

## Disclosures

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

## Abstract - Introduction

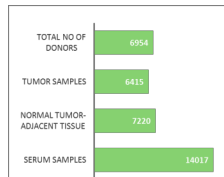
The purpose of PATH is to provide high quality fresh frozen breast cancer specimen for research, annotated with highly differentiated datasets. To this end, we have developed and established standardized methods for collection, processing, labeling, longterm storage, retrieval and distribution of the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

## Procedures

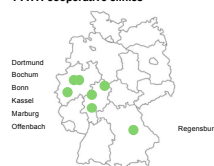
### 1. Decentralized biorepository

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



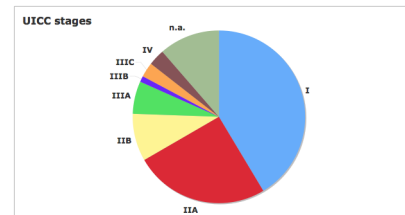
#### PATH cooperative clinics



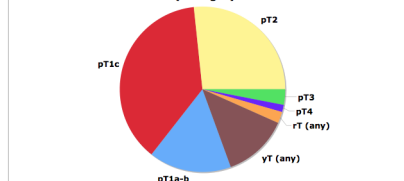
- ### 2. Centralized database
- Data storage using Oracle® software  
Containing an in-house LIMS solution
  - Standardized broad informed consent  
Ethical approval (University of Bonn)
  - Collection of follow-up data  
Directly questioning the breast cancer patient

## Results - Biobanking

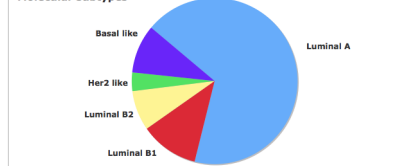
Since 2004, more than 7,200 breast cancer patients have given informed consent. From 59% of all donors a tumor tissue specimen could be stored. The same applies to 62% of all cases in accordance to adjacent normal tissue specimen and in 92% with blood serum samples.



#### Distribution of tumor size (T-stages)



#### Molecular subtypes

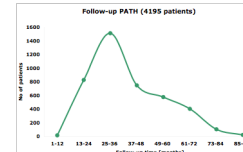


• Subtypes according to St. Gallen International Expert Consensus, Tumor Grading as surrogate marker for Ki-67 expression<sup>(1), (2)</sup>

• The distribution of the molecular subgroups is comparable to published distributions<sup>(3)</sup>

## 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, in a test-collective (108 patients, 4.8 years median follow-up time ) only 5% were "lost to follow-up".



Follow-up informations contain self reported data and are validated by practitioners, registration offices and cancer registries

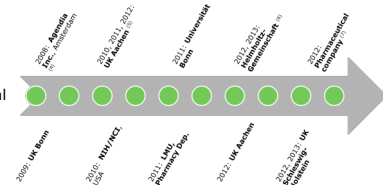
Reported follow-up events:

- distant metastases: 203
- local recurrence: 109
- death from any cause: 325

## 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.

Research groups having used PATH Biobank applied different techniques successfully for their investigations. Several publications and presentations demonstrate the quality of PATH Biobank (4)(5)(6)(7).



## References

- (1) Strategies for subtypes - dealing with the diversity of breast cancer: Highlights of the St. Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2011. Ann Oncol. 2011 Aug;22(8):1736-47.
- (2) Applying the 2011 St Gallen expert of prognostic markers on a large single hospital cohort of consecutively treated primary operative breast cancers. Ann Oncol. 2012 Oct;23(10):2578-84.
- (3) Defining breast cancer prognosis based on molecular phenotypes: results from a large cohort study. Breast Cancer Res Treat. 2011 Feb; 126(1): 185-192.
- (4) Comparison of MammaPrint and TargetPrint results with clinical parameters in German patients with early stage breast cancer. Int J Mol Med. 2010 Dec;26(6):837-43.
- (5) Promoter hypermethylation of the tumor-suppressor genes E7H5, DNK3, and RASSF1A as novel biomarkers for blood-based breast cancer screening. Breast Cancer Res. 2013 Jan 15;15(1):P4.
- (6) Tamoxifen Resistance in Breast Cancer: Reprogramming of the ERα and ERα Target Gene Landscape. Under Review.
- (7) AKT1 (E17K) mutation: coexistence with oncogenic alterations, prevalence, and correlation to clinical parameter in a large series of breast cancer patients. Proceedings AACR 2014, Abstract 569.