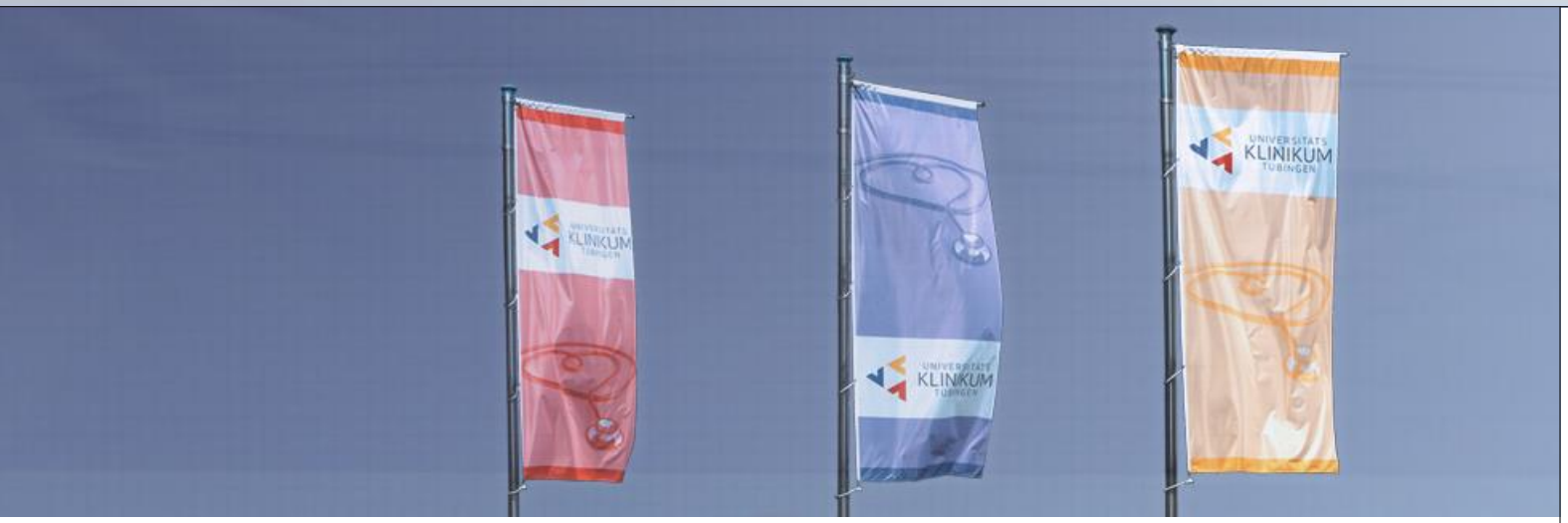

CPCS Kinderklinik Tübingen

Data Management in H2020 Clinical Trials

Challenges & best practice

Dr. biol. hum. C. Engel, Biometrician

Head of CPCS and Ressort IV (Datamanagement and Biometry)

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Data Management in H2020 Clinical Trials: challenges & best practice

- Introduction of the Center for Pediatric Clinical Studies (CPCS)
- Introduction of the Albino-Project
- Organisation of Datamanagement
- Organisation of Monitoring
- Support of overall study coordination

The Idea behind the Center for Pediatric Clinical Studies (CPCS)

- Before: calculation of dosing for children by body weight
- Now: new therapies have to be approved in the population they are used
- New medicines are not approved for use on children
- Rare diseases, very vulnerable population
- Development of therapies not appealing for industries

Center for Pediatric Clinical Studies (CPCS)

2010: Childrens University Hospital Tübingen decided to build up an internal organisation

Support of development of therapies for children

Ability to perform pediatric clinical studies from one end (planning, writing of study protocols) to the other (analysis and publication)

Expertise and experience not only available to the University Hospital Tübingen but also to other private and public customers

Actually about 23 stuff members (physicians, scientists, study nurses, medical software engineers, information specialists and monitors)

Center for Pediatric Clinical Studies (CPCS)

CPCS Kinderklinik Tübingen

CPCS-Steering Committee

Dr. biol. hum. C. Engel | Prof. Dr. med. A. Franz | PD Dr. med. J. Riethmüller

ISO9001:2008

Department Methodology/Planning

Prof. Dr.
A. Franz

- selected study design for specific questions and clinical reasearch problems
- systematic reviews
- development of study design
- study protocol in keeping with ICH GCP standards
- application (competent regulatory authorities, ethics committees, DFG, Federal Ministry of Education and Research, etc.)

