



Academic trials and the challenge of sponsor responsibility

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Funded by



Federal Ministry
of Education
and Research

Legal Situation

- 2001: DIRECTIVE 2001/20/EC
 - The European „Clinical Trials Directive“
- 2004: The 12th amendment of the German Drug Law (AMG)
 - National implementation of the Directive 2001/20/EC
- 2005: RL 2005/28/EG
 - The European “GCP-Directive“

Relevance for Investigator Initiated Trials (IITs)

- Legal definition of „Sponsor“ and „Clinical Trial“
 - Legal implementation of Good Clinical Practice (GCP)
- ➔ German Drug Law (AMG) became binding for IITs



Sponsor...

- ... is a natural or legal person who assumes responsibility for the commissioning, organization and financing of a clinical trial on human beings.

[AMG § 4 (24)]

Sponsor for IITs

- Institution (University, Hospital)
- Investigator (rare!)

Challenges for the Academic Institution

- Defined roles and responsibilities
- Controlled delegation
- Quality management (GCP)
- Know how (law, background, methodology)
- Resources (human and financial)
- Risk management



Structure



University of
Cologne

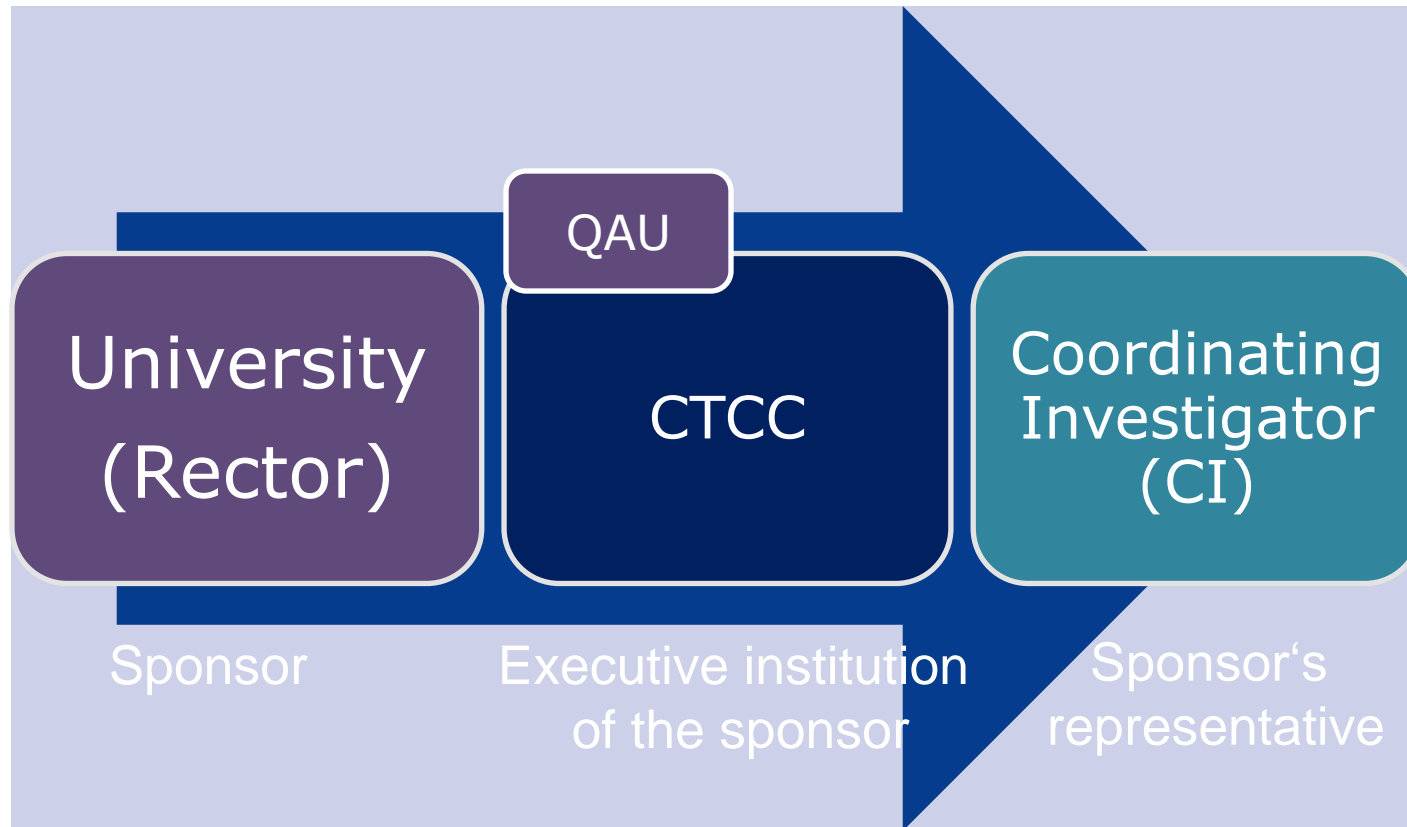


University
Hospital

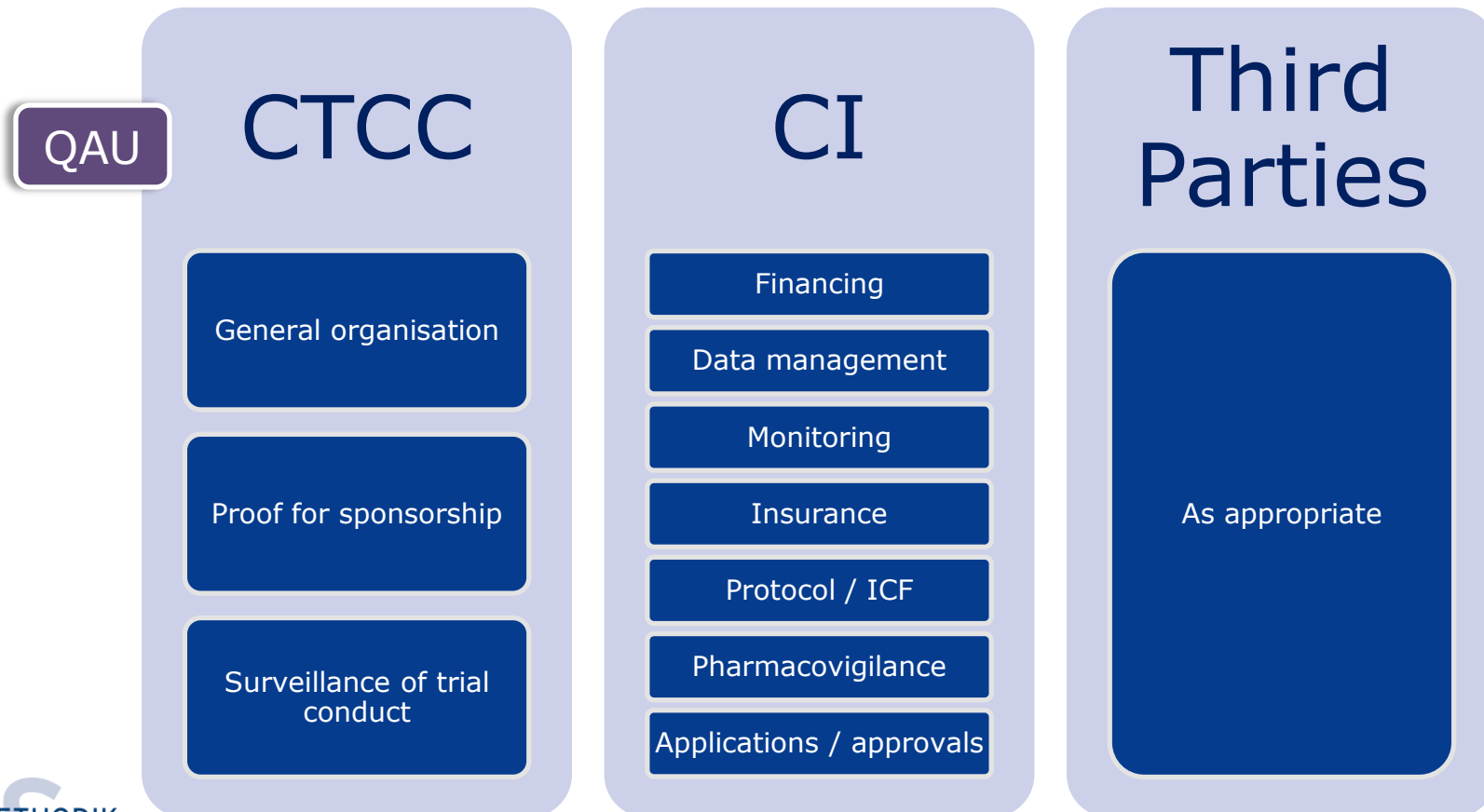




Cologne Sponsor Model



Delegation of sponsor duties



Proof for Sponsorship: GCP Check

QAU

- Protocol, ICF, IMPD (SmPC),
- Financing, contracts
- Insurance
- Investigational medicinal product (IMP release)
- Involvement of other countries and trial sites
- Pharmacovigilance
- Monitoring-concept
- Delegation of tasks to third parties, contracts and qualification



Surveillance of Trial Conduct

- QAU
- Audits according to a risk-based auditprogram
 - Control samples of monitoring reports
 - Annual trial status reports from sponsor's representatives (CI)

