Harmonized Standard Operating Procedures for Academic Trials

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Outline

- SOPs
  - Definition and Significance
- Clinical Trials Centers
- QM working group
- Scope of the SOP project and Overview
- Challenge of implementing harmonized processes in a federal structure
- Experience with harmonized SOPs
What are SOPs?

ICH-GCP (1.55):
‘Standard Operating Procedures’ are detailed, written instruments to achieve uniformity of the performance of a specific function.

ICH-GCP (5.1.1):
Sponsor is responsible for implementing QA- and QC-systems with written SOPs
Application of SOPs in Clinical Trials

- Essential instrument of QM within clinical trials of pharmaceutical companies

- Rarely used in academic trials (Investigator Initiated Trials, IITs) until 2000
Clinical Trials Centers (CTCs)

- Central support units all over Germany
- Network of:
  - 15 CTCs
    - 6 of them associated with trial sites (□)
  - 1 associated members (●)

www.kks-netzwerk.de
Purpose

- Developing operational competence in academic clinical trials considering the characteristics of IITs
- Establishing national standards for IITs
- Simplifying cooperation between CTCs
QM working group

- Founded in 2002
- Focus: SOP project
  (Preparation of harmonized SOPs for most aspects of clinical trials)
- Funded by Federal Ministry of Education and Research (BMBF 01EZ0931) since 2008
- Trigger: Legal implementation of GCP in 2004
  (German Drug Law (AMG) became binding for IITs)
Scope of the SOP project

- SOPs for IITs
- Specific SOPs in the fields of
  - Pharmacovigilance
  - Medical Devices
  - Trial Sites
- Translated SOPs for international IITs
Overview (I)

- 9 Thematic Modules
- 66 SOPs

**General Topics (3)**
- How to write SOPs
- Contracts
- . . .

**Trial Planning (8)**
- Trial Protocol
- Clinical Trials Insurance
- . . .

**Adverse Events (16)**
- Handling AEs in clinical trials (AMG)
- Annual Safety Report
- . . .

**Monitoring (5)**
- Pre-Study Visit
- Initiation Visit
- . . .
Overview (II)

- Ethical & Regulatory Topics (6)
  - Informed Consent
  - Ethics Committee (German Drug Law)
  - ...

- Quality control and assurance (4)
  - Preparing for Audits
  - Froud and Misconduct
  - ...

- Biometrics (7)
  - Statistical Trial Design
  - Randomization
  - ...

- Investigational Product (1)
  - Logistics of investigational product

- Trial Sites (16)
  - Handling Adverse Events at Trial Sites
  - Trial Inclusion
  - ...
Challenge of SOP Implementation in a Federal Structure CTCs Network

- Commitment of each CTC to implement the harmonized SOPs
- But variable structures of CTCs require local adaptation
- Challenge: Restricting local adaptations to local structural characteristics
Advantages of the QM working group

- Consolidation of expert knowledge
- Avoiding redundant activities
- Timesaving benefit
- Simplifies cooperation between CTCs in multicenter trials
Distribution / Application

- SOPs available as open source (www.tmf-ev.de*)
  * TMF e.V. Technology, Methods, and Instructions for Networked Medical Research

- application in collaborative clinical trials with the following competence networks:
  - Sepsis
  - Cardiac insufficiency
  - HIV
  - Parkinson’s disease
  - EuroNet study group
Experience with these harmonized SOPs

- Feasible and supporting in daily routine work
- CTCs were audited and inspected several times with positive results

→ great acceptance of the harmonized SOPs
QUESTIONS
Thank you very much for your attention

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