

Alternative approach to using OpenClinica in “Offline” mode: A case of WHO Buruli Study.

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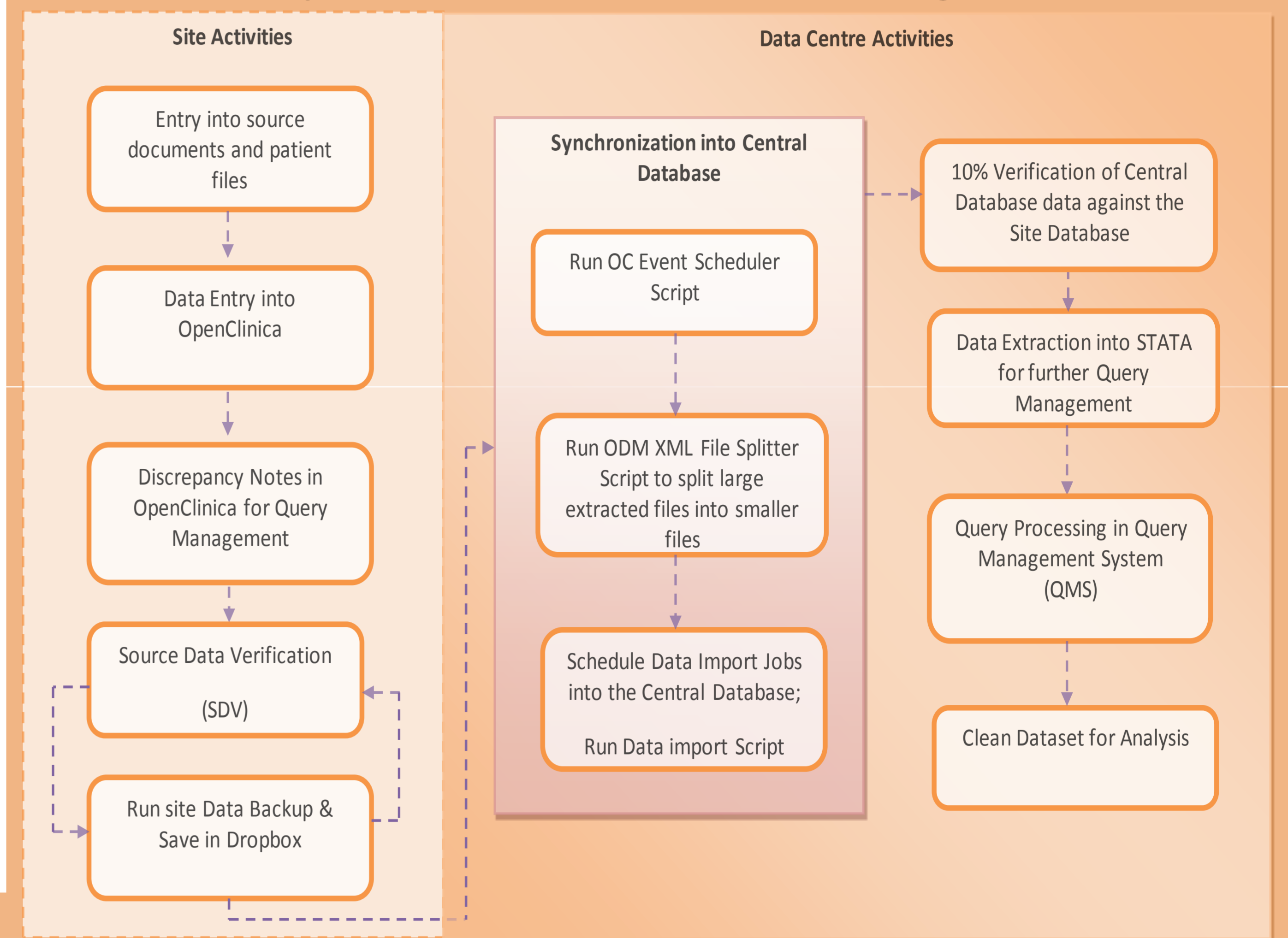
INTRODUCTION

OpenClinica¹ (www.openclinica.com) is one of the world’s most widely adopted Clinical Trials software which is currently being used to manage Clinical Trials data in over 100 countries across the world. DNDi² Africa Data Center is currently using the Community edition of the software to manage a multi-site, multi-country WHO Buruli ulcer study in West Africa (ClinicalTrials.gov: NCT01659437³) in an offline mode. This approach was adopted due to weak internet infrastructure across the study sites which makes it difficult to use online version of OpenClinica.

METHODS / RESULTS

In operating OpenClinica (OC) in offline mode, we setup the final OC study database the normal way, first creating the electronics CRFs in Excel templates followed by validation of the same. When the final database is ready for use, the study database dump is used to replicate the study database in all study site computers, site users then proceed to collect data in their respective computers and then generate database dump which is then sent back to DNDi Data Center (DC) for synchronization with the central database. At the DC, OC Event Scheduler (Python Script⁴) which adds subjects and schedules their event in the central database through web services is executed. Once this is done, the site data is imported in the central database using OC Data importer (A Python Script utility which uses Web services). A report /Log file showing the status of the imported data is then generated and filed.

