

**BMBH**

**BioMaterialBank Heidelberg**

# **NCT-Tissue Bank**

## **The Nucleus of BMBH**

# Aims

- Central and comprehensive **tissue bank structure**
- **Research not collective-oriented:** ‚Making research possible‘
- Comprehensive **ethical/legal frame**
- ‚**Good scientific practice**‘; **Quality management**; Quality assessment:
- **Integration** of clinical and pathological experts; support of CCC/NCT-concept; role model
- **Technology platform and development**

# Tasks

- Pro- und retrospective collection of tissues; optimal scientific use of tissues
- Compilation of tissue collectives, links to clinical data (Data Pool)
- Technology-platform (e.g. Multi-Tissue Arrays, Virtual Microscopy)
- Quality management (good scientific practice)
- Project management (broker funktion; management; training)

# Structural Association

University

Medical  
Faculty

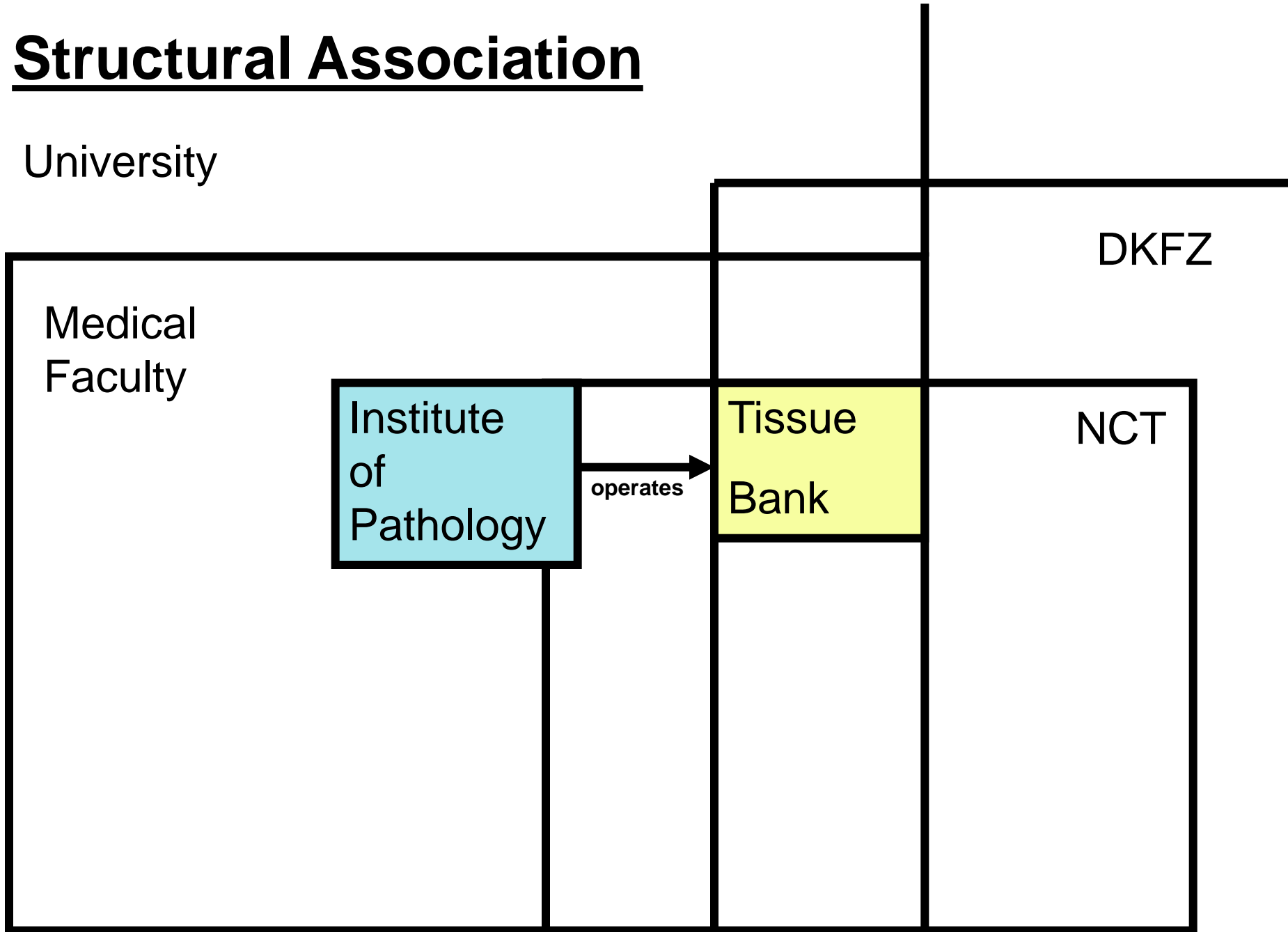
Institute  
of  
Pathology

operates

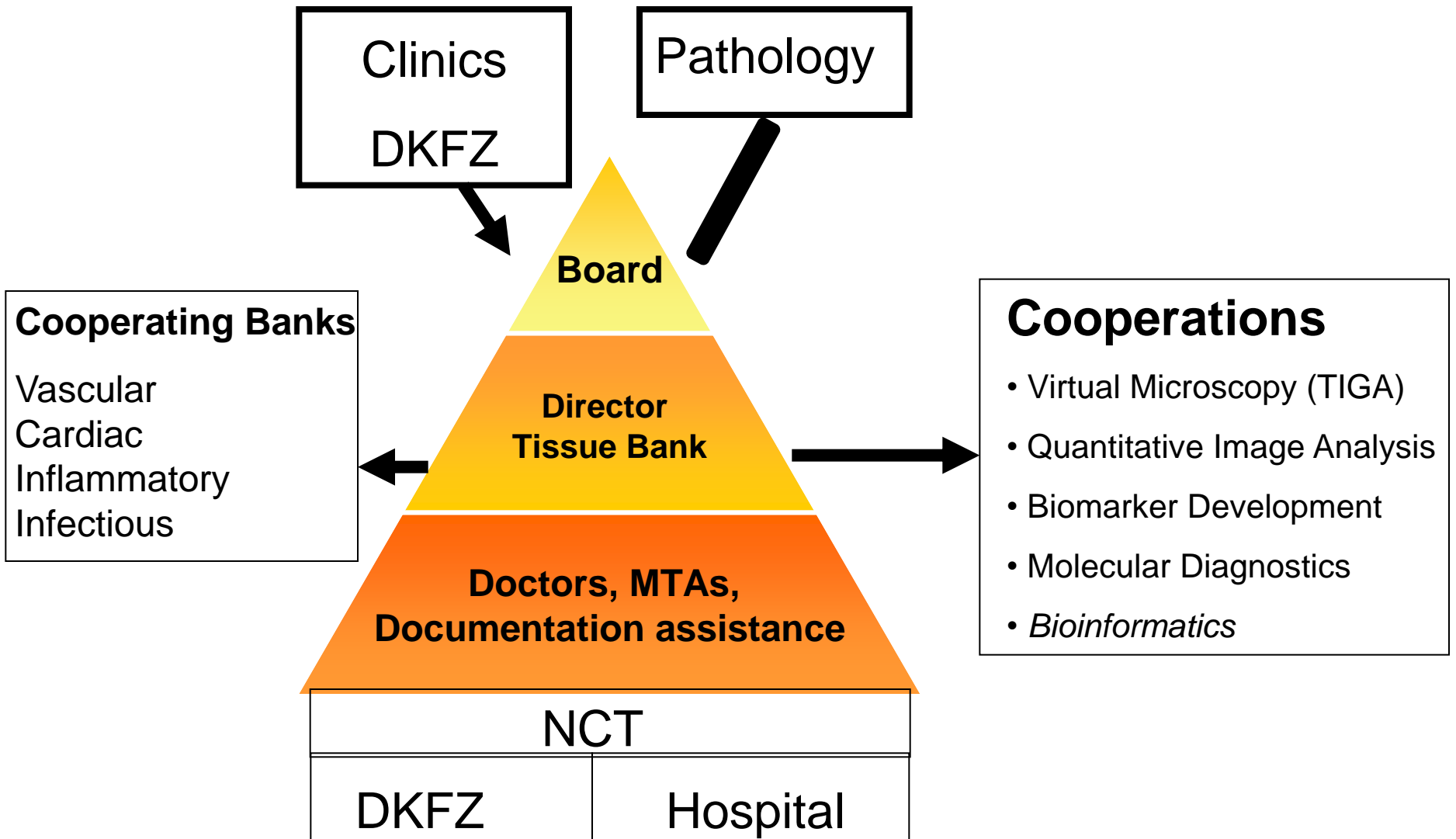
Tissue  
Bank

DKFZ

NCT



# Internal Structure NCT-Tissue Bank



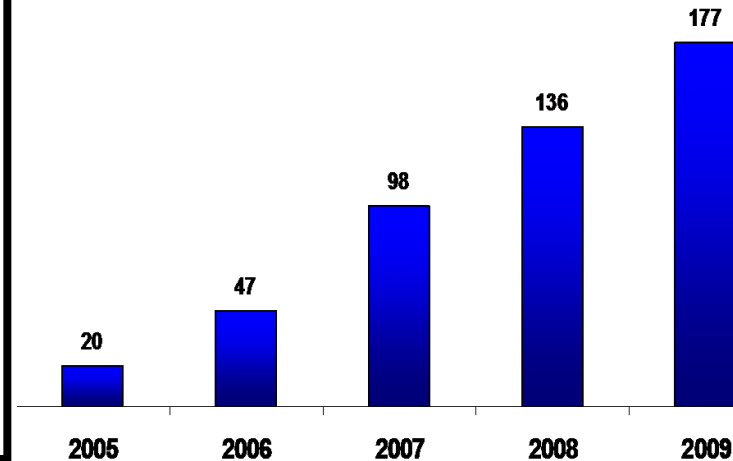
# **Structural Measures**

- Standing orders (2005)