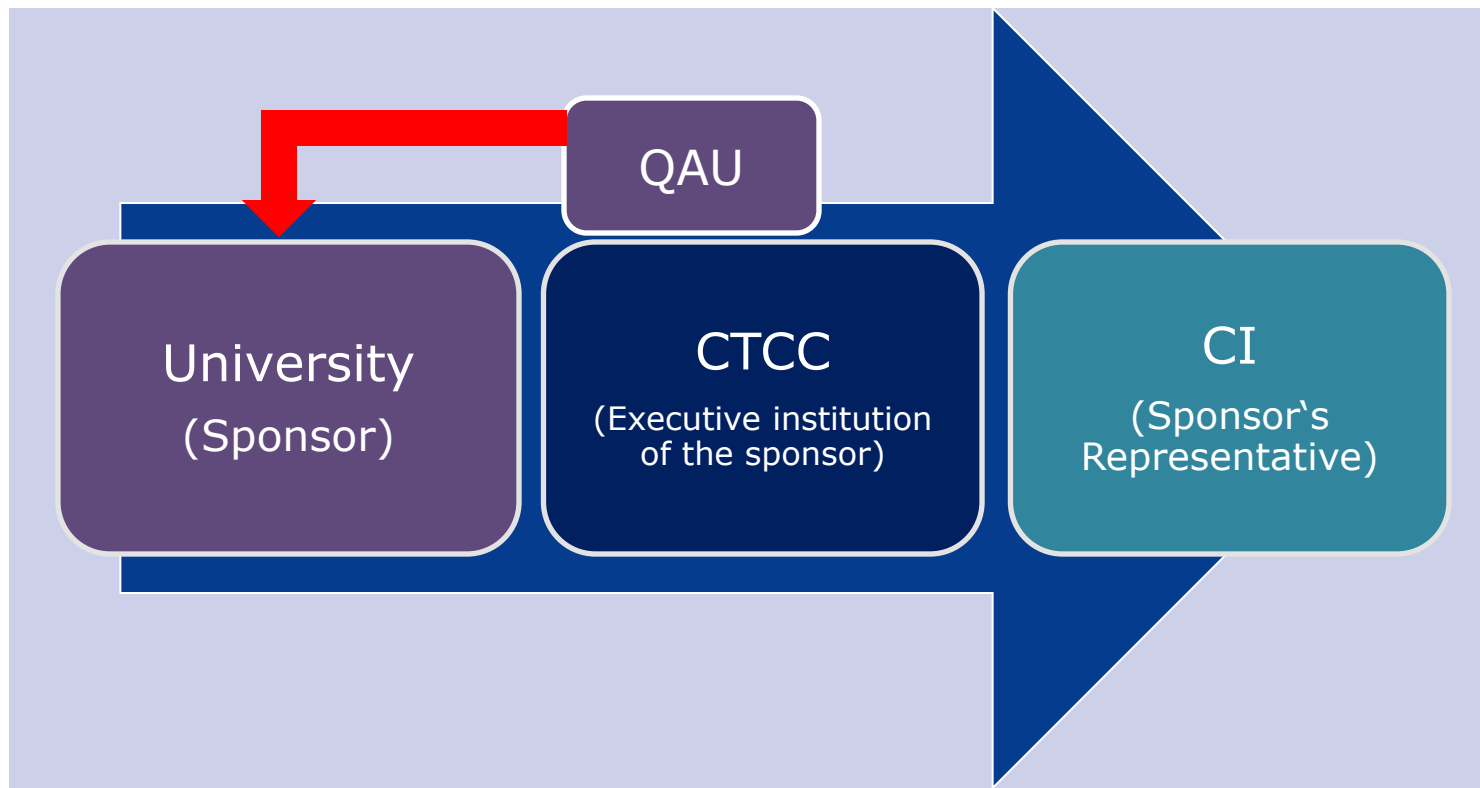


Risk-based Auditprogramm

- 3-4 audits per year
- System- and on-site- audits
- Focus of Audit:
 - Fulfillment of assumed Sponsor duties
 - GCP-Compliance
- Criteria/Raster (e.g.):
 - AMG / MPG Trial
 - multicenter
 - phase I
 - Low Monitoring extent



Reporting Line of Quality Assurance Unit



Experiences I

- 52 applications for University sponsorship
- 36 trials accepted (5 international)
 - All with subsequent improvement
- 16 remaining
 - In preparation, cancelled or postponed (financing, organisation, other reasons)

Experiences II: Audit Findings

- CI (trial conducting unit)
 - Roles and responsibilities unclear
 - Missing approval processes
 - Clinical monitoring low, follow up and consequences of findings missing
 - ...
- Trial
 - ICF incorrect
 - SAE not reported or delayed
 - Delay in documentation
 - Violation of in- and exclusion criteria
 - ...



