

Single Day Event

Advancing the Maturation of Standardized
CRF Design

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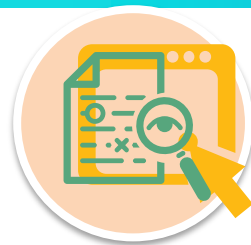


Agenda

- Why a Stable Framework is Crucial?
- Data effectiveness roadblocks
- CRF analysis: Uncovered insights
- Journey towards clean data
- Rethinking technology choices
- Innovative vision, quality outcomes!



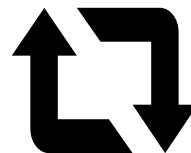
Why a Stable Framework is Crucial?



eCRF



Processed
Datasets



TLFs

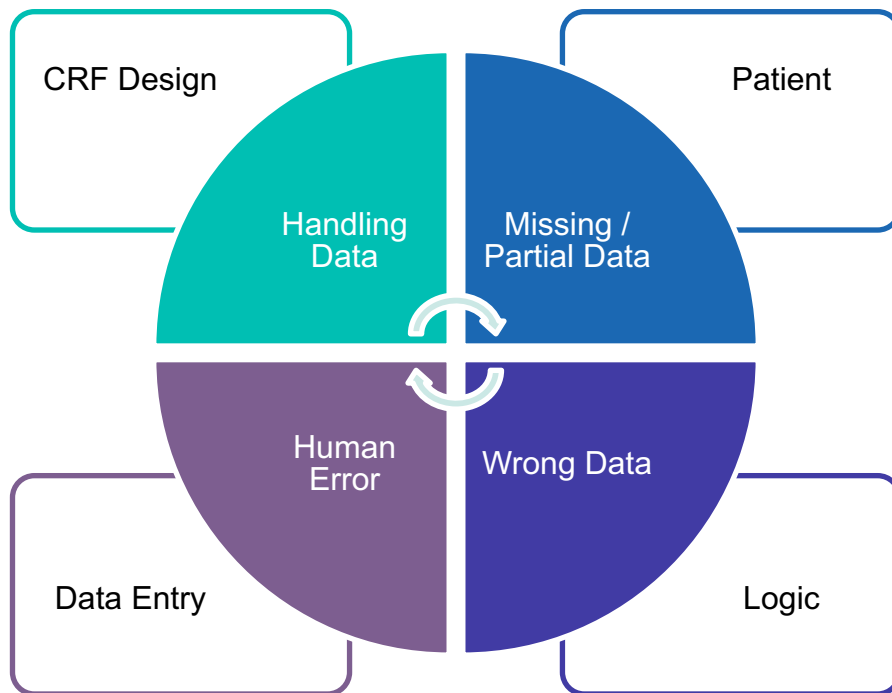


CDISC





Data effectiveness roadblocks



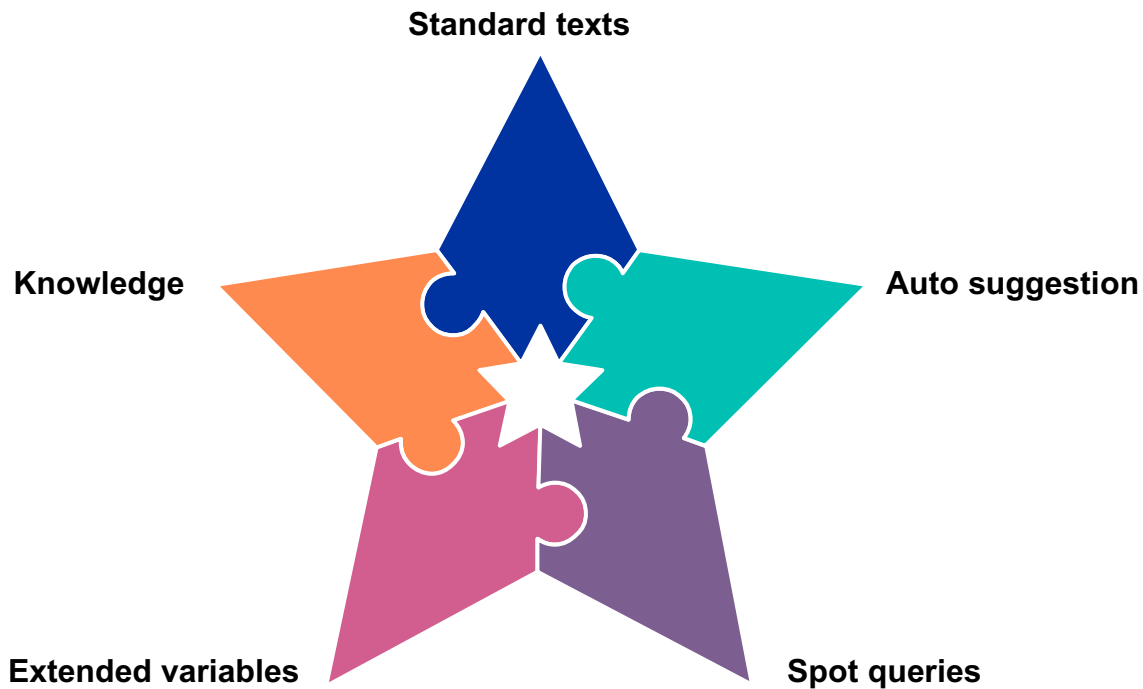


CRF analysis: Uncovered insights

Adverse Events (1)		
AE Term	qqq	⚙️
Start date		⚙️ ①
Start time	:	⚙️ (HH24:MI)
End Date		⚙️ ①
End Time	:	⚙️ (HH24:MI)
Start and stop times only provided when the AE is less than 24hrs		
Severity	☐ Grade 1 - Mild ☐ Grade 2 - Moderate ☐ Grade 3 - Severe ☐ Grade 4 - Life threatening ☐ Grade 5 - Fatal	⚙️ ①
Severity is in accordance with CTCAE criteria and worse grade only is recorded		
Is this AE an SAE?	☒ Yes ☐ No	⚙️ ①
