

Document 53

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

02 May 2019

TC



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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 preparation for the Interactive Session on Sprint 5 is completed, the meeting with the CT Champions is scheduled for 30/04
 - Validated and closed another 14 bugs within the R0.7 bug fixing scope. In total 21 items have been closed by the CT Champions out of the 52.
 - The fixing of the Safety Reporting regression bugs from the second second second is on-going in Sprint 6
 - Sprint 6 development activities are underway, and planned to be finished by the 02/05
 - 11 improvements out of 17 are already completed
 - 90% of the Safety Reporting bugs from development that were carried over from previous development sprints have been fixed
- **[DevOps]** The first stable version of the Sprint 6 implementation (v0.9.6.0) was deployed to the Sandbox environment on 15/04.



Progress Status Update - Reporting Period

KEY HIGHLIGHTS

- [Feature Backlog Management team]
 - Analysis & Design:
 - Second iteration: ongoing. Final scope agreed with the POs: 38 high business value items related to 14 UCs from Application Evaluation Theme
 - **Product Vision:** was reviewed by CTIS Expert Group (The Coordination Group will revisit it to provide their endorsement)
 - Backlog Management:
 - Second backlog grooming session held (25/04):
 - Validate "Ready" items (25 items)
 - Provide Business Value on the Blocker-Critical-Major
 - Present and discuss the strategy to continue with the review of pending issues by PO
 - Present and discuss the methodology to associate backlog issues with Product Vision milestones.
 - Define together with EMA- Technical team on how to proceed with the outstanding technical debt
 - Overall and change management:
 - Increase predictability, by sending Outlook invitations for MS Product Owners till June 2019
 - Involve Sponsors POs, by scheduling general meeting with Sponsors explaining the new Delivery Model (25th of April)



R0.9 Progress Status Update - Reporting Period (15/04 - 26/04)

	<u> </u>				
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					

^{*} The implementation of R0.9 and R0.7 bug fixes are divided and reported separately. The competition percentages of the group activities can be lower than last week, because of the content of the groups were changed.

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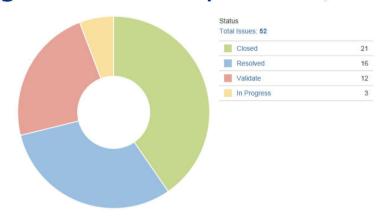


R0.7 bug fixing Progress Status Update - Reporting Period (15/04 - 26/04)

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					
5 th batch					
6 th batch					



Progress Status Update - preUAT7 Bug Fixing



- In the 2nd bug validation session another 14 bug fixes were presented to the Champions and all of them were successfully closed
- The goal is to demo all the bug fixes to the Champions by 7th May, before the development of Sprint 6 will finish

Priority	IN PROGRESS	RESOLVED	VALIDATE	CLOSED	T:
⊘ Blocker	0	0	1	0	1
↑ Critical	1	3	1	2	7
★ Major	2	6	7	11	26
¥ Minor	0	6	2	7	15
↓ Trivial	0	1	1	1	3
Total Unique Issues:	3	16	12	21	52



Progress Status Update – preUAT7 Bug Fixing

Net progress of the period

Bug Status	Previous Report #1	Previous Report #2	Previous Report #3	Previous Report #4	Current Report
OPEN	24	12	8	3	0
IN PROGRESS	8	9	9	7	3
RESOLVED	17	5	7	15	16
REOPENED	0	6	3	2	0
VALIDATE	3	20	25	19	12
CLOSED	0	0	0	6	21
TOTALS	52	52	52	52	52

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

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Progress Status Update - |

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

Blocker Critical Major Minor Trivial

- 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 ______ May 2019

 - The nature and categories of these bugs will be analyzed as part of the Backlog grooming activities

Blocker

Critical

Minor

Maior

Trivial

- New Bugs (these issues are under analysis to be properly typified): (Not Closed)
 - Sources:
 - R0.7 codebase merge bugs
 - R0.9 codebase merge bugs
 - unidentified R0.7 bugs
 - bugs requiring additional testing to verify their source
 - These bugs, alongside with other new bugs that will be found in **Experimental May** (May 2019), are to be addressed throughout the Iterative Delivery (June 2019 onwards)



Progress Status Update –

Bug Status	Current Report
OPEN	
IN PROGRESS	
RESOLVED	
VALIDATE	
CLOSED	
TOTALS	

Work plan for the next 2 weeks



KEY HIGHLIGHTS

[Sandbox environment]

• The latest stable application version may be deployed to the Sandbox environment in the beginning of May.