- Affiliation (NCT), Start Operation (2005)
- Basic Personnel and hardware budget (2005)
- Standard Operating Procedures (2005-7)
- Quality Management (since 2006)
- Accreditation (since 2009)

# Project Status



- Projects: 685 (03/2011)
- Completion rate: >96%
- Multi-Tissue-Arrays: 60 (trial quality)
- Frozen tissues: 11.000 probes (increasing; + 10.000 old probes)
- Paraffin archive (>500.000 probes)



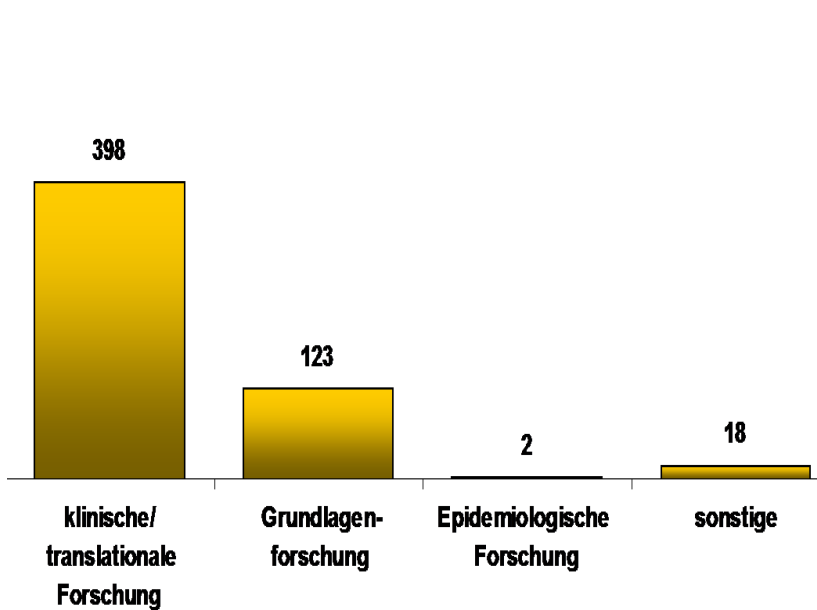
**High efficiency; one of the most active tissue banks**



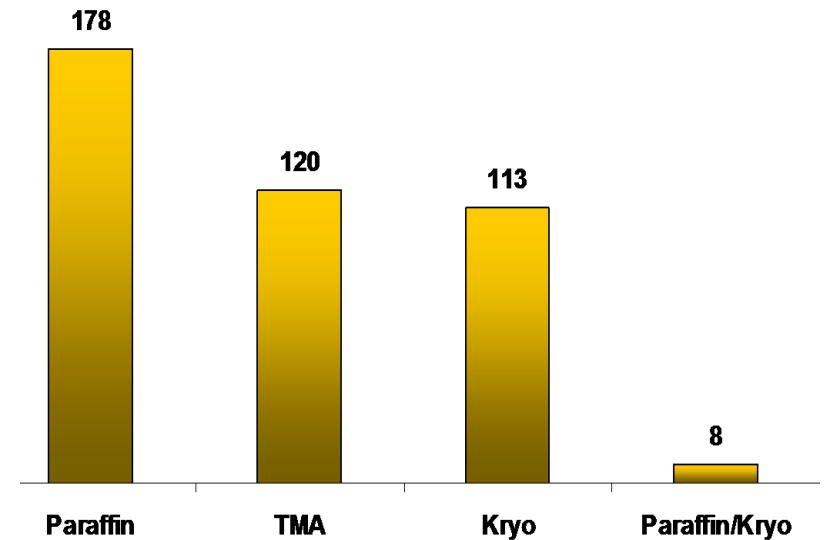
# Guardian of the tissue

- Individual project assessment (amount, type of tissue; downscaling?)
- TMA-program
- Project tracking
- Sanctions

## Project types



## Materials



# Consortional Projects

- Population-based national and international epidemiological studies (e.g. DACHS, IMPACT, EPIC (colon/pancreas Germany), ColoCare)
- Research Consortia: SFB/TRR77 (HCC); KOSAR (Sarcoma)
- Clinical Trials (e.g. INNOVATION, SELECT)

# Cooperation Epidemiology

- Population based, national and international epidemiological trials (DACHS, IMPACT, EPIC, ColoCare)
  - Project planing
  - Collectives
  - Core-Functions