OpenClinica in offline mode activities flow diagram



OBJECTIVES

To setup a clinical data management system that is:

1. ICH-GCP Compliant
2. Easy to learn and use.
3. Affordable.
4. Platform Independent for the end user.

RESULTS

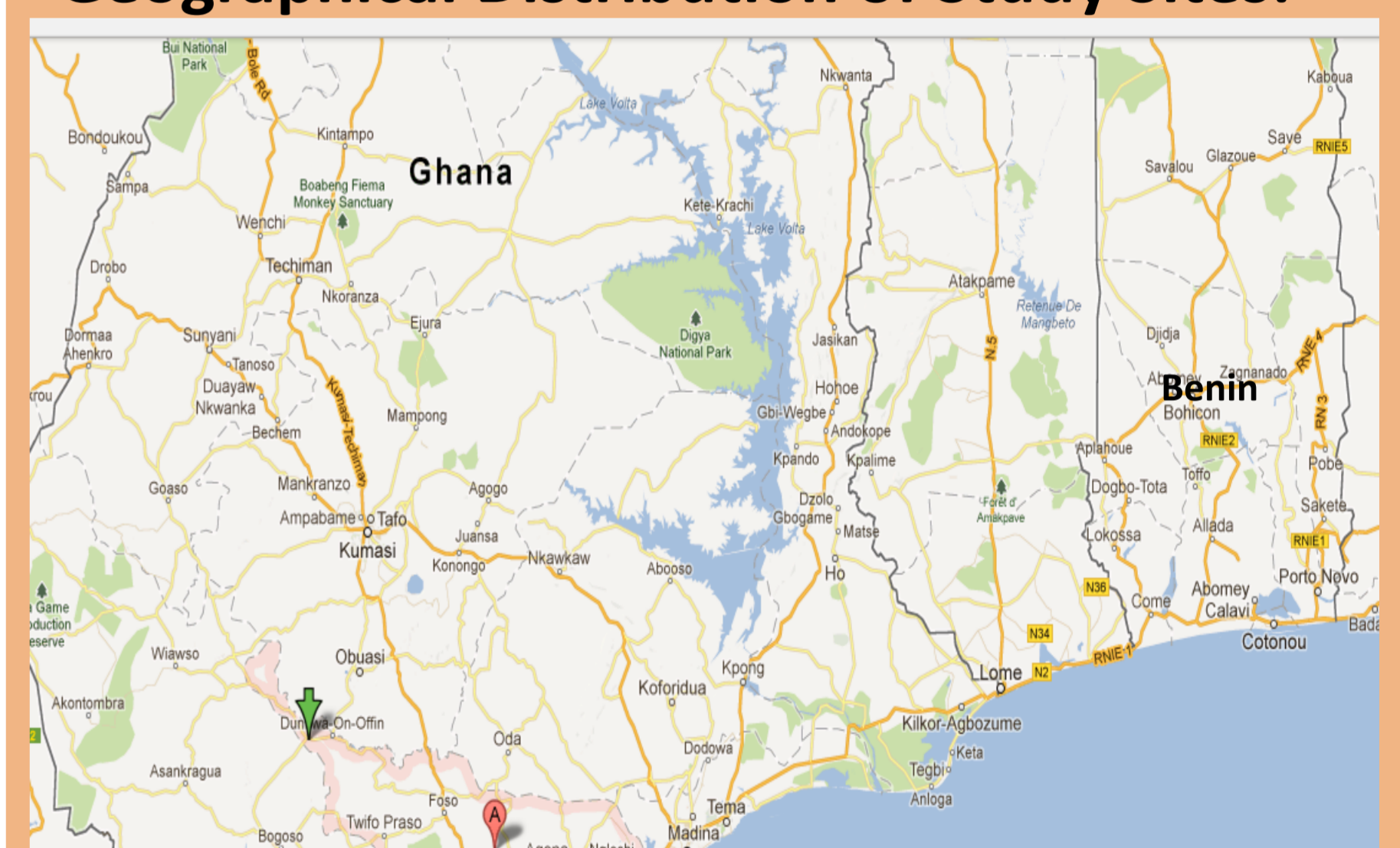
Benefits of Offline use of OpenClinica:

- No need for internet at data entry; internet only needed periodically for synchronization.
- Data entry is fast since issues of slow internet and bandwidth congestion is avoided.
- Data Management Capacity at the site is greatly improved. Site Data Managers are fully in charge of the study database.
- OpenClinica is Affordable- free to download and use; open-source tools used for synchronization.

Challenges with offline implementation:

- **Large Data imports**
-Takes much time; scheduled to run over the weekend
- **Standardize OC installation between sites and DC**
-Any change on the central DB is replicated across all site DBs.
- **OC is designed to work in online mode**
-Limited use and acceptance in the presence of poor and unreliable internet infrastructure
- **A number of processes are involved**
-Most of them automated making the whole process feasible

Geographical Distribution of Study Sites:



What Is OpenClinica?

- It is an open source software which is free to use for collecting and managing Clinical Trial Data
- OpenClinica is 100% web-based so all that a user needs is a computer, a web browser and an internet connection to use the software.
- It allows data submission to Electronic CRF’s, management and monitoring of that data and extraction of the data for analysis

OpenClinica-Study Subject Listing

OpenClinica Event Scheduler

OpenClinica Sync Log

Why Use OpenClinica?

- It has a large and growing user base.
- It meets regulatory requirements (21 CFR part 11⁵) including audit trails.
- It is designed to minimize data errors.
- It allows remote management of multisite trials.
- It allows rapid checking/monitoring of data.
- Free to use for non- Commercial purposes- based on Open Source LGPL License

CONCLUSIONS

OpenClinica remains one of the world’s preferred software in Clinical Data Management for clinical trials; however, lack of an offline version for this software is limiting its acceptance and use in sub-Saharan Africa due to poor and unreliable internet infrastructure. This has prompted us to come up with ways [6] that can help researchers in using the free version of OpenClinica in offline mode, a number of processes are involved but most of it is automated making its implementation feasible.

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