UniversityHospital Heidelberg

Coordination Centre for Clinical Trials (KKS)

Structures and Functions

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Support provided by KKS

- Academic, non commercial trials
- Support of all aspects of clinical research
  - Sustainable, quality-assured study projects
- Optional services
  - For members of the University Hospital and for others
- Independence from University departments
  - No own academic ambitions
- Cost recovery

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Head (1)

Administration (1,4)

HR (0,4)

IT (2,9)

Cooperations:

FIM HD	- First in Men Heidelberg; joint unit with different clinical partners
IMBI	Institute for Medical Statistics and Informatics
NCT	National Centre for Cancer
SDGC	Study Centre of German Society for Surgery; joint unit with Dept. Of Surgery

Scientific PM (4,9)

Biometrics (1)

Pharmaco-vigilance (2,6)

QA/ Audits (1,5)

Clinical Monitoring (11)

Site Management (1,4)

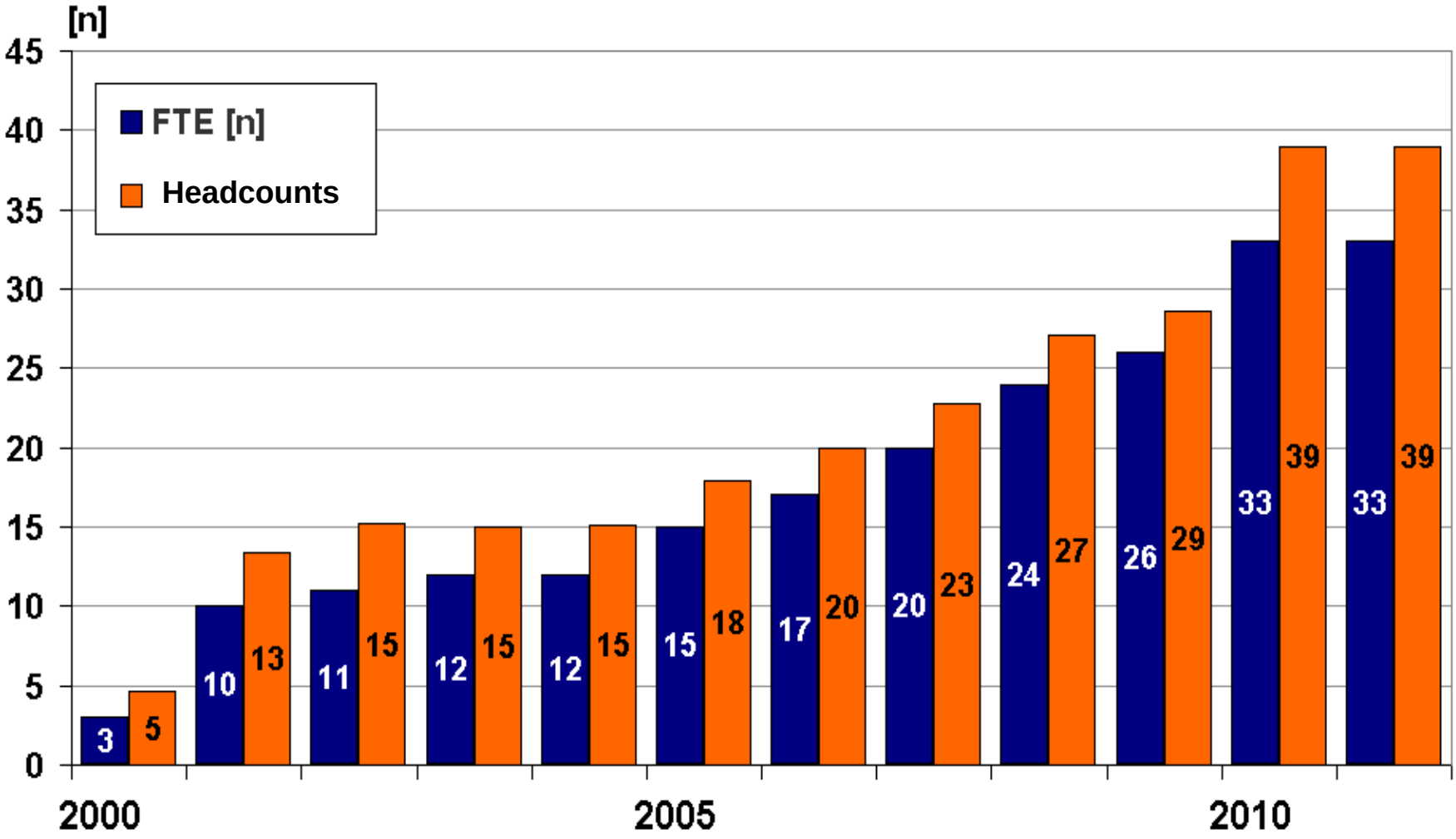
IEC / CA Procedures (0,7)

Data-Management (4,5)

Training (1,5)

31.12.2011 (FTE / Function)