Tissue

Histology

Clin. data

Follow-up

Risk actors

Non-biased, prospective



# Ethical Issues

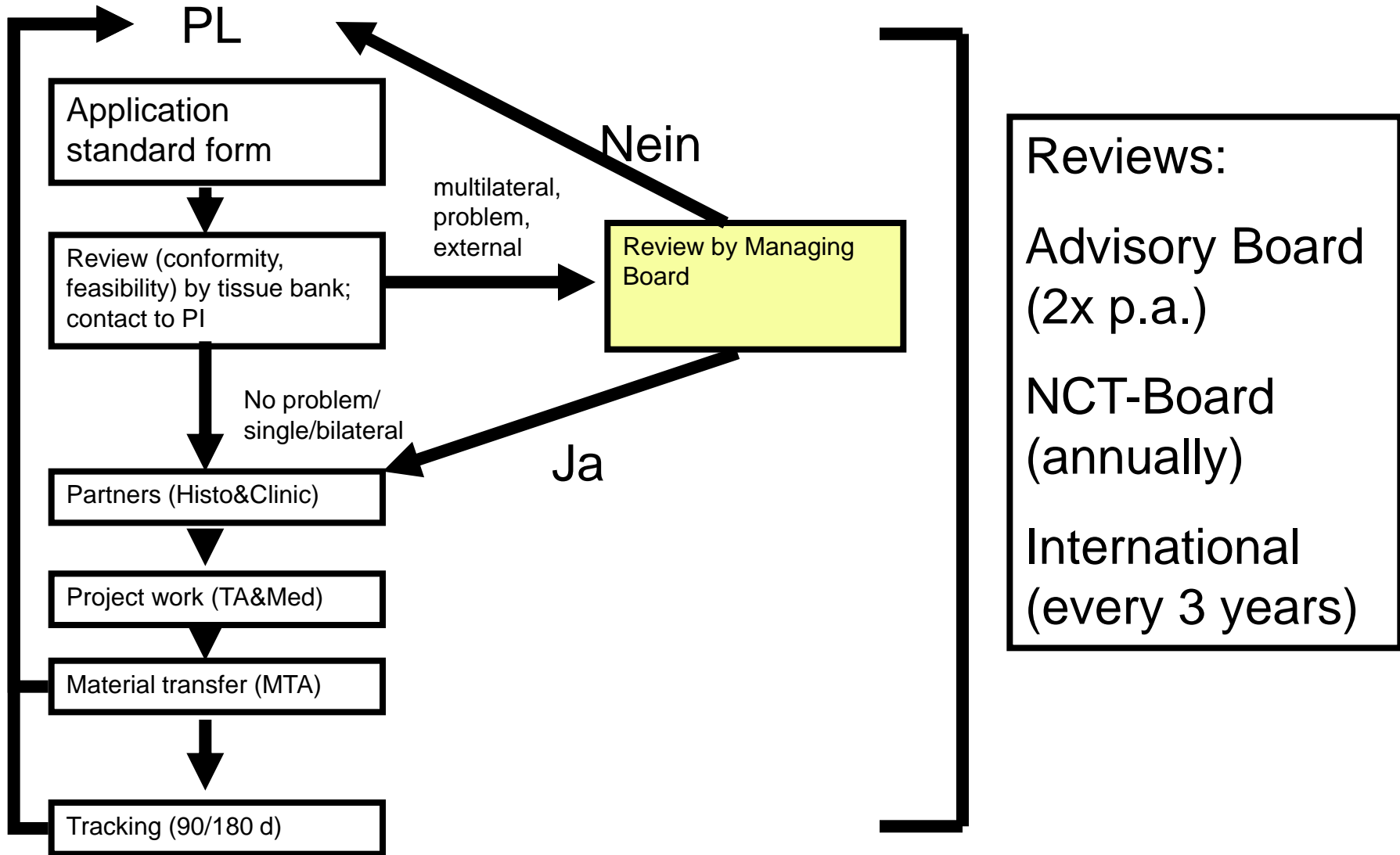


- **Comprehensive Ethical Votes**
  - Prospective collection (project independent)
  - Retrospective tissue collectives (2005)
  - Accepted by DFG, Deutsche Krebshilfe (2006)
- **Informed Consent**
  - Uniform for all sites and projects (2006; broad, project independent, altruistic)
  - Admission contract (2009; automatic negative information)
- **Data safety concept**

# Biobank - Safety Concept

- Pseudonymisation
  - Coded for user
  - Can be broken by tissue bank
- Separated data bank
- Admission control
- Regulations of standing orders
- Regular instructions of personnel
- Material Transfer Agreement (Instruction of user)
- Regular assessment by local data safety officer

# Project Management/Reviews



# SOPs


<b>Structural SOPs</b>	<b>Scientific/Procedural SOPs</b>
Responsibilities of leadership	Patient consent/documentation
Definition of politics	Entry controls of fresh tissues and other materials by pathologists
Definition of aims	Asservation of fresh tissues
Organisation	Storage of fresh frozen tissues
Description of functions	Processing of tissues/materials
Training schedules	Project coordination
Training plans	Exit control of requested material including expert pathological-anatomical report
Withdrawal of consent	Tracking of projects



# Quality Management

Structural components	Processual/scientific components
1. Organisation/Structure	1. Tissue characterisation and quality control (entry/exit control)
2. Regulations	2. Project evaluation and management
3. Internal and external review system	3. Project tracking and documentation

**Anforderungsbogen Gewebekbank**  
 Anforderungsbogen Seite 15 DRUCKBUCHSTABEN  
 Ausfüllen und unterschreiben an:  
 Servicebüro: [service@nct.med.uni-heidelberg.de](mailto:service@nct.med.uni-heidelberg.de)  
 Sekretariat: Tel. +49 6221 56 35994 Fax: +49 6221 56 8521



**Gebebewunsch**  
 Kryogewebe  
 (incl. Anzahl der Proben)

**Projekt**  
 (Titel, Projekt-Nummer, Kurzbeschreibung des Projekts)

**Institution/ Klinik**

Name: \_\_\_\_\_ Unterschrift: \_\_\_\_\_  
 Datum: \_\_\_\_\_ Tel.-Nr.: \_\_\_\_\_  
 E-Mail: \_\_\_\_\_

**Projektleiter**

**wird von der Gewebekbank ausgefüllt:**

Antragsnummer: \_\_\_\_\_  
 Projekt-Nummer: \_\_\_\_\_

**Proben ID**


**Berät**


Name: \_\_\_\_\_ Unterschrift: \_\_\_\_\_  
 Datum der Genehmigung: \_\_\_\_\_

**Datum der Ausgabe**  
 09.03.09


**Kooperationspartner**

Histologie: \_\_\_\_\_ Klinik: \_\_\_\_\_

**Bemerkungen**



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 E-Mail: \_\_\_\_\_

**Projektleiter**

**wird von der Gewebekbank ausgefüllt:**

Antragsnummer: **8001**  
 Projekt-Nummer: **160**

**Proben ID**


**Berät**


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 Datum der Genehmigung: **09.03.09**

**Datum der Ausgabe**  
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
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Histologie: \_\_\_\_\_ Klinik: \_\_\_\_\_


