The PATH Biobank - procedures and results of a breast cancer biospecimen research resource
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Abstract - Introduction
The purpose of PATH is to provide high quality fresh frozen breast cancer specimen for research, annotated with highly differentiated datasets. To this end, we have developed and established standardized methods for collection, processing, labeling, long-term storage, retrieval and distribution of the specimen. PATH is a non-profit, patient-driven biobank in Germany.

Disclaimers
DISCLOSURES: Foundation PATH has received donations and has sponsoring relations with the following companies: Amgen, AstraZeneca, GlaxoSmithKline, Novartis, Pfizer, Pierre Fabre and Roche.

Results - Biobanking
Since 2004, more than 7,200 breast cancer patients have given informed consent. From 59% of all donors a tumor tissue specimen could be stored. The same applies to 62% of all cases in accordance to adjacent normal tissue specimen and in 92% with blood serum samples.

Results - Follow-up
In a sub-cohort, comprising the years of diagnosis 2006 - 2009, 76% of all individuals could be reached through follow-up inquiries by PATH. Subsequently, a test-collective (108 patients, 4.8 years median follow-up time) only 5% were "lost to follow-up".

Using PATH Biobank
Researchers write a request for samples or data. These requests are reviewed by independent experts. PATH’s managing board decides on sample allocation: a material transfer agreement is signed. A reimbursement for the samples and logistics is requested.

Procedures
1. **Decentralized biorepository**
   - At seven Institutes for Pathology, being part of certified German breast cancer centers
   - **Unique SOPs**
     - For processing, labelling and long-term storage
   - **Fresh frozen conditions**
     - Using vapor phase of liquid nitrogen
   - **Tumor tissue**
     - Edge length at least 3 mm
   - **Normal adjacent tissue**
     - Edge length at least 3 mm
   - **Blood serum aliquots**
     - Minimum volume of 1ml

2. **Centralized database**
   - Data storage using Oracle® software
   - Containing an in-house LIMS solution
   - Standardized broad informed consent
   - Ethical approval (University of Bonn)
   - Collection of follow-up date
   - Directly questioning the breast cancer patient

Results - Follow-up
Follow-up informations contain self reported data and are validated by practitioners, registration offices and cancer registries
- Reported follow-up events: 203
  - distant recurrence: 109
  - death from any cause: 325

References
The following publications demonstrate the quality of PATH Biobank: (1)(2)(3)(4)(5)(6)(7)


Molecular subtypes
- Subtypes according to St. Gallen International Expert Consensus, Tumor Grading as surrogate marker for Ki-67 expression (1)(2)
- The distribution of the molecular subgroups is comparable to published distributions (3)(4)(5)(6)(7)

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Saved by the Bell, Saved by Hope, PATH-kooperative clinics