



# DATA MANAGEMENT CHALLENGES

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Powering research  
to prevent epidemics

# Data Management

- ❑ The purpose of data in our context is to gather information needed to answer research questions and proving or disproving a hypothesis.
- ❑ The primary objective of data management processes is to provide high-quality data, keeping the number of errors and missing data to the lowest minimum and gathering maximum data for analysis.

# **Good Clinical Practice (GCP) E6(R3) ICH Consensus Guideline: 19 May 2023**

## **3.16 Data and Records**

- (a) The sponsor should ensure the integrity and confidentiality of data generated and managed.*
  
- (b) The sponsor should apply quality control to the relevant stages of data handling to ensure that the data are of sufficient quality to generate reliable results...*

# Data Integrity Principles

The clinical research data must possess the following attributes:

- Attributable:** the who, when, what and why?
- Legible:** readable and permanent?
- Contemporaneous:** at the right time?
- Original:** unaltered state and 'true copy'?
- Accurate:** is it the right value/action?
- Complete:** is all information available?
- Traceable:** does it have an audit trail?

# Electronic Data Capture Vs Paper-based Data Management

- ❑ With the exponential advancement in technology, electronic data capture (EDC) has gained more acceptability over paper-based data management systems.
- ❑ The advantages of EDC over paper-based data management include:
  - **Enhanced Data Quality:** built-in validation checks, minimises errors.
  - **Efficient Data Management:** streamlines the data management process, enabling real-time data collection, monitoring, and analysis.
  - **Cost and Time Savings:** eliminates the need for paper-based data entry, transcription, and archiving.
  - **Data Security and Accessibility:** robust security measures to protect sensitive patient information.

# Data Management Challenges – our Field Experience

## Infrastructural

- Poor internet connectivity.
- Poor electricity supply/power outages
- Lack of data capturing devices

## Technology

- Issues with software
- Lack of validation
- Outdated software
- Cyber security issue

## Operational

- Absence of data management plan
- Lack of SOPs for data management
- Failure to comply with SOPs
- Distraction during data entry
- Failure to synchronize entered data timely

# Data Management Challenges – from Literature

<b>Pain Point (n=62)</b>	<b>Percent of Respondents Experienced</b>
Planned Mid-Study Updates / Protocol Amendment Delays	56.5%
Unplanned Mid-Study Updates / Protocol Amendment Delays	48.4%
Flexibility and Customization Challenges	43.6%
Database Go Live Delays	32.3%
Lack of Integrated Patient Engagement / eCOA Applications	32.3%
Solution Cost	30.7%
Data Incompatibility Between Platforms	25.8%
Customer Support Problems	22.6%
Solution Complexity / Slow User Learning Curve	19.4%
Other	16.1%

2024 MJH Life Sciences, global survey - September and October 2020

# Overcoming the Challenges

- Develop an appropriate data management plan.
- Ensure human resource capacities for data management
- Provide adequate resources for data collection, processing and archiving.
- Train personnel on process documents and procedures
- Put in place an effective quality control system to ensure the data quality.
- Use up-to-date technology with a validated electronic system.
- Effective access control must be put in place.
- Audit trail is critical.
- Use solutions that can run on low-band network – in LMICs
- Paper-based records should be handled carefully to avoid mutilation, destruction due to environmental factors, and unwarranted accesses.
- Back-up in case of unforeseen act of God.

# *Conclusion*

To be prepared for a future filovirus outbreak, data management challenges should be identified in each study site with the aim of mitigating any risk such challenges could pose.

**Thank you for  
your attention**

# References

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- ❑ Krishnankutty B, Bellary S, Kumar NB, Moodahadu LS. Data management in clinical research: An overview. Indian J Pharmacol. 2012 Mar;44(2):168-72. doi: 10.4103/0253-7613.93842. PMID: 22529469; PMCID: PMC3326906.
- ❑ Beth Harper et al. Feb 2021. Characterizing Clinical Data Management Challenges and Their Impact Applied Clinical Trials. Applied Clinical Trials 02-01-2021. Volume 30; Issue ½.