**Bemerkungen**



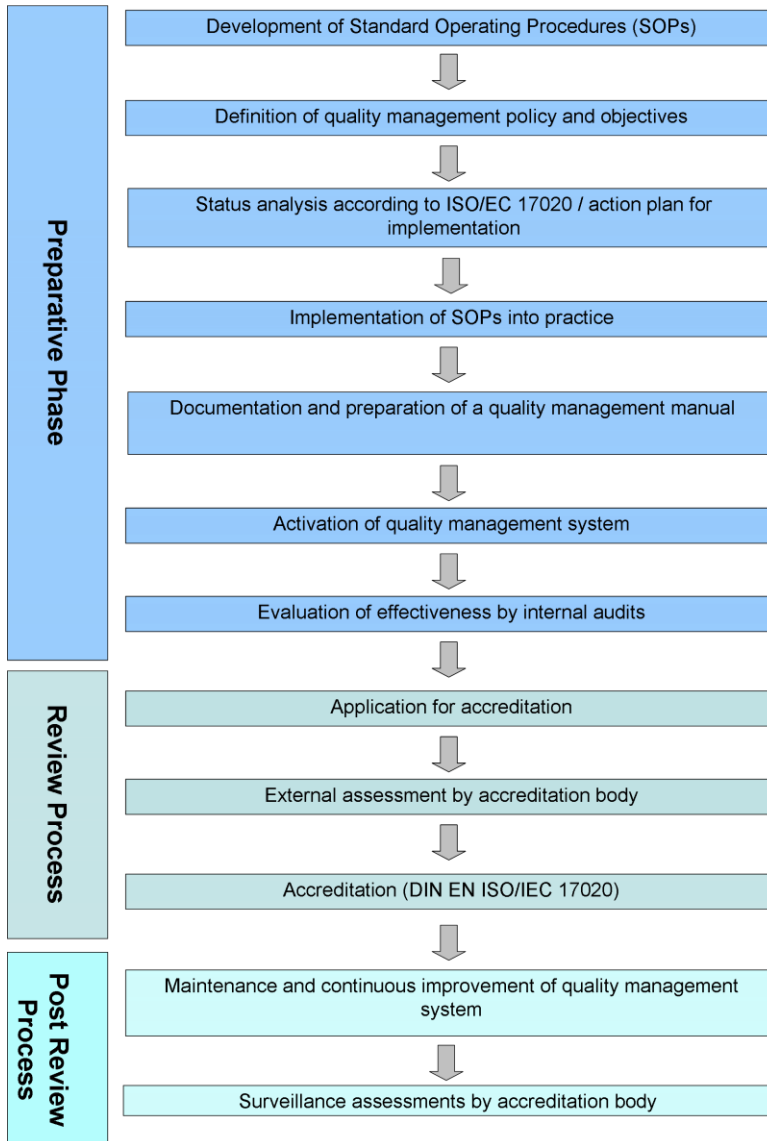
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ACT-Nr.	GEWEBE	TUMOR VITAL (%)	TUMOR NERVEN (%)	TUMOR STROMA (%)	DIAGNOSE/LOKALISATION/ANMERKUNG	
<b>TUMOR</b>						
1	216	PLECA	50	7	50	pleurocarcinom gering differenziertes, invasives Pleuroepitheliom (Pleurocarcinom)
2	256	PLECA	70	7	30	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
3	258	PLECA	70	10	20	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
4	300	PLECA	70	10	20	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
5	303	PLECA	60	10	30	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
6	329	PLECA	60	10	10	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
7	341	PLECA	30	30	40	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
8	351	PLECA	40	10	10	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
9	398	PLECA	60	5	35	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
10	420	PLECA	60	10	10	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
11	481	PLECA	40	10	50	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
12	548	PLECA	70	10	20	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
13	562	PLECA	60	7	40	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
14	603	PLECA	60	7	10	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
15	680	PLECA	60	10	30	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)
16	716	PLECA	40	10	50	pleurocarcinom, hoch differenziertes Pleurocarcinom (Pleurocarcinom) (Pleurocarcinom)

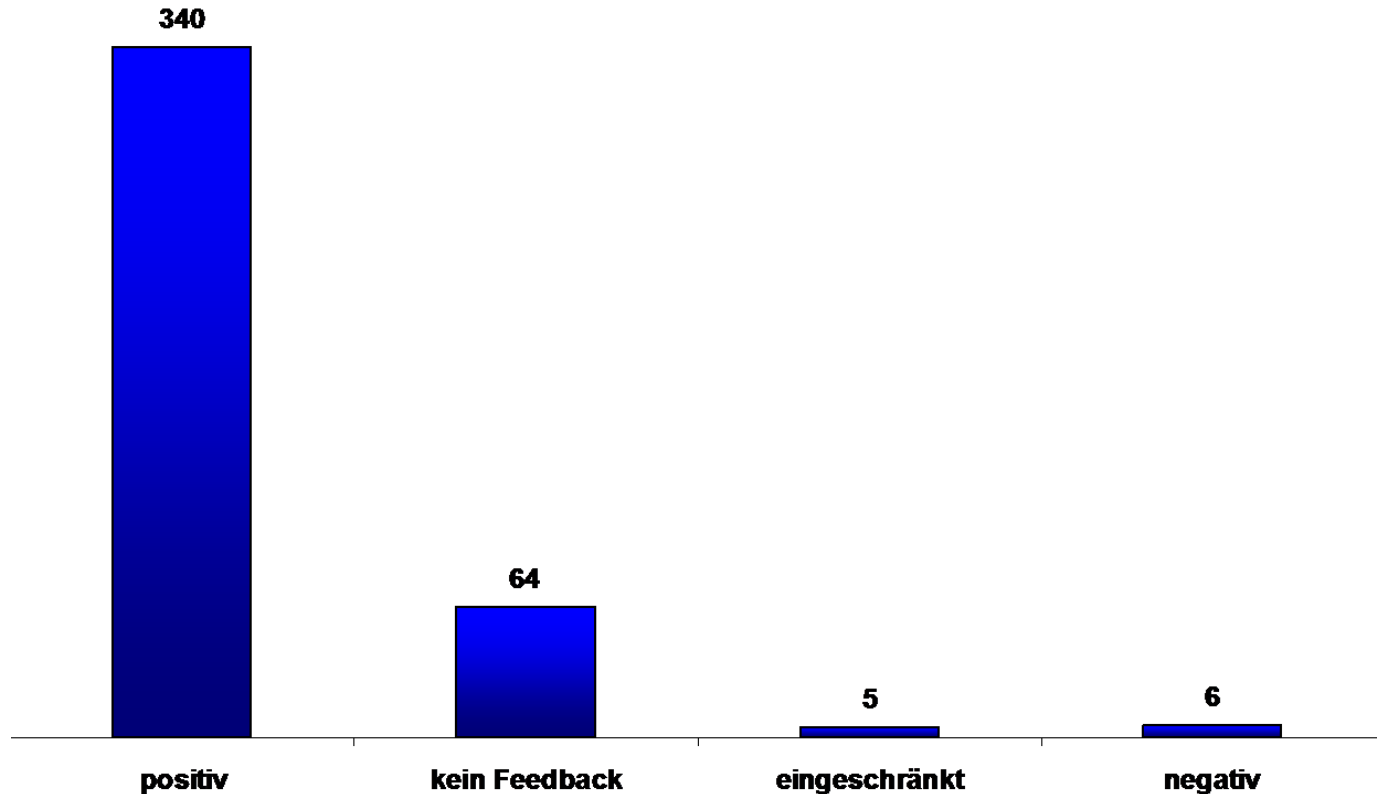


# Accreditation Process



- 2005 First SOPs
- 2006 Start quality management
- 2007 Sektorkomitee der DAP (heute DAkKS): Gewebekbanken sind akkreditierbar
- 2009 Akkreditierung der NCT-Gewebekbank nach DIN EN ISO/IEC 17020 : 2004