Personnel Development



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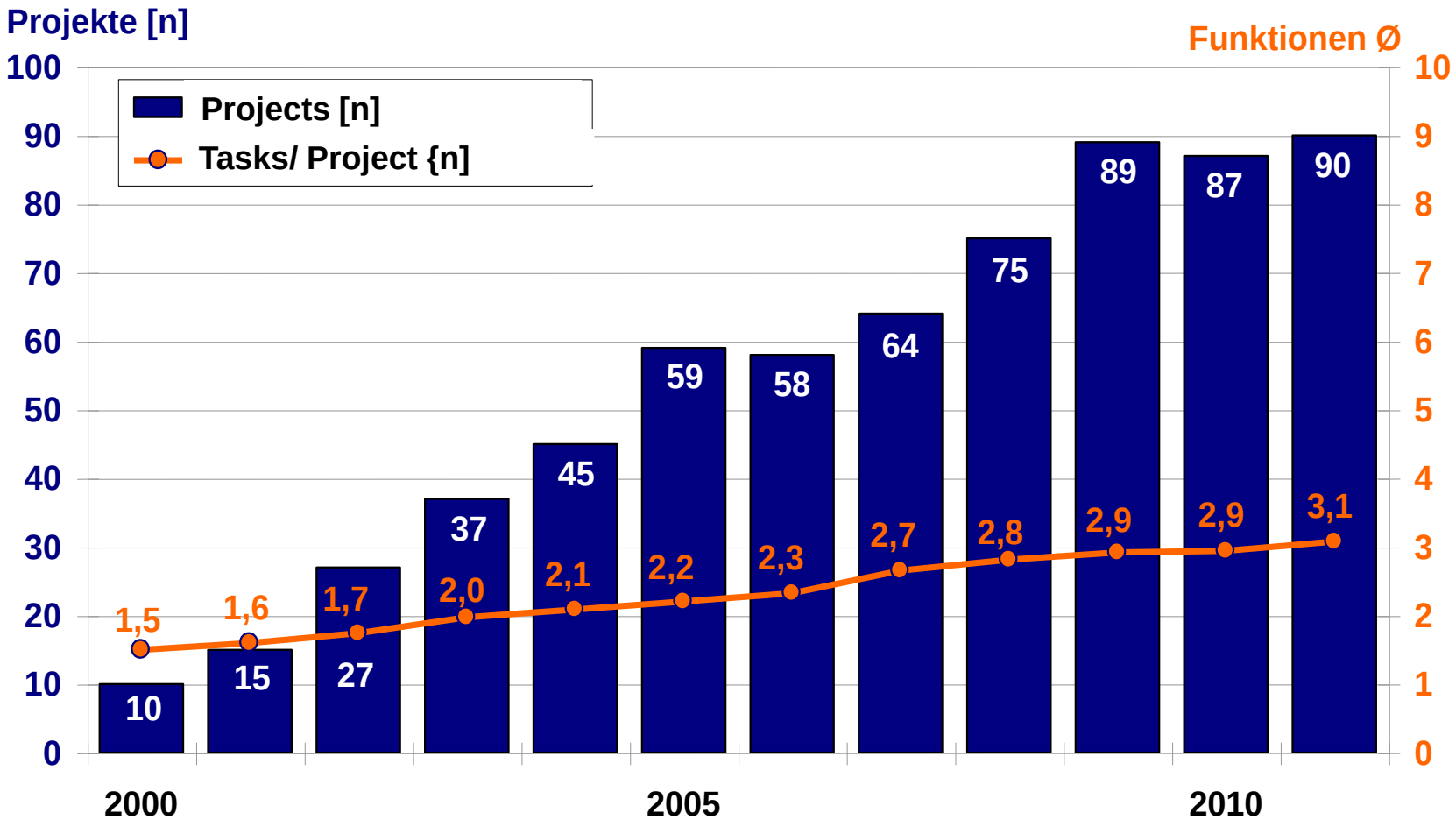
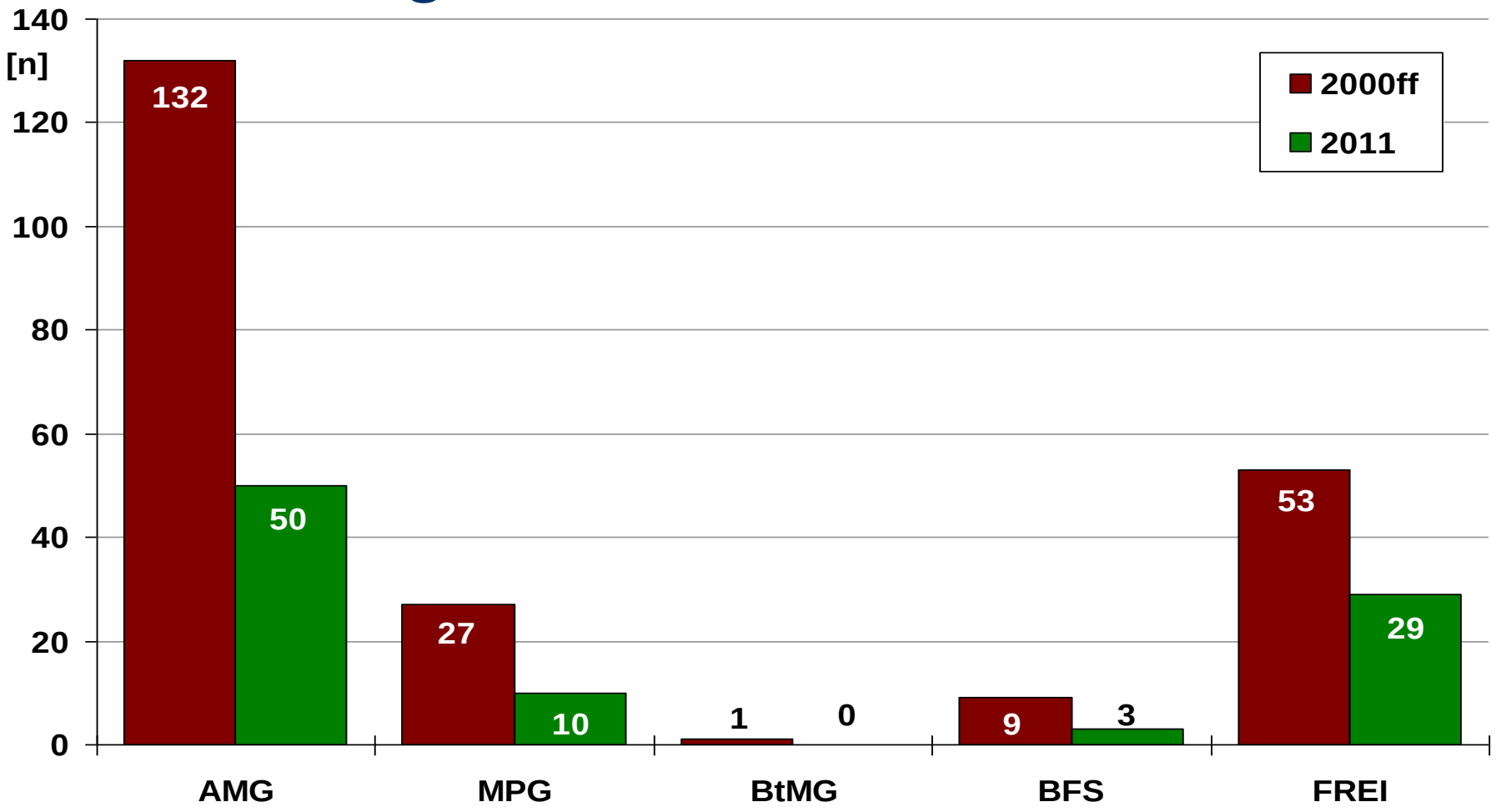
Active Studies



