SCDM Live

August 26, 2023, Mumbai

SCDM India Single Day Event

THEME

CDM — Revisiting fundamentals in an evolving clinical research landscape

Disclaimer: The thoughts and opinions expressed by the speaker are his own and not reflective of the company.

"The good physician treats the disease; the great physician treats the patient who has the disease."

"You caught a virus from your computer and we had to erase your brain. I hope you've got a back-up copy!"

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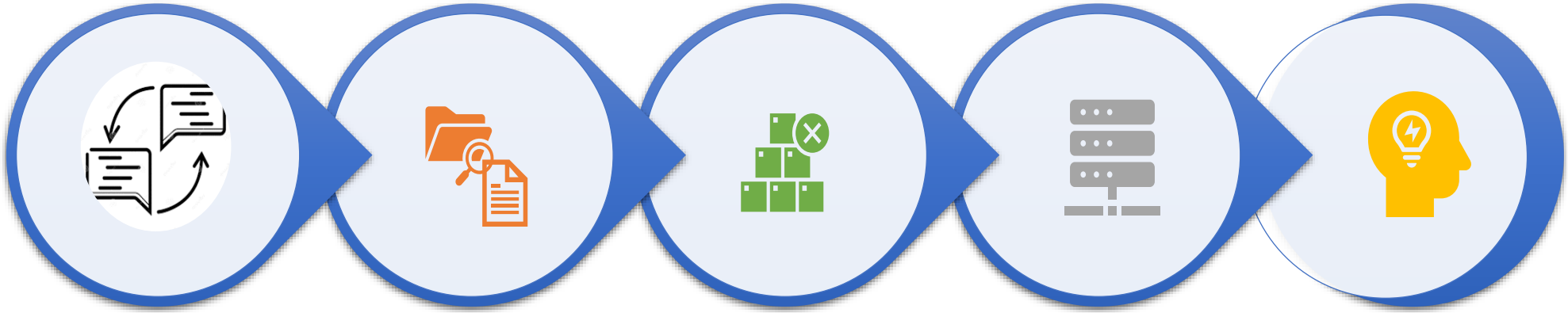
Guidance To Efficient CRF Design

❑ CURRENT CRF DESIGN PROCESS

- Many countries' health authorities (HA) and IRB require draft CRFs for protocol approval long DM is on boarded. Study data quality relies on the quality of the (CRFs) used to collect data.
- Pre-configured standard libraries, for building CRFs within EDC tools are used to streamline data collection across trials. Standard libraries contain CRFs that can be global and therapeutic area specific

❑ DESIGN AND DEVELOPMENT PROCESS



- First step is to translate the protocol into data.
- If Protocol and CRFs are designed concurrently, the quality of both the protocol and the CRFs can be improved
- Avoid duplication of data collection- e.g., collecting patient's age & their date of birth.
- CRFs should be appropriately versioned & dated - especially in the case of a protocol amendment that may lead to changes in the design of the CRFs
- Analyze previous studies, guidelines, and literature relevant to the therapeutic area to identify common data points and best practices.

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Guidance To Efficient CRF Design

❑ BEST PRACTICES

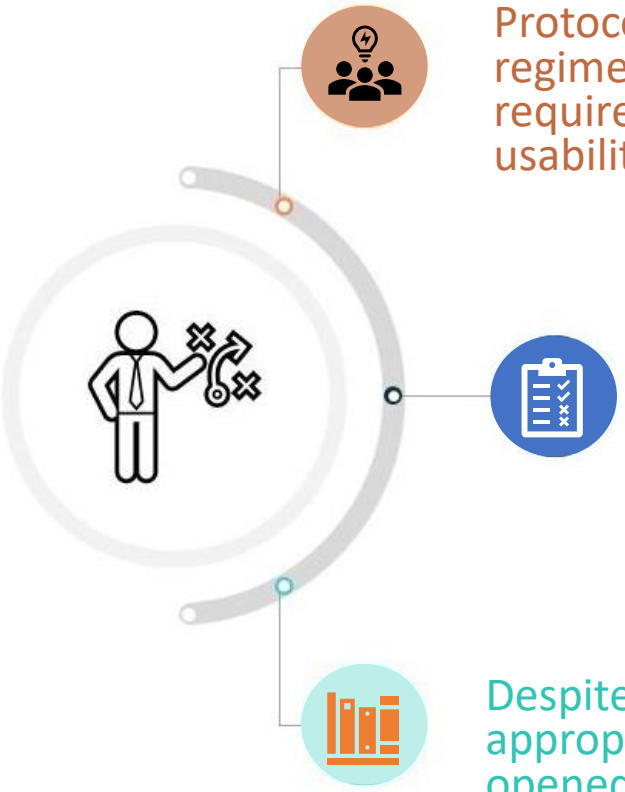
- Multidisciplinary need team to provide inputs into the CRF design & review (e.g data management, biostatisticians, and clinical operations).
- Design the CRF to capture data required by regulatory agencies, and ensure that it adheres to Good Clinical Practice (GCP) guidelines
- Organize the CRF in a logical sequence, following the natural flow of patient visits and assessments
- Design CRFs with study safety and efficacy endpoints in mind.
- Keep the CRF's questions, prompts, and instructions clear and concise.
- Comply with CDISC- CDASH standards and use standardized medical terminology and coding (e.g., MedDRA) to ensure consistency across sites and studies.