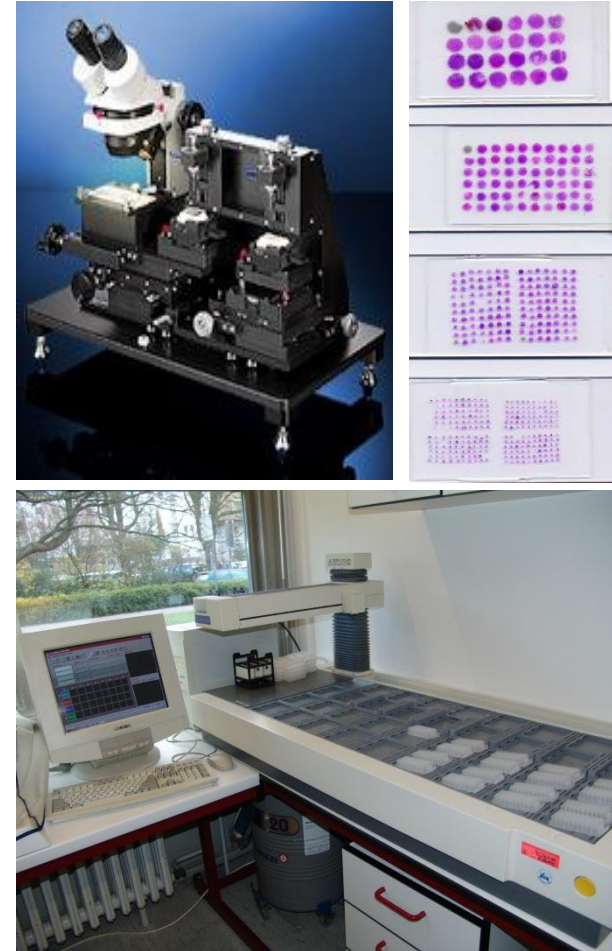
# Project Tracking – Tissue Quality



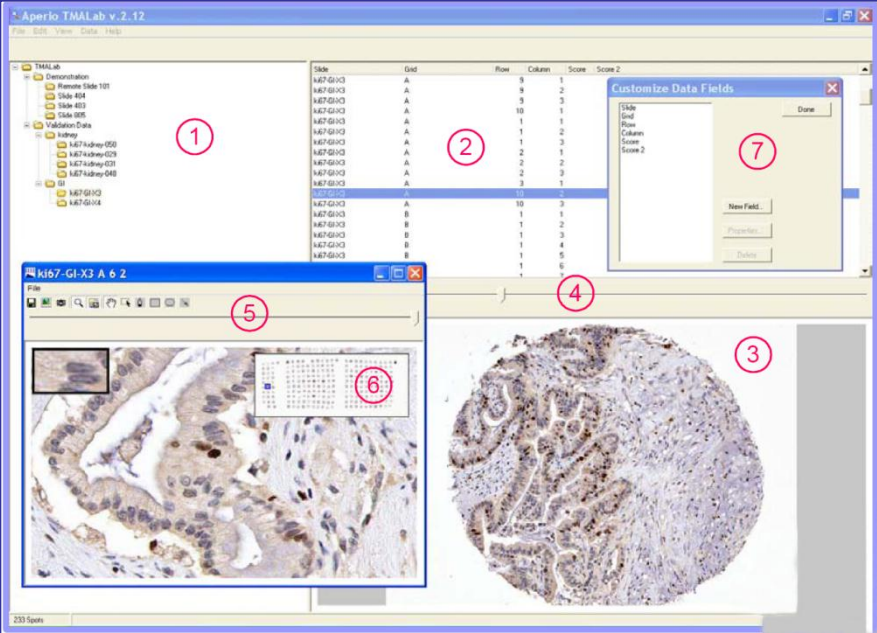
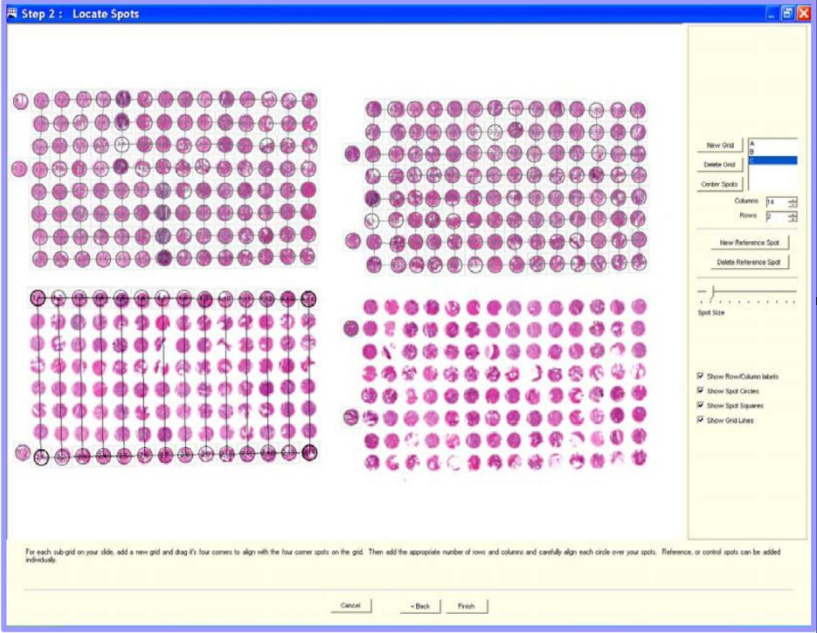
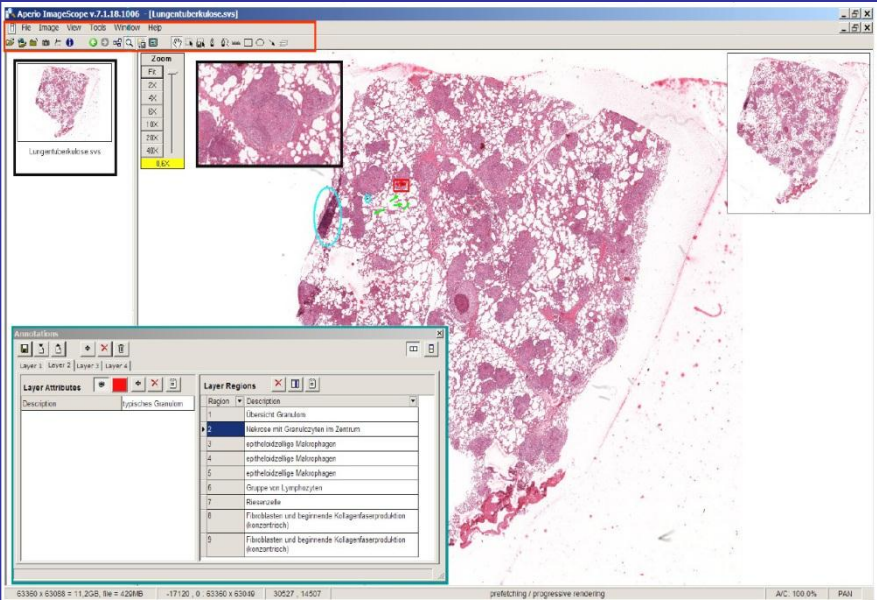
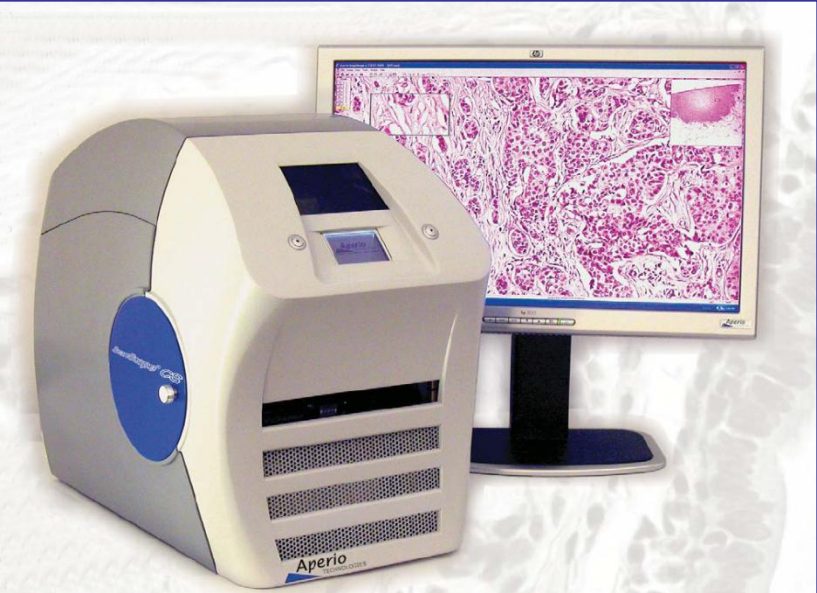
Standardized tracking after 90 and 180 days

