SCDM India
Single Day Event

THEME
CDM — Revisiting fundamentals in an evolving clinical research landscape

August 26, 2023, Mumbai
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

FPFV

Timelines
CDASH - EDC
SDTM - EDC

SDTM — Vendor Data
TFL Shells
ADaM

Dry Run — Test Data

Dry Run
Final Run

Milestone
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

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<thead>
<tr>
<th>Challenges</th>
<th>Mitigation</th>
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<tbody>
<tr>
<td>Adjusting SDTM programming deliverable</td>
<td>Phased transformation and realignment</td>
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<tr>
<td>Additional effort to enter clean data</td>
<td>Consider entering clean data as part of Screen UAT</td>
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<td>Project plan change</td>
<td>Phased transformation and realignment</td>
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<td>Mindset change</td>
<td>Include as part of the process and measure</td>
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Further Improvements

• Incorporate CDASH standards for collection
• Increase standard collection for CRF and 3\textsuperscript{rd} Party vendor
• Early setup of 3\textsuperscript{rd} party vendor data
• Process and tool to coordinate tasks
• Know your data, understand point of failures and mitigate with Quality checks.