ICH E6 R3 Expert Working Group Perspectives

L. Bregnhøj (DKMA), G. Schwarz (BfArM), R. Stanbrook (EFPIA), S. Nørskov (EFPIA)

Rebecca Stanbrook on 3 June 2020
On behalf of the aforementioned colleagues

Gabriele Schwarz
Head of GCP Inspectorate, EMA GCP-IWG. German Federal Institute for Drugs & Medical Devices (BfArM), (European Commission)

Lisbeth Bregnhøj
Medicines Inspector, GCP, EMA GCP-IWG. Danish Medicines Agency (DKMA) (European Commission)

Rebecca Stanbrook
Global Head, Quality Regulatory Strategy, Novartis (EFPIA)

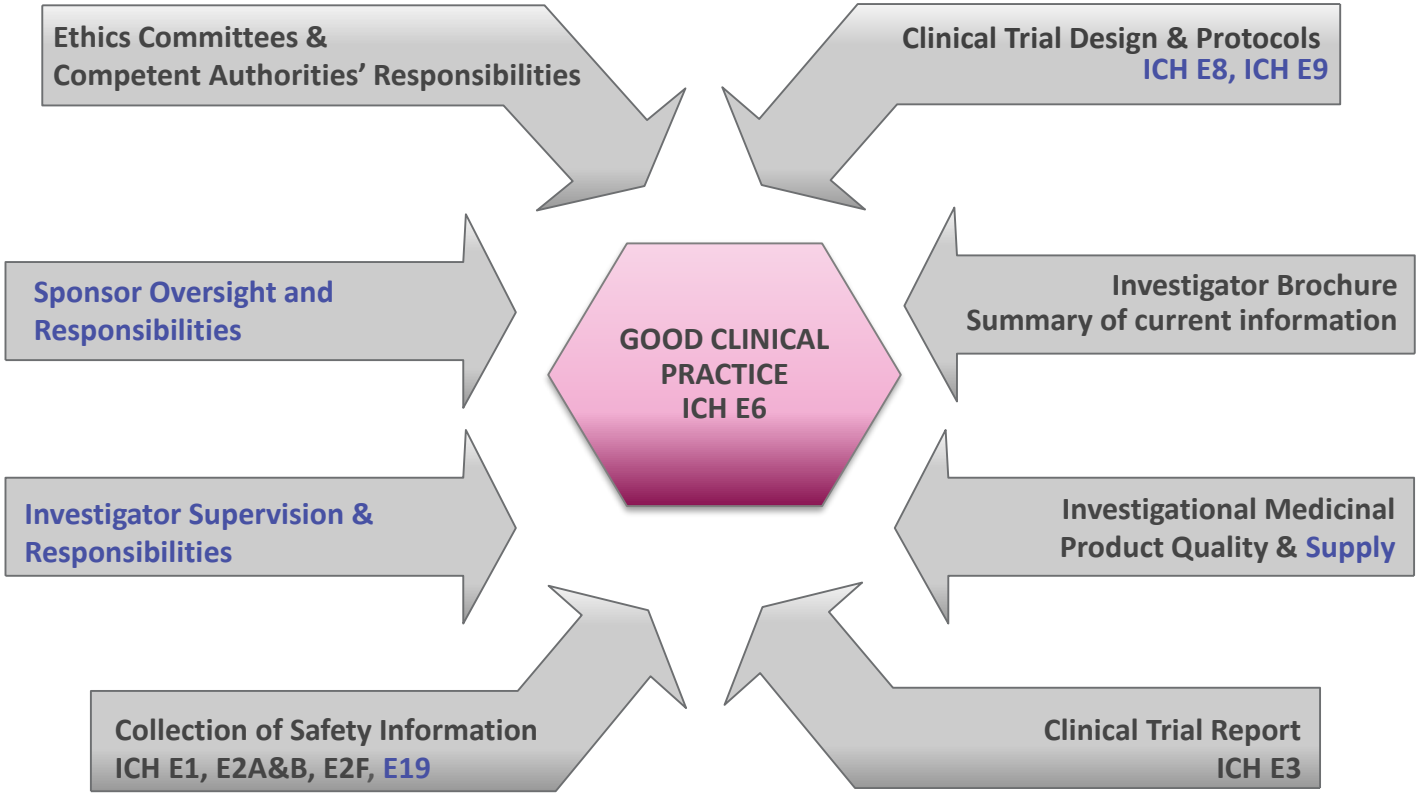
Susanne Nørskov
Vice President, Global Clinical Compliance, R&D Quality, Novo Nordisk (EFPIA)

Agenda

- Good Clinical Practice – E6 and the interdependencies with other guidelines.
- Potential areas for intensive update:
  - Clinical Trial Design
  - Sponsor Oversight and Responsibilities
  - Investigator Supervision & Responsibilities
  - Safety Information
  - Investigational Medicinal Product

Trials are not only for registration purposes, but can provide standards for the future care of patients.

The Essence of Good Clinical Practice



Protection of participants

Generation of reliable results

Procedures and Documentation

Clinical Trial Design

Participant involvement in trial design.