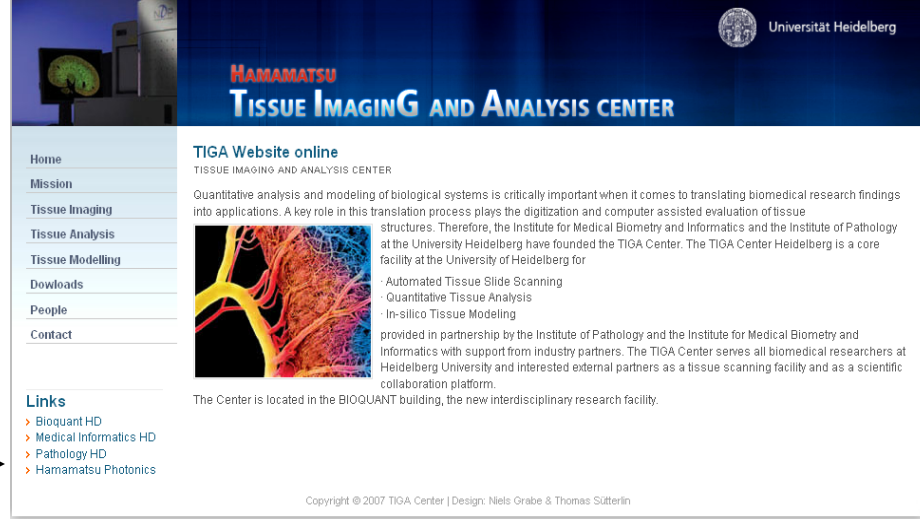
# Central Laboratories Tissue Bank

- Histotechnology
- Immunohistology (aut.)
- Multi-Tissue-Arrays (aut./man.)
- *Extracts (Nucleic acids)*
- *Laser-Microdissection*
- Virtual Microscopy/Image analysis
- Project work
- Compilation of collectives
- Documentation and archiving
- Reference and training



# Image acquisition and analysis





MTA-VM  
(Pathology)

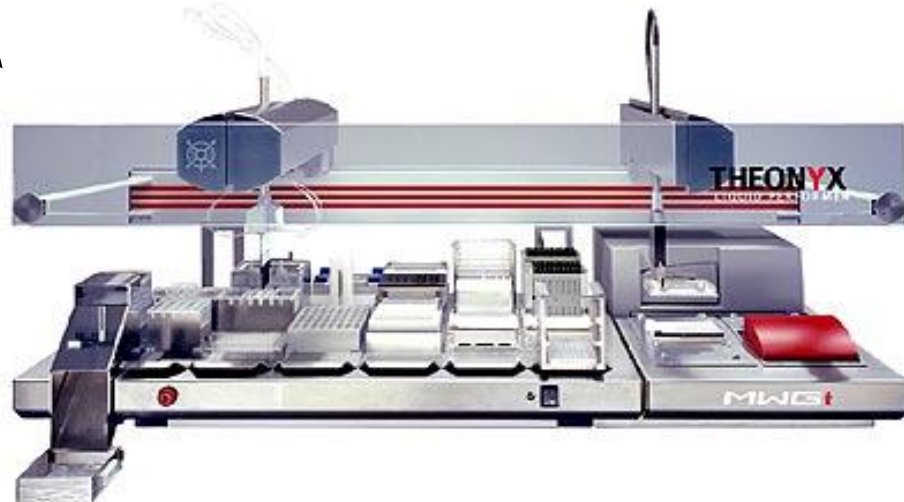
Technology Development/  
quantitative Marker-Analyses (TIGA)

Tissue Bank NCT Heidelberg



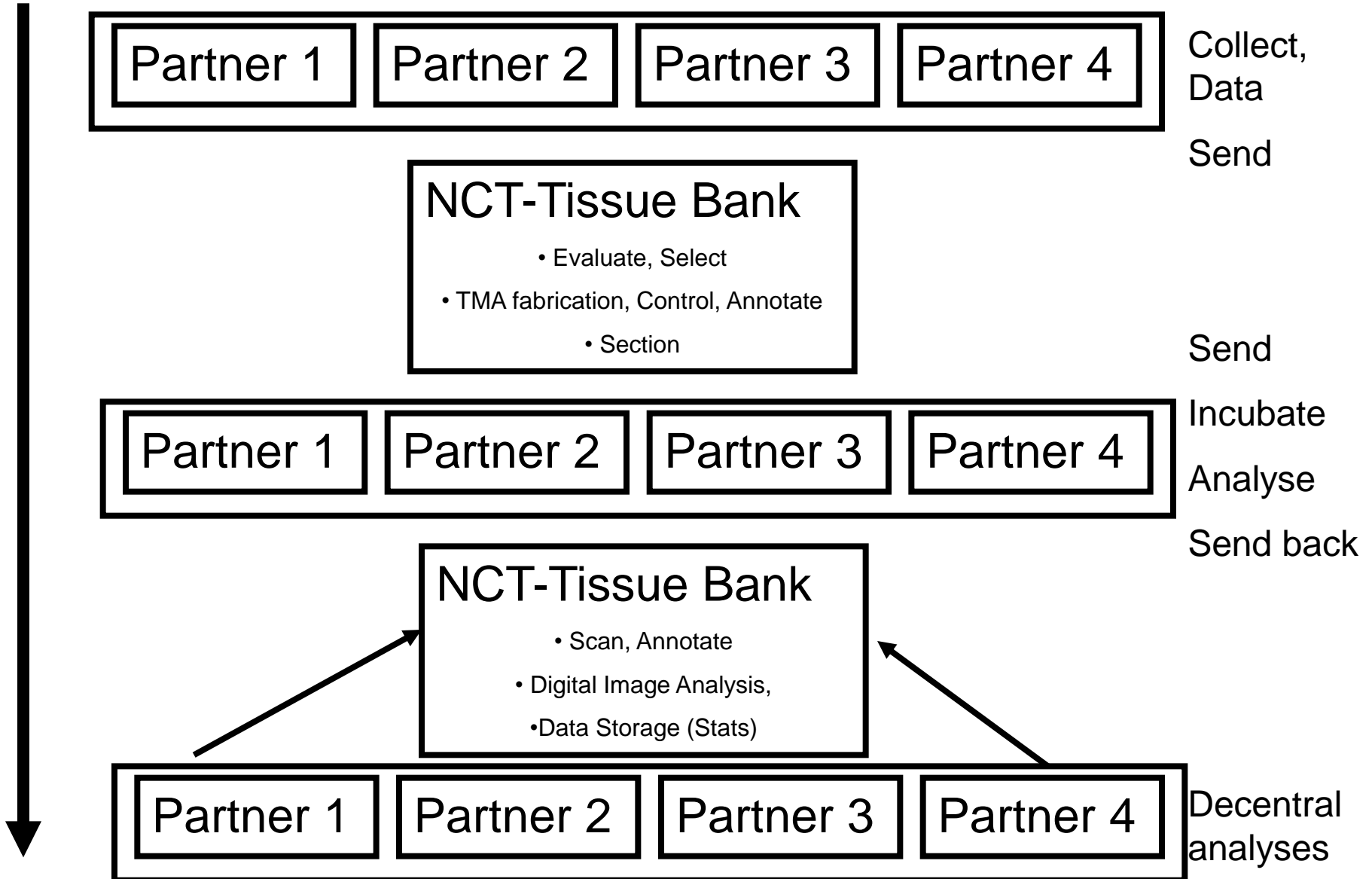
Bioinformatics  
Epidemiological Trials

Paraffin-Profiling (Pathology)