Side step: Support by CTCC



- Know How:
 - IIT manual
 - Academy (basic and advanced training)
 - QM-Coaching: establishment of quality management in the CI's facility (i.e. SOP & contract templates, audit action plan)
- Service Provider:
 - Services of all aspects of a clinical trial (methodological and medical)

Acceptance and Financing of the Cologne Sponsor Model

- High acceptance
 - by public and corporate financiers of IITs as well as authorities!!
- Financing:
 - 2 FTE (1 Medical Faculty, 1 funded by Federal Ministry of Education and Research)
 - Sustainability by project-specific take over of audit costs (planned)

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Summary

- The Cologne Sponsor Model provides...
 - ... a “risk-based” system
 - ... with a combination of central management, control and support
 - ... and of decentral measures
 - ...that offers a sensible option for fulfilling the legal and GCP requirements for the academic environment.



Thank you for your attention

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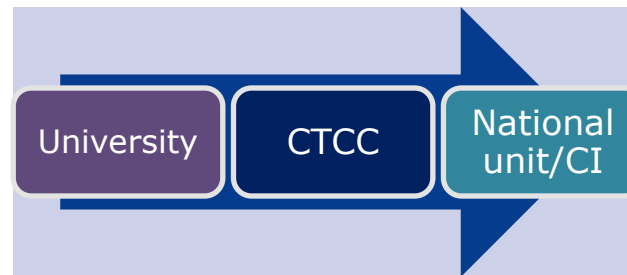
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Perspective / International Trials

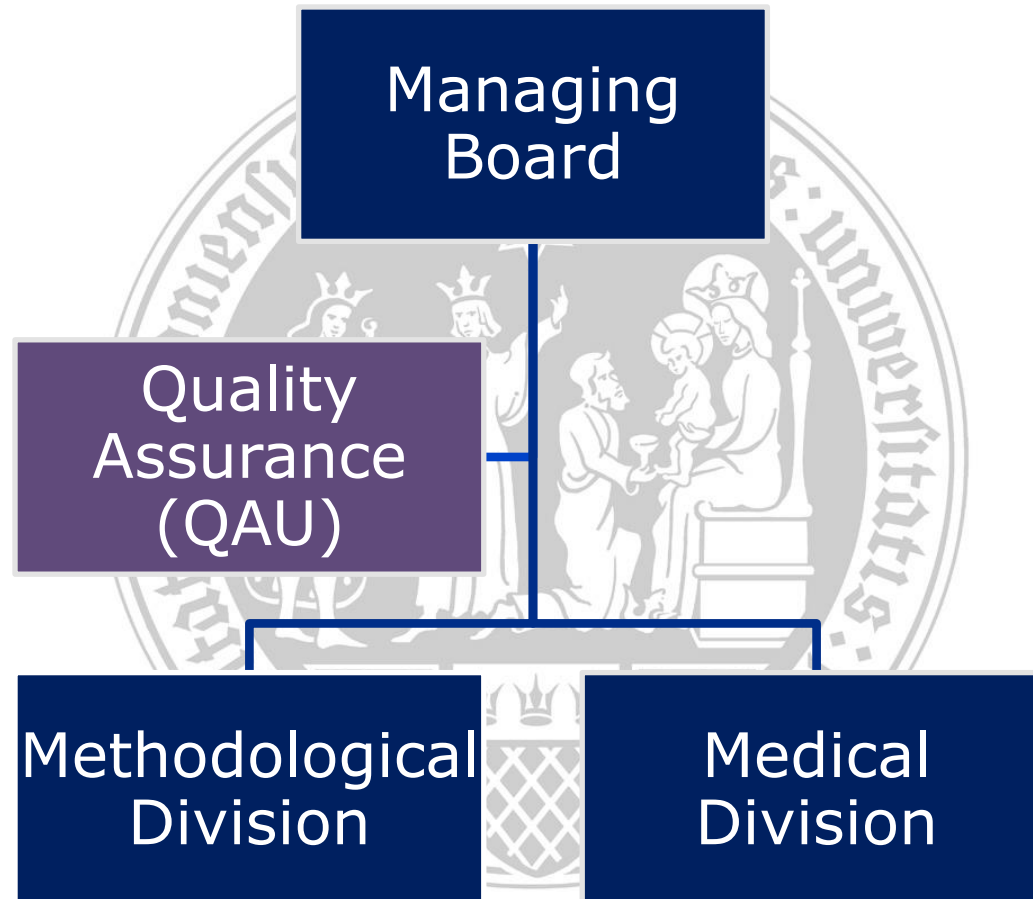
- Analogous delegation model
 - **Allocation of entire** sponsor duties
 - **One** national organizational unit



- Synergies with ECRIN in international Trials



CTCC: Clinical Trials Center Cologne



CTCC Services

