

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

## Abstract

**Purpose:** Breast Cancer Patients established PATH in 2002 to collect tumor samples, blood samples and data at high ethical standards and under uniform SOPs. Since 2004 more than 4500 women and men in Germany gave their informed consent for the collection. In addition, PATH has successfully started to collect follow-up data from all patients, covering both disease and therapy process.

**Design:** Specimen are stored in liquid nitrogen tanks (fresh frozen quality) operated by pathologists at seven certified breast cancer centers in Germany. To provide a benefit for the donors, the first aliquot is stored exclusively for the patient. The rest of the material is donated to research purposes. Processing, handling and labelling of the samples is defined in rigid SOPs, accompanied by monitoring. Data regarding clinical findings, tumor biology and sample processing are collected and centrally managed. In order to annotate the samples follow up started in early 2009. As a patient driven, non-profit organization PATH has a special reliability. Thus, the Foundation is given the right to establish direct contact with any patient that has given informed consent. This approach was confirmed by ethics committee, the Bavarian Commission of Data Protection and a university professor of medical law. In order to get the follow-up data, PATH contacts the patient by letter. A structured phone call follows, carried out by female medical students, who are specially trained. The patient is asked to provide details on their individual course of disease. Additionally they are asked about their compliance with therapy. Procedure, data volume and data quality are specified and standardized. If patients could not be reached by call they are asked to complete an additionally mailed questionnaire. As the last source for data PATH will try to get data from tumor registers. In case of recurrence the data obtained from the patients is validated by check-ups with medical reports from the practitioners.

## Objectives and Methods

Main objectives:

- tissue and serum storage for patients at no cost
- support of clinical and genetic research

PATH tissue bank contains fresh frozen:

- tumor specimen (at least 3mm edge length)
- normal tissue samples
- blood serum aliquots (1 ml)

Quality monitoring:

- compliance and implementation of SOPs is monitored by biannual visits and meetings with each cooperation partner

Data collection:

- all data are collected in PATH's centrally managed database
- patient related data
- sample processing data (e.g. time of ischemia)
- clinical and tumor associated data
- follow up data (disease and treatment history)

## Follow up - methods and results

1. Initial contact by letter
2. Structured phone call (carried out by specially trained female medical students)
3. Patient could not be reached by call --> additionally mailed questionnaire
4. Patient's report not clear --> Validation by check-ups with medical reports from practitioners
5. "last source of data": local tumor registries registration offices

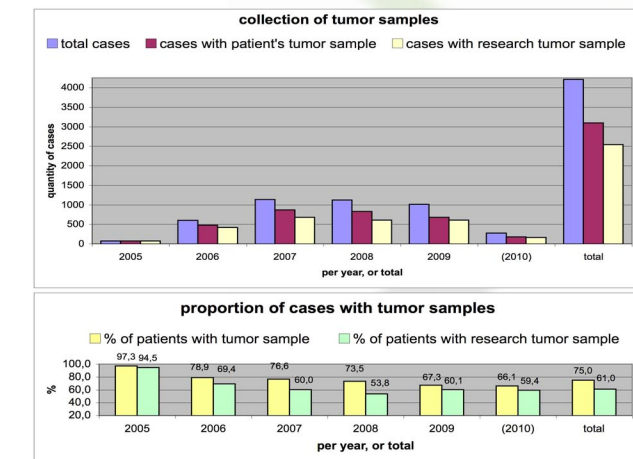


### Individuals contacted and events reported in follow up

		%
contacted overall:	2436	100,0
data obtained by phone call:	1617	66,4
contacted by questionnaire:	515	21,1
data obtained by questionnaire:	226	9,3
<b>total cases with follow up data</b>	<b>1843</b>	<b>75,7</b>
events of death:	64	3,5
events of progression:	134	7,3
cases with metastases:	96	5,2
cases with recurrence:	38	2,1
mean follow up time:	approx. 3,1 years	
% of cases with informed consent*:		42,3

\* date of evaluation 31.08.2010, total cases with informed consent 4358

## Results - collecting tumor samples



### Number of cases and samples

subgroups	cases total	cases with samples	samples	% of total population
<b>ER +</b>	3152	1941	4100	78,9
<b>Her-2/neu +</b>	488	305	689	12,2
<b>triple negative</b>	455	297	676	11,4

## Giving away of samples

Research groups (academic and industry) submit a request according to PATH's terms & conditions for giving away of samples (ask the poster-presenters for this document). The project is evaluated and reviewed by PATH's advisory boards (scientific board, board of trustees). Final decision making is business of the board (patient majority)

## Conclusion

Within 16 months PATH contacted more than 40% of all patients included in the bio bank for at least one time and gained follow up data. Thus PATH will provide a great variety and quantity of fresh frozen tissue and blood samples with excellent quality and a mean follow up of 5 years in less than 12 months.