overall 187 studies since 2000

* only projects with contracted KKS-participation are considered

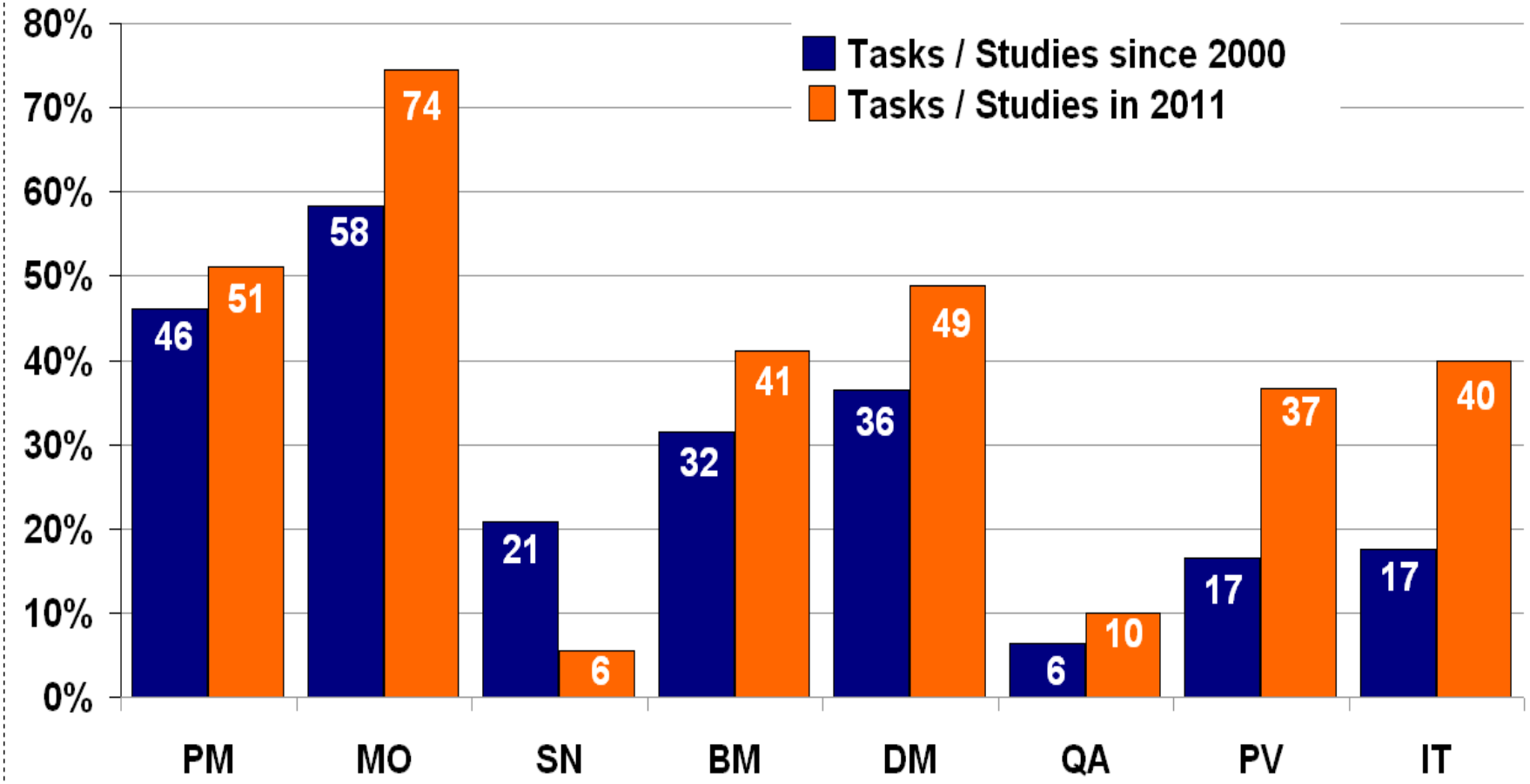
Legal Framework 2011*



AMG = Arzneimittelgesetz (German Drug Law), MPG = Medizinproduktegesetz (German Medical Device Law), BtmG = Betäubungsmittelgesetz (Narcotics Law), BfS = Bundesamt für Strahlenschutz (German Federal Office for Radiation Protection), Frei = Not regulated by specific law

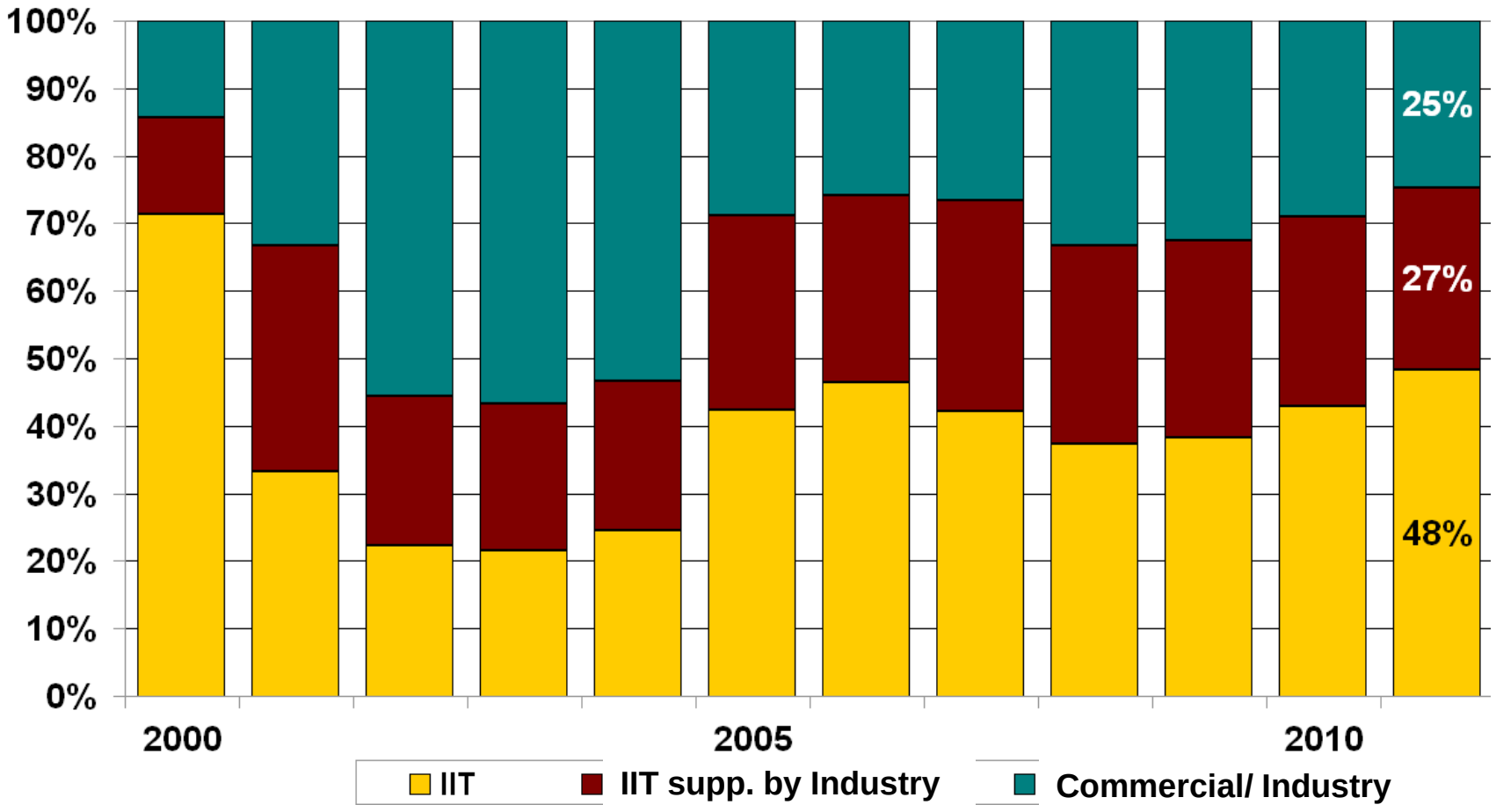
* only projects with contracted KKS-participation are considered