Department Realisation

PD Dr.
J. Riethmüller

- coordination of clinical investigator(s) and study nurses
- development of study protocols, TMF and ISF
- data management (data entry)
- monitoring / query management
- pharmacovigilance
- calculation of costs

Department Datamanagement/ Biometry

Dr. biol. hum.
C. Engel

- participation in study protocol design
- CRF (case report form)
- development of study data base
- data management plan
- statistical analyses
- preparation of biometric interim and final reports
- participation in publication

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The Albino Projekt - Background

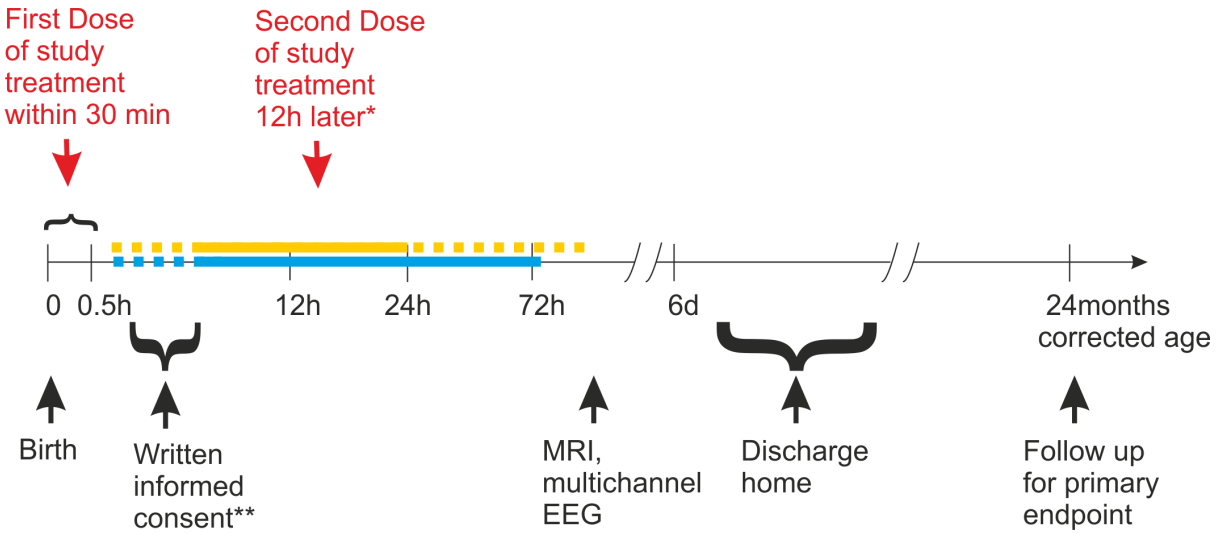
Albino: Effect of **AL**lopurinol in addition to hypothermia for hypoxic-ischemic **B**rain **I**njury on **N**eurocognitive **O**utcome

- Neonatal hypoxic-ischemic encephalopathy (HIE) affects about 1-2 / 1000 term life births (5000-10000 infants per year in Europe)
- Treatment: Hypothermia and neonatal intensive care
- 45-50% of affected children die or suffer from long-term neurodevelopmental impairment
- Early adjuvant neuroprotective intervention with Allopurinol
- Reduces the production of oxygen radicals
- Reduces brain damage in experimental, animal and preliminary human studies of ischemia

The Albino Projekt - Background

- 20% mild / 52% moderate / 28% severe HIE
- Primary endpoint: 10% reduction of death or NDI in the group with moderate HIE
- No effect for mild and severe cases
- Not distinguishable at first dose
- Inclusion and randomisation of 846 term born children with HIE in 14 countries

