

CHALLENGES IN GCP GUIDELINES IMPLEMENTATION

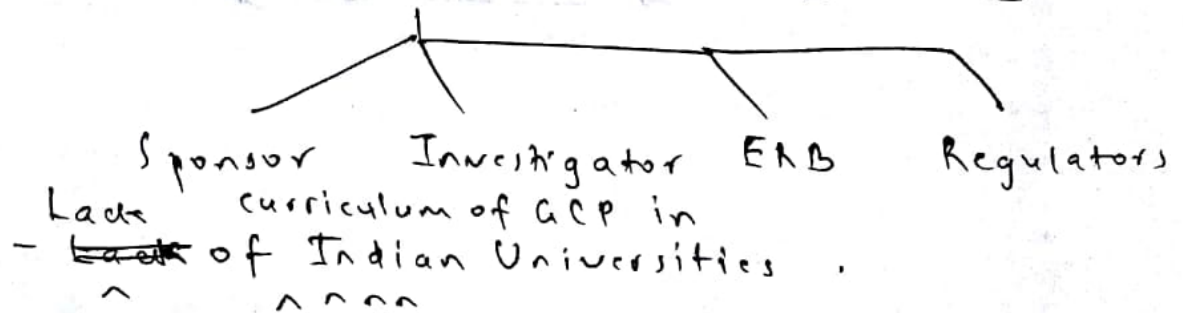
1. PROFESSIONAL TRAINING ON GCP:

- Lack of GCP-trained professionals



Hindrance to implement GCP
Guidelines.

- Lack of professional training, among :



2. INFRASTRUCTURE:

- Most hospitals in India



Fail to meet infrastructure needs,
as per GCP norms.

- Lack of proper labs & diagnostics (with
proper accreditation)



Another obstacle.

3. REGULATORY ENVIRONMENT:

- Lack of implementation of GCP guidelines on clinical trials adherence
- No regulatory ~~body~~ monitoring system to check compliance to guidelines

4. ERB/IRB/IEC:

- Although GCP guidelines require written SOPs on ERB/IRB/IEC
↓
No standard guidelines available on the same.

- Most hospitals



Either do
not have

SOPs for ERB

Or have improper,
unsatisfactory guidelines.

- No provision to monitor SOP adherence.

5. ICD ADMINISTRATION:

- Blind faith of patients on doctor



Leads them to sign documents, without going through it -

(Indirect influence of physician) .

- In most situations



Common man can't understand content of ICD.

- During vernacular translations

(Especially, without proper validation)



Situations become worse .

- Lack of patient advocacy groups



↑ susceptibility of patients to abuse in clinical trials .

6. SAFETY REPORTING:

- Investigator + sponsor



Reports serious & unexpected ADRs to

} Normal cases

IRB / EMB & regulatory authorities.

- Lack of proper implementation of regulatory pharmacovigilance for ADH handling & review.

7. INVESTIGATIONAL PRODUCT:

- Storage, handling & access control of investigational product



Big challenge.

- Lack of:

(i) Evidence to justify proper temperature ^{of investigational drug} ~~maintenance~~ maintenance during shipment.

~~(ii) No standard~~

(ii) Standardization & validation of thermometers provided by sponsor.

(iii) Standard solutions for storage.

8. RECORD-KEEPING / SOURCE DOCUMENTS:

- Storage & retrieval of med. records



Major challenge in most Hospitals.

- Insufficient documentation of patient disease, T/E & progress report.
- Question ~~of~~ on completeness & correctness.
- Maintenance of electronic records is also a major challenge.

9. GRANTS & PAYMENTS:

- No incentives for investigator(s) for working extra time, efforts & investment of capital.

10. TRIAL REPORT / PUBLICATION:

- Negative trials



Rarely published.



One gets to know positive results only



Threats to EBM Validity.

X ————— X