



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Document 51

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

17 April 2019

TC

EMA



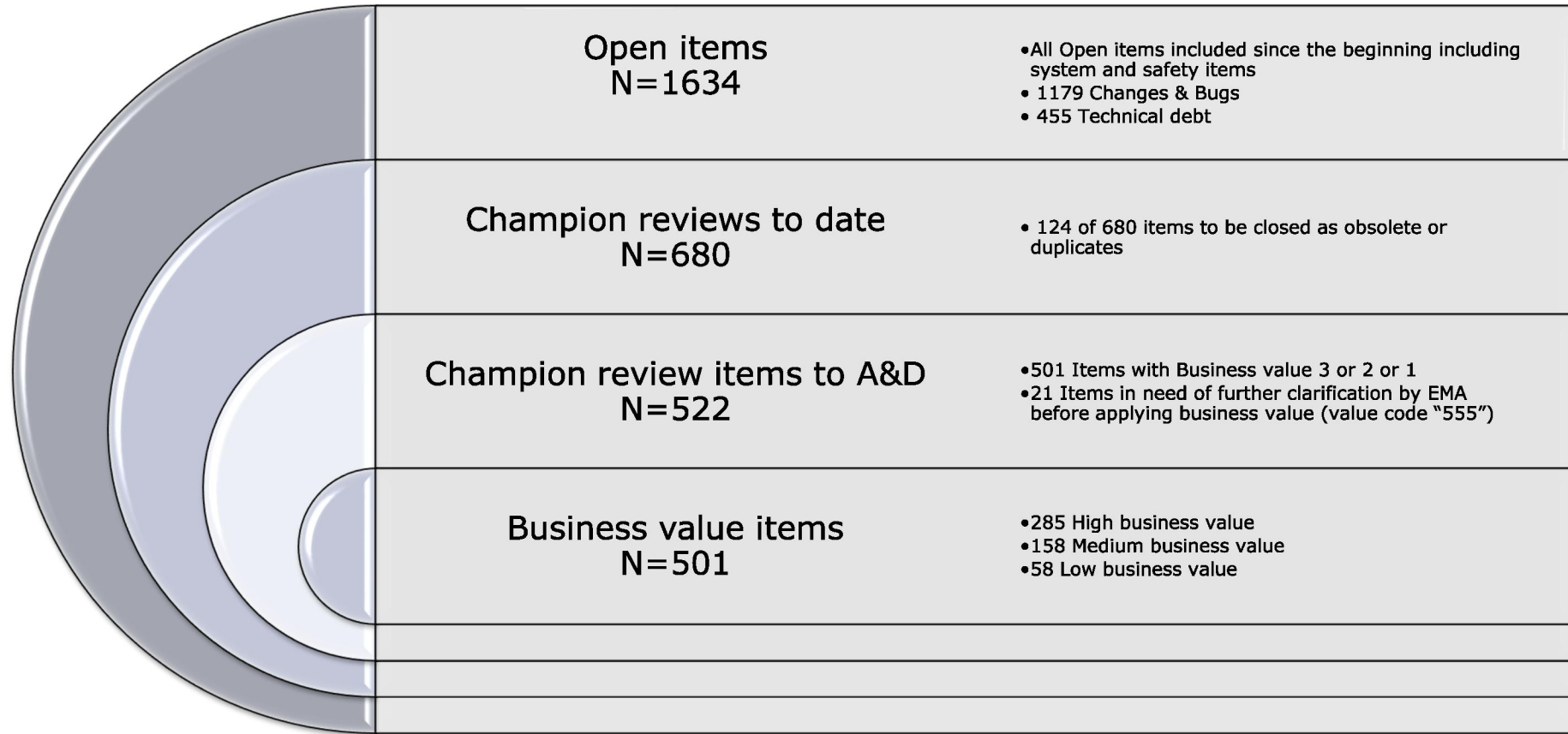




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Progress Status Update – Reporting Period

