



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Document 57

CTIS project update for the Monitoring subgroup of the EU CTR Coordination Group

29 May 2019





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Progress Status Update – Reporting Period

KEY HIGHLIGHTS

- **[Implementation team]** The list below shows the key activities undertaken by the implementation team during the reporting period:
 - The main Safety Reporting workflow functionalities have been presented to the Expert Group. The last Interactive Session on Sprint 6 improvements will be held on 28/05 with the CT Champions
 - Another 19 bugs (plus one with conditions) were validated and closed within the R0.7 bug fixing scope. In total 50 items have been shown to the Product Owners and 49 are closed out of the 52. In the last session 5 items were shown and closed from the R0.7 patching scope
 - The FAT testing of the Sprint 6 development has been successfully completed
 - Iteration 4 (encompassing Sprints 5 and 6) SAT testing started on 20/05 and planned to be completed by 28/05, with 2 days of delay against the baseline
 - The official set of deliverables, together with the analysis of the performance issues, were sent to EMA for review by 24/05 (which is a key contractual milestone). The testing reports will be shared after a successful SAT.
- **[DevOps]** The sandbox environment was updated on the 13/05 with the latest stable CT version of Sprint 6 (V0.9.6.4)



Progress Status Update – Reporting Period

KEY HIGHLIGHTS

- **[Feature Backlog Management team]**
 - **Analysis & Design:**
 - Iteration 2: closed with 41 items analysed, 33 items completed
 - Iteration 3: launched and on-going. 43 items in the scope
 - **Release Plan:** endorsed by CTIS Expert Group
 - **Sprint Plan:** 1st sprint plan of the new model agreed (Sprint 7)
 - **Backlog Management:** - Continue with backlog grooming sessions.
 - Continue providing Business Value on the historical backlog
 - Continue linking the backlog issues with the Product Vision milestones, especially for the audit.
 - Identify items that won't require Analysis & Design prior to their implementation and categorise them
 - Review new and re-opened backlog items
 - Establish the process to manage technical backlog items
 - **Overall and change management:**
 - New Delivery Model setup activities:
 - Deal with POs daily communication
 - Set-up the future operational model communication / presentations
 - Improve communication and training:
 - Sponsor POs and MS Rapporteurs appointed and engaged, on-boarding session on 13th May
 - Analysis of the current communication channels and tools related to the new model (meeting with [redacted] and [redacted])
 - Propose continuous improvement actions:
 - Organise and conduct a Lesson Learnt sessions



Safety Reporting (Release 0.9) Progress Status Update – Reporting Period

Tasks	Actual % completion	Expected % completion	SPI	Forecast end date	Baselined end date
Iteration 4 (Development phase)					
Implementation and testing					
Regression testing cycle 1					
Sandbox environment preparation					
Sprint 5					
Sprint 6					
Development					
FAT of Sprint 6					
SAT of Iteration 4					
Interactive session on Sprint 5					
Interactive session on Sprint 6					
Demo on Iteration 4 (*)					
Regression testing cycle 2					

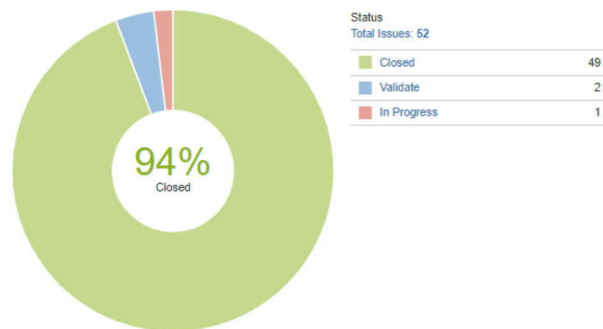
(*) Date changed at POs' request to enable a good presentation on adobe.



R0.7 (52) bug fixing Status Update – Reporting Period (13/05 - 24/05)

Tasks	Actual % completion	Expected % completion	SPI	Forecast end date	Baselined end date
R0.7 bug fixing in Iteration 4					
Implementation and testing					
Sprint 5					
Sprint 6					
Development					
FAT of Sprint 6					
SAT of Iteration 4					
Bug fixing validation					
1 st batch					
2 nd batch					
3 rd batch					
4 th batch					
Demos of the reopened ones I.					
Demos of the reopened ones II.					