The Albino Projekt - Realisation



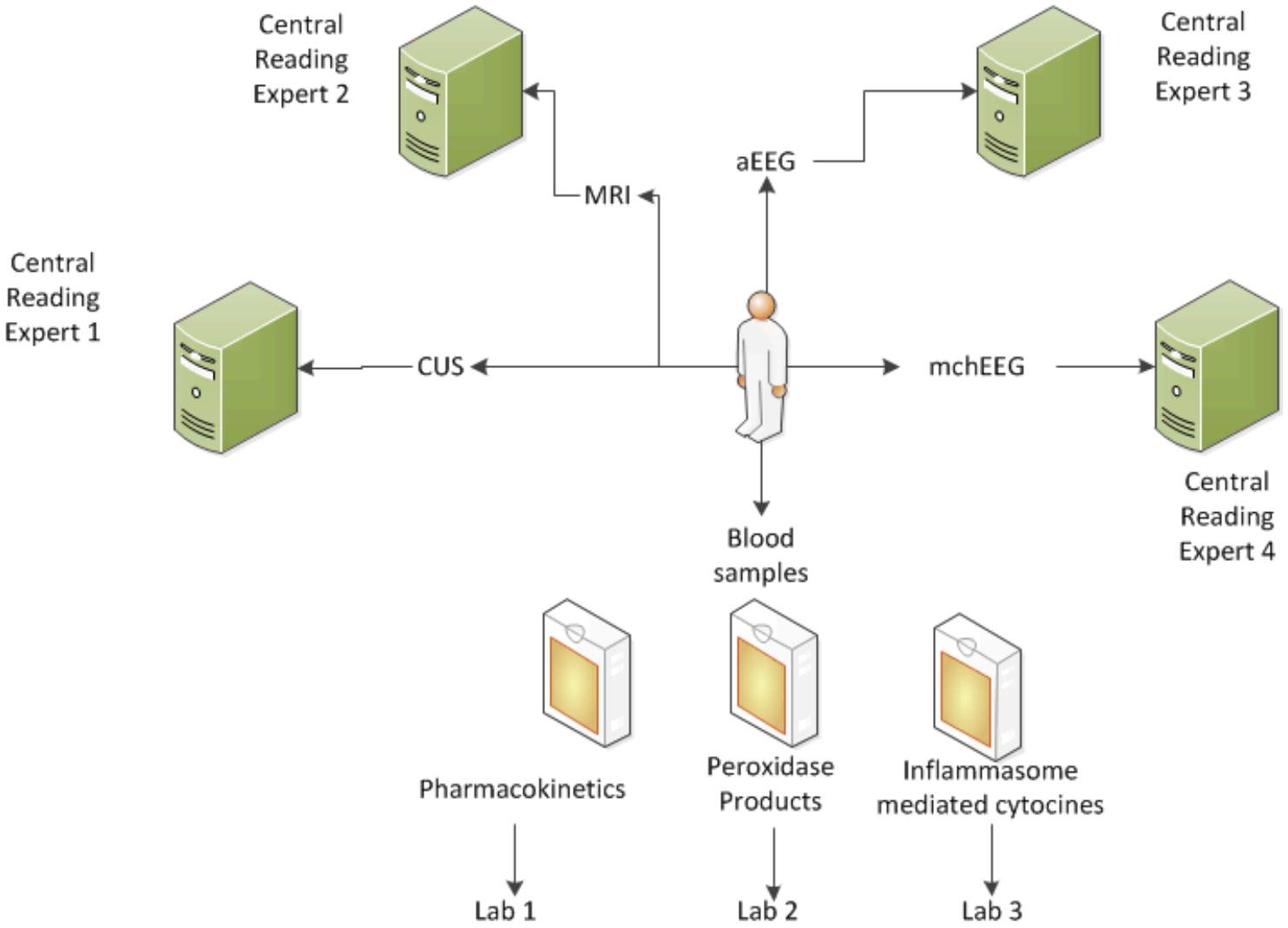
Hypothermia treatment starting at 1- 6 hours after birth (if indicated)

aEEG (at least for 24 hours and in case of therapeutic hypothermia until 12h beyond rewarming)