KEY HIGHLIGHTS

- **[Implementation team]** The list below shows the key activities undertaken by the implementation team during the reporting period:
 - Finished the development and testing of the outstanding core Safety Reporting functionality for Sprint 5
 - The list of improvements planned for the last sprint was shared with the CT Champions and the scope of Sprint 6 was finally agreed
 - Validated and closed 6 out of 25 bugs in Sprint 5 (52 bugs of R0.7 scope)
 - Finished the analysis of the [REDACTED] results
 - Sprint 6 development activities are underway, and planned to be finished by the 02/05
- **[DevOps]**
 - The Sandbox environment is currently up and running, and the users have been given training and credentials/accesses for it



Progress Status Update – Reporting Period

KEY HIGHLIGHTS

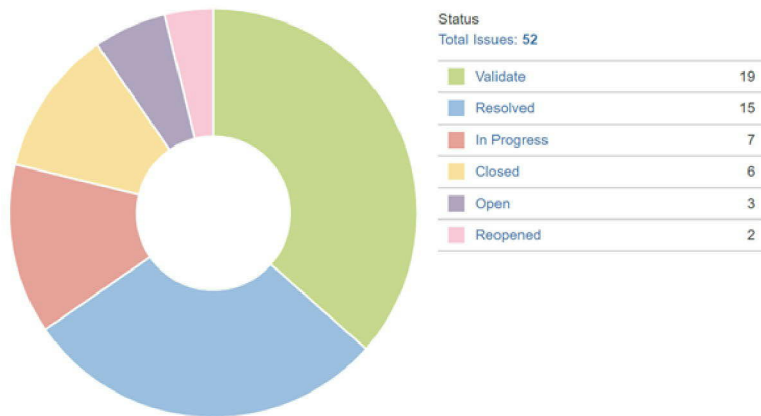
- **[Feature Backlog Management team]**
 - **Analysis & Design:**
 - First iteration completed, 36 items analysed and 22 ready for development
 - Second iteration: ongoing. Scope: 40 items, mostly Application Evaluation Theme
 - **Product Vision:** Draft shared and discussed with Expert Group
 - **Backlog Management:**
 - First backlog grooming session done
 - **Overall and change management:**
 - Set up of 2019 activity calendar and invitations sent by Outlook till December 2019
 - Propose set of KPIs to measure throughput and performance of the Delivery Team under the new Iterative Model
 - Propose finetuned EMA roles/responsibilities involved in the New Delivery Model, with the feedback received from BUS and IT



Progress Status Update – Reporting Period (01/04 - 12/04)

Tasks	Actual % completion	Expected % completion	SPI	Forecast end date	Baselined end date
Sprint 4 Interactive session					
Iteration 3 (Sprints 3 and 4) demo					
Iteration 4 (Sprints 5 and 6)					
Implementation and testing					
Regression testing cycle 1					
Sandbox environment preparation					
Sprint 5					
Development (R0.9 + R0.7 bug fixing)					
FAT of Sprint 5					
Interactive session on Sprint 5					
Sprint 6					
Development - R0.9					
Development - R0.7 bug fixing					
FAT of Sprint 6					
SAT of Iteration 4					

Progress Status Update – preUAT7 Bug Fixing



- This period showed a good push on the RESOLVED issues (pending test verification), from 7 to 15. 9 VALIDATE bugs were demo'ed to the CT Champions and 6 of them were actually closed. Another 2 were closed with caveats and 1 reopened

Priority	OPEN	REOPENED	IN PROGRESS	RESOLVED	VALIDATE	CLOSED	T:
🛑 Blocker	0	0	0	1	0	0	1
🚨 Critical	1	0	0	3	2	1	7
🔥 Major	1	1	5	6	11	2	26
✅ Minor	1	1	2	4	4	3	15
↓ Trivial	0	0	0	1	2	0	3
Total Unique Issues:	3	2	7	15	19	6	52



