



Strengthening Clinical Research Through Institutionalized Clinical Conduct Management

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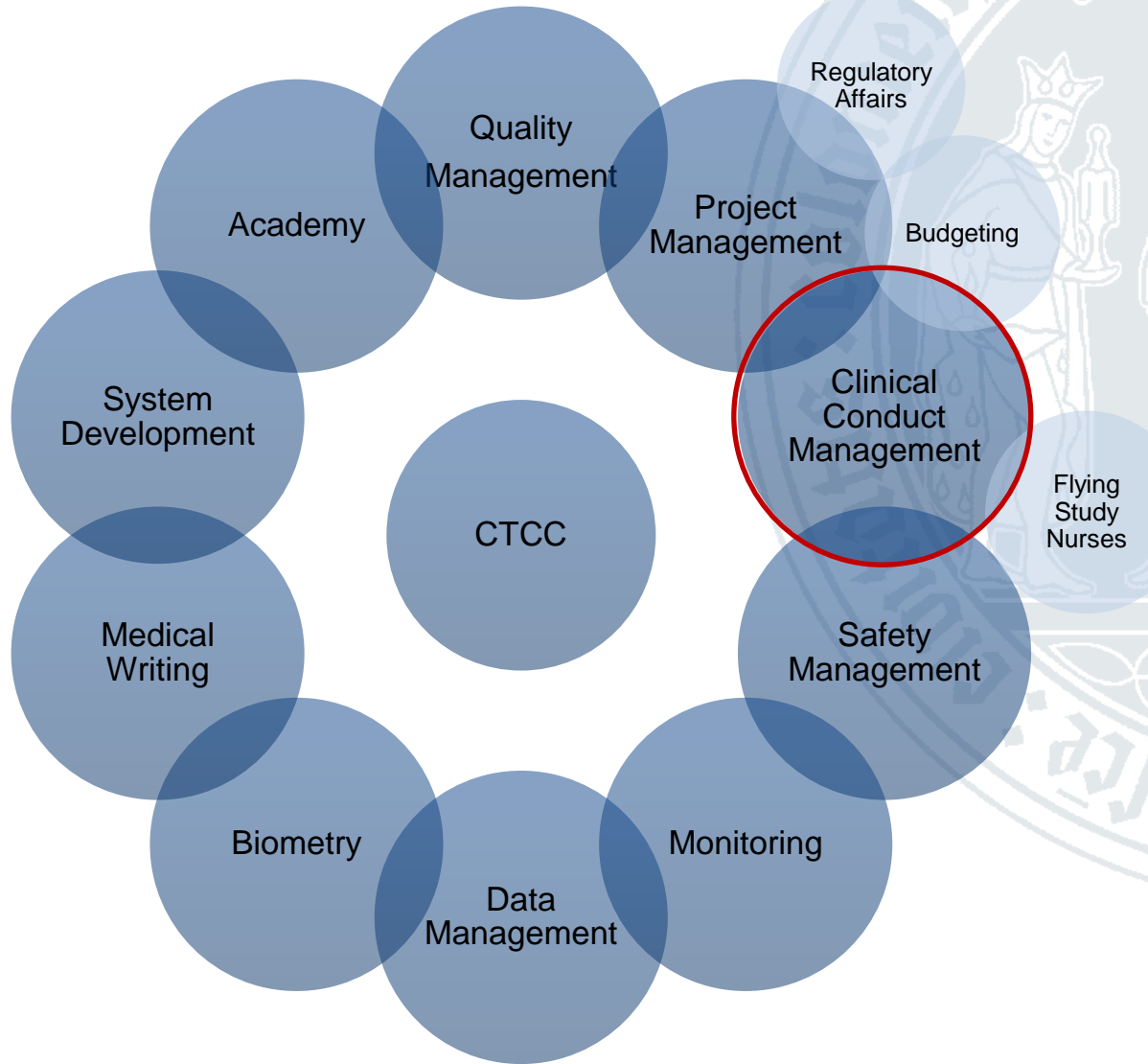
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Clinical Conduct Management