# TMA-Core

(EPIC, Columbia University, SFB/TRR77, ColoCare)



# Working Group Tissue Banks of the CCCs

- Berlin
- Bonn
- Dresden
- Düsseldorf
- Frankfurt
- Freiburg
- Göttingen
- Halle
- Hannover
- Heidelberg
- Innsbruck
- Jena
- Köln
- Mainz
- Mannheim
- Marburg
- Münster
- LMU München
- TU München
- Regensburg
- Tübingen
- Ulm

## Meetings

- 7.12.2006
- 7.7.2007
- 28.2.2008
- 3.12.2008
- 14.05.2009
- 04.11.2009
- 21.6. 2010
- 02/2010

Supported by Deutsche Krebshilfe (since 2010)



# WG Tissue Banks of the CCCs

- Structure tissue banks
- Ethical votes; Patient consent
- Legal issues
- Quality management/Accreditation
- Cost structure and –calculation
- IT solutions and data banks
- Industry cooperation
- Guidelines
- Tissue bank interactions; Joint projects
- Grants applications
- Info-platform

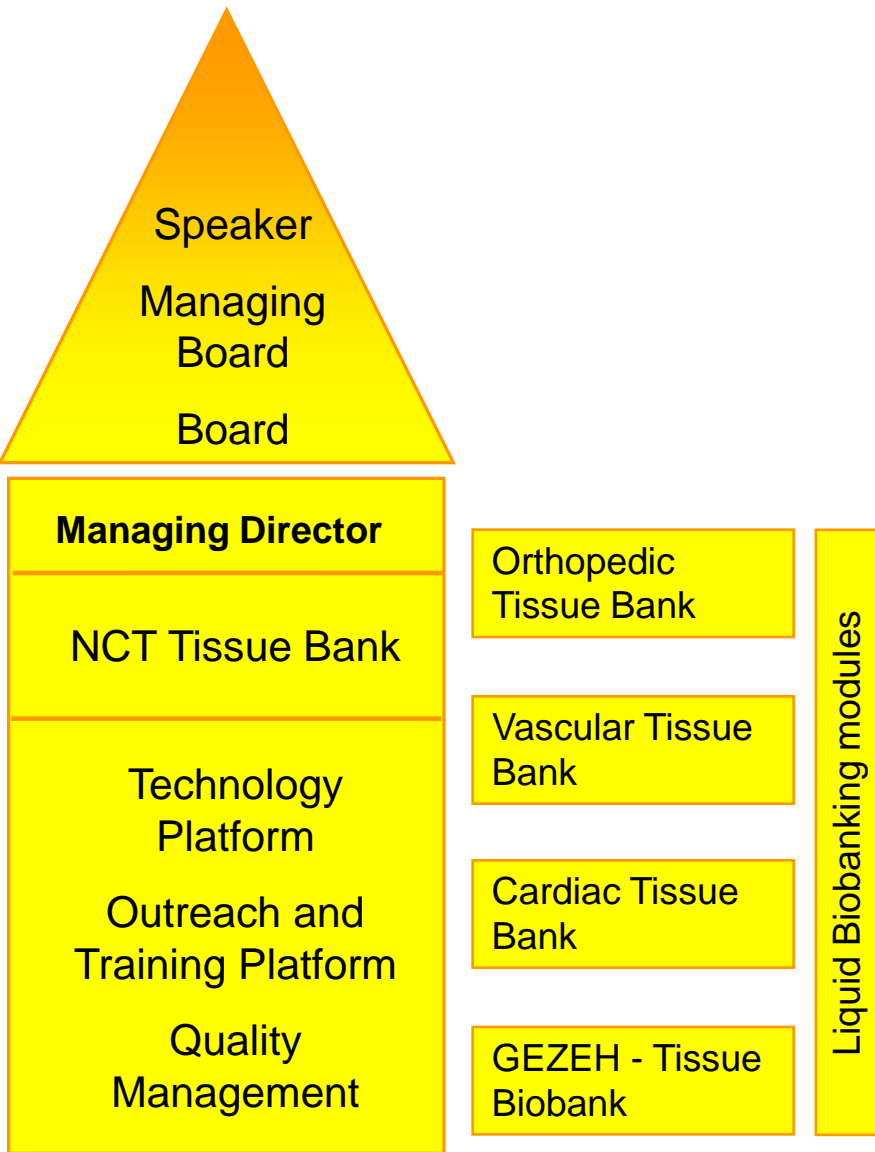
- Internal structure (Board, assembly)
- Embedded in WG CCCs
- Organisational support by Deutsche Krebshilfe
- Cooperation Deutsche Gesellschaft für Pathologie
- Kooperation TMF

# **The BMBH Concept**

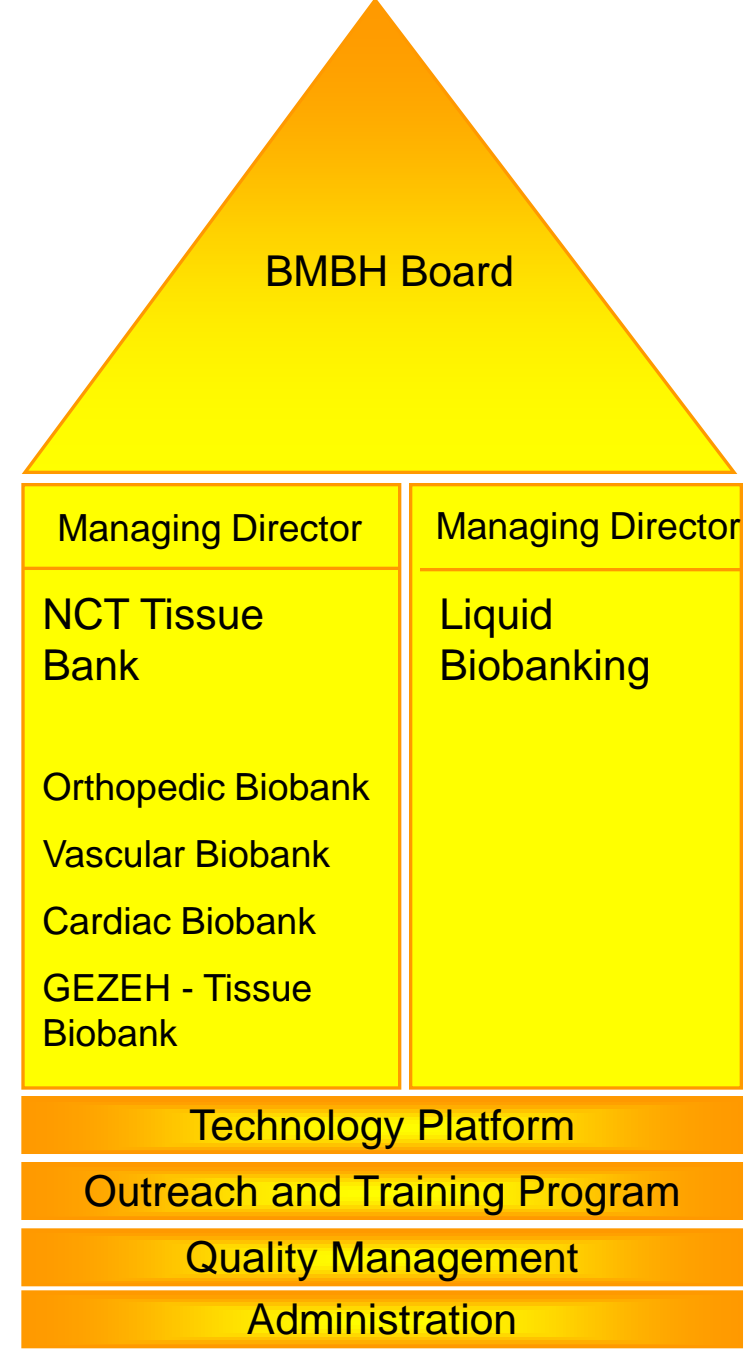
# The BMBH Concept (initiated 2/11)