Tasks Assumed by KKS



PM = Project Management
SN = Study Nurse Activities
DM = Data Management
PV = Pharmacovigilance
MO = Clinical Monitoring
BM = Biometry
QA = Quality Assurance

Funding



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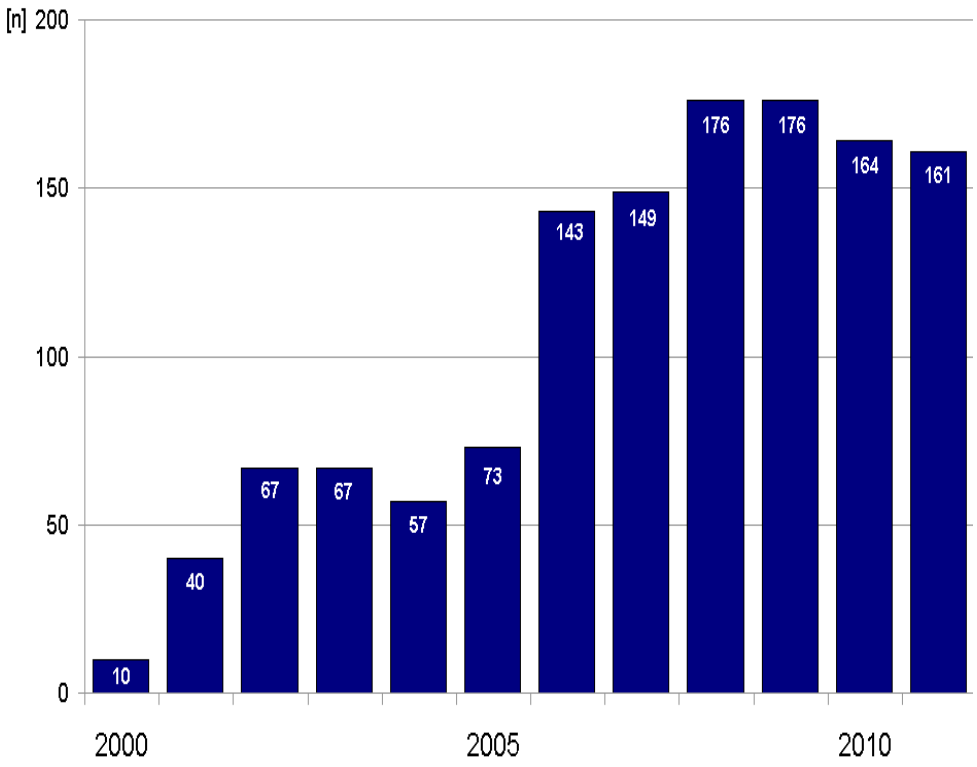
Consultations



Expenditure 2011

- N=161
- ∑ 440 h, Ø 2.7 h,
  Several staff members (BM, PM, IT, QA etc.) involved, when necessary
- Specific services, such as providing templates, etc.

Compensation

- Generally free of charge

Contents

- General
  - AMG, insurance, etc.
- Project-related

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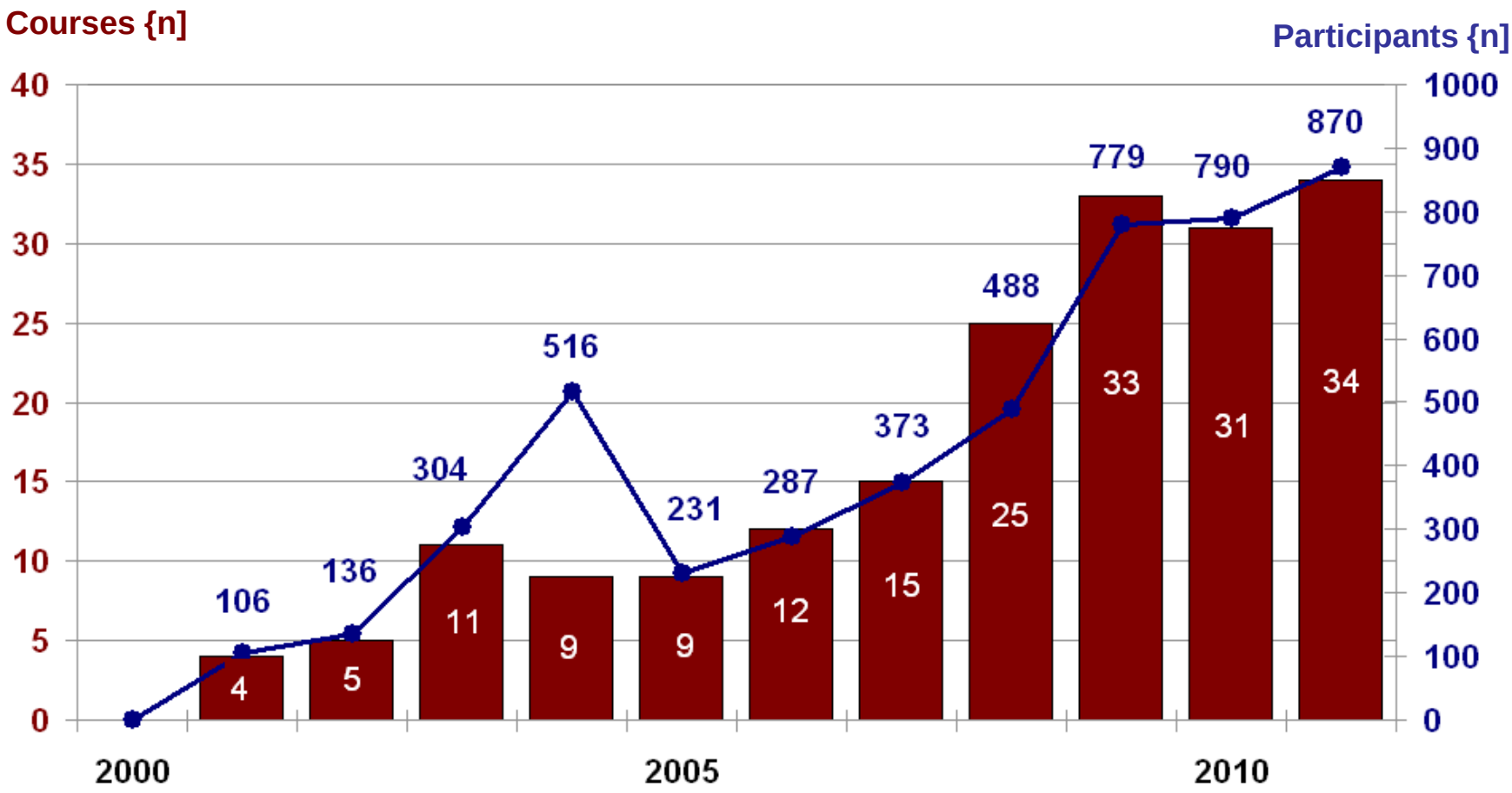
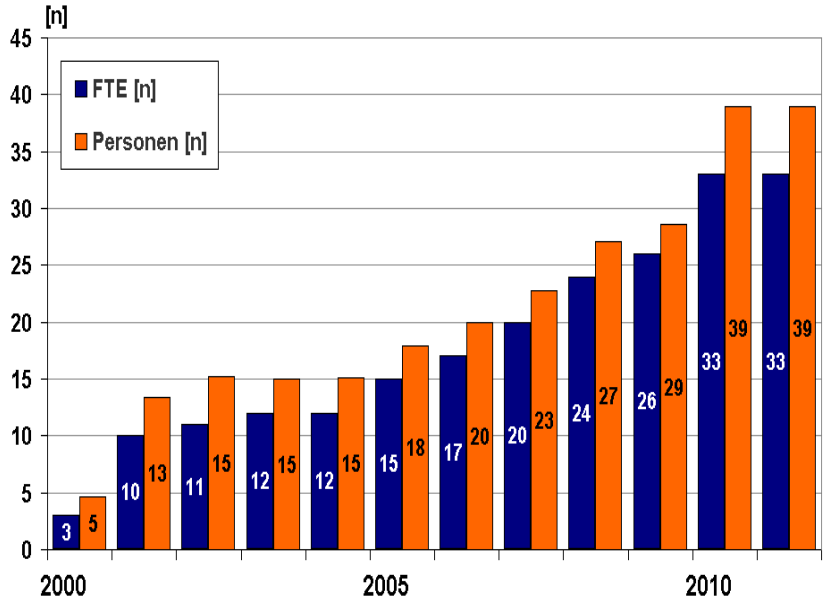
Training Offers*