- 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)

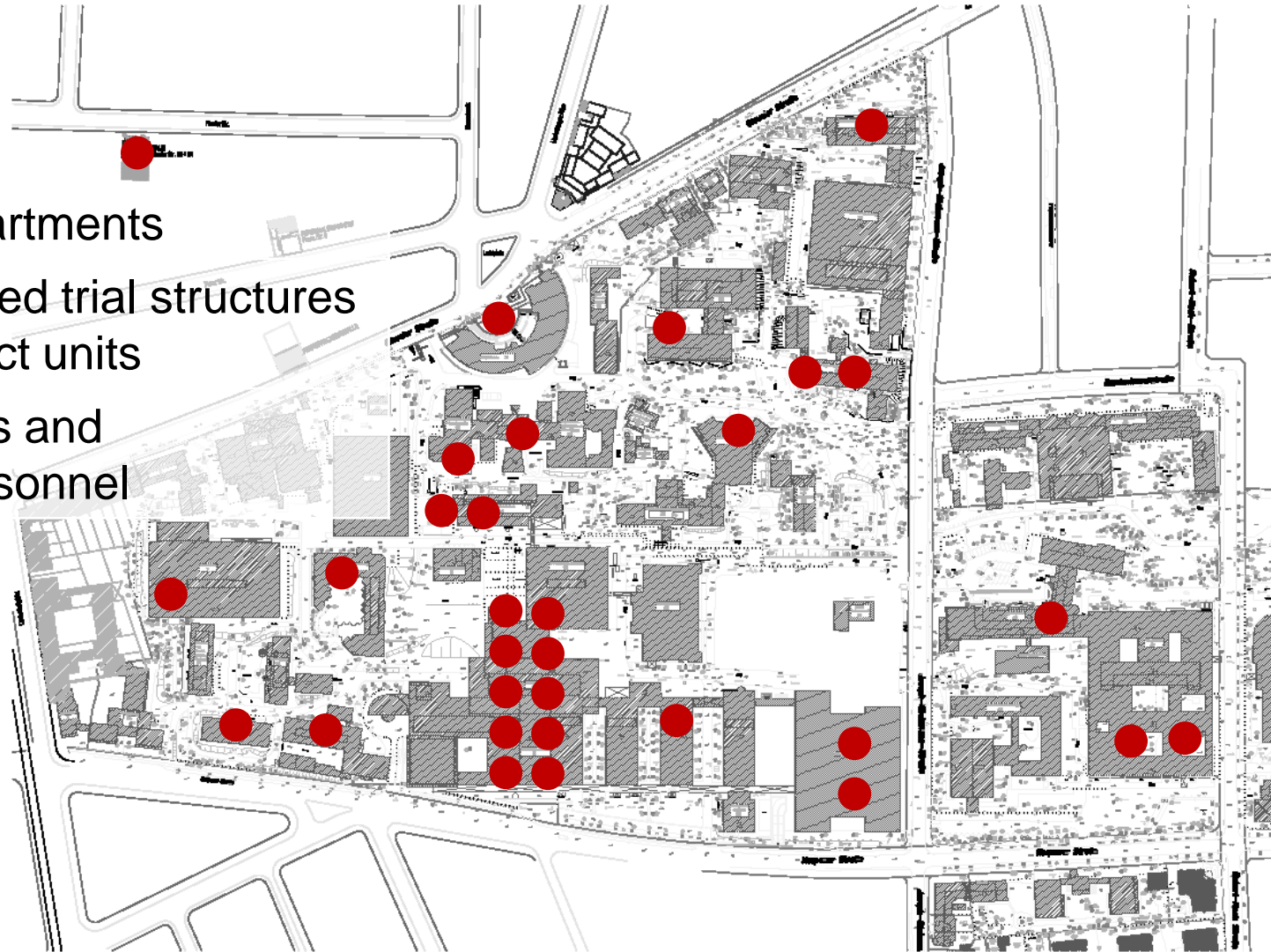


- 2002 CTCC founded at the University of Cologne
- 2007 Set-up of clinical conduct activities in separate division
- 2014 Clinical conduct management integral part of the CTCC



