplified since there will only be 1 backlog for 1 system that integrates both the development of the Data Base and Safety
- Slide 7 showing the Actual % of completion and SPI is indicative of the type of report to be provided:
 - Extra note on Schedule Performance Index (SPI):
 - *The Schedule Performance Index indicates how efficiently project is actually progressing compared to the planned project schedule.*
 - *It gives information about the schedule performance of the project.*
 - *“The Schedule Performance Index (SPI) is a measure of schedule efficiency, expressed as the ratio of earned value to planned value.”*
 - *It is the efficiency of the time utilized on the project:*
 - *SPI the performance of time in a unitless dimension:*
 - > 100%: *project ahead of schedule*
 - = 100%: *project on time*
 - < 100%: *project delay*

Conclusion

- [REDACTED] reminded IT4U that it is necessary to focus on monitoring and clearly mention deviations from the schedule:
- Everis has been asked to provide an update for each release on:
 - **Completion level**
 - **Schedule Performance Index**
 - **Forecast end date**
 - **Baseline end date**
 - **Variances between Forecast and Baseline**
 - This will allow for better monitoring and for clear Project Picture.
- Next meeting is planned on 20 March 2019.
- A date must be set for the next coordination meeting at the end of March