Progress Status Update – preUAT7 Bug Fixing

- Progress in the period

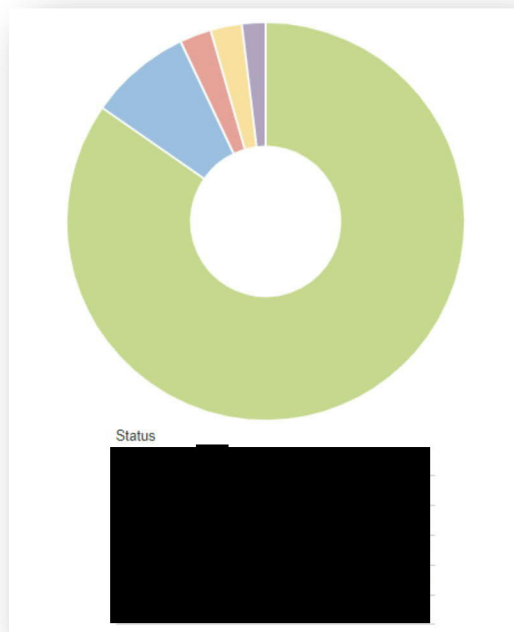
Bug Status	Previous Report #1	Previous Report #2	Previous Report #3	Current Report
OPEN	24	12	8	3
IN PROGRESS	8	9	9	7
RESOLVED	17	5	7	15
REOPENED	0	6	3	2
VALIDATE	3	20	25	19
CLOSED	0	0	0	6
TOTALS	52	52	52	52

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



Progress Status Update – [REDACTED]

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



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



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:

Blocker	Critical	Major	Minor	Trivial
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- [REDACTED] R0.7+R0.9 codebase merge bugs
- [REDACTED] unidentified R0.7 bugs
- [REDACTED] bugs requiring additional testing to verify their source
- 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)