- Coordinates all tissue banks (incl. Non-neoplastic) and liquid biobanking at Heidelberg site
- Central administration, IT-management, quality management, project management, guidance and coordination
- 3 stage sustainability concept
- Consortional core function

# BMBH-Structure



Current Tissue Bank Structure in Heidelberg



Plannend cBMB-Heidelberg BMBH Structure

# Integration of all Partners

- Access
- Scientific Quality
- Cooperation,  
Publication
- Participation
- Grants, financial  
aspects
- Marketing

- Clinical Units
- NCT
- Pathology
- Research Centers  
(DKFZ)
- Investigators
- Funding  
Organisations

# Milestones

- Year 1
  - Positions
  - Formal implementation
  - IT- und Barcoding-System
  - Hardware
  - Comprehensive Liquid Biobanking concept
- Year 2
  - QM in all tissue banks (SOPs, standing orders, Projektmanagement)
  - Implementation of Clinical Liquid Biobanking Concept
  - Functional IT and Material Administration in all areas
- Year 3
  - Extension of Accreditation to all tissue banks
  - QM Liquid Biobanking
  - Quality Assessment Programm
- Years 4-5
  - Certification Liquid Biobanking
  - Biobanking further education program
  - Sustainability

# Ethical/Legal Issues

- Transfer ethical concept of NCT Tissue Bank
- Adaptation of consent procedures?
- Switch to consent via admission contract?

# Sustainability

## 3-Stage Model

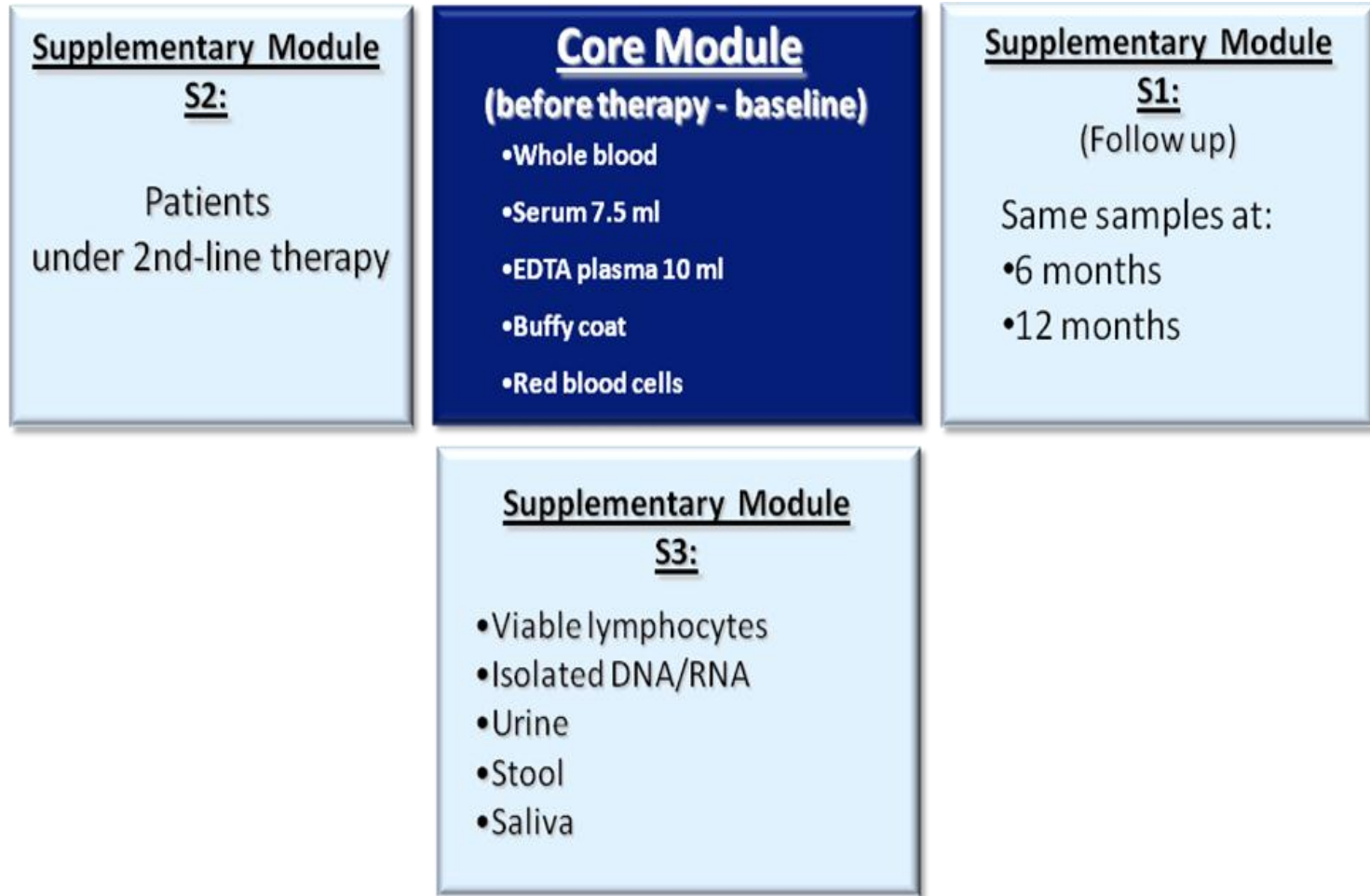
- Basic budget (local, [cBMB])
- Participation in research grants (consortia; german networks (DNTK, *DZL*, *DZI*))
- Fee-for-service (specified technical support)



# Liquid Biobanking

- Existing banking efforts (status, conceptual integration?)
- Comprehensive Concept for Clinical Liquid Biobanking
  - Work flow analysis
  - Need, Modeling and Testing
  - Hardware
  - Financing
- Implementation

# Clinical Liquid Biobanking Concept



# Novel Projects

- Tissue quality assessment programs
- Tissue quality factor research
- Automated derivatives work-flow
- Biobanking further education program

# Thanks to

Members, partners and funding institutions  
of the NCT Tissue Bank Heidelberg and  
BMBH

All participating researchers

Ethics Comitee Heidelberg

Working Group Tissue Banks of the CCCs

Funding institutions