[Implementation team]

- Sprint 6 development/testing scope:
 - Implement the rest of the 6 Safety Reporting improvements out of the 17 in Sprint 6
 - Complete the FAT testing on the completed development of the last sprint, including all the 52 bug fixes in the R0.7 bug fixing stream
 - Interactive Session on Sprint 5 with the CT Champions
 - The next two business validation demos on the next batches of the R0.7 bug fixes

[Feature Backlog Management team]

- Analysis & Design: Complete second iteration and prepare scope and effort estimates for iteration 3
- **Product Vision:** support its final endorsed by the Coordination Group (6-7th May)
- Release Plan: support its first version (meeting with CTIS Expert Group on 10th of May)
- Backlog Management: Continue with backlog grooming sessions.
 - Continue providing Business Value on the historical backlog
 - Agree on the strategy to continue with the review of pending issues by PO
 - Continue linking the backlog issues with the Product Vision milestones, specially for the audit.
 - Start reviewing technical debt

Overall and change management:

- Start elaborating a Change Management plan for the full implementation of the New Delivery Model
- Prepare the information to be able to calculate the KPIs and other indicators needed

Preparations for new delivery model

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



Proposed KPIs for monitoring sub-committee: Key elements



We propose to use indicators that allow to **regularly** monitor project performance and the achievement of the set objectives in an **automatised** way

Draft

Measure performance

of the project and of the extent to which the project objectives are being achieved

Show continuous progress

serve as a reporting tool to show progress to the CT monitoring sub-committee on a continuous basis

Support automatisation

Develop automatised trackers and avoid error-prone calculation

KPIs to measure





^{*} In this KPI there is a main indicator that can be broken down into additional ones



	•	What do we want to measure?
ı	•	Proposed approach to calculate it:
ı	•	Formula:
	•	Frequency:
ı	10	Dependencies:
	•	When will the KPI be ready for consultation?
	•	What does success look like?

^{*} Based on the new JIRA workflow proposed

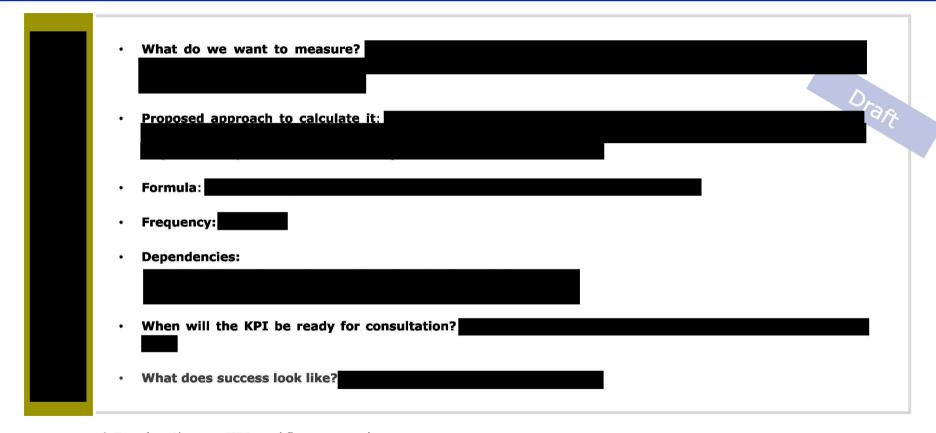


	What do we want to measure?
	Proposed approach to calculate it:
	Art.
٠	Formula:
٠	Frequency:
•	Dependencies:
٠	When will the KPI be ready for consultation?
	What does success look like?