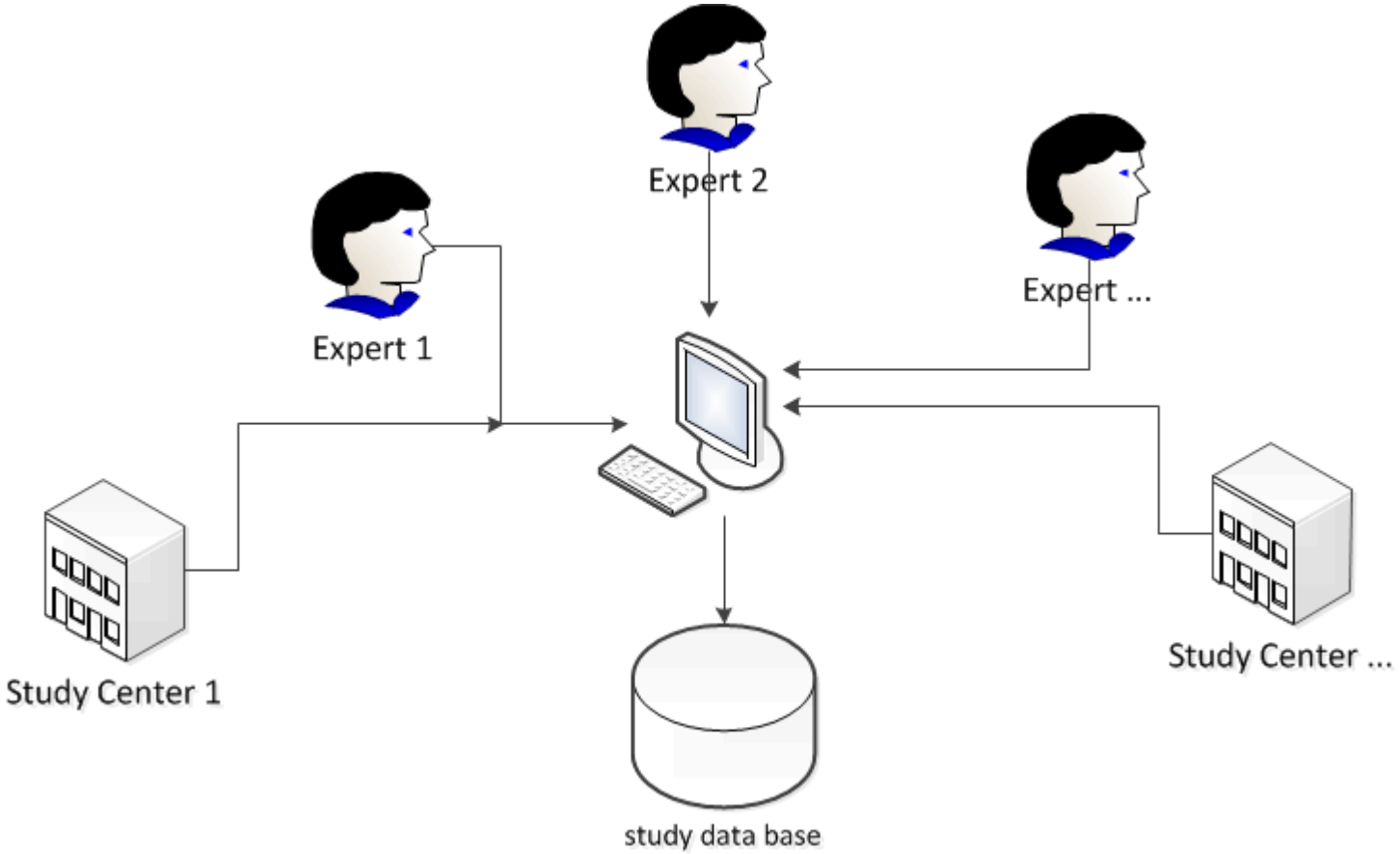
* in infants undergoing hypothermia treatment