Work plan for the next 2 weeks

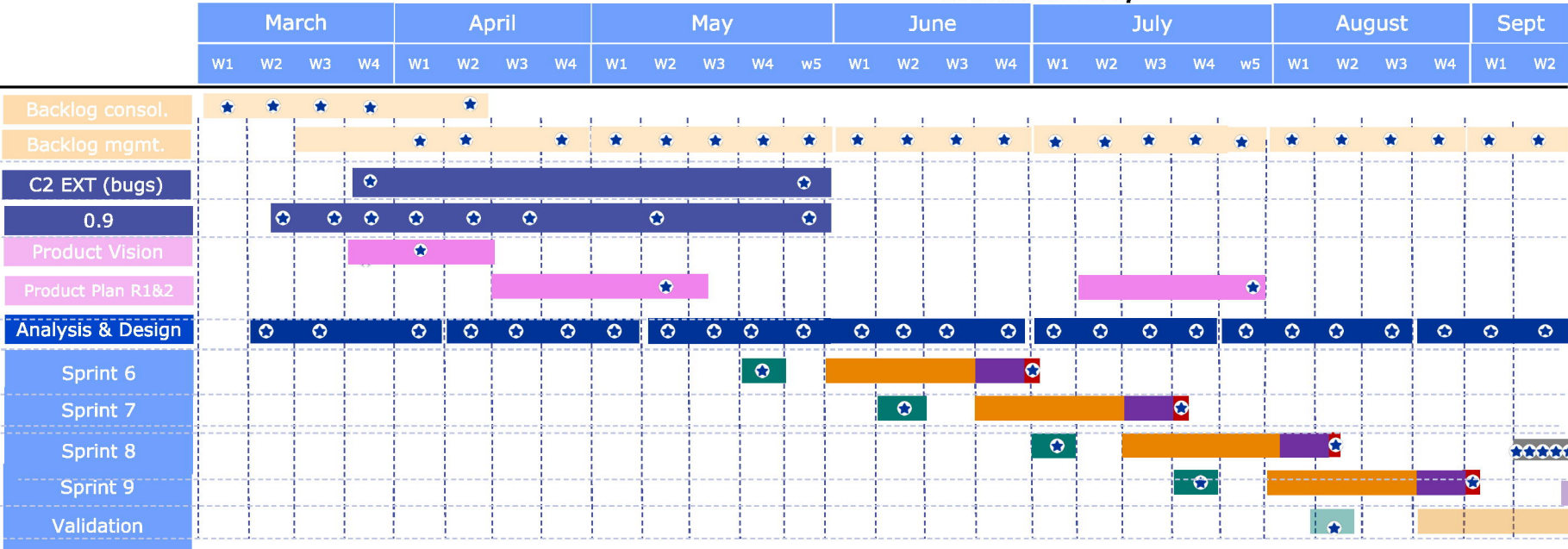
KEY HIGHLIGHTS

- **[Sandbox environment]**
 - Define the Roadmap (Upgrade version) plan: Calendar definition to promote new version to Sandbox environment aligned to Analysis and Design activities as part of New Delivery model (without business impact)
- **[Implementation team]**
 - Sprint 6 development/testing scope:
 - R0.9 accumulated technical debt fixing
 - Carryover bugs from R0.9 backlog fixing
 - 17 Safety Reporting improvements that have been agreed with the Product Owners
 - Four Business validation demos to review –and hopefully close- R0.7 bug fixes
- **[Feature Backlog Management team]**
 - **Analysis & Design:** Undertake planned activities of the second A&D assignment
 - **CT Product Vision:** Support the review and approval process alongside with EMA and stakeholders
 - **Release Plan:** Draft first version in sync with the Product Vision
 - **Backlog Management:** Stabilize the recurrent activities as the backlog grooming 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



- 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)

*We propose to use indicators that allow to **regularly** monitor project performance and the achievement of the set objectives in a **semi-automated** way*

1 Measure performance

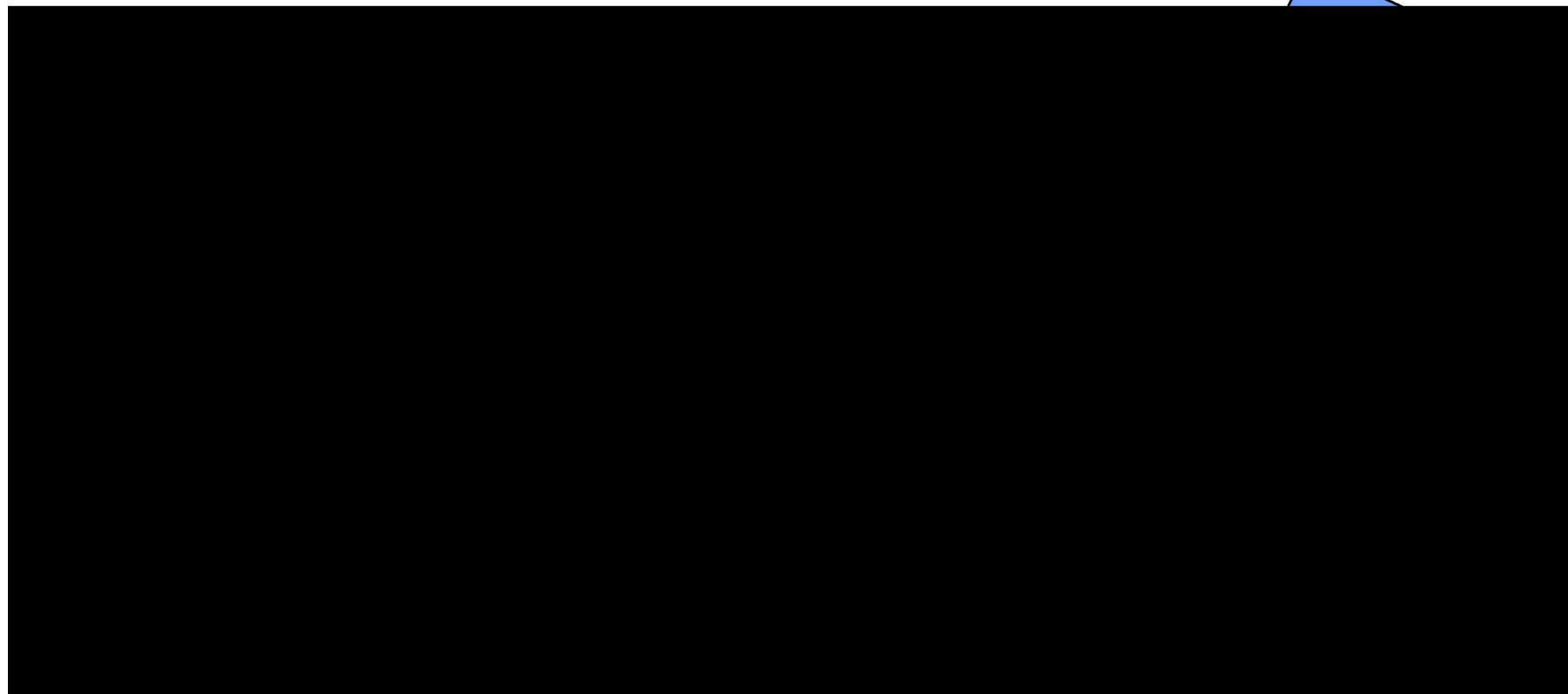
of the project and of the extent to which the project objectives are being achieved

