Biobanking for Successful Translational Oncology

National Day – Germany’s Way Towards Excellence in Biobanking

April 5, 2016/Berlin

PD Dr. med. Esther Herpel
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Central role of biomaterial in translational oncology

Journal of the National Cancer Institute Monographs, No. 42, 2011
But....

Research: increasing value, reducing waste 2

Increasing value and reducing waste in research design, conduct, and analysis

John P A Ioannidis, Sander Greenland, Mark A Hlatky, Moin J Khoury, Malcolm R Macleod, David Maher, Kenneth F Schulz, Robert Tibshirani

An open investigation of the reproducibility of cancer biology research

The American Journal of Pathology, Vol. 185, No. 1, January 2015

EDITORIAL

Science Isn’t Science If It Isn’t Reproducible

Kevin A. Roth and Aandra E. Cox

Stakeholder Research on Biospecimen Needs and Reactions to the Development of a National Cancer Human Biobank by the National Cancer Institute

Ravinder Nylam, Holly A. Maukett, Gaurchan Conney, Nancy Adamson, Dea Allsop, Carolyn Grimmison

THE CANCER TEST

A nonprofit’s effort to replicate 50 top cancer papers is shaking up labs

By Jocelyn Kaiser

zined in Richard Ovchinnikov 2014 was to write a part of the paper by ourselves or his team to help with the materials and methods. The group may need help with the figure and materials. His team identified the design, but they also provided a full description of the materials and methods. They also identified other methods that were used in the protocol. After weeks of emails back and forth and sending him the draft, he still wanted to report it. But they needed more information about the protocol. After weeks of emails back and forth and sending him the draft, he still wanted to report it. But they needed more information about the protocol.
Which issues are important?
1. Align your Biobank upon your objectives and local circumstances

Clinical Departments with Oncological Activities of the Heidelberg University Medical School and Medical Faculty

Translational Cancer Research Groups of DKFZ and the Heidelberg University Medical School and Medical Faculty

NCT Departments
- Medical Oncology
- Translational Oncology
- Preventive Oncology
- Radio-oncology
- Neuro-oncology
- Tumor Immunology

NCT Core Services
- NCT Trial Center
- NCT Tissue and BioMaterial Bank
- NCT Cancer Registry
- NCT Information- & Counseling & Social Services
- NCT – Heidelberg School of Oncology
1. Align your Biobank upon your objectives and local circumstances

NCT Tissue Bank
since 2005, Head: E. Herpel
- Focus: cancer
- Cryopreserved Tissue: >25,000 FFPE (archive): >500,000 Proben
- >1900 successfully completed projects
- Established quality and project management, technology platform
- Accreditation since 2009

NCT Liquid Bank
since 2011, Head: R. Kirsten
- Focus: cancer
- Liquid samples: blood and derivatives, urine, stool, sputum, DNA/RNA,..
- >200,000 samples, 35 projects
- SOP guided sample storage and processing
1. Align your Biobank upon your objectives and local circumstances

One comprehensive Biobank.....

Because the benefits are e.g. .....

- Efficient use of valuable biomaterial resources
- Use of synergies (sample preparation, data storage, informed consent, sample storage systems, staff and training)
- Implementation of common quality standards
- Transparency and an interdisciplinary structure (core-function, consistent regulations, access)
- Platform for numerous project designs (epidemiological studies, complex projects, joint research, international co-operations)
- Reduced stress for patients (blood draw, informed consent procedure, data safety)
2. Note the legal requirements and ethical aspects

- Comprehensive ethical vote for tissue acquisition
- Compliance with legal regulations
- Data safety concept
- Standardized informed consent for all biomaterials and respective data
- Hospital admission contract
- Priority of clinical diagnostics and therapy
- Release of retrospective tissue collection
3. Take care for clear data management

- Control completely by QR-codes / Touchscreen
- Automatic label printing with receipt number, time and dignity
- Duplicate- and error checking

Access to sample data

- Informed consent documentation

Sample management, Quality assurance (SOPs)

Rack scanning and analyser compatibility
4a. Build a "living" quality management (QM)

Only high sample quality may ensure successful translational oncology

QM = active and integrated system that ensures the quality of a process/project.

- Written SOPs
- Data management
- Emergency management
- Measurable quality objectives (Feedback of customers, publications…)
- Quality control (Entry-/ Exit control)

NCT Tissue Bank:

Accreditation since 2009/2013 in accordance with DIN EN ISO/IEC 17020
4a. Provide high quality of biomaterial

- >50% of studies using homogenised human tissue derivatives are based on insufficiently characterized/documented starting material (Perren, Nature 2011)
  - Lack of:
    - Expert-evaluation (diagnosis, quality, composition of collective)
    - Trial specific parameters
    - Standardized entry- and exit-controls
    - Standard reporting and documentation

- Good scientific practice in pre-experimental tissue assessment and selection is the decisive basis of work with human tissues
4b. Provide high Quality of biomaterial

- Processing of biomaterial under regard of the respective research projects

- Projects require different quality
  - Type of fixation (FFPE vs. Fresh Frozen)
  - Immunohistochemistry vs. homogenization

- Result report (exit-control) = quality control

- Handover protocol including a MTA (e.g. instructions on how to handle the samples, quoting in publications)

- Tracking
5. Ensure transparency and clear structures

- Resources/Infrastructure
- Interdisciplinary structure
- Advisory Board
- Competent head of biobank
- Rules of procedure/ Organisation chart

- Access rules, project management:
6. Protect your samples and data

*Things always seem to happen when you least expect them...*

*It does not matter to foresee the future but to be prepared for the future*

An emergency management defines preventive and reactive measures

- Which measures in case of emergency?
- Responsibilities, information?
- How will “normal” conditions be recovered?
6. Protect your samples and data

Some Measures of NCT Tissue Bank:

- 24 hours monitoring of freezers + daily visual controls of temperature
- Emergency phone list
- Access restriction
- Labeling of freezers
- Backup-Freezer; alternative storage location
- Regular “emergency training”
- Separate servers for data
- Daily data backups
7. Be open to new scientific developments

Science is constantly changing...
- New issues
- New technologies

Medical Treatment options change...
- Less "aggressive" surgical therapies
- Preoperative (neoadjuvant) treatment forms
- New methods for early detection
8. Be willing to share

Private collection

Institutional collection

Biological ressource center

Single Biobank

Network
9. Provide sustainability

In terms of

- Standardized quality
- Guaranteed data safety
- Provision of resources/biomaterial

Development of a sustainable financing concept

- Acquisition and documentation of single expenses and structures
- Consideration of these expenses in case of biomaterial requests
- Where applicable, fees for services (internal customer vs. external customer)
- Commercial activities (e.g., industrial co-operations)
- Integration at local centers

High efforts – high costs
Insufficient infrastructure and financing options
10. Do good things and talk about it

Talks/Poster with topic Biobanking

Open House Day NCT

http://www.biobank-heidelberg.de
Conclusion

10 biobanking issues for successful translational oncology

1. Align your biobank upon your objectives and local circumstances
2. Note the legal requirements and ethical aspects
3. Take care for clear data management
4. Build a "living" quality management
5. Ensure transparency and clear structures
6. Protect your samples and data
7. Be open to new scientific developments
8. Be willing to share
9. Provide sustainability
10. Do good things and talk about it