ZKS Köln Zentrum für Klinische Studien

METHODIK & MEDIZIN

Harmonized Standard Operating Procedures for Academic Trials

Heike Moenkemann*, Miriam Olderog*, Ursula Paulus**

* Clinical Trials Center Cologne
** Clinical Trials Center Cologne and Head of QM working group of the CTCs-network

funded by the

Federal Ministry of Education and Research

BMBF 01KN0706

ZKS Köln

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

ZKS Köln

What are SOPs ?

ICH-GCP (1.55):

´**S**tandard **O**perating **P**rocedures` 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 **SOP**s

ZKS Köln

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

ZKS Köln

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

METHODIK & MEDIZIN

ZKS Köln

Purpose

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

ZKS Köln

QM working group

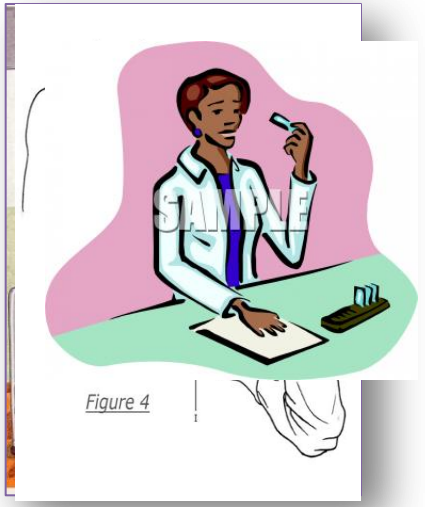
- Founded in 2002
- Focus: SOP project

  (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)

ZKS Köln

Scope of the SOP project

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



ZKS Köln

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 • . . .

METHODIK & MEDIZIN

ZKS Köln

Overview (II)

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

METHODIK & MEDIZIN

ZKS Köln

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

ZKS Köln

Advantages of the QM working group

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

ZKS Köln

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
  - Parcinson´s disease
  - EuroNet study group

METHODIK & MEDIZIN

ZKS Köln

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

ZKS Köln

QUESTIONS

ZKS Köln

Thank you very much for your attention

Dr. Heike Mönkemann
Qualitymanagement

Tel: (+49)221 478 88251 Fax: (+49)221 478 88209
heike.moenkemann@zks-koeln.de

ZKS Köln – Clinical Trial Center Cologne

Methodological Department
Gleueler Strasse 269
50935 Cologne

Medical Department
Herderstrasse 52
50931 Cologne

www.zks-koeln.de