Type of SAE	☒ Death ☐ Life-threatening ☐ Disability or Permanent Damage ☐ Initial or Prolonged Hospitalisation ☐ Congenital Anomaly/Birth Defect ☐ Other Medically Important Event	⚙️ ①
Other Specify		⚙️
Action taken with Study Drug	☐ None ☐ Reduced dose ☐ Temporarily discontinued study drug ☐ Permanently discontinued study drug	⚙️ ①
Treatment for Adverse Event	☐ Yes ☒ No	⚙️ ①
If medication given for treatment of Adverse Event, please record on the Concomitant Medication Log		



Journey towards clean data





Rethinking technology choices

01

AI integrated CRF

02

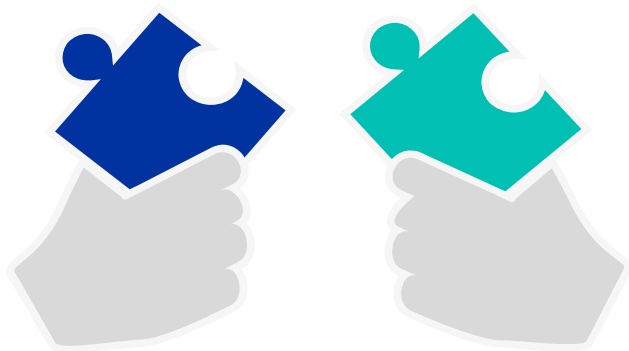
Double entry of data
AI entry vs Manual entry

03

Validation using AI

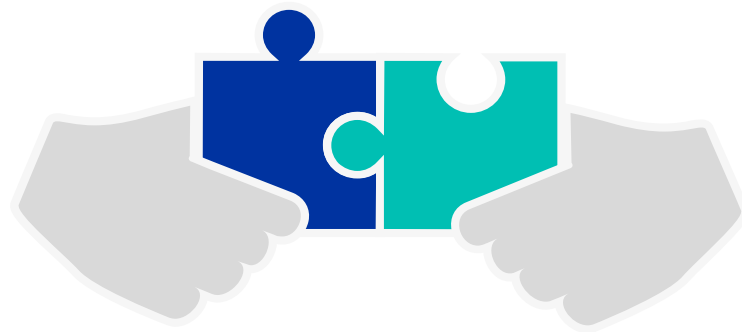


Innovative vision, Quality outcomes!



Challenges

- Assurance of actual data
- AI also influenced by human technology
- A quality understanding / entry of data



Opportunities

- Increased quality of data
- Reduction of rework
- Time and effort saved in SDTM / ADaM programming

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