



MAKERERE UNIVERSITY

Infectious Diseases Institute

College of Health Sciences, Makerere University



TECHNICAL BRIEF

UNVEILING UGANDA'S HUB FOR MANAGING CLINICAL DATA WITH GCP-COMPLIANCE FOR MULTI-NATIONAL CLINICAL TRIALS AND BEST BUSINESS PRACTICE

BACKGROUND

Increasingly, government and non-government research organizations are handling large amounts of health-related data, which must be collected, processed and analyzed; whether that data is initially captured remotely and directly from clinical sites.

In countries burdened with infectious diseases, clinical trials and academic research form a bedrock for generating evidence to inform policies and strategies suitable for those settings.

In the advent of Global Health Security Agenda, Big Data-driven programming, longitudinal cohort clinical trials, and bioinformatics, good clinical and laboratory practice (GCLP)-compliant data management takes precedence for decision making in both resourced and resource limited settings (RLS).

PROBLEM

Implementing GCLP-compliant data management standards in RLS is complicated because:

1. There are not many hubs/centers of excellence for multinational clinical trials complying with the international regulations and standards.
2. Implementing these standards (fig1) is costly, requiring expertise, IT setup, big data sources, routine software license maintenance cyber and security infrastructure.

SOLUTION

Implementing FDA 21 CFR Part 11 requirement:

In 2009, the US Office of Cyber infrastructure and Computational Biology, (OCICB) National Institute of Allergy and infectious Diseases (NIAID), National Institute of Health (NIH), NIH-Uganda and ICER primed the Infectious Diseases Institute (IDI) of the College of Health Sciences, Makerere University to implement a clinical data management unit called DataFax/DFdiscover at IDI to produce high quality, timely, and reliable data arising from its research activities.

DataFax/ DFdiscover: is a client server application, hybrid paper Fax and Electronic data capture system, compliant to FDA regulations under 21 CFR part 11. The software implements controls including Audit trails, System validations, Electronic signatures and Password aging.

