$\mathbf{D}\mathbf{N}\mathbf{D}\mathbf{1}$ **Drugs for Neglected Diseases** *initiative*

Alternative approach to using OpenClinica in "Offline" mode: A case of WHO Buruli Study. Michael Ochieng¹, Raymond Omollo¹, Rhoda Owiti¹, Seth Okeyo¹, Truphosa Omollo¹, Brian Mutinda¹, Kingsley Asieudu², Monique Wasunna¹ ¹Drugs for Neglected Diseases *initiative*, ²World Health Organization

INTRODUCTION

EINUUS/ KESULIS

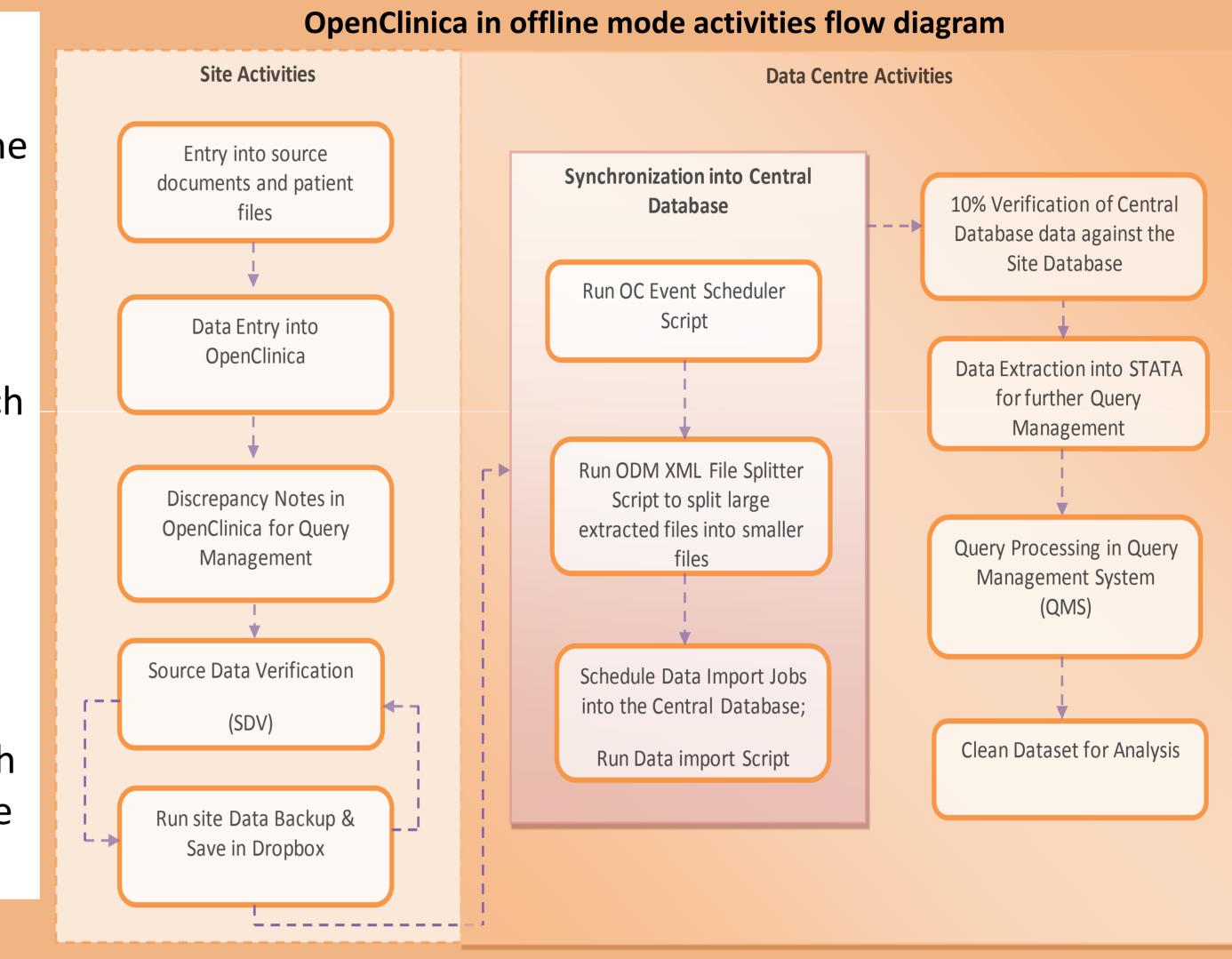
OpenClinica¹ (<u>www.openclinica.com</u>) is one of the world's most widely adopted Clinical Trials software which is currently being used to manage Clinical Trials data in over 100 countries across the world. DNDi² Africa Data Center is currently using the Community edition of the software to manage 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.

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.



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.

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

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.

