



IT4U
consortium

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Document 41

Clinical Trials Programme

Progress Report – January 2019

ESP-DIMSIS
EMA/2016/36/IMFWC

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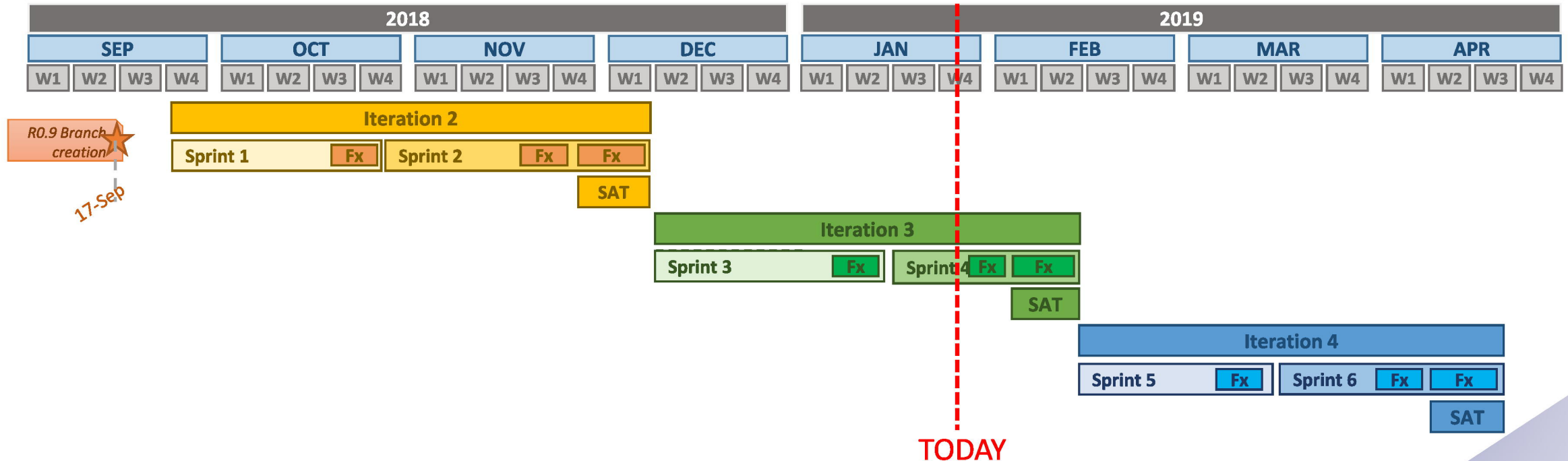
Key highlights:

- SAT Testing finished by the 19th of December
- The review and acceptance process of this final delivery is ongoing throughout January 2019 for the SAT milestone, and eventually until end of February for Handover and contract Closure