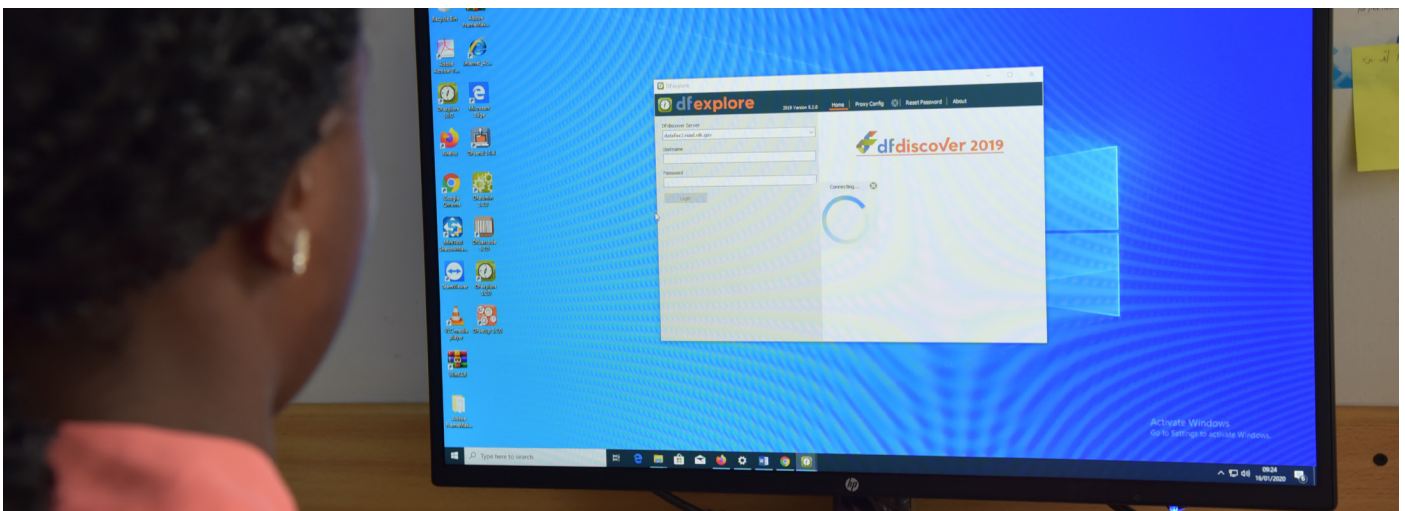
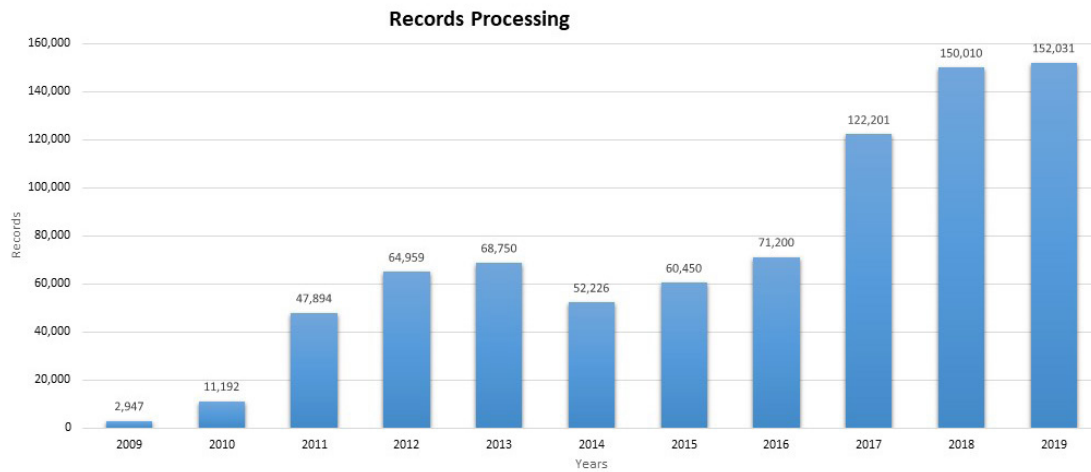
Building National Capacity: Mulago National Referral Hospital in collaboration with IDI currently implements DataFax/DFdiscover, Adobe FrameMaker on 10 computers.

DFdiscover software upgrade: In 2018/2019, OCICB/ NIAID/NIH supported IDI to upgrade DataFax to DFdiscover to match up to the new evolving technologies in health. It now includes DFcollect a mobile based app and DFweb a web based app bringing the power of DFdiscover to your computer.

Acknowledgments

IDI DataFax Team: Agnes Kiragga, Betty Agwang, Brian Isaaya, Bruce Atukunda, Nankungu Lydia, Eunice Akiror, Harold Ndawula, Stella Nawenja, Peter Ssenkungu, Justus Kimera.

IDI Documentation & Communications team: Daisy Munduru, Tania Diakite, Abubaker Kazibwe, Kenneth Mulindwa, Caroline Asimwe.



CALL TO CONNECT

IDI invites indigenous and international research institutions to use the DFdiscover platform for big data management, data security services.

Interest groups include, big data handlers (Academia, Government agencies, Pharma companies, Development agencies, PhD students, Research fellows)

TESTIMONIALS

“The IDI DataFax team is very professional and offers superb service. Ultimately, it’s using technology to be more efficient. DataFax has lower cost than hiring a data entry clerk to manually type in the data, and the advantages are astronomically better.” David R. Boulware, M.D., MPH, CTropMed - & NOAT

“The DataFax system is a breath of fresh air in the management PI COAT of massive data arising from clinical studies like ours. The system ensures that; 1) we are not dealing with human errors in the abstraction of our data from CRFs, 2) our data is available in a timely manner and 3) it’s easier to conduct pre-analysis data checks to confirm the validity of our data.” Amara Ezeamama-Onye, PhD - Co-PI TOV

“Because of the impressive DataFax system - a system we are using to manage, input and store data related to the trial - the trial database will be maintained in real time. I, as an external monitor, can log into the system and check for inconsistencies at home, at any time. That makes life a bit easier.” Angela Colbers - Trial Monitor - DOLPHIN Study