Progress Status Update – preUAT7 Bug Fixing

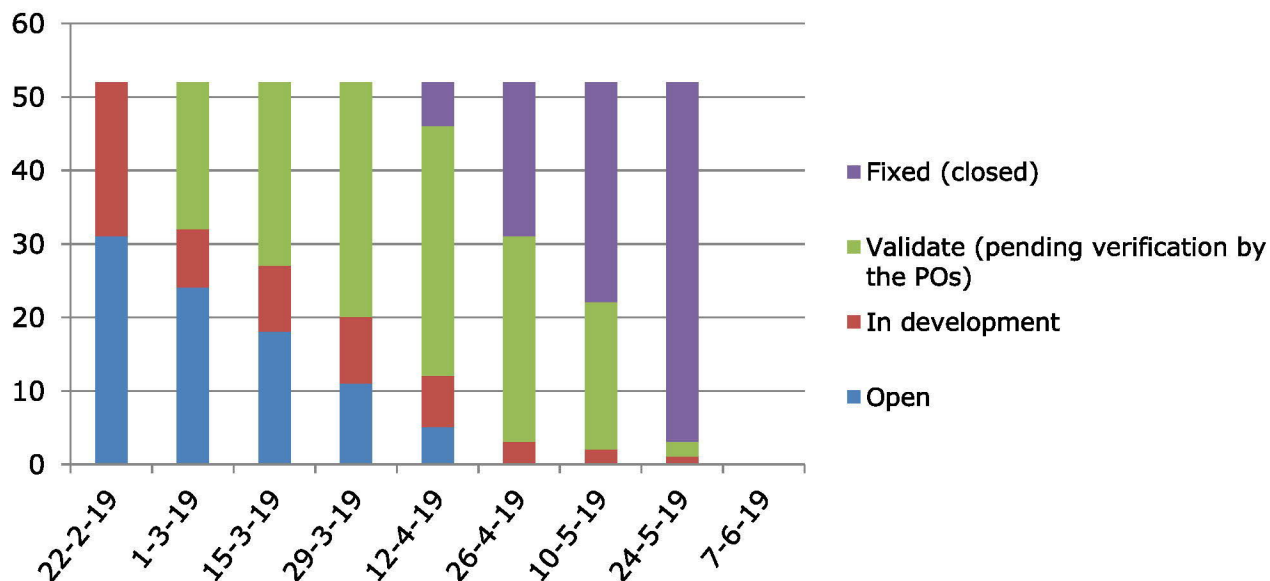


- In the 4th and 5th bug validation sessions another 20 bug fixes were presented to the Champions and 19 of them were successfully closed. One more will be validated by EMA Tech and Business Teams.
- The last 2 will be shown in the last session, scheduled for 06/06 together with the next batch of the pre-UAT bug fixes.

Priority	IN PROGRESS	VALIDATE	CLOSED	T:
🚫 Blocker	0	1	0	1
🔴 Critical	0	0	7	7
🔴 Major	0	1	25	26
🟢 Minor	0	0	15	15
🟡 Trivial	1	0	2	3
Total Unique Issues:	1	2	49	52

Progress Status Update – preUAT7 Bug Fixing

- Net progress of the period



Progress Status Update – Regression Testing

Regression Test Cycle 1:

- After the code merge of releases R0.7 and R0.9 (Safety Reporting), the Regression Test Cycle 1 was performed in February
- The Safety Reporting regression bugs that were identified within this cycle (21) have been fixed in the context of the Safety Reporting delivery
- The other outstanding issues have been catalogued in the backlog to allow easy identification and management

Regression Test Cycle 2:

- A second regression cycle is planned after the successful delivery of Safety Reporting in order to identify regression issues caused since the Regression Test Cycle 1 was run and make sure that the quality has not decreased. The findings of this second cycle will be added to the existing cycle 1 issues, to come up with a final “Regression backlog” to be fixed during the forthcoming iterations
- The Suite for cycle 2 will be improved as compared to the one used in cycle 1 by reviewing:
 - The findings from pre-UAT activities, including the 52 R0.7 bugs in scope of the [REDACTED].
 - The focus areas with EMA Business Team and adjust the test coverage accordingly.

KEY HIGHLIGHTS

- **[Sandbox environment]**
 - The latest application version of Clinical Trials will be deployed into the Sandbox environment after the successful SAT testing (28/05). The final deployment date to be confirmed and communicated to EMA.
- **[Implementation team]**
 - Sprint 6 development/testing scope:
 - Validate the remaining R0.7 bug fixes with the Product Owners (1 item with EMA Tech team)
 - Demo the next batch of pre-UAT bugs from the R0.7 patching scope (Dec '18) (37+16)
 - Complete the SAT testing on the Safety Reporting delivery
 - Start the Regression Testing Cycle 2 with the improved Test Suite (29/05 -> 11/06)
 - EMA to review all the official deliverables of R0.9 and R0.7 bug fixing streams and IT4U to update them according to the feedback provided

