

Friday 15 of February

Draft

3rd Meeting of the monitoring sub-group of the Coordination Group

EU Clinical Trials Regulation

Date:

- **Wednesday 13 february 19**
 - Audioconference 4 -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

Adoption of the agenda

- Minutes were adopted: they will integrate remarks of EMA and ES

1st Topic: Project update by EMA

Contract

- The new contract with IT4U should be finalized in the coming weeks
 - Negotiating this contract is very challenging
- Most of the contract's restructuring elements have been adopted
 - The quality criteria and the penalty model have yet to be resolved
- Part of the contract is based on the fixed price model:
 - It includes the resolution of 52 bugs identified during pre UAT 7 that do not require further analysis
 - These 52 bugs can be fixed in the very short term and validated with the help of the Champions
 - Bugs will be fixed in sprint 5 and sprint 6 which takes place in parallel with the development of R0.9
 - Other more complex bugs and CR's should will be treated later in the iterative part

- The contract would provide more flexibility for the execution of iterative sprints
 - Not all aspects of the timeline are determined by the restructured contract.
 - During the iterative part, it will be possible to determine which releases to include in the next audit

Next UAT and Audit

- Timing of "UAT of the audit version", formerly called UAT "0.7", and the audit will be decided by Coordination group: agreeing on what is required for audit
 - As safety reporting is now delivered prior to the audit, all the time after the audit is for new functionality:
 - No further time investment needed for building safety reporting
 - More capacity will be allocated after the audit

Timeline


- Ambition is to reduce the delay somewhat by combining elements of safety and the portal
- Merge process, which includes the development of safety reporting, R 0.9, both sprint 5 and 6 and the resolution of the 52 bugs in the pre-UAT should end in June, just before the iterative part
- A first significant deadline should be July after the sprint 1 .

Methodology

- Methodology integrates a new deliverable model
- The development will be agile, iterative, according to defined cycles:
 - 1 year for vision,
 - 3 months for scope definition,
 - Analysis, design, sprint organization and testing: \pm every month
- At each cycle decisions will be made in the short term
 - The effort will be quantified for each sprint
- The champions will have the opportunity to meet IT4U managers every three weeks
 - The business value will be determined by the champions
- Consolidation of the backlog continues in 9 steps
 - Purpose is to be able to determine what will be allocated to each sprint
 - Main objectives are to eliminate duplicate and allocate a business value to all times
- Some process issues need to be clarified, including:
 - prioritization of items,
 - integration of all champions, experts and MS's into the process

2nd topic: Presentation IT4U

R 0.9

- The development of the release 09 is proceeding according to schedule
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High level plan

- Slide 6 shows:
 - Content of the Merge part which will run according to a fixed Price contract
 - The more flexible iterative part according to the Agile mode
 - Sprint 1 and 2 will focus on CR's and on the "left bugs" or identified defects

Handover

- The handover is going according to plan :
 - There are no significant changes from the presentation of 15 days ago
- Transfer knowledge and technical transfer is almost completed
- Asset handover takes longer:
 - Migration to the EMA repository

Summary

- The contract is expected very soon
- Backlog management requires a lot of resources
- Methodology is still discussed between EMA & IT4U
- The timelines and sprint/release cycle will be further clarified