CHAPTER-II

CHALLENGES IN THE IMPLEMENTATION OF GCP GUIDELINES

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Challenges are:

- Professional training on GCP
- Infrastructure
- Regulatory environment
- ERB/IRB/IEC
- ICD Administration
- Safety reporting
- Investigational product
- Record keeping/ source document
- Grants & payments
- Trial report/ Publication

1)Professional training on GCP

The scarcity of GCP trained competent professionals pose a major challenge in the implementation of GCP guidelines

2) Infrastructure

Majority of hospitals in India are not geared up to meet the infrastructure requirements as per the GCP guidelines

3) Regulatory environment

We do not have a regulatory inspection system in place to monitor the adherence and compliance to these guidelines

4) ERB/IRB/IEC

GCP requires written standard operating procedures (sop) for ERB/IRB/IEC however there are no standard guidelines on what should be the content of an ideal SOP so that there is uniformity across various hospital

5) ICD Administration

Administration of ICD is a major challenge in a country like India when the patient/ legal representative has an immense faith on doctor that they insist on signing the document with out reading it or by reading it superficially

6) Safety reporting

It is the joint responsibility of the investigator and the sponsor to report all the serious unexpected adverse event ERB/IRB and other authorities

7) Investigational product

Investigational product storage, handling and control is a major challenge in the implementation of GCP guidelines

8) Record keeping/ source document

Record retention and retrieval is a major challenge in majority f hospitals. The documentation of patient disease, treatment ,progress is adequate to meet the standards of good documentations practice that ensures data completeness and correctness.

9) Grants & payments

Trials agreements are based on the are based on the institutional practice where the research grant goes to a centralized research account. There is no incentive for the investor for investing extra time, efforts and intellectual capital.

10) Trial report/ Publication

Negative trials or trials that get terminated prematurely are rarely published. This is a major threat towards validity of Evidence based Medicine as one gets to know the positive results only.

THANK YOU