Quality Systems in Clinical Trials

Day & Date:	Saturday, 7th May 2016
Time:	11:15 am to 12:15 pm
Venue:	Convention Hall, Symbiosis International University, Lavale campus, Pune
Speaker:	Dr. Suneela Thatte
Report prepared by:	Mr. Varun Joshua V., Student, MBA - HHM (2015-2017)
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Dr. Suneela Thatte is Vice President, Global Operations; Quintiles India has worked extensively to establish clinical research in India and is currently the President of Indian Society for Clinical Research.

ICSR- Indian society of clinical research launched in June 2005. It includes: Institutions, companies, investigators, ethics committee, trained in Clinical research.

ICSR COUNCIL

- Ethics council
- Regulatory council
- Investigatory
- Training
- Clinical data media council pharmacovigilance

Indian regulatory environment

- In 2005 In year 2005, India became fully compliant to TRIPS. Since then the policymakers have been trying to make changes in the policy framework and regulatory environment in order to promote clinical trials in India. These changes are known to have

encouraged the international Clinical Research Organisations (CROs) to expand their clinical research programs in India.

- Pre 20005, India was lagging one phase in phases of clinical trial.

ICSR ROLE

- Broader stake holder involvement
- Advocacy on operational challenges and policy matters
- Engaging with patients
- Active role ,includes in providing feedback

With great effort ICSR have brought the clinical research in India and is enhancing the Clinical research process.

Quality in clinical research:

A quality is a set of characteristics that a product or service must have to satisfy needs and expectations of the customer requirements.

Quality is important as outcome has great impact on patient and has the ability to effectively answer the benefits and risk of a medical report product or procedure etc.

Quality Management System

Set of policies, process and procedures that required to enhance clinical research process.
It includes:

- Quality Assurance
- Quality assurance
- Monitoring

Building quality with quality management System

- Build in quality right from protocol development.
- Identify risk and effectively target resources to potential risk areas.

- Defines to control prevent errors, identify potential problems and intervene before issues become endemic.

Elements of quality management system

- Commitment
- Quality policy
- Qualified, experience trained staff
- Complaint written procedure
- Appropriate infrastructure
- Decision making structure
- Right communication

How to test:

- Self-monitoring - Routine monitoring visit, Co-monitoring visit etc.
- Independent reviews- Audit and Inspection

Quality-Clinical Research Customers:

- Regulatory authorities
- Hospital
- Sponsor
- patients

CYCLE OF CLINICAL TRAIL: it involves:

- Say what you do
- Do what you say } SOPs, protocol- clearly define the objective of the trail, train sponsors, set clear expectations and responsibilities at operational team levels, identify the right investigators, train site personnel, conduct of trial
- Prove: Operational techniques and activities to verify that the requirements are fulfilled, monitoring, project management
- Improve

MONITORING AS A COMPONENT OF QUALTY RISK MANEAGEMNET:

- PLAN- Identify the quality objectives and ethics and risk to quality development
- DO- study conduct
- CHECK- measure/ monitor
- ACT- Respond to deviation

QC- MONITORING:

In process

- Regular assessment
- Provides training collaborates proactively
- Guides site in CRF completion
- Ensure protocol compliances
- Patient safety

QA- MOMITORING

Snapshot

- Selected sites
- Sample of subjects
- Cross section reviews
- Evaluate quality system independently

Audit by sponsors-Done by independent group, gives assurance to management regarding trial conduct as well as oversight.

IMPROVE:

- Sharing lessons learned from audits/ inspections
- Developing and implementing good CAPA (corrective and preventive action plans)
- Avoid repeat observation

INSPECTION:

The act by regulatory authority of conducting an official review of documents and facilities, records. It looks for anything and everything associated with clinical trial. It is of two types:

- Routine: when approval is sought for new medical product
- Direct: For-cause inspections

CAPA

- Corrective action: action taken to correct the noncompliance for the involved site
- Preventive action
  - These are developed in response to identified issues that affect quality
  - It is done by root cause analysis
  - Those that reasonably be identified, management is under control,