

For proteomics analysis, high quality of biomaterials is mandatory. The PATH foundation runs a biobank that can offer best quality of tissue and blood specimen and annotating data sets in the field of breast cancer. PATH Biobank is a non-profit organization and coordinates a network of five certified breast cancer centers in Germany. There, breast cancer samples are collected according to standardized protocols and stored in the vapor phase of liquid nitrogen. Scientists from academic institutions and industry can receive samples and annotating data sets after application with a scientific rationale and a positive vote on ethics.

PATH Biobank stores high-quality tissue and serum specimen



Figure 1: Samples are processed and stored decentralized at the five participating certified breast care centers.

- **Rigorous SOPs for processing, labelling and long-term storage**
- **Cold ischemia time < 45 min**
- **Snap-frozen in liquid nitrogen**
- **Storage at -160 °C in the vapor phase of liquid nitrogen**
- **Tumor tissue**
 - Edge length ≥ 3 mm
- **Adjacent (benign) tissue**
 - Edge length ≥ 3 mm
- **Blood serum**
 - ≥ 1 ml
- **FFPE breast cancer tissue available**

Biomaterial from more than 12,800 breast cancer patients has been collected since 2004

Sample	Number
Tumor	10.000
Adjacent (benign) tissue	11.268
Serum	13.672

Table 1: Current number of biospecimen in -160 °C storage at PATH biobank.

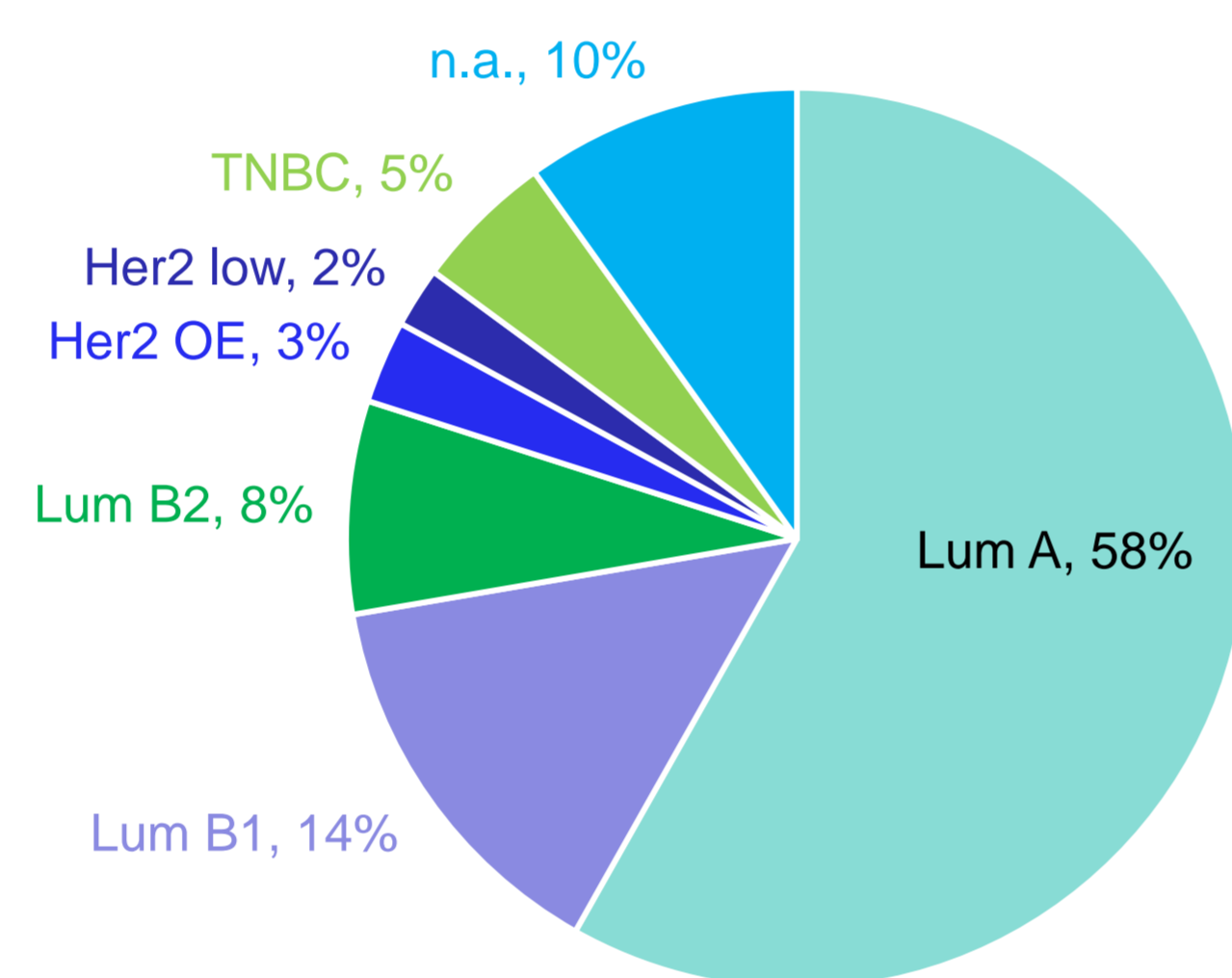


Figure 2: All molecular breast cancer subtypes (according to St. Gallen criteria) are available.