^{*} Based on the new JIRA workflow proposed

^{**} Currently, a full regression cycle can take as long as 9 days. The frequency and scope of regression cycles is under discussion among EMA and IT4U





^{*} Based on the new JIRA workflow proposed

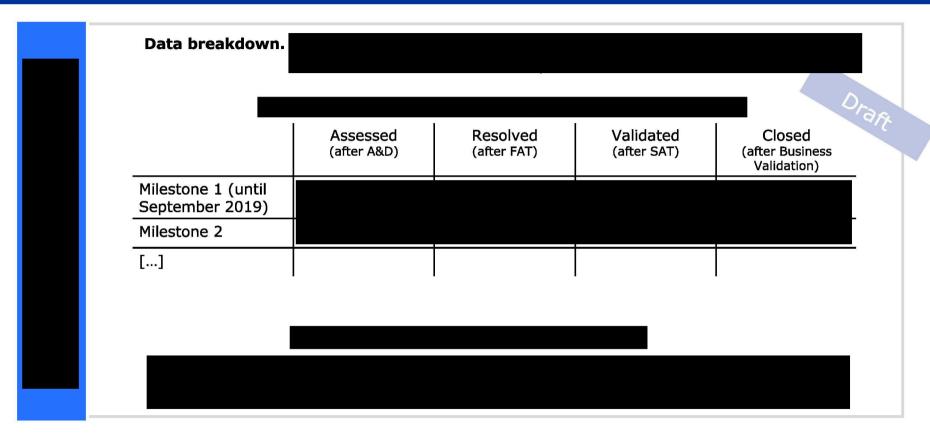
^{**} Currently, a full regression cycle can take as long as 9 days. The frequency and scope of regression cycles is under discussion among EMA and IT4U



•	What do we want to measure?
•	Proposed approach to calculate it*:
	Main formula:
•	Frequency:
٠	Dependencies:
•	When will the KPI be ready for consultation?
	What does success look like?

^{*} Based on the new JIRA workflow proposed







What do we want to measure?	
Proposed approach to calculate it:	ran
• Formula:	
• Frequency:	
· Dependencies:	
When will the KPI be ready for consultation?	
What does success look like?	



	•	What do we want to measure?
	•	Proposed approach to calculate it:
I		Formula:
	•	Frequency:
	•	Dependencies:
		When will the KPI be ready for consultation?
	•	What does success look like?



ANNEX



Progress Status Update - preUAT7 Bug Fixing

14 Issues have been closed after preUAT7 Business Validation (25/04/2019)

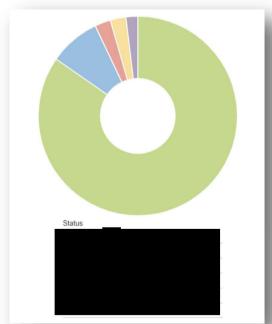
Issue Type	Key	Summary	Priority	Status
Bug	CTCS-9389	MS API - Application comments missing in UI	Major	Closed
Bug	CTCS-9363	183. Unclear if Registration request contact details are referring to organisation details	Major	Closed
Bug	CTCS-9280	122. Unable to view 'supporting documentation' uploaded as part of the ad hoc assessment	Major	Closed
Bug	CTCS-9273	137. search	Minor	Closed
Bug	CTCS-9248	124. Responses entered by the Q-IMPD preparer were automatically deleted by the system	Critical	Closed
CT Change	CTCS-9229	093. Cannot view disagreement submitted as part of an Additional MSC application	Major	Closed
Bug	CTCS-9213	Additional MSC can't download the Final assessment report for the initial application.	Major	Closed
Bug	CTCS-9193	070. Supporting documentation submitted as part of an RFI is not displayed	Major	Closed
Bug	CTCS-9192	069. There is no link between the original consideration and the adapted one	Major	Closed
Bug	CTCS-9124	030. Within an RFI response clicking to "View submitted application" takes user to trial summary page rather than submitted application	Trivial	Closed
Bug	CTCS-9120	017. Documents uploaded to other sections of Part I are not shown in the Documents section of Part I	Minor	Closed
Bug	CTCS-9064	No character restriction in 'Other medicinal product' field, resulting in error message	Minor	Closed
Bug	CTCS-9055	Arm details not clear for multiple arms within the same period	Minor	Closed
Bug	CTCS-5044	008. Use of NOA organisation for National admin	Major	Closed