- More readily understandable Informed Consent.
- Trials objectives being more relevant for the participants
- Data collection tools being already part of some people's everyday lives.
- Lower the burden – not only participant, but also the Healthcare Professionals

Healthcare Professional involvement in trial design

- What is the standard of care for the disease and the population, and hospital routines?
- Lower the burden – e.g. trial specific data collection tools, monitoring

Protection of participants

Generation of reliable results

Clinical Trial Design (2)

Non- traditional trial designs and data collection methods:

- Platform Trials
- Pragmatic Trials
- Umbrella Trials
- Decentralised trials
- Digital developments
- Real World Evidence

Protection of participants

Generation of reliable results

Protection of participants

Sponsor oversight and responsibilities

Risk based concept to be applied throughout the trial

Service Providers - Agreements, qualification and oversight

- Increasing use of subcontractors/services providers
- Increasing use of DSMBs, adjudication committees

Monitoring obligations

- Risk based approach – safety and efficacy are the key.

Informed Consent – patient rights

Proportionality - What are the important data points?

Generation of reliable results

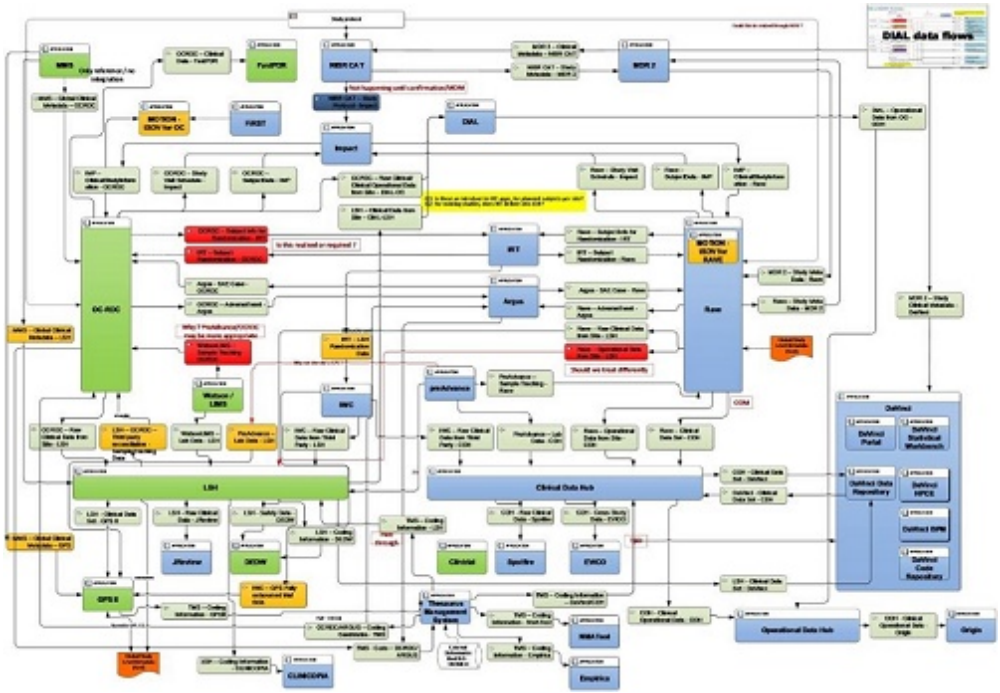
Sponsor oversight and responsibilities (2)

IT systems:

- Fit for purpose – designed to capture the information from the protocol.
- Data collection tools should meet acceptable feasibility and performance characteristics such as accuracy, precision, and consistency of measurements over time, and uniformity of measurements across technologies. (from CTTI mobile tech).
- Data Privacy
- System and Software Security

Electronic systems in clinical trials

Sponsor oversight and responsibilities (3)



IT systems

- Complicated landscape.
- Multiple parties involved:
  - Provision of the system
  - Entry of the data
- Relies on robust computer system validation to ensure data integrity.
- Transfer of data between systems – data transfer protocols need to be robust.
- Consideration for where the data resides, who is the owner, who is the data controller?

Typical applications landscape in large organisations

Investigator Supervision & Responsibilities

Proportionality

- What are the important data points?
- Risk based approaches, risk assessment essential elements of trial design.

Supervision/oversight:

- Home nursing, investigator needs to still supervise.
- Involvement of the general practitioners or satellite centres/sites. Use of local laboratories
- Telemedicine usage.
- Supervision of contractors – proposed by the sponsor or the institution
- Increased use of electronic patient reported outcomes/bring your own device

Safety information

Up to date safety information available to the investigator and the participants.

Use of available data from other sources (compassionate use, real world) to guide the collection of additional information. E.g. products already marketed, classes of product.

Proportionality

- E19 – avoid duplication of effort. Sponsor's consideration of what safety data is important and the format and frequency of dissemination of that information to investigators.
- E8 – The design of a clinical study should reflect the state of knowledge and experience with the drug.

Investigational Medicinal Product

Non- traditional trial designs:

- Direct to patient shipments
  - How is drug accountability assured?
  - How is Investigator oversight maintained?
  - Data privacy considerations.
  - Storage conditions.
  - What information is provided to participant on shipments, handling, storage and use of the IMP?
  - Complex treatment regimens – new IMP, different routes of administration.
  - Participant preparedness (different participant populations e.g. elderly, vulnerable)

Summary

- ICH E6 R3 started as Expert Working Group in November 2019, one of first considerations was engagement of academia and patient advocacy groups as not represented directly in ICH.
- We want to understand your needs and we are listening.
- We want to build it into the GCP guideline which is modernised and fit for purpose.

Thank you

Any questions