** informed consent must be obtained before administration of 2nd dose of study medication

The Albino Projekt - Examinations



The Albino Projekt – Data Flow



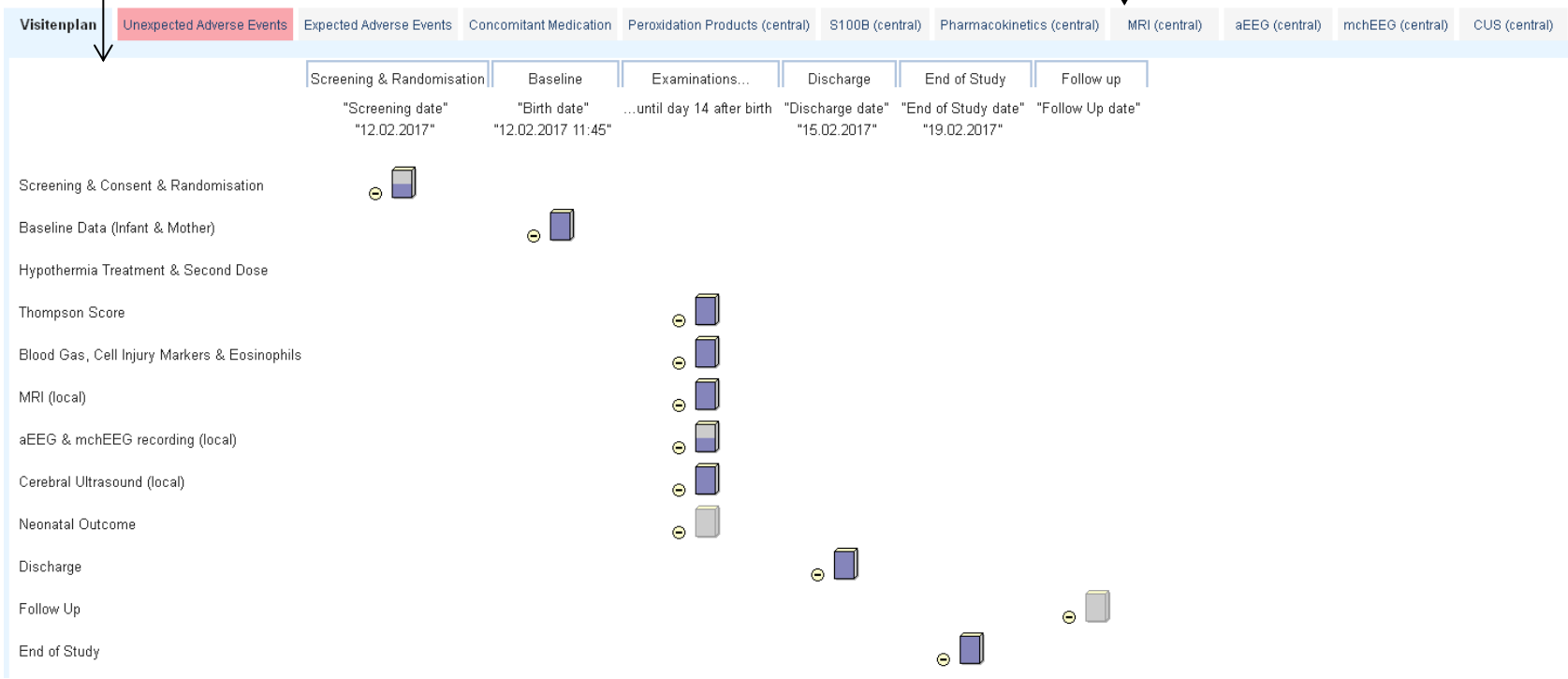
The Albino Projekt – Data base system

- Oracle-based
- Completely web-based
- Audit Trail
- Annotated CRFs
- Center specific and patient specific eCRF forms
- Querymanagement and plausibility checks within the database
- Reports within the database (Query status, recruitement status)
- Concept of roles and rights
- Integrated testing area
- Standardised export interface of data into SAS, SPSS, CSV and TXT datafiles
- Fullfills FDA 21 CFR Part 11- and ICH-GCP-requirements