Personnel Development



Growth through

- Extension of existing tasks
- New tasks
- More comprehensive projects

Competence through

- Long-term employment
- Structured initial training and professional development
- Internal and external further education

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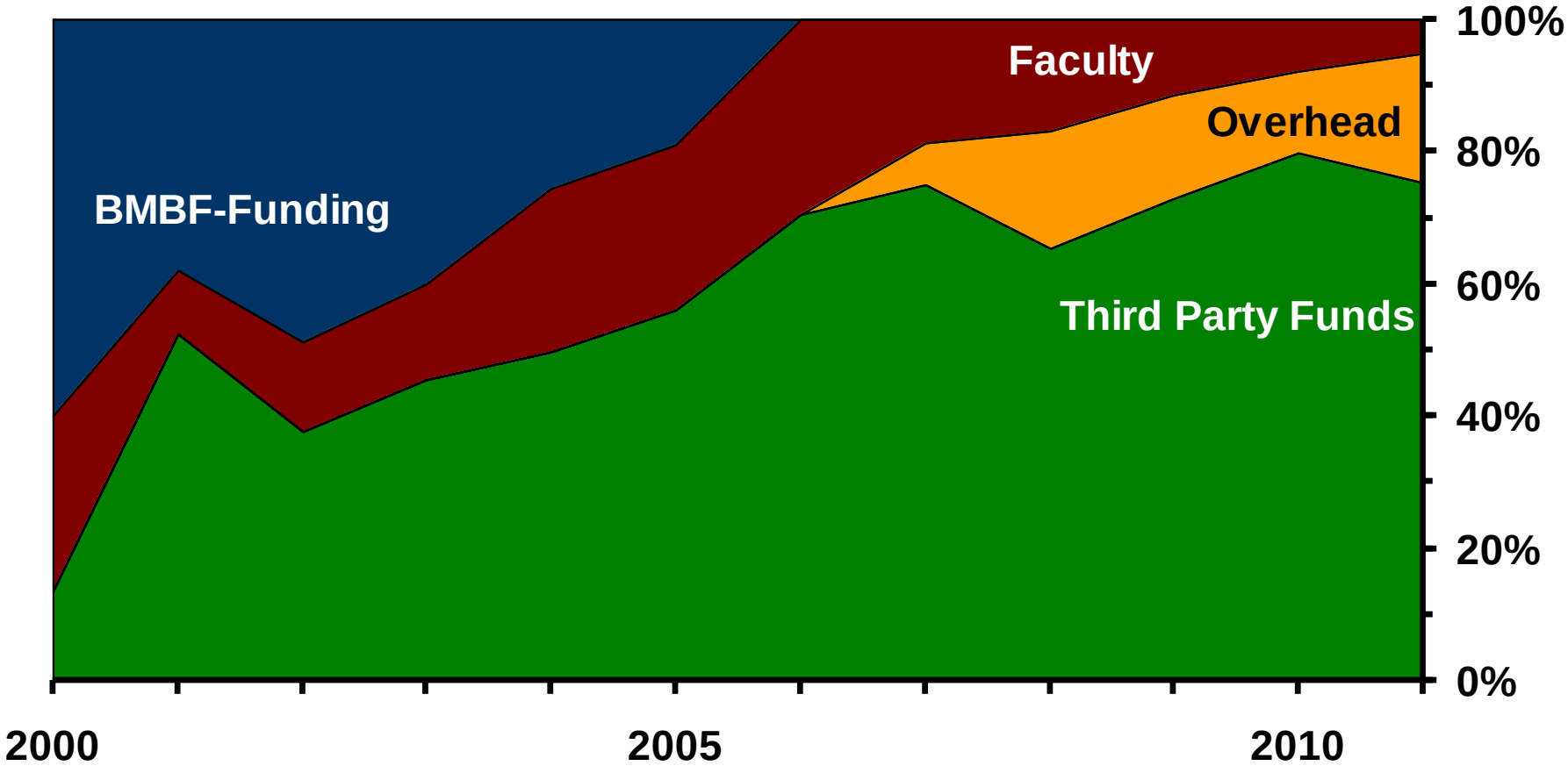
Funding Shares



