

**SCDM** Live

August 26, 2023, Mumbai

# SCDM India Single Day Event

THEME

CDM — Revisiting fundamentals in an evolving  
clinical research landscape

# Agenda

- Current process
- Challenges
- Process Change
- Positive outcome & Benefits
- Further improvements

# Current Process

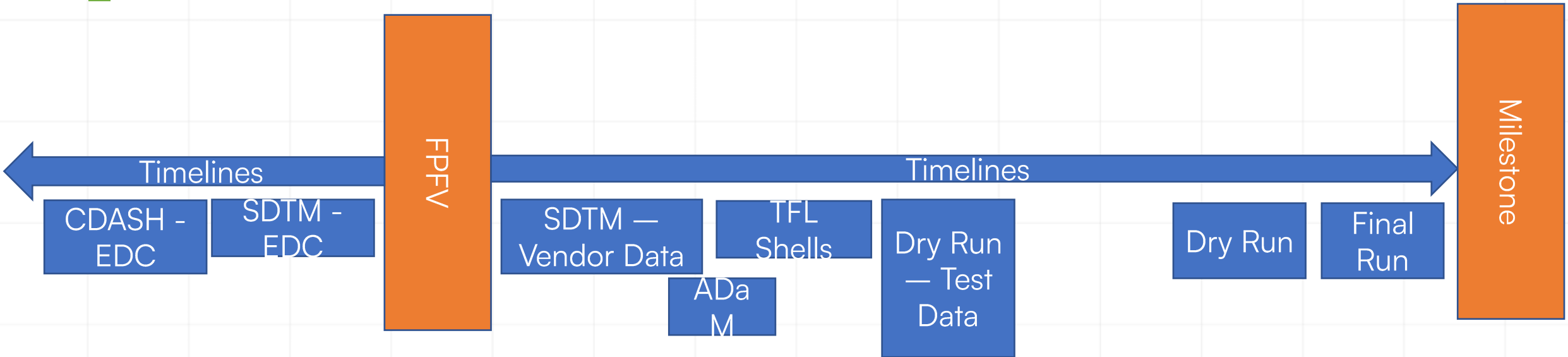
- SDTM and ADaM dataset creation timelines based on Milestones (DMC, IA, Final Lock).



# Challenges

- Unanticipated Issues identified and identified late.
- Under pressure to fix the issue. Becomes more complex when multiple stakeholders are involved.
- May impact quality

# Process Change



# Process Change to meet the FPFV milestone

- Key stakeholder meet (DM, EDC programmer, Vendor, Statistical programmer, Clinical Standards Representative, Clinical etc) before EDC Design
- SDTM Creation timelines based on First Patient First Visit
- SDTM validation based on Clean Data Entry
- Sponsor specific checks on top of P21 checks

# Positive Outcome

- Better SDTM delivery management and encourages better planning for downstream activities.
- Majority of the structural and programming issues identified early
- Clean Test Data in and Quality SDTM Data out

# Benefits

- Increase in Quality (In pilot studies, the number of structural and programming issues identified in production was close to zero).
- Better preparation for milestone and submission.
- Reduction in efforts and timeline impact during milestone.

# Test Data

- Cover scenarios based on the protocol (Cross-over, Parallel, Multi branching). Do not stop at just 3 scenarios (screen failure, Completed, early withdrawal)
- Simulate the production data. Ex. Adverse Event Serious = Yes and seriousness criteria selected. This will avoid unnecessary P21 issues.
- Tracker to identify the subject and scenarios used in the test data.



# Challenges & Mitigation

Challenges	Mitigation
Adjusting SDTM programming deliverable	Phased transformation and realignment
Additional effort to enter clean data	Consider entering clean data as part of Screen UAT
Project plan change	Phased transformation and realignment
Mindset change	Include as part of the process and measure

# Further Improvements

- Incorporate CDASH standards for collection
- Increase standard collection for CRF and 3<sup>rd</sup> Party vendor
- Early setup of 3<sup>rd</sup> party vendor data
- Process and tool to coordinate tasks
- Know your data, understand point of failures and mitigate with Quality checks.