❑ CRF REVIEW AND QUALITY PROCESS

- Review against the protocol to ensure all protocol specified data are captured by relevant stakeholders including clinicians, statisticians, data mangers & regulatory experts
- CRFs translated into multiple languages should be carefully reviewed (e.g., back-translations).
- eCRF should undergo User Acceptance Testing (UAT) by concern team members.
- Maintain an audit trail that tracks any changes made to the CRF during the review and quality control process

Guidance To Efficient CRF Design

❑ CURRENT CHALLENGES WITH CRF DESIGN



Protocols can be highly intricate, with multiple arms, treatment regimens, and assessments. Designing a CRF that captures all the required data points accurately while maintaining clarity and usability can be challenging.

There can be several significant impacts of poor CRF review beyond just increased costs such as

- Data Integrity & Quality Issues
- Regulatory Non-Compliance
- Patient Safety concerns
- Delayed timelines
- Resource wastage
- Scientific validity etc

Despite the creation of these robust standard libraries, the process of selecting appropriate CRFs continues to be time-intensive, since every standard CRF must be opened separately, reviewed, and then selected based on the protocol specifications

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❑ CRF DESIGN - CONSIDERATIONS FROM THERAPEUTIC AREA (TA) AND STUDY PHASE PERSPECTIVE

Therapeutic Area Considerations:

- Disease Characteristics
- Endpoint Relevance
- Safety Parameters

Study Phase Considerations:

- Study Objectives
- Sample Size
- Data Collection Frequency
- Adaptive Design

By considering both the therapeutic area and the study phase, we can tailor the CRF design to effectively capture the necessary data and support the successful execution of the clinical trial. Collaborating with experts in the field and utilizing previous research can provide valuable insights for designing a robust CRF.

Guidance To Efficient CRF Design

❑ RISK & CONSEQUENCES OF POORLY MANAGED CRF DEVELOPMENT

- Increase the time of CRF creation which will have direct impact on the costs
- Errors and issues arising from poorly managed CRF development can lead to delays in study timelines, impacting recruitment, data collection, and study completion.
- Collection of redundant data (*A 2014 survey by the Medical Device Innovation Consortium of 22 pivotal clinical studies revealed that only about **57%** of data points captured in CRFs were ultimately used in regulatory submissions. The rest simply added time and cost to collect and verify)*
- Increase number of queries leading to additional data cleaning timelines
- Create strain on study team resources due to multiple review circles
- Increase downstream impact on programming such as remapping of variables

Poorly designed

Date of visit: _____

Blood pressure: ____ / ____

Pulse: _____
Temperature: _____
Respiration: _____

Well designed

Date of visit: ☐☐/☐☐/☐☐☐☐ (DD/MM/YYYY)
Blood pressure: ☐☐☐/☐☐☐ (mmHg)
Pulse: ☐☐☐ (beats/min)
Temperature: ☐☐.☐ (°C)
Respiration: ☐☐ (/min)

Guidance To Efficient CRF Design

❑ REVOLUTIONIZING CRF DESIGN : HARNESSING THE POWER OF ARTIFICIAL INTELLIGENCE

By using AI, it is possible to automate certain aspects of CRF design and make it easier to collect and analyse data.

By using ML algorithms, it is possible to identify patterns & trends in data that may not be easily visible to humans which can help to improve decision-making & facilitate more efficient and effective data-driven decision-making.

Some of the benefits of using AI for CRF design

- Improved efficiency
- Enhanced accuracy
- Increased flexibility
- Cost savings
- Data quality


Thank
You
Merci
Mamana
GRAZIE
Kiitos
Juspaxa
MATONDO
Obrigado
Kia Ora
DANK JE
ASANTE
Vinaka
Multumesc
Matondo
Chokrane
Asante
Arigato
SPASIBO
Cam on ban
NIRRINGRAZZJAK
Mochchakkeram
Raibh Maith Agat
Terma Kasih
Maake
Ua Tsaug Rau Koj
Matur Nuwun
Salamat
Nirringrazzjak
Mamana
Grazie