The Albino Projekt - Documentation

local documentation

central documentation

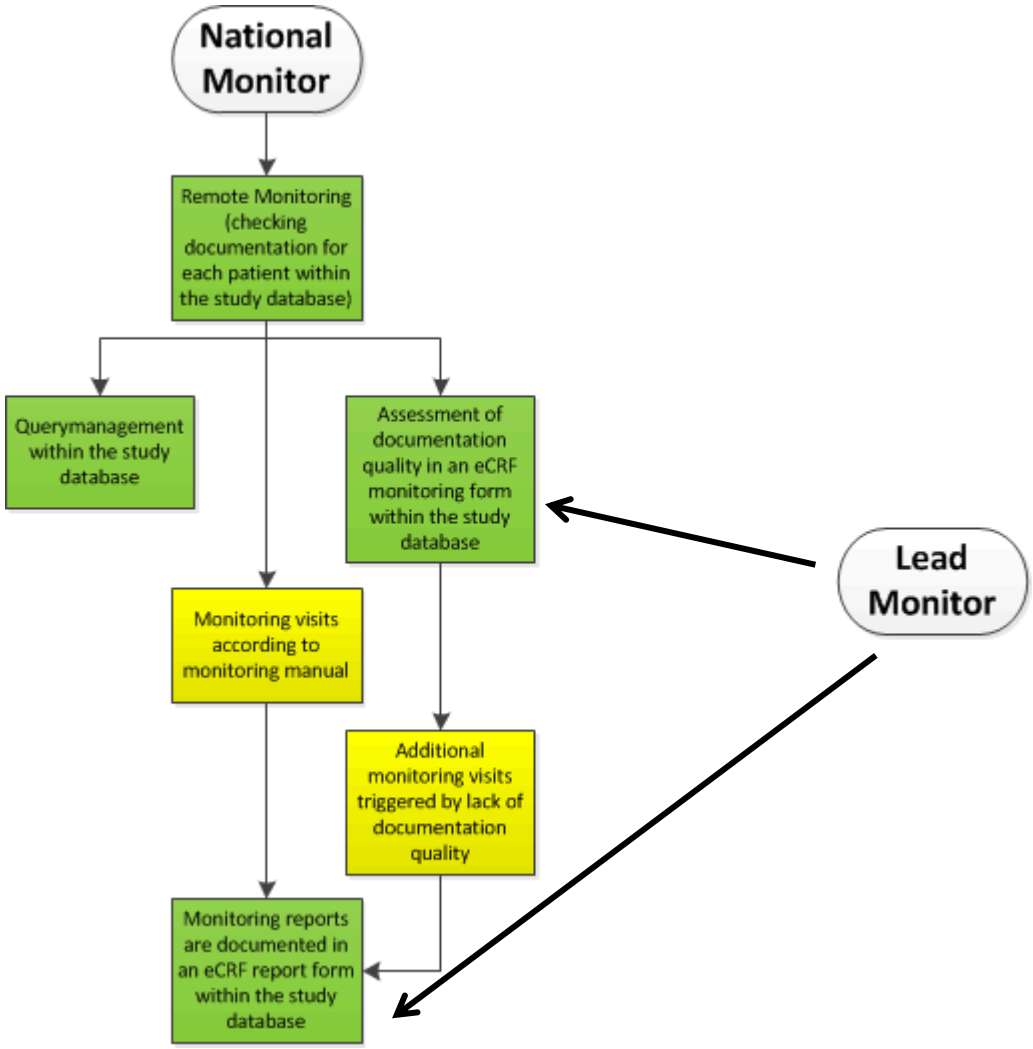


The Albino Projekt - Monitoring

Participating centers in 14 countries

Organisation of monitoring: 12 national monitors, one lead-monitor

The Albino Projekt - Monitoring



The Albino Projekt - Coordination

Study Database	Study Homepage
Welcome page with download area for study documents i.e. study protocol, data base manual, etc.	Members area gives the possibility to distribute information
Administration of participating study centers only within the study database to have one list, which is always up-to-date	

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Thank you very much for your attention

Universitätsklinikum Tübingen

Kompetenz mit Herz

www.uniklinikum-tuebingen.de

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