

EXPERIENCES AND PERSPECTIVES ON READINESS AND PREPAREDNESS ACTIVITIES FOR THE PHARMACY EMA INSPECTION

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AGENDA

1. Site overview
2. Site selection
3. Pharmacy Plan/Strategy
4. Preparation Activities
5. Inspection week
6. Post inspection
7. Challenges or Points to Note
8. Lessons learnt



1. SITE OVERVIEW

SITE:

- Gaborone CRS, site 12701, Pharm Org ID: 61042
- Service multiple studies

INSPECTED STUDY:

- HPTN 084 pre OLE phase

PHARMACY STAFF COMPLEMENT:

- 1 pharmacy manager
- 2 pharmacists
- 2 pharmacy technicians

- The pharmacy data and documents are 100% paper based

2. SITE SELECTION

The support structures;

- HPTN 084 Protocol team
- Sponsor support –DAIDS
- PAB protocol pharmacist (The 5 P's)
- CRO Pre-inspections
- CTU and study management support
- Clinic and pharmacy team-work

The support carried the team through the rigorous preparation period

3. PHARMACY PLAN/STRATEGY

Developed a list;

- Worksheet: Activities assigned to personnel. Timely review and update, PoR verifying completion.
- PID spreadsheet with notable events e.g. EAEs, pregnancies, early study drug termination.
- 100% QA of participant folders
- Regulatory submissions, PAB reportable incidents, TERFs, NTFs and CAPA reviews



Mental Welfare

- Choose to have a positive attitude

4. PREPARATION ACTIVITIES

- Assign roles to pharmacy personnel
- Review of documents
 - Check all boxes
 - ALCOA-C
 - Storyboards, CAPAs
- **NB: The SOPs should be in alignment with practice on ground**
- Communicated work balance
- Site meetings and Mock RUNS
- Site Area organisation
- Review with support teams
- Look-out for possible time-sensitive requests from PAB on behalf of the inspectors.



***Team work
is key!***

5. INSPECTION WEEK

Front Room scribes;

- The overall inspection scribe -a live note capturing system
- Pharmacy specific scribe

DAIDS team were on standby to give support

1 hour long Pharmacy tour covered the following;

- Pharmacy staff component and roles
- Stock management processes-ordering, receipt, storage and final disposition
- Processes of maintaining blinding
- Study treatment assignment and randomization
- Temperature monitoring systems- temperature records and equipment calibration
- TERFs and temperature excursion management procedures
- Equipment calibration records

5. INSPECTION WEEK cont..

The inspector reviewed

- PID record against Lot number specific Study Product Accountability Record (as shown in the survey List)
- PIDs with notable events reviewed at the clinic were followed up at the pharmacy
- Study IP preparation procedures in detail;
 - Prescription review
 - Treatment allocation and use of iMedidata,
 - Study Product Accountability,
 - Steps of study product preparation
 - Study product Delivery to the clinic and administration (Chain of Custody).
- Pharmacy Quality Management
 - Quality control measures including:
 - QC by Q1 and Q2
 - QA by the pharmacists

6. POST INSPECTION

Staff debrief;

- Sponsor
- Site staff
- Await and receive final report
- Organise staff leave/rest days
- Takes time to be back to normal

7. CHALLENGES OR POINTS TO NOTE

- The first alert can be daunting- sponsor and site management support crucial
- Requests with tight deadlines
- Time difference (Completion of assignments and meetings)
- Pharmacy regular work continues- balance
- All the pharmacy procedures and processes are inspected (Not only specific to the study inspected)
- Preparations take time and need diligence and commitment-overtimes
- Keeping the team motivated through all steps
- Catch-ups post inspection
- Fatigue, time offs and scheduled leave days management

8. LESSONS LEARNT

- i. Be prepared (Tedious but worth it!). The inspection week becomes less stressful

- ii. Monitoring and Evaluation
-The feedback from the pre-inspection and the inspection was used to update SOPs and systems. Immediate implementation

- iii. Training
NB especially if there is staff turnover. Site SOPs, NTFs, CAPAs and improvements. Retrain when need arises

- iv. A learning and fulfilling experience that has led to all team members appreciating their impact on evidence based decisions

Thank you

Appreciation: Gaborone
CRS, Pharmacy team
and all stakeholders that made the
EMA inspection a success

Questions or Comments