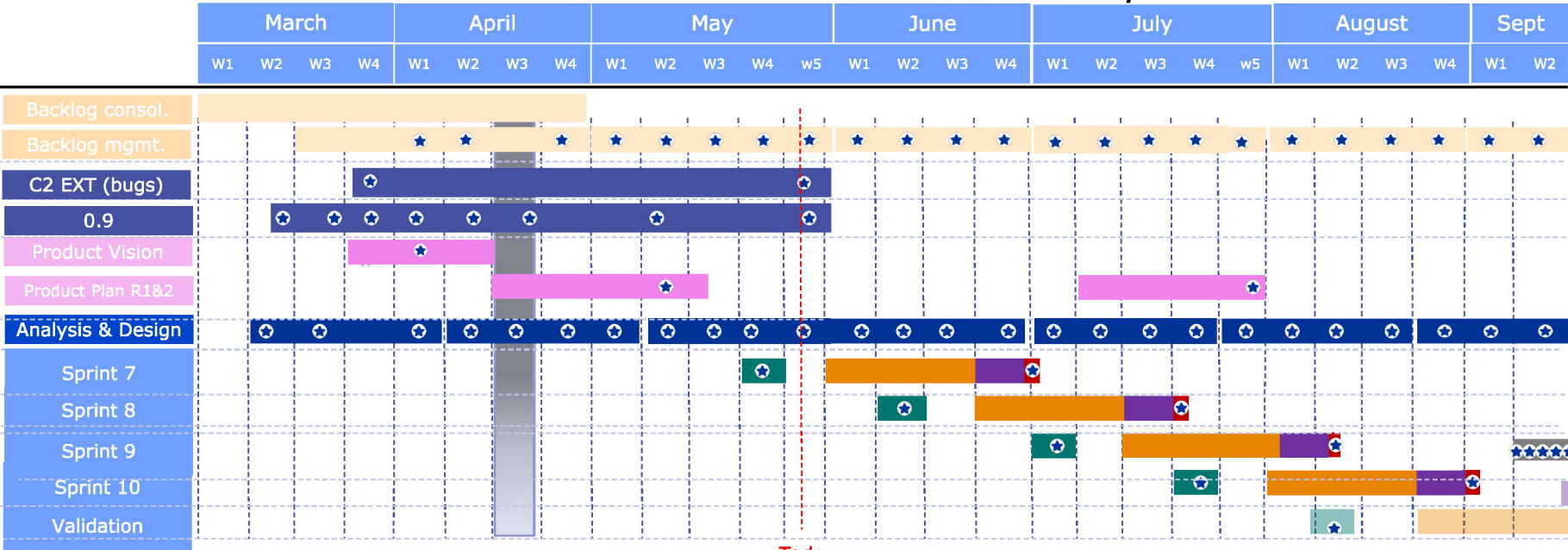
KEY HIGHLIGHTS

- **[Feature Backlog Management team]**
 - **Analysis & Design:**
 - Iteration 3: expected delivery date – 7th of June
 - Iteration 4: to be launched – 5th of June
 - **Sprint Plan:** To be put in place on the 11th of June
 - **Backlog Management:** - Continue with backlog grooming sessions.
 - Receive on the 7th of June the integrated Business Value on the historical functional backlog (for MS PO) and link them to Product Vision Milestones, with focus on audit items
 - Identify “track fast” items and discuss them
 - Review new and re-open backlog items
 - Start managing technical backlog items
 - **Overall and change management:**
 - Continue setting up the New Delivery Model:
 - Prepare the implementation of KPIs
 - Improve communication and training:
 - Finish the As-Is and To-Be proposal of the current communication channels and tools related to the NDM
 - Propose continuous improvement actions:
 - Define continuous improvement actions based on Lesson Learnt sessions

Preparations for new delivery model

Please note: ***UAT and Audit dates will depend on the decision on scope of the auditable release by the EU CTR Coordination Group***

Release
1



Today

Backlog consolidation & management (1 meeting per week)
Release Planning (5 meetings per year in total)
Analysis and Design (1 meeting per week)
Sprint Planning (1 meeting per week)
Development
SAT
Sprint Validation (1 day)
Release Validation (1 week)
Envisaged meeting (onsite or offsite)



ANNEX



Progress Status Update – [REDACTED]

Existing Bugs (raised before Regression Testing Cycle 1): [REDACTED] (Not Closed)

Blocker	Critical	Major	Minor	Trivial
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- Sources:

- Backlog of R0.7 Minor and Trivial issues (to be prioritized and implemented throughout the Iterative Delivery - June 2019 onwards)
- R0.7 Bugs identified as part of R0.9 Testing cycles (to be prioritized and implemented throughout the Iterative Delivery - June 2019 onwards)
- R0.7 Tolerance List bugs: to be delivered with the [REDACTED] - May 2019
- preUAT7 bugs under [REDACTED]: to be delivered with the [REDACTED] - May 2019
- The nature and categories of these bugs will be analyzed as part of the Backlog grooming activities

