

PRACTICAL EXPERIENCE IN GCP INSPECTIONS - GHANA



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Presented by
Mrs. Delese Darko



... Working for your Safety!

LEGAL MANDATE GOVERNING CLINICAL TRIALS IN GHANA

- Food and Drugs Act of 1992, (PNDCL 305B)Section 23;
 - Any person who carries out a clinical trial test of a new drug on humans in the absence of documentary evidence that human pharmacodynamic and pharmacokinetic studies on healthy volunteers have been properly carried out commits an offence
 - Any application for a clinical trial certificate or animal trial certificate shall be made to the Board in such form **as may be prescribed*** and may be granted subject to such conditions as the Board may determine
- The Food and Drugs Board started GCP inspections in year 2005

Types & Phases of Clinical Trials Being Conducted Currently

- Phase I - 1 pending final report
- Phase II - 1 on-going
- Phase III - 7 of which 6 are on-going and 1 awaiting final report
- Phase IV - 3 (all on-going)

A total of 40 trials have been authorized since 2004

Inspections in Ghana

- **Sites most commonly inspected:**
 - Clinical Investigator
 - Analytical Laboratory (part of research centre)
- Currently 9 approved centres for clinical trials

Inspection Finding 1

- **Improper witnessing of Informed Consent Forms**
- **ICFs for all study participants had been witnessed by one and the same community elder**
 - In certain local settings, community elders play very key roles and some clinical trials cannot take place without their consent and involvement.

Reference: ICH E6(R1) sub-section 4.8.9

An **impartial** witness should be present during the entire informed consent discussion.

- ***Impact: Minor (Graded as such after interview process with witness)***

Comment

- (a) How impartial is the one witness**
- (b) If there is a misunderstanding, all trial participants are affected.**
- (c) Is there the possibility of coercion by the community elder (consent???)**

CAPA

- (a) Insisting on a well consented process by ensuring witnesses are competent enough to clearly understand the whole process**
- (b) In such cases, the witnesses are interviewed by inspectors to ensure/verify complete understanding of consent process and ICF**

Inspection Finding 2

- **Delegation of some clinical responsibilities to "unqualified" field workers. {qualification vrs experience}**
- Some trials activities have to be conducted at sites outside clinical facility. Fieldworkers usually not qualified medically, are delegated the responsibility of conducting these activities e.g dispensing of tablets, taking participants temperature, collecting initial ADR information.
- These responsibilities are not clearly stated in the delegation logs and sometimes these fieldworkers may perform more complex duties like providing medical care on the field.

CON' T

Reference: ICH E6(R1) Section 4.1.5, 4.2.3, 4.3

- The Investigator should maintain a list of appropriately qualified persons to whom the Investigator has delegated significant trial related duties
 - The Investigator should have available an adequate number of qualified staff (and facilities) for the foreseen duration of the trial
 - Qualified physician should provide medical care to trial participant.
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- ***Impact of Finding: Critical/Major***

Comment

Distance of health facilities in some communities

**"Experienced" but not necessarily qualified field workers are trained appropriately to perform some activities
Medical care provided is usually basic as per protocol**

CAPA

Training and its impact is assessed by interviewing randomly selected team members

- functions of team members are clear and unambiguous in delegation log**
 - parenteral administration is done solely by qualified personnel e.g Nurse**

Inspection Finding 3

- **Improper Transport and Storage of some Investigational Products:**
 - In field trials, investigational products like vaccines, may sometimes have to be transported from the pharmacy to the field and back. The cold chain is kept using in ice-chests with icepacks.
 - This transporting process although effective, is not usually fully validated
- **Reference: ICH E6(R1) sub-section 4.6.4**
To store in accordance with sponsors specification and requirements

Impact: minor

Comment

Usually dummy shipment records are available using empty storage devices and containers

**Repeated with dummies of the same volumes and densities as the quantity of IMP
CAPA**

Ensuring cold chain with limited resources like nitrogen pack, temperature reading is done with thermometers at regular intervals of the day on the field

This system is being validated as far as possible although currently is acceptable from GCP Inspections

Provisions of products with VVMs would be beneficial

Inspection Finding 4

Lack of Formal Autopsy report for a serious (fatal) adverse events

- In some sites, fatal cases are sometimes accompanied only by verbal autopsy reports
 - No consent given for formal autopsy due to religious/cultural reasons
 - Participants usually interred within 24 hours due to religious reasons

Reference: ICH E6(R1) sub-section 4.11.1 and 4.11.3, FDB GCP Guidelines Sub-section 10.3

Inspection Finding 4 contd

To adhere to regulatory requirement and FDB requirement in Sub-section 10.3- all cases that are fatal shall be accompanied by formal autopsy report in a exceptional circumstances where a formal autopsy is not practicable provision of a verbal autopsy report shall be prior approved by the FDB

Impact: Minor

**Ensure that appropriate procedures for
evaluating verbal autopsy reports are
followed (WHO)**

**When the event happens in the
hospital a formal autopsy report is
required**

THANK YOU



