Document 43

Clinical Trials Programme

Progress Report – February 2019

ESP-DIMSIS

EMA/2016/36/IMFWC

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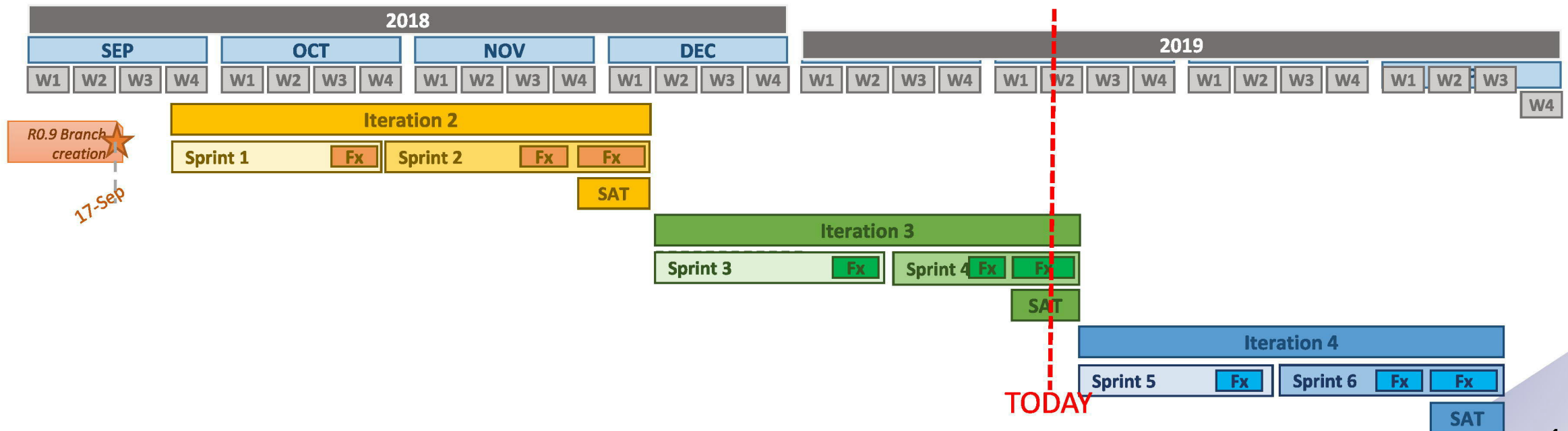- ❖ Overall Status

Update of CT Programme Management
- ❖ High Level CT Programme Plan
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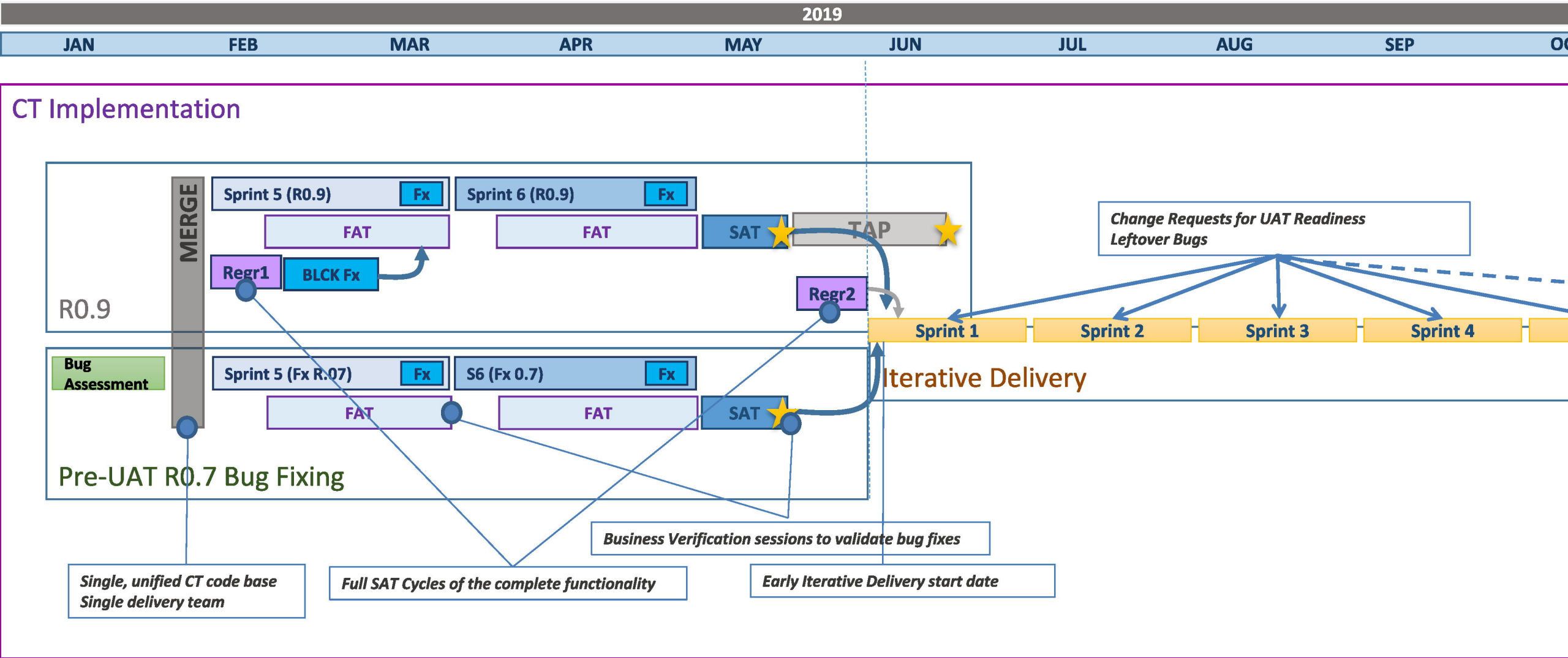# R0.7 Progress Status

