NeuroHub – Establishing a standardized pre-analytics and biomarker management for clinical studies

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Background
The NeuroCure Clinical Research Center (NCRC) at the Charité Berlin supports researchers in the implementation of clinical studies. This includes own investigator-initiated trials as well as studies in cooperation with the industry. In clinical biomarker studies not only biological sample determinants but also technical, structural and logistic issues with a well performed standardized pre-analytical phase are of utmost importance for the reliability of sample analysis. The lack of detailed knowledge and documentation may lead to bias or misinterpretation of data. However, an appropriate expertise for sample management is not always available within study teams.

Aim
Set-up and implementation of a professional pre-analytics biomarker management platform for investigator-initiated clinical biomarker studies. The aim is to offer:
• expert support already at the stage of study planning and to help with the implementation of quality-assured sample management
• infrastructure for professional sample management in biomarker studies

Standardization, documentation and quality control for all crucial steps of sample management

Often unsatisfactory performance and documentation in clinical bio-sampling

Conditions for

Results

NeuroHub – Support in pre-analytics and biomarker sample management

NeuroHub pre-analytics and biomarker platform was successfully established and is now available to clinical neuroscientists. Various studies of different working groups were already implemented.

EXPERTISE AND ADVICE on sample management & pre-analytics

Manuals, SOPs & templates for study documents

Quality management
• integrated into the clinical study and quality management of the NCRC
• DIN ISO 9001 certified

Professional training

Set-up of pre-analytical workflows
• based on intended use of samples and analyses

Documentation in LabVantage

Analys

Preparation Sample collection Sample processing Storage Sample retrieval

Short time! Short time!

Barcode Labelling & Sample Tracking
• Printing directly from LabVantage for allocated samples
• Printing ad hoc or prior to patient visits
• Label templates or individual set-up available
• 1D or 2D barcodes
• Labels for samples, storage location, boxes, sample types etc.

Quality-controlled temporary sample storage
• Quality controlled material (tubes, boxes, labels, etc.)
• NeuroHub freezers -80°C, N2 planned
• Easy documentation in LabVantage
• Long-term storage at Charité Biobank

NCRC Clinical Laboratory

LabVantage Laboratory Information Management Software (LIMS)
• IT configuration and support through NeuroHub bioinformatician
• Individual set-up for each study (incl. online documentation option)
• Easy to use sample management workflows for study teams
• Configuration promotes adherence to best practices and documentation of pre-analytical conditions
• Detailed user training including training material
• SPREC (Sample PREanalytical Code) implemented

Data Reports
• Standard reports or set-up of custom report templates
• Easy one click access for lab users
• Excel, PDF or HTML formats

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