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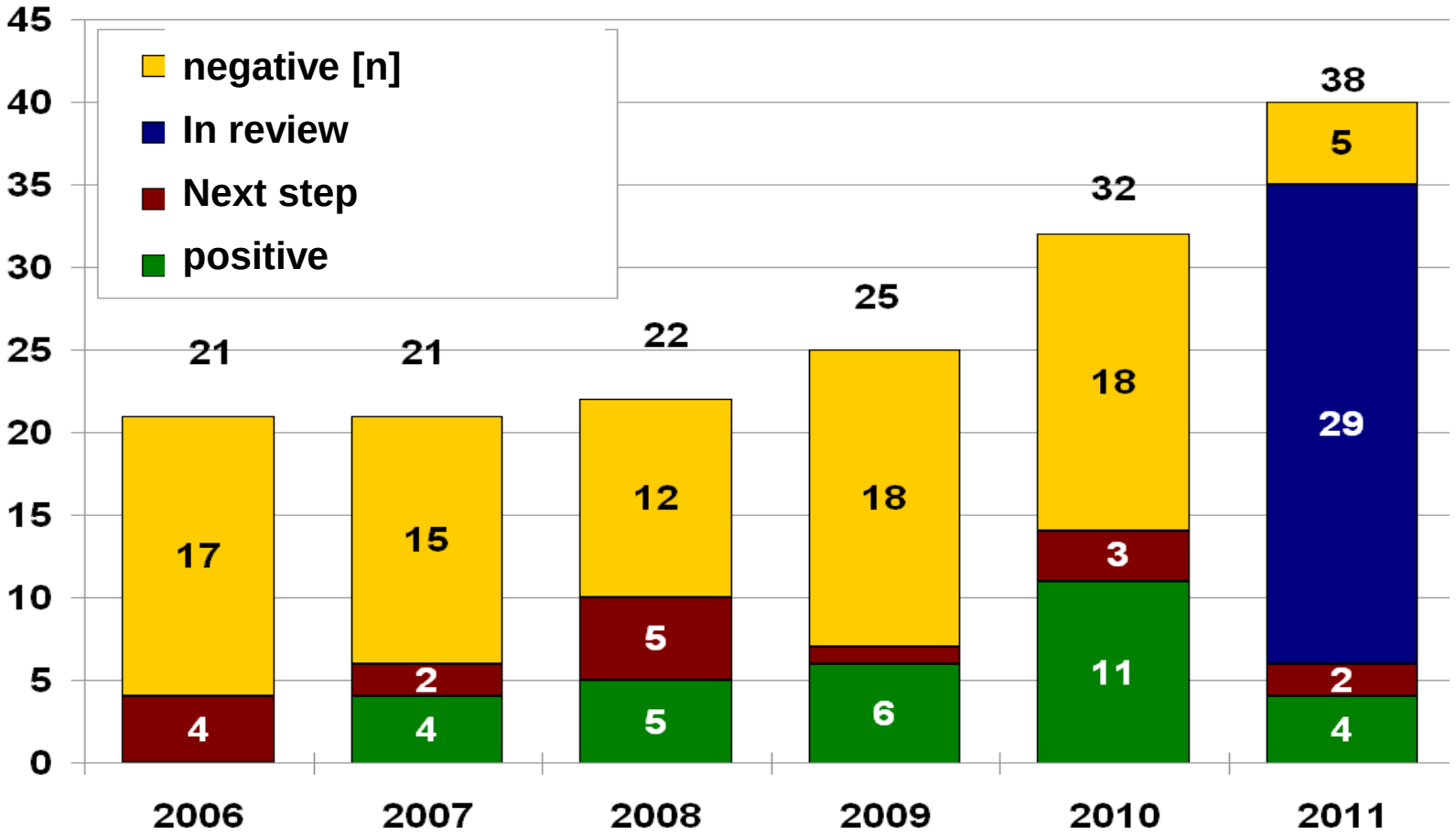
Grant Applications



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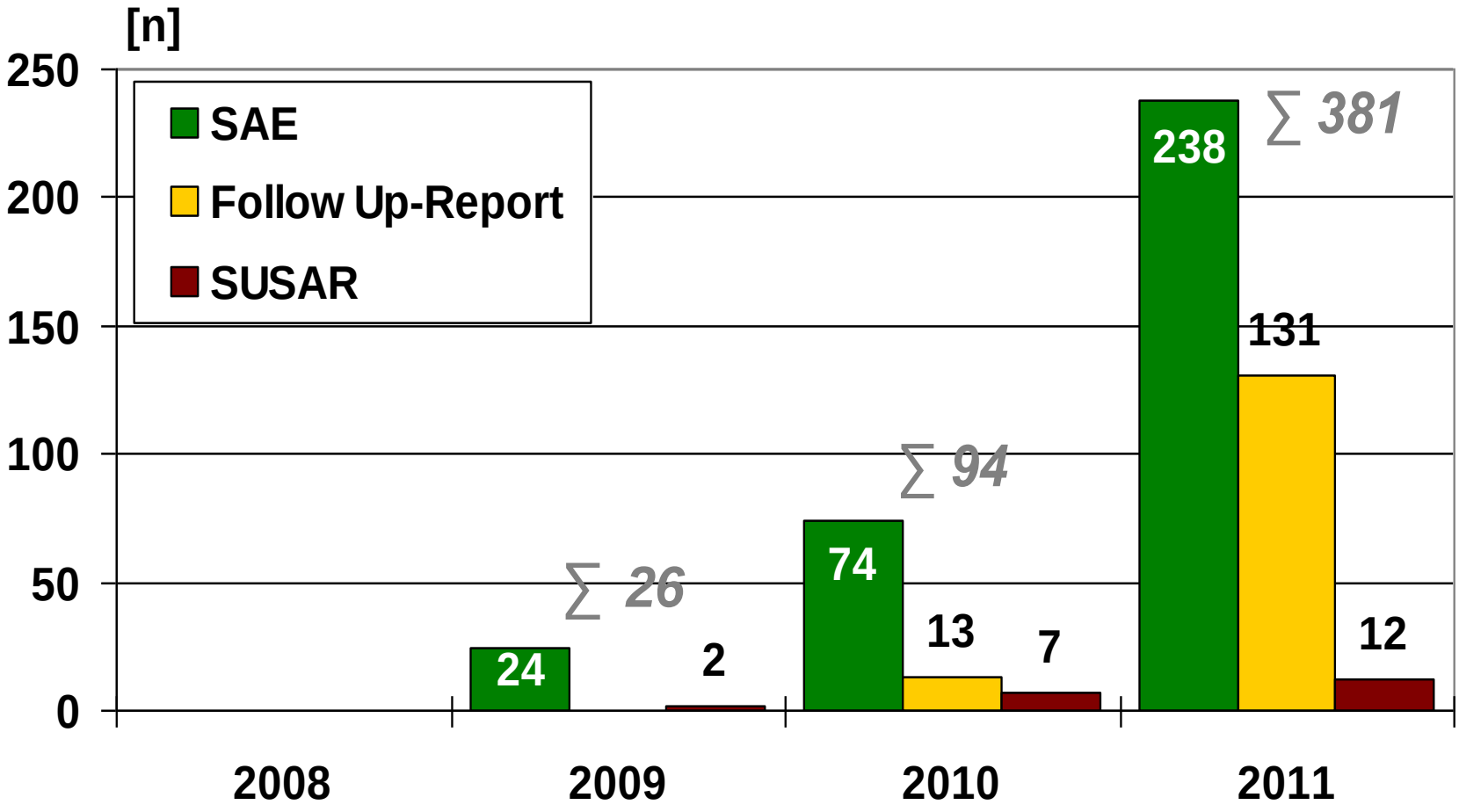
Safety Reports