2 Show continuous progress

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

3 Support automatisisation

Develop automatised trackers and avoid error-prone calculation





Metric

Formula/description

DRAC



ANNEX TO SLIDE 5

Progress Status Update – Detailed activities

Tasks	Description of the activities
Sprint 4 Interactive session	Session where IT4U present the business functionalities that are implemented in Sprint 4 to the R0.9 Champions.
Iteration 3 (Sprints 3 and 4) demo	Session where IT4U present the business functionalities that are implemented in Iteration 3 (Sprints 3 and 4) to the R0.9 Champions.
Iteration 4 (Sprints 5 and 6)	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	<p>The technical setup of the sandbox environment was performed by IT4U. The following activities were completed:</p> <ul style="list-style-type: none"> • <i>Validating that the test data available in the sandbox environment are suitable to allow any user to work with the environment smoothly</i> • <i>Validating, as part of sanity checks, the proper access to the application, applying the proper permissions configured according to the specifications.</i> • <i>Validating that the interfaces with the external systems work successfully.</i>

Progress Status Update – Detailed activities

Tasks	Description of the activities
Sprint 5	Group task
Development (R0.9 + R0.7 bug fixing)	The development of the business functionalities of Safety reporting that were planned for Sprint 5. In addition 26 bug fixes (out of 52) as part of the R0.7 bug fixing stream.
FAT of Sprint 5	The factory acceptance test of the Sprint 5 development in IT4U 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.
Sprint 6	Group task
Development - R0.9	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.
Development - R0.7 bug fixing	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 in IT4U premises.
SAT of Iteration 4 (Sprints 5 and 6)	The site acceptance test of the Iteration 4 (Sprint 5 and Sprint 6) development at EMA premises.



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).



ANNEX

SLIDES 12 TO 14



DRAFT

- **What do we want to measure?** [REDACTED]

- **Proposed approach to calculate it:** [REDACTED]

- **Dependencies:** [REDACTED]

- **Frequency:** [REDACTED]

- **Formula:** [REDACTED]

- **What success looks like?** [REDACTED]



DRAFT

- **What do we want to measure?**

- **Proposed approach to calculate it:**

- **Dependencies:**

- **Frequency:**

- **Formula:**

- **What success looks like?**



DRAFT

- **What do we want to measure?** [REDACTED]
- **Proposed approach to calculate it:** [REDACTED]
- **Dependencies:** [REDACTED]
- **Frequency:** [REDACTED]
- **Formula:** [REDACTED]
- **What success looks like?** [REDACTED]



- **What do we want to measure?** [REDACTED]

DRAFT

- **Proposed approach to calculate it:** [REDACTED]

- **Dependencies:** [REDACTED]

- **Frequency:** [REDACTED]

- **Formula:** [REDACTED]

- **Comments:** [REDACTED]

- **What success looks like?** [REDACTED]



DRAFT

- **What do we want to measure?** [REDACTED]

- **Proposed approach to calculate it:** [REDACTED]

- **Dependencies:** [REDACTED]

- **Frequency:** [REDACTED]

- **Formula:** [REDACTED]

- **What success looks like?** [REDACTED]



- **What do we want to measure?**

- **Proposed approach to calculate it:**

- **Dependencies:**

- **Frequency:**

- **Formula:**

- **What success looks like?**

DRAFT

- **What do we want to measure?** [REDACTED]
- **Proposed approach to calculate it:** [REDACTED]
- **Dependencies:** [REDACTED]
- **Frequency:** [REDACTED]
- **Formula:** [REDACTED]
- **What success looks like?** [REDACTED]

DRAFT

- **What do we want to measure?** [REDACTED]

- **Proposed approach to calculate it:** [REDACTED]

- **Dependencies:** [REDACTED]

- **Frequency:** [REDACTED]

- **Formula:** [REDACTED]