OpenClinica-Study Subject Listing

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Alerts &	Messages 🔻	1						
Instructi	ions 🔻	View Subje	cts in T	irap VAC Study 😰				
Info	•		15 🗸	Show More Select An Event	Add New Subject			
Icon Key	-				Systemic AE Follow-up to Day 3	Systemic AE Follow-up :Day	4-7 Clinic Visit: Day 14	Pre Vaccination Check Two
Statuse	5							
	Not Started	TRAPVAC027	E	Ē	Ē		B	Ē
@]	Scheduled	TRAPVAC019	E	E	ß		E	B
8	Data Entry	TRAPVAC024	Ē	Ē	Ē		E	Ē
_	Started	TRAPVAC010	E	B	ß		E	B
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	Completed	TRAPVAC014	E	Ē			Ē	Ē
<u> </u>	Signed	TRAPVAC022				_		
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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

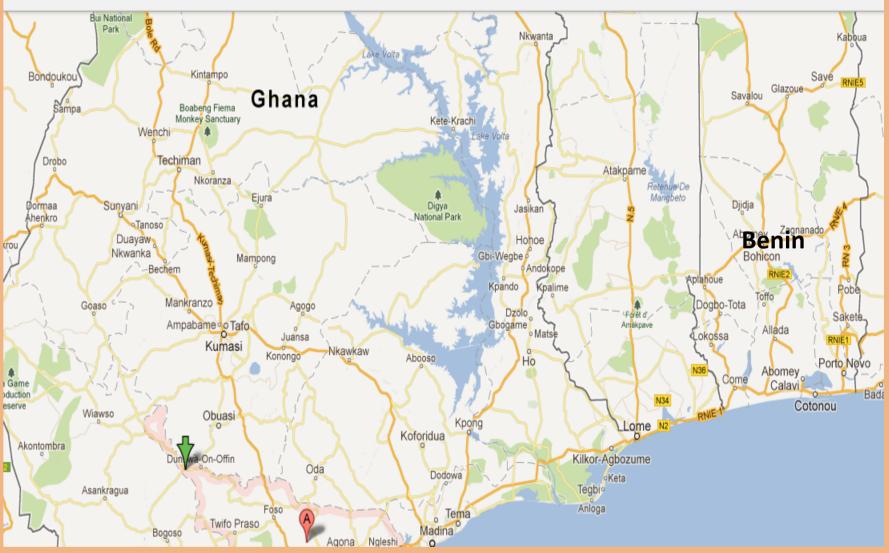
-Limited use and acceptance in the presence of poor and unreliable internet infrastructure •A number of processes are involved

-Most of them automated making the whole process feasible

OpenClinica Event Scheduler

	1	OpenClinica Sync Tool							
		- Central Database Paramet	ers	ite Database Parame	Database Parameters				
		Central DB Name:	buruli_study		Site DB Name:	buruli_agogo			
		Central DB Host IP:	localhost		Site DB Host IP:	localhost			
on Check Two		Central DB Username:	clinica		Site DB Username:	clinica			
		Central DB Password:	*******		Site DB Password:	*******			
				JL					
					Clear Imp	ort Subjects and Sched	lule Events		
		Subject I	mport and Schedule Log						
		*					- F		

Geographical Distribution of Study Sites:



OpenClinica Sync Log

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A1 • (*			(•	fx 9/30/2013 10:53:00 AM								
	А	E	3	С	D	E	F	G	Н	I.	J	к
1	##########	Data_Impo	ort	INFO	BURULI ST	UDY						
2	##########	Data_Import		INFO	Site Data Import into Central OpenClinica Database							
3	****	Data Import		INFO	Data Impo	ort Report						
4	****	Data_Import		INFO	Date:2013-09-30 10:53:07.551000							
5	****	Data_Import		INFO	Study Site Identifier:BURULI Study-Agogo							
6	****	Data_Import		INFO								
7	****			INFO	Attempting database connection							
8	****	*#####################################		INFO	Connected to the DB!							
9	****	##### Data_Import		INFO	Importing Subject Data							
10	****	# Data_Import		INFO	AG 015							
11	****	Data_Import		INFO	AG 015	WK 8	ECG_CRF	CG_CRF Success All Items Imported Succe		Successfully		
12	****	Data_Import		INFO	AG 015	WK 8	PREGNAN	Success	All Items Imported Successfully			
13	##########	Data_Import		INFO	AG 015	WK 8	Haematol	Success	All Items Imported Successfully			
14	*****	Data_Import		INFO	AG 015	WK 8	BIOCHEMI	Success	All Items Imported Successfully			
15	*****	Data_Import		INFO	AG 015	WK 8	URINALYS	Success	All Items Imported Successfully			
16	##########	# Data_Import		INFO	AG 015	WK 8	LESION_A	A Success All Items Imported Success			Successfully	
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18	****	Data_Impo	ort	INFO	AG 015	WK 8	WOUND_	Success	All Items I	mported S	Successfully	

Why Use OpenClinica?

CONCLUSIONS

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• 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

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-Sahara 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.