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Clinical Monitoring / CRA

- (on-site) support and monitoring of clinical trials
  - Adding to competence of investigators and coordinating investigators (LKPs)
  - Continuous quality control, adapted to each study and risk assessment

Objective

- Support of trial site
- Protection of trial subjects
- Best data quality and integrity
- Compliance with protocol and regulatory requirements

Scientific Study Support / PM

- Unbureaucratic, confidential project consultation
- Study design and trial protocol development
- Project management
  - Ethics, regulatory affairs, (drug) safety
- Broad experience, independent of indication
  - AMG, MPG, non-AMG/ non-MPG, RöV, StrV, etc.
  - Comprehensive templates
- Document review
- Submission procedure to DFG, BMBF, EU etc.
- Consultation regarding research structure and contracts

Site Management Organization (SMO)

- On-site support of the clinical trial
  - Scheduling of patient visits, conduct, documentation
  - Sample logistics
  - Preparation/ support of visits of (external) monitors and auditors
  - Updating of central documents (ISF)

Objective

  - Well-planned and timely executed clinical trials
  - Relief of medical personnel

Biometry

- Conceptual consultation
  - Study design, sample size, etc.
- Biometric parts of the protocol
- Randomization procedures
- Statistical Analysis Plan, analyses
  - Sensitivity analyses for model assumptions and missing values
- Participation in the integrated final report

Data Management

- Implementation of the clinical trial protocol
  - Variable lists
  - Case Report Forms (paper based, RDE)
- Data entry masks
  - Development, validation and data entry
  - Training for RDE systems
- Data Validation Plan (DVP)
  - Incl. query tracking
- Central randomization
- Support for the analysis

Quality Management

- SOP system
  - Development, refinement and maintenance
  - Staff Training (incl. documentation)
  - Harmonized with the KKS Network and the TMF (Telematic Platform for Medical Research)
- Improvement of the staff's professional skills
  - On-the-job training and development plans
  - Internal and external training
- Consultancy services for trial centers
- QA review of essential documents
- Internal Audits

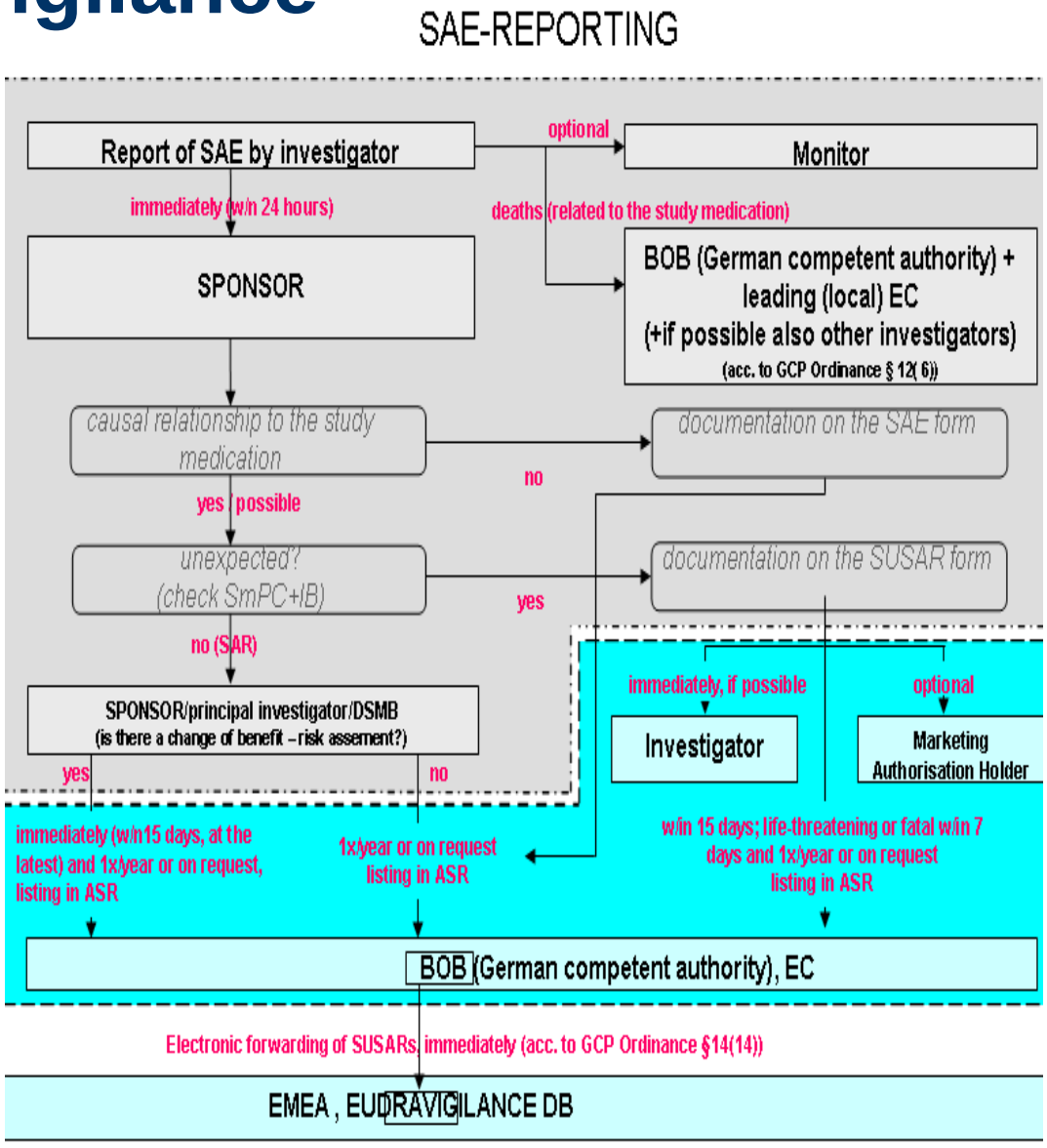
IT Services

- Validated systems for
  - Primary data entry in electronic format (RDE)
  - Data management
  - Statistical analyses
- Processes defined in SOPs
- Conceptual tasks regarding „IT-landscape“ Clinical Research in Heidelberg