- New Bugs** (these issues are under analysis to be properly typified): [REDACTED] (Not Closed)

- Sources:

- [REDACTED] R0.7 codebase merge bugs
- [REDACTED] **R0.9 codebase merge bugs**
- [REDACTED] unidentified R0.7 bugs
- [REDACTED] bugs requiring additional testing to verify their source

Blocker	Critical	Major	Minor	Trivial
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- These bugs, alongside with other new bugs that will be found in [REDACTED] (May 2019), are to be addressed throughout the Iterative Delivery (June 2019 onwards)

Progress Status Update – preUAT7 Bug Fixing

- 9 Issues have been closed after preUAT7 Business Validation (07/05/2019)

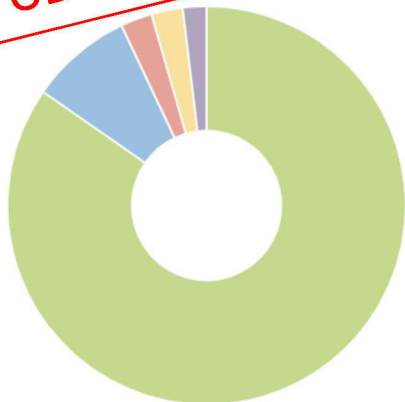
Issue Type	Key	Summary	Priority	Status
Bug	CTCS-9112	1018_no MSC have expressed willingness by day 3_the system assigned the RMS candidate by default this is incorrect	Critical	Closed
Bug	CTCS-9317	151. 1) default candidate in scenario 5b (assignor is proposed rms)	Minor	Closed
Bug	CTCS-8893	UC1026 - Additional MSC accessing the part I evaluation folder	Critical	Closed
Bug	CTCS-9223	102. 'SM Document considerations on Part I' task displays as completed and does not navigate to the Evaluation page	Major	Closed
Bug	CTCS-9053	New user creates trial via CT Centric approach and does not have appropriate CT Admin tabs or ability to lock certain sections of the Part I	Major	Closed
Bug	CTCS-9243	113. Corrective measures sorting dysfunctional.	Minor	Closed
Bug	CTCS-9311	170. important clarifications in disagreement - RMS candidate	Major	Closed
Bug	CTCS-9197	074. Name of 'Response to RFI Submitted' notice should be updated to specify Part I or Part II	Trivial	Closed
Bug	CTCS-9316	150. 1) not possible switch several times willing/unwilling	Critical	Closed

(*) Bug Workflow Status: Open -> In Progress -> Resolved -> Validate -> Closed (*Issues to be Closed by the end of Sprint)



final results (as of 17/04)

OBSOLETE



Status

Priority	OPEN	REOPENED	IN PROGRESS	RESOLVED	VALIDATE	T:
⛔ Blocker						
↑ Critical						
⚠ Major						
✓ Minor						
↓ Trivial						
Total Unique Issues:						



Scope of Sprint 5

Sprint 5

- **Development of Safety reporting business functionalities:**
 - View ASR summary by MS.
 - Request additional information (MS): all functionalities
 - View alerts and notices related to RFIs
 - Assess additional information: all functionalities:
 - Save, share, cancel
 - Create, edit, submit an RFI
 - Create a discussion on an RFI.
 - View RFI and Respond to RFI: all functionalities
 - Search for RFI.
 - Download ASR details.
 - Search & View ad-hoc assessment details: search and display information.
 - Display ASR Assessment.
 - Download ASR Assessment attached documents.
 - Display ASR Submission with RFI information.
 - Download ASR Submission attached documents.
 - Search & View ad-hoc assessment details: download and clear search results
- **Addressing regression testing findings** that block execution of other test cases and impact demo paths.
- Within the **R0.7 bug fixing** stream, fixing **26 bugs** (out of 52).



Scope of Sprint 6

Sprint 6

- Development of **17 improvements** that agreed with EMA and shared with the R0.9 Champions. The source of 9 improvements (out of the 17) are previous R0.9 Interactive sessions and 2 are from other feedback of Stakeholders (like R0.7 preUAT).
- **Implementation of bug fixes** from previous sprints.
- Addressing **R0.7 performance related issues**.
- **Improvement** of the current the **front end unit testing coverage**.
- **Fixing quality findings** identified by the **Sonarqube**, the quality tool used by EMA.
- **Addressing SR bugs** that were introduced **by the code merge** between R0.7 and R0.9.
- Within the **R0.7 bug fixing** stream, fixing the remaining **26 bugs** (out of 52).