University Hospital Cologne

- 36 clinical departments
- 31 with dedicated trial structures
- trial conduct units
- 353 investigators and
trial site personnel



● Trial conduct units

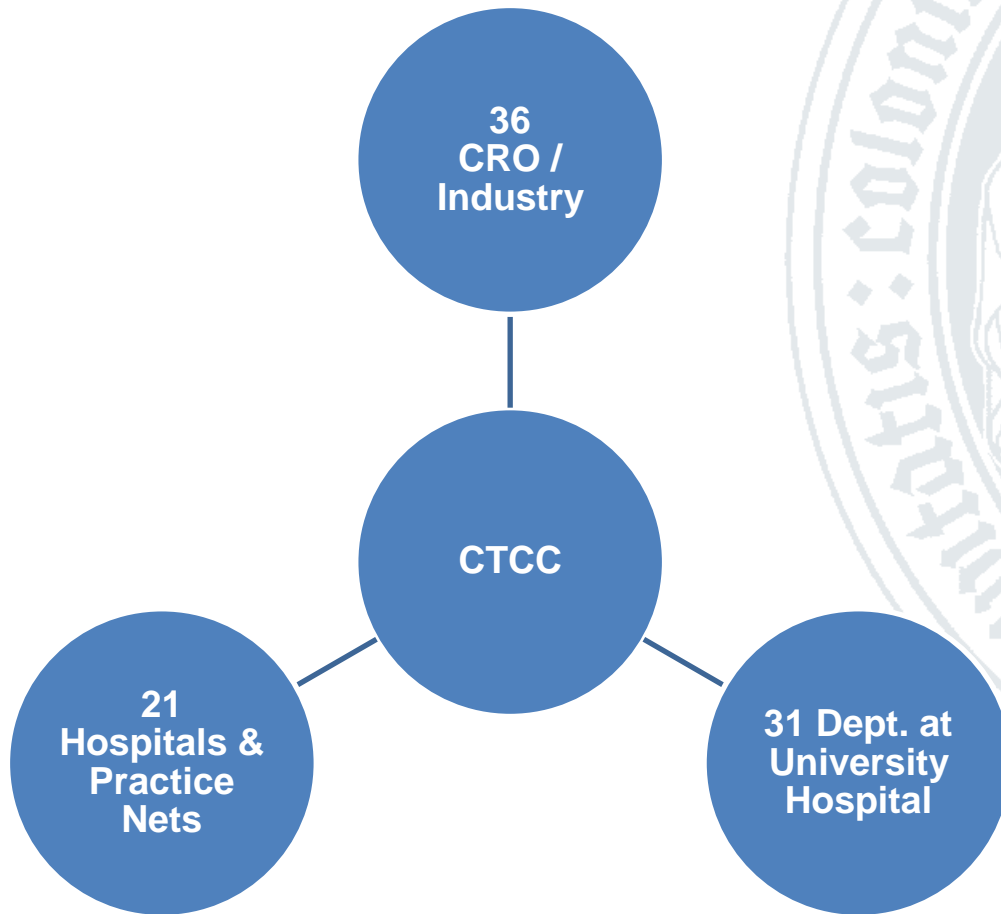


Flying Study Nurses

- 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

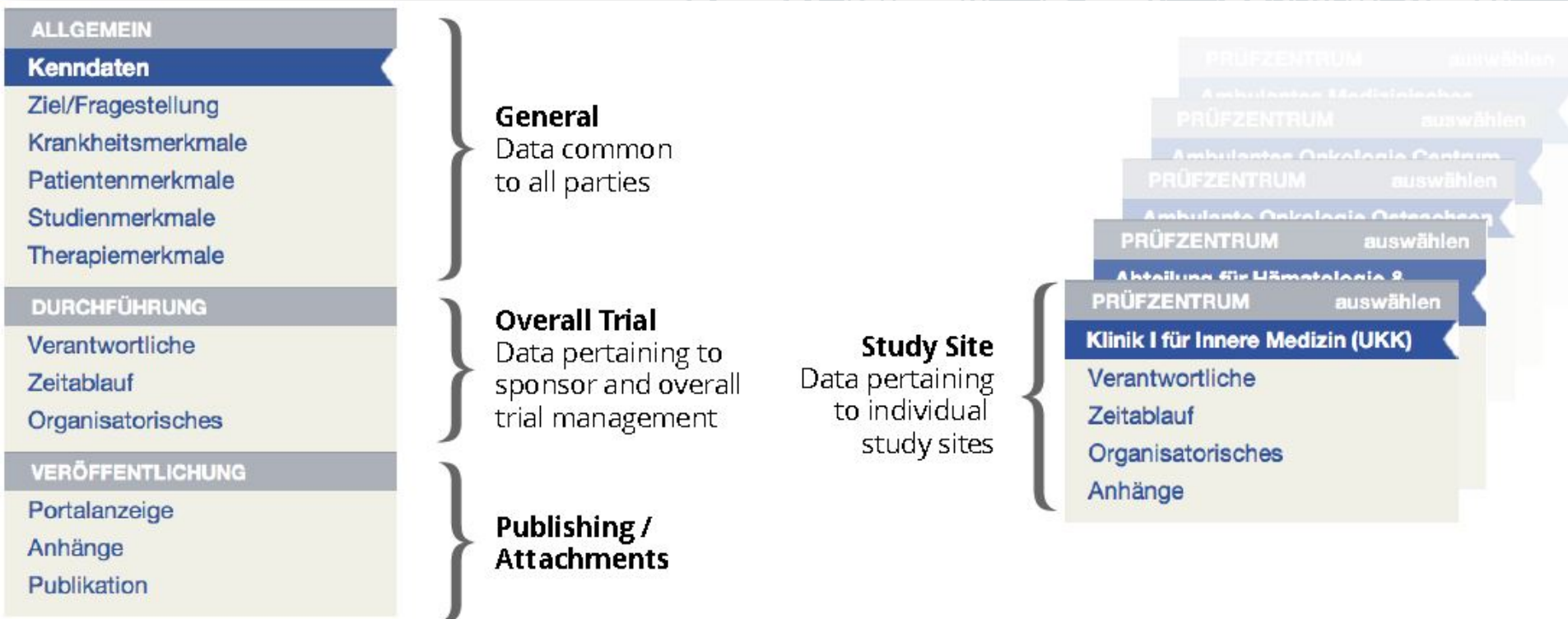


- Central contact for feasibility requests to the university hospital
- Direct connection to all PIs
- Check for doubling
- Tracking of requests
- 164 requests in 2014

SiteManagementSystem

www.clinicalsite.org

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



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 β -version: **Studget™**
- studget.clinicalsite.org

▼ Baseline visit (starting the intervention phase)				
Visit		number	time [h] per procedure	total
review of selection criteria, when indicated inquiry to sponsor	PI		0,25	31,25€
review of selection criteria, when indicated inquiry to sponsor	SC		0,5	25€
physical examination and assessment	SI		0,5	39€
randomization/inclusion	SC		0,5	25€
ordering, issuing and tracking of study medication	SC	1	0,5	25€
blood sampling (including preparation)	SC	1	0,5	25€
possibly blood sampling by physician	SI	0	0,25	0€
possibly processing of sample	SC	0	0,5	0€
possibly shipment of sample	SC	1	0,5	25€
vital signs	SC	1	0,25	12,50€

Development of Clinical Trial Performance at the University Hospital of Cologne

	2008	2014
Patients in active observational studies, cohorts, registries	9719	13288
Patients in active interventional clinical trials	4722	5242
Interventional clinical trials	318	567
Phase I trials	19	47
Trial conduct units	21	31
Tailored phase I units	1	4

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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