Pharmacovigilance

Tasks

- Workflow Definition (Safety Manual)
- Preparation of the study-specific data base
- SAE Management
- Follow-up of SAEs (obtaining of missing information)
- SAE/SUSAR Reporting
- Preparation of Annual Safety Report(s) (ASR)



Training

- Continual training offers
  - Impart practical knowledge
  - Qualification of attendees
  - Improvement of training situation in clinical research
- Curricula of several days or weeks for
  - Investigators
  - Study Nurses
  - Clinical Monitors
- Topical lectures and training
  - E.g. on recent amendment to the German Drug Law, drug safety, sponsor‘s role
- Lecture Series on Clinical Trials
  - Continual education as required by ICH GCP

Compulsory Consultation

- Support the principal/coordinating investigator (LKP) in
  1. Designing clinical trials in compliance with German Drug Law, GCP Ordinance, data protection law, etc.
  2. Completely define the responsibilities associated with the clinical trial
  3. Avoiding funding shortfall
- Protection of the faculty‘s interests

Indirect

- Synergetic effects for parallel projects
- Enhancement of the reputation and competitiveness of clinical research

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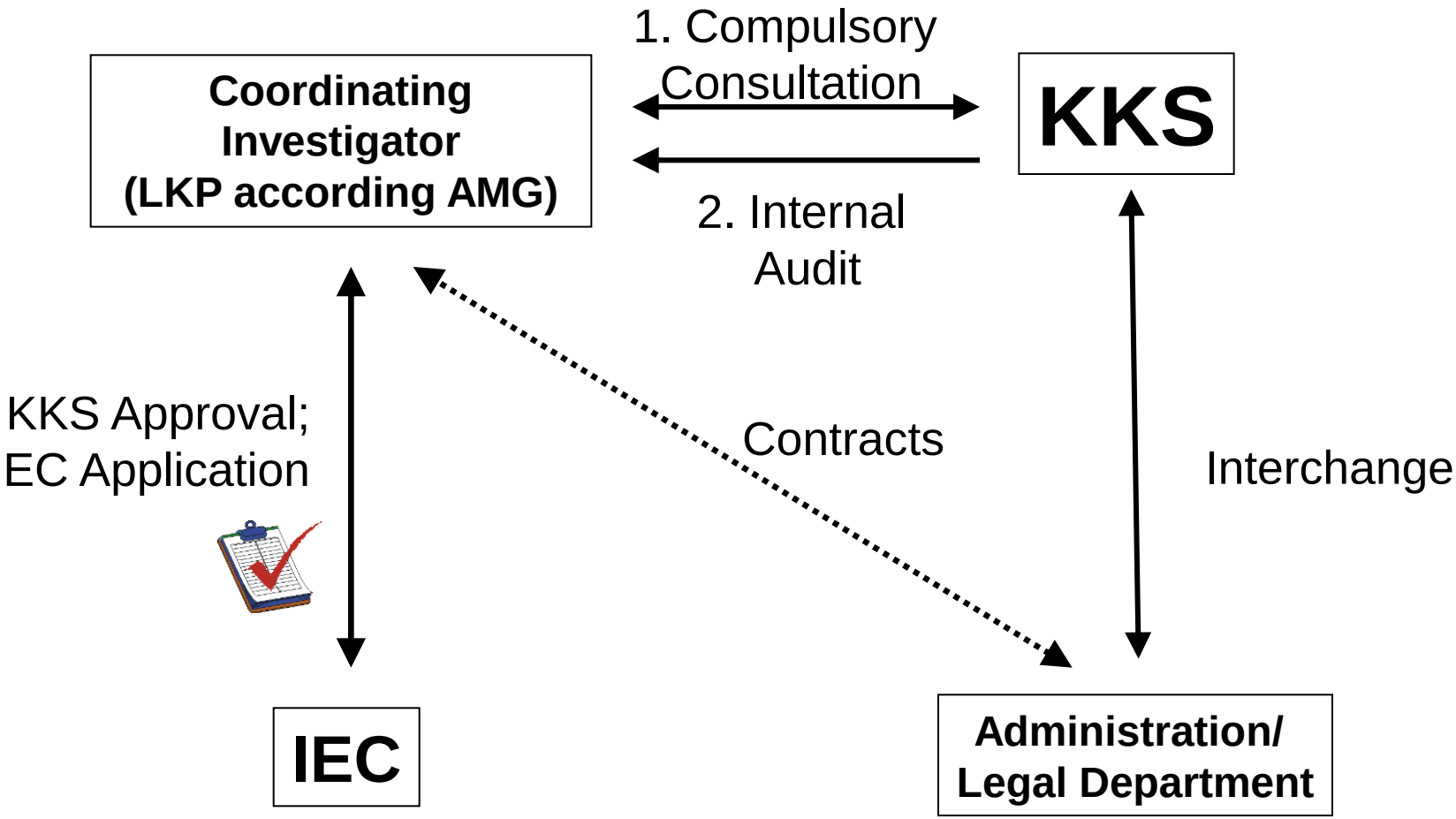
Supervision of the Sponsor‘s Activities



Auditing

- Support for external audits and inspections
- Recommendations for corrective actions
- Audits on behalf of Medical Faculty
  - Focus: trials regulated by the German Drug Law with principal/coordinating investigator in Heidelberg
  - Supervision of the sponsor‘s activities

FIM Heidelberg

First in Man Studies ...

- „One stop shopping“ strategy (planing, conducting and reporting)
- Multidisciplinary
  - KLIPS (Phase I Study Site on Clinical Pharmacology)
  - KKS (Coordination Centre for Clinical Trials)
  - IMBI (Medical Biometrics and Statistics)
  - NCT, DKFZ (pre- and clinical oncology)
  - Further clinical partners
- Contact

  http://fim-hd.kks-hd.de

  Email: fim@med.uni-heidelberg.de

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FIM First in Man Heidelberg

(Inter)national Activities

National

- KKS Network Coordinating Centres for Clinical Trials
- SDGC, Chir-Net
- TMF (Telematikplattform)
  (German meta-organisation
  for networked medical research)
- Competence Networks

International

- ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK European network

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KKS Network
Coordinating Centres for Clinical Trials

Activities

Interaction with funding organisations, currently regarding

- Pay scale grouping in grant applications
  - TV-Ä*, TV-L#
- Applicability of GCP in psychotherapy trials
- Financing plans for clinical trials
  - Overhead costs, full costs
- Review process and statement for grant notification
  - E.g. Integrated Research and Treatment Centers (IFB):
    43 applications, only 3 accepted, reasons?

Exchange with ministries

- Comments on draft laws
  - Currently: German Radiation Protection Ordinance, X-Ray Ordinance, Drug Guidelines (AMR)

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*Sector pay scale for University Hospitals
Public Sector Collective Agreement on Länder

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