

Effective Query Management in Visceral Leishmaniasis Study Using An In-house Built System.

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INTRODUCTION

Query management is a major processes in data management used in identifying and resolving discrepancies in clinical trials data. This directly impacts on data quality and also the integrity of research outcome. Query management vary from one organization to another, at DNDi¹ Data Center (DC), we use an in house built system called QMSPlus together with STATA² for query management. QMSPlus is a result of continued improvement on previous versions based on our experience in Query management in several studies over the last 8 years.

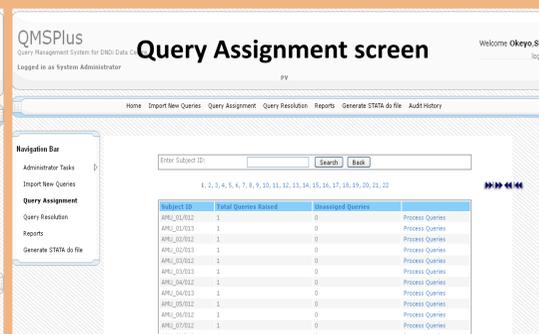
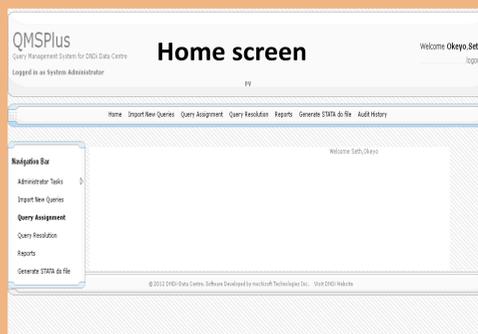
METHODS

QMSPlus is a java based web application which runs on Tomcat Server using Postgres Open source Database at the back end. The web interface makes it easy to setup the Query Management System in five simple steps namely;

1. Setting Up a study on the QMSPlus
2. Adding Users to the study on QMSPlus
3. Defining Query Definitions
4. Defining query Variables
5. Importing Queries to Process into QMSPlus.

QMSPlus setup process

- Once the study setup in QMSPlus is complete. The Queries to process csv file is imported into QMSPlus. This will add new subjects with Queries and group all subject queries together for ease of assignment.
- The Data Manager (DM) then reviews subject Queries one by one assigning them to Site, Monitors or DC for resolution.
- The DM then downloads in pdf or prints Query/Data Clarification Forms from the system then forwards to respective recipients for resolutions.



OBJECTIVES

To setup a clinical query management system that :

- 1.meets regulatory requirements (21 CFR part 11³)
- 2.Is easy to learn and use.
- 3.Is affordable.
- 4.Is fast and scalable.

RESULTS

On receiving Query responses from the sites, the Study Data managers either;

1. update the QMSPlus with the received resolutions from the site, or
2. Update OpenClinica database with the received resolutions.

If option 1 above is used, the DM will then generate a STATA do-file from the QMSPlus with resolutions which will be run in STATA to apply changes on the dataset extracted from OpenClinica in order to get a resolved/clean dataset.

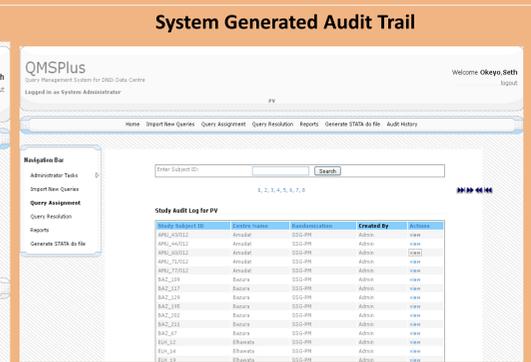
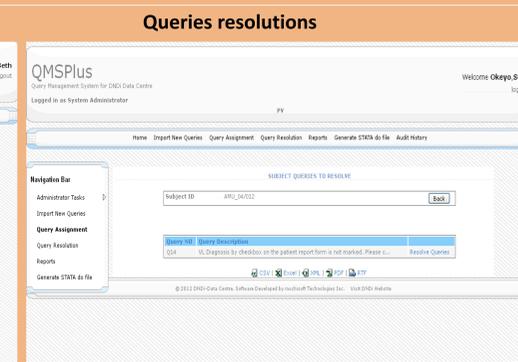
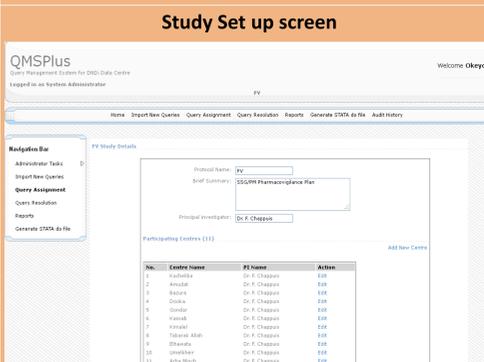
The query resolution process meets the desired ICH-GCP⁷ Compliance including maintenance of Audit trails, system security and Quality Assurance in all the steps.

Trials Managed in DNDi QMSPlus

Study	QMS Version
LEAP 0106	Access Based QMS
LEAP 0208 ⁴	Access Based QMS
PV Study	QMSPlus v 1.0.0
KATEX	QMSPlus v 1.0.0
Buruli Study ⁵	QMSPlus v 1.0.0
FEXI Study ⁶	QMSPlus v 1.0.0

What Is QMSPlus?

- It is a java based web application for clinical query management developed on open source technologies.
- Allows import of study queries in .csv format; query resolutions are then exported from the system in .do file format.
- Study Queries are assigned to various respondents and Data Clarification Forms downloaded in pdf format.
- Developed by DNDi Data Center.



Why Use QMSPlus?

- QMSPlus is designed to achieve efficient Clinical Trials Query handling by;
- Simplifying query generation exercise.
- Eliminate redundant query to sites
- Providing a better way of categorizing queries; queries can be sent to Sites, can be resolved by the Data Center, or by the Clinical Trials Coordination office.
- Generating study Final Query Report by a click of a mouse.

CONCLUSIONS

The use of QMSPlus in query management for clinical trials has made it possible to simplify the process while at the same time improving data quality. The system is based on open source technologies which are readily available and has the potential of revolutionizing query management in Clinical Trials conducted in Sub Sahara Africa and beyond.

Query Management in Clinical Trials is a key component of Data Management and gives an assurance that the final data used for analysis can be trusted to be of highest integrity. Using QMSPlus makes this a reality for any study on which it is used.

REFERENCES

1. Drugs for Neglected Diseases initiative. Available: <http://www.dndi.org>. Accessed 3 Dec 2013.
2. STATA Available: <http://www.stata.com> Accessed 3 Dec 2013.
3. FDA (2012) 21 CFR 11. Available: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/cfrsearch.cfm?cfrpart=11>. Accessed 26 June 2013.
4. <http://clinicaltrials.gov/show/NCT01067443>
5. <http://clinicaltrials.gov/ct2/show/NCT01659437>
6. <http://clinicaltrials.gov/ct2/show/NCT01980199>
7. ICH-GCP Guidelines. Available: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf Accessed. 03-Dec-2013