Key highlights:

- SAT Testing finished by the 19th of December
- Handover and Closure activities are taking place, with the aim of having all activities completed and accepted by the end of February 2019 (more details in following slides)
- Tight follow up mechanisms (EMA and IT4U PMs working jointly) are being put in place to ensure this deadline is met with all the needed actions completed and accepted in due time

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. All deliverables of Iteration 2 have been formally accepted by EMA during this last period
- Iteration 3 (second –and most relevant- development iteration) finished main development activities, currently halfway through the SAT testing prior to formal delivery. ████████████████
████████████████████

High Level CT Programme Plan

2019

| JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OC |

CT Implementation

MERGE

R0.9

Sprint 5 (R0.9) — Fx
Sprint 6 (R0.9) — Fx

FAT
FAT
SAT ⭐ TAP ⭐

Regr1   BLCK Fx

Regr2

Change Requests for UAT Readiness Leftover Bugs

Sprint 1   Sprint 2   Sprint 3   Sprint 4

Iterative Delivery

Bug Assessment

Sprint 5 (Fx R.07) — Fx
S6 (Fx 0.7) — Fx

FAT
FAT
SAT ⭐

Pre-UAT R0.7 Bug Fixing

Business Verification sessions to validate bug fixes

Single, unified CT code base Single delivery team

Full SAT Cycles of the complete functionality

Early Iterative Delivery start date

CT Programme Management

Update of R0.7 Handover and Closure activities

- As part of the Handover and Closure phases of the CT1 contract, several activities have been planned and executed, and there are ongoing discussions to schedule further actions that will cover all identified gaps (both from Knowledge Transfer and handing over all project assets from the incumbent team to EMA's infrastructure)
- **Business knowledge transfer** sessions have been almost completed, with one missing topic still to be covered to consider this area as successfully closed
- Some **additional Technical knowledge transfer** sessions are to be scheduled, in co-ordination with EMA staff and the CT2 team, in order to fully cover some specific areas of complexity of the platform
- All knowledge transfer sessions are being recorded and are EMA assets –seen as training material- ans are already stored and available at EMA repositories
- **Asset handover** activities are ongoing and under control, namely:
  - Migration of Open Jira tickets into EMA Jira repository
  - Migration of all generated Testware (Test cases, traceability matrix, User stories, etc...) into EMA Jira repository
  - Delivery of all knowledge based articles generated in the incumbent systems into EMA repositories

CT Programme Management

IT4U CT Team ███████████████████ **chart (as of 25/01/2019):**

Team	Profile		
R0.9			

Team	Profile		
FBM			

Thank you

Any questions?