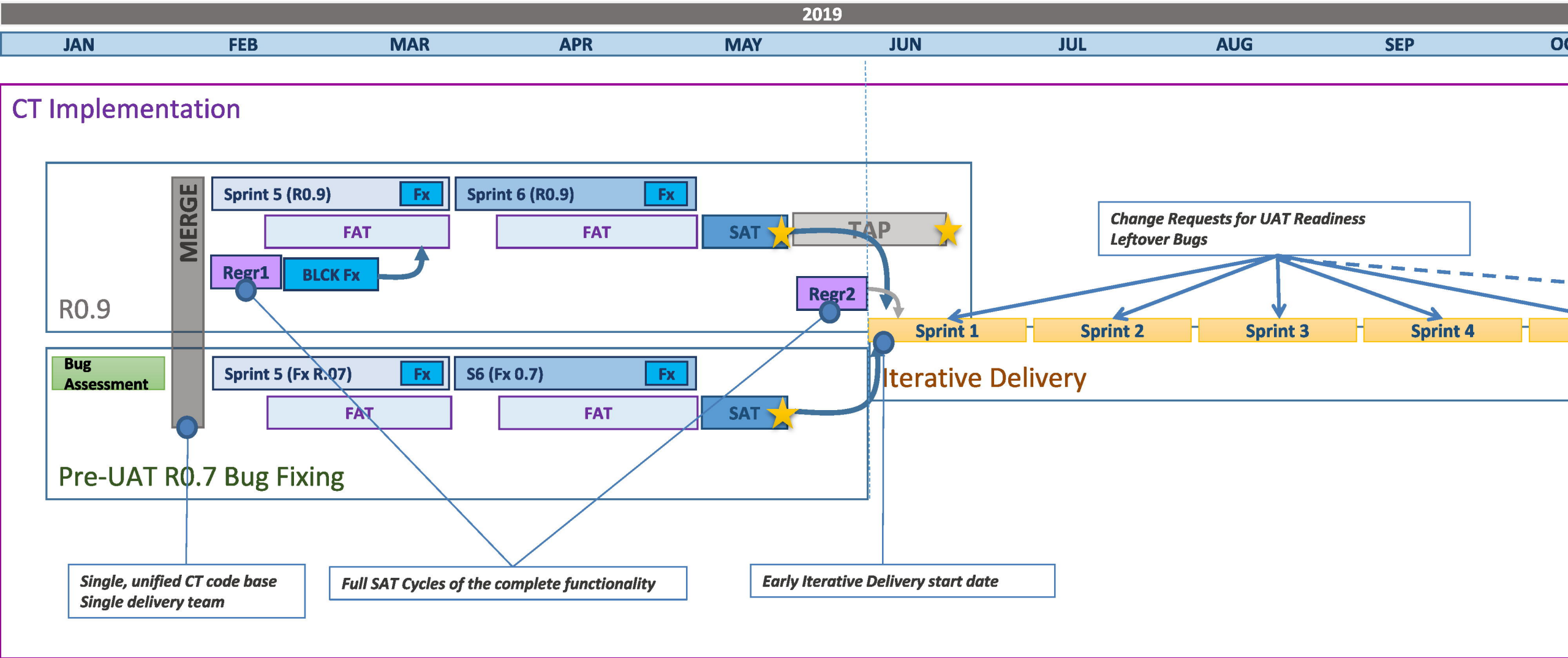
R0.9 Progress Status

Key highlights and timeline of activities:

- Iterations 1 (Detailed Design) and 2 (first Development iteration) were delivered as per the plan
- Iteration 3 (second –and most relevant- development iteration) currently underway
- The ongoing CT Reconstruction impact might affect this R0.9 Plan below (team members, timelines and future activities)



High Level CT Programme Plan



R0.7 Handover

- The existing CT2 Team (Everis) –in collaboration with the incumbent CT1 Team (Unisystems) as well as some key EMA staff- has planned and hitherto performed a series of activities to expand and enhance its acumen of the whole Clinical Trials platform –since its expertise and knowledge was mainly focused on the Safety Reporting functionality
- The activities of this mentioned plan effectively started during November 2018, and will carry on until end of February 2019. These activities mainly encompass:
 - Analysis of existing R0.7 functional documentation
 - R0.7 pre-UAT support and validation of fixes
 - Execution of existing R0.7 UAT end-to-end scenarios and test scripts
 - Analysis of the outstanding backlog of requirements, changes and enhancements to be implemented in future releases
 - Participation on Handover workshops delivered by the incumbent team of R0.7

IT4U CT Team relocation to Amsterdam:

- Ever since the new Agency site was made public:
 - IT4U upgraded its [REDACTED] operations by [REDACTED] to deal [REDACTED] with its EMA commitments and relationship
 - [REDACTED]
- The majority of the key [REDACTED] CT resources of IT4U will [REDACTED], in co-ordination with our EMA peers, planned [REDACTED]
- [REDACTED]
- The picture in the next slide shows the current layout of [REDACTED]

IT4U CT Team [redacted] chart (as of 25/01/2019):

Team	Profile	[redacted]
R0.9	[redacted]	[redacted]

Team	Profile	[redacted]
FBM	[redacted]	[redacted]

Thank you

Any questions?