Federal agency for medicines and health products

CTR EU Portal and Database

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Activities since User Acceptance Test6, UAT6

- Governance adapted to context: simplified and more agile.
  - Clinical trials expert group (co chaired EMA – MS, with EMA and member states, can decide, provides the priorities on the change requests) who reports to the CTR Coordination group (EMA, Commission, MS)

  -> Very much welcomed

- Prioritisation of future change requests via Moscow (*must haves, should haves, could haves, …*) technique.
- Member state Program interface API group mandate supported by CTR coordination group.
- Safety specifications are being drawn.
- Preparation for testing of release 0.7
  - UAT champions (test scripts, acceptance criteria)
- Access to a sandbox based upon release 0.6.

Prioritisation of future change requests

- From UAT6 feedback (principal feedback: usability) and further workshops with member states, EMA prepares a long list with possible change requests, member states use the Moscow technique to indicate the priority for each line:

  Must Have
  Should have
  Could have
  Would not have

- And consolidated feedback (based upon median score with possible comments) goes to EMA. Priorities will be decided upon (e.g. available budget, timing).

- This exercise was iterated several times: with clear conclusive priorities for the member states (e.g. type of dashboard to aid the workflow, the API V1).

Preparation work for testing release 0.7 (1/3)

- On this release 0.7 –> audit is planned -> date of CTR live will be defined.

- User acceptance testing: UAT, 2 weeks **on site**, 4 weeks **off site** testing.

- The four weeks off site testing is meant to cover the test scripts which could not be tested in the 2 weeks on site – owing to time, but will also be taken into account for the audit' findings.

Preparation work for testing release 0.7 (2/3)

- Test scenario's : are representative for daily work, covering end to end (from initial submission to publication, substantial modifications, art 14 adding extra Member state concerned, and e.g. an unexpected event to publication).

- Need to cover the happy flow, but also the unhappy flow (e.g. lapsing a timer).

- Scripts are now being finalized for UAT7, with acceptance criteria. Is a Huge work.

- Member state API (application programmers interface) testing is also being planned. A large simultaneous operation between human testing of release 0.7 and verifying the output on the API.

- On the 5th November a Pré–UAT7 starts to verify (similar test scripts) if system is ready to be tested in UAT7.

Results from Pre-UAT7 (5-15 Nov 2018):

- Although substantial progress, the unanimous conclusion of both participating member states as sponsors was: EUDP is not ready for UAT7.

- API (Application programmers interface for member states) ready for UAT7, although fixes to be done.

- Continuous *access* to the Pre-UA7 environment.

Next steps:

- More agile working with smaller incremental steps, with intense implication of member states.
- Inside the EU consortium: internal change of supplier (the one for release 0.9 - the safety release - does now also release 0.7).
- Release 0.8 is meant for bug fixing (correcting the audit findings) and release 1.0 is the go live release.

- Consolidation of all bugs to be fixed into one list, then time and cost estimations for each line (or the most priority ones), then UAT7, followed by audit.

- Timeline (to be confirmed): bugs fixed till April 2019, followed by implementation of priority change requests till summer.

- Further planning awaited.

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