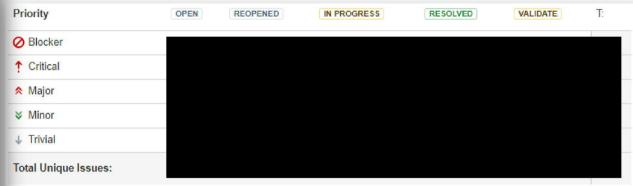
^(*) Bug Workflow Status: Open -> In Progress -> Resolved -> Validate -> Closed (*Issues to be Closed by the end of Sprint)



Progress Status Update -

The charts and tables below show the summary of the results. The detailed analysis
of the new findings is completed (Slide 9)







R0.9 Progress Status Update – Reporting Period (15/04 - 26/04)

Tasks	Description of the activities
Iteration 4 (Development phase)	Group task
Implementation and testing	Group task
Regression testing cycle 1	After the code merge between R0.9 (completed Sprint 4 version) and R0.7 (final version after SAT in Dec `18) the software was regression tested.
Sandbox environment preparation	The technical setup of the sandbox environment was performed by IT4U. The following activities were completed: • Validating that the test data available in the sandbox environment are suitable to allow any user to work with the environment smoothly • Validating, as part of sanity checks, the proper access to the application, applying the proper permissions configured according to the specifications. • Validating that the interfaces with the external systems work successfully.
Sprint 5	The development of the business functionalities of Safety reporting that were planned for Sprint 5.



R0.9 Progress Status Update – Reporting Period (15/04 - 26/04)

Tasks	Description of the activities
Sprint 6	Group task
Development	The development of the list of improvements that agreed with EMA and shared with the R0.9 Champions. 11 improvements out of the 17 came from the feedback of the Product Owners. In addition the team worked on bug fixes from previous sprints, improving the front end unit testing and fixing quality findings identified by the Sonarqube quality tool.
FAT of Sprint 6	The factory acceptance test of the Sprint 6 development in IT4U premises.
SAT of Iteration 4	The site acceptance test of the Iteration 4 (Sprint 5 and Sprint 6) development at EMA premises.
Interactive session on Sprint 5	Session where IT4U present the Safety reporting business functionalities that are implemented in Sprint 5 to the R0.9 Champions.
Interactive session on Sprint 6	Session where IT4U present the Safety reporting improvements that are implemented in Sprint 6 to the R0.9 Champions.
Demo on Iteration 4	Session where IT4U present the Safety reporting business functionalities that are developed in Sprint 5 and the improvements that are implemented in Sprint 6 to the R0.9 Champions.
Regression testing cycle 2	The merged code between R0.9 (completed and final Iteration 4 SAT version) and R0.7 (final version after SAT in Dec `18) will be regression tested.



R0.7 bug fixing Progress Status Update - Reporting Period (15/04 - 24/04)

Tasks	Description of the activities
R0.7 bug fixing in Iteration 4	Group task
Implementation and testing	Group task
Sprint 5	The development of 26 bug fixes out of the 52 defined issues that have to be implemented in scope of R0.7 bug fixing stream.
Sprint 6	Group task
Development	The development of rest of the 26 bug fixes (out of 52) as part of the R0.7 bug fixing stream.
FAT of Sprint 6	The factory acceptance test of the Sprint 6 development (26 bug fixes) in IT4U premises.
SAT of Iteration 4	The site acceptance test of the Iteration 4 (Sprint 5 and Sprint 6) development (52 bug fixes) at EMA premises.
Bug fixing validation	Group task
1 st batch	Session where IT4U present the $1^{\rm st}$ batches of the bug fixes to the Champions.
2 nd batch	Session where IT4U present the 2 nd batches of the bug fixes to the Champions.
3 rd batch	Session where IT4U present the 3 rd batches of the bug fixes to the Champions.
4 th batch	Session where IT4U present the 4 th batches of the bug fixes to the Champions.
5 th batch	Session where IT4U present the re-opened bugs to the Champions.
6 th batch	Session where IT4U present the re-opened bugs to the Champions.



Progress Status Update – 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).

Progress Status Update – 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).