Strengthening Clinical Research Through Institutionalized Clinical Conduct Management

Dorothee Arenz
Team Lead Clinical Conduct Management
Acting Manager Monitoring
Clinical Trials Centre (ZKS Köln) of the University of Cologne, Germany
dorothee.arenz@zks-koeln.de
Clinical Conduct Management

• Aims
  – Support trial conduct throughout clinical departments
  – Avoid redundancy at decentralized trial conduct units
  – Identify and address unmet needs across the research community

• Services
  – Flying study nurses
  – Feasibility management
  – Site Management System
  – Cross-clinic trial conduct management meetings
  – Task forces
Clinical Trials Centre Cologne (CTCC)

2002 CTCC founded at the University of Cologne

2007 Set-up of clinical conduct activities in separate division

2014 Clinical conduct management integral part of the CTCC
36 clinical departments
31 with dedicated trial structures
- trial conduct units
353 investigators and trial site personnel
Flying Study Nurses

• Support investigators in the clinic
  – Departments without trial structures
  – Trials spanning several departments
  – Need for independent blinded / unblinded staff
  – Staff shortage

• Individual support measures or

• Full study nurse service
Central Feasibility Tracking

• Central contact for feasibility requests to the university hospital
• Direct connection to all PIs
• Check for doubling
• Tracking of requests
• 164 requests in 2014
SiteManagementSystem
www.clinicalsitereg.org

- System manages information on
  - Trials – Staff – Organizational units – Documents

- Reports on
  - Trials with institutions and staff involved
  - Site activity (grant applications)
  - Site and staff qualifications

- Customizable web portals
- Recruitment support

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ALLGEMEIN

Kenndaten
- Ziel/Fragestellung
- Krankheitsmerkmale
- Patientenmerkmale
- Studienmerkmale
- Therapiemerkmale

DURCHFÜHRUNG

Verantwortliche
- Zeitablauf
- Organisatorisches

VERÖFFENTLICHUNG

Portalanzeige
- Anhänge
- Publikation

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General
Data common to all parties

Overall Trial
Data pertaining to sponsor and overall trial management

Study Site
Data pertaining to individual study sites

Publishing / Attachments
Cross-clinic trial conduct management meeting

• Exchange and active link between
  – Trial-conducting clinical departments and
  – CTCC departments

• Topics of interest across clinical trial community, e.g.
  – Use of electronic systems for trial conduct
  – Contract management – review, tracking, templates
  – Services of the central laboratory

• Invitation to involved departments
• Discussion and set-up of task forces if needed
Task force: SOPs for trial sites

• Enable implementation of quality management systems at trial conduct units
• Harmonize trial processes across departments
• Mutual development of SOP templates
  – Interdisciplinary group
  – Guided by CTCC quality and clinical conduct management
• Adaptation to individual settings of clinical departments
Task force: Study site budgeting tool

- Enable sites to estimate adequate reimbursement in advance of a trial
- Cost approximation through allocation of staff hours
- Extensive reliability testing
- Web-based ß-version: Studget™
- studget.clinicalsite.org
## Development of Clinical Trial Performance at the University Hospital of Cologne

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<thead>
<tr>
<th>Category</th>
<th>2008</th>
<th>2014</th>
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<td>Patients in active observational studies, cohorts, registries</td>
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<td>13288</td>
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<td>Trial conduct units</td>
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<td>Tailored phase I units</td>
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Summary

• At the Clinical Trials Centre Cologne we have set-up a new model for **clinical conduct management**

• Clinical trials are conducted in this **collaborative setting** between a **central structure** and decentralized trial **conduct units**

• Trial conduct units face a diversity of similar challenges, which are addressed by a central structure **avoiding redundant work**
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