PATH offers rich annotated clinical data sets stored in a central database

Central database

- Oracle® software and LIMS developed in-house
- Standardized and GDPR compliant forms of patients' broad informed consent
- Approval by ethical review commission

Clinical data

- Age, menopause state
- Expression of the oestrogen receptor (ER), progesterone receptor (PR) and the epidermal growth factor receptor *ErbB2/Her2* (Her2 positive)
- Proliferation marker (Ki-67)
- Tumor biology / histopathology
- Grading, staging
- Tumor infiltrating lymphocytes (TILs)
- Therapy

Extensive long-term follow-up program

- Response rate: 66 %
- Up to 15 years follow-up time
- Overall survival
- Progression free survival
- Breast cancer therapy

Storage of isolated breast cancer samples in the vapor phase of liquid nitrogen compared to storage at -80 °C RNA revealed significantly higher RIN values¹

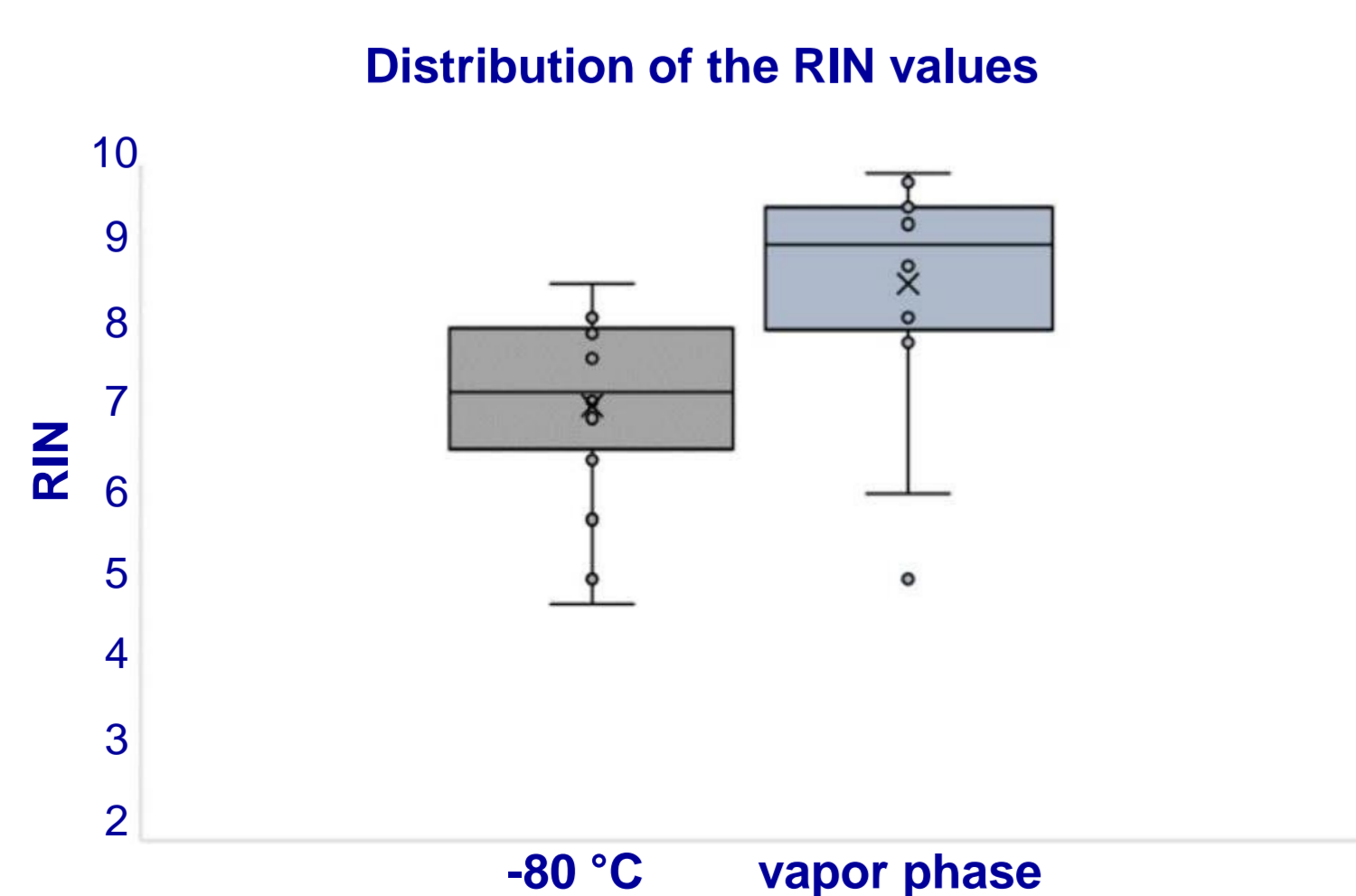
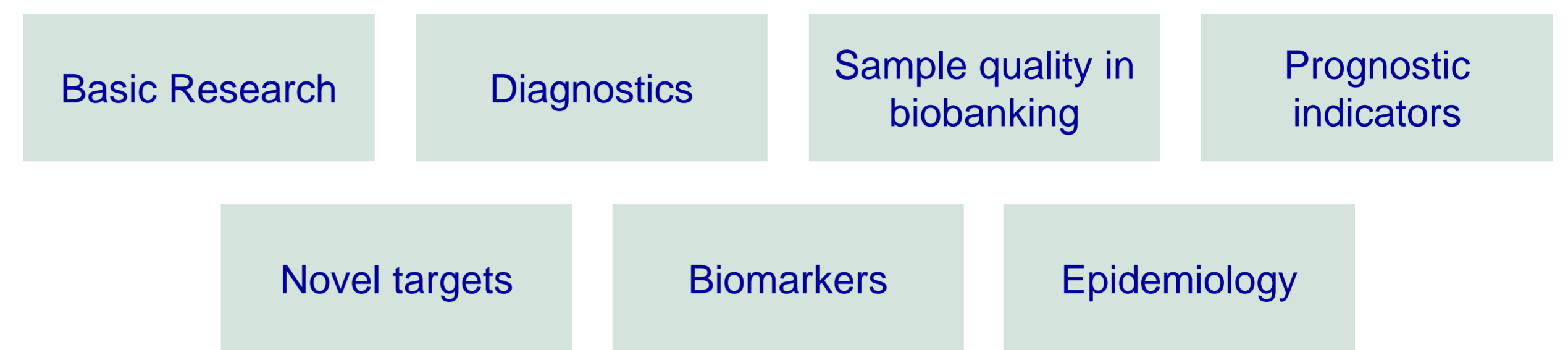


