PATH Biobank: German breast cancer patients approve of genome wide association studies.

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Disclosures

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Introduction

PATH is a biobank providing high-quality fresh-frozen breast cancer specimen to research groups. Being a patient-driven foundation, PATH operates according to high ethical standards.

The need for a re-consent for genome wide association studies (GWAS) on biobank material is a subject of controversial discussion. The recent consent form template, provided by the German Group of Medical Ethical Committees, includes genomic research [1]. Yet, only 12/30 German biobanks mention genomic information in their consent forms [2].

Here, we present an overview over our biobank and our approach for obtaining consent to GWAS.

Procedures

Decentralized biorepository

- PATH biomaterial is stored at 7 certified German breast cancer centers (figure 1)
- Tumor tissue, *≥3 mm edge length*
- Normal tumor adjacent tissue *corresponding to the tumor, ≥3 mm edge length*
- Blood serum, *≥ 1mL volume*
- All samples in fresh frozen-quality at *minus 152° C or in the gas phase of LN2*

Figure 1: PATH cooperative clinics

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

Re-contacting patients for GWAS-consent

Informed consent for the storage of their specimens and its use for research is obtained from patients before storage in the PATH biobank. However, GWAS have not been explicitly mentioned in these consent forms. A letter explaining GWAS was sent out to 31 PATH patients. The letter explained both the benefits and risks associated with GWAS and the patients were informed that their consent is optional. The patients were also encouraged to contact our project leader and physician about questions and concerns.

Results I: The PATH collective

The molecular subtypes were determined according to St. Gallen International Expert Consensus, using tumor grading as surrogate marker for Ki-67 expression [3,4]. Only primary breast cancer cases without neoadjuvant therapy were included in the analysis. The molecular subtype was assignable for 96% of all tumor samples. The distribution of the molecular subtypes (figure 2) is comparable to published distributions [5]. Tumor stages T1 or T2 were present in 93% of donors.

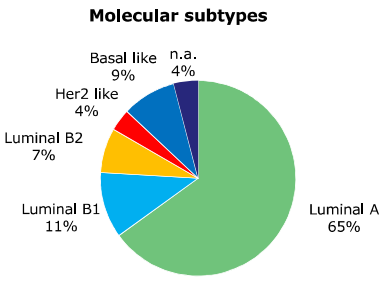

Figure 2: PATH samples

Results II: Biobanking

Since 2004, 7403 breast cancer patients have given informed consent. A total of 6655 tumor samples are stored in the PATH biobank (figure 3).

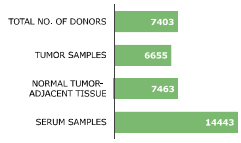

Figure 3: Stored samples

Follow-up information is available for 4195 PATH patients, with a follow-up time of up to 96 months (figure 4).

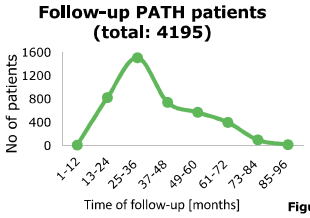

Figure 4: Follow-up

Results III: Re-consent to GWAS

In a pilot study, we have re-contacted 31 PATH patients with a letter explaining genome-wide association studies. The results are summarized in figure 4. PATH will set out to ask all PATH specimen donors for their consent to GWAS.

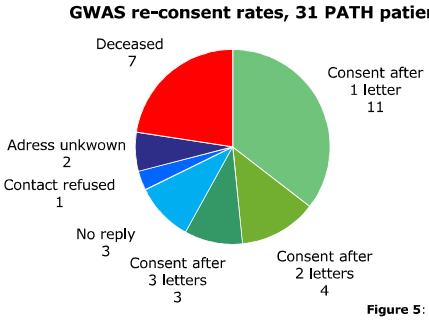

Figure 5: Re-consent rates

Conclusions

The PATH biobank, along with its detailed clinical and follow up information, is a valuable resource for breast cancer research. PATH will set out to ask all tissue donors for their consent to GWAS. We will also try to increase the response rate by enclosing a newsletter along with the consent request. A subset of PATH material will be available for GWAS after re-consent of the respective donors.

Using PATH Biobank as a resource

Researchers from academic or industrial groups may apply for sample allocation. A sample request is reviewed by independent experts. PATH's managing board decides on sample allocation. A material transfer agreement is signed, which also includes reimbursement for the samples and logistics. For more information visit:
www.path-biobank.org
info@stiftungpath.org

References

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