Figure 3: Of all samples stored at -80 °C, 81.5% reached RINe-values of ≥ 6.0 but only 31.3% of the samples were found correlating to the highest fit for purpose group with RINe-values ≥ 8.0. The mean RINe-value from samples stored at -80 °C was 7.1. In contrast, 93.8% of samples that were stored in the VPLN reached RINe-values of ≥ 6.0. Also, 81.3% of all samples were found in the highest fit for purpose group with RINe-values of ≥ 8.0. The mean RINe-value of samples stored in the VPLN was 8.6. Statistical analysis of the means of the RINe-values revealed significantly lower RINe-values in samples stored at -80 °C compared to samples stored in the VPLN ($p = 0.0024$, student's t-test).

PATH supported 45 research projects from different research areas



20 peer-reviewed manuscripts were published with PATH biospecimen and data

- ETH Zurich, Switzerland^{2,3}
- DKFZ Heidelberg, Germany⁴
- University of Regensburg, Germany¹
- RWTH Aachen, Germany⁵
- LMU Munich, Germany⁶
- BioNTech Diagnostics GmbH, Mainz, Germany⁷
- Bayer Pharma AG, Berlin, Germany⁸

How to access samples and data from PATH Biobank

Researchers of academic or corporate institutions contact PATH biobank and request samples or data by submitting a research proposal.

PATH checks availability of requested samples

Proposals are reviewed by independent specialists

Researcher provides positive ethics vote for research project

A bilateral signed Material Transfer Agreement (MTA) is part of every cooperation

PATH requests a cost recovery fee for samples, data and logistics

PATH organizes the handling and transport of the samples, and provides the biomaterial with pseudonymized data

Summary

PATH Biobank offers

- More than **34.000** high-quality biospecimen in storage at -160 °C
- High tumor content samples
- Rigorous standardized operating procedures for samples preparation
- Extensive annotated clinical data sets

Disclosures

PATH Foundation has sponsoring relations with Novartis Pharma GmbH.

References

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