standards in the management of tumour banks (and most generally biobanks), in order to guarantee some degree of homogeneity in biological materials obtained from different hospitals and institutions, (ii) to establish and make publicly available catalogues of "validated" collections of biological materials obtained from patients with cancers, usually treated at several or numerous institutions, (iii) to promote the prospective constitution of new collections, based on a minimal definition of a scientific project that justifies this effort, as an alternative to the retrospective re-qualification of already existing collections.

S5

The "Blood Donor Biobank" – A new approach for identifying and validating biomarkers

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Introduction: The recently established "Blood Donor Biobank" at the blood transfusion service of the Bavarian Red Cross (BSD) offers a unique resource for biomarker researchers. By using blood samples from patients collected and cold stored under standardized procedures before the onset of a certain disease the prognostic value of known biomarkers could be investigated or new biomarkers identified.
Main Message: 400,000 registered blood donors at the BSD are the basis for this innovative project. 250,000 donors donate approximately 500,000 whole blood units each year. A small amount from every blood donation is stored for a possible follow up test at a later date. Today there are already over 3.5 million plasma samples stored in a fully automated cold room at −42ºC.
The "Blood Donor Biobank" which was officially announced in 2006 provides access to some of the samples for diagnostic research and development projects. The responsible ethics committee and data protection board have agreed on the project and the participating blood donors have given their written informed consent that their blood samples and data can be used for medical research. The fact that there are so many blood donors at the BSD is key to having a sufficient number of potential biobank participants. Each year approx. 1200 donors develop a disease that is of interest for the "Blood Donor Biobank" such as cancer, diabetes, CNS or heart disease. On average these blood donors donated blood at least twice a year for several years before the diagnosis. These samples taken from one person over a period of several months or years before the onset of a disease could be used for biomarker research and give new insights in the development of a disease.
Plasma samples from the "Blood Donor Biobank" are currently being used in several collaborations with both academic and industrial research institutes. Various diagnostic techniques are applied to screen for potential biomarkers in particular in the field of cancer research.
Conclusions: The "Blood Donor Biobank" maintains a continuous collection of samples and related data before the diagnosis of a disease. Whereas worldwide similar biobank projects are currently being set up, this biobank is already in existence and contains a sample and data collection that has been continuously build up under standardized procedures during the past seven years and comprises data from approximately 10,000 participants and in excess of 100,000 plasma samples.

S6

Development of clinical biomarkers – the importance of SOPs and quality assurance

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Introduction: Timely development of novel biomarkers for clinical use depends on access to high quality material collected in a uniform manner, with proper regard for ethics relating to the use of human material in research. Quality assurance (QA) is an essential component of research tissue banking. Biological material should be subject to pathological and molecular biological QA prior to release which validates the SOPs used for collection and storage. The Wales Cancer Bank (WCB) has been collecting different types of biosamples (blood, frozen and paraffin embedded tissue) from patients in NHS hospitals in Wales since 2005, and has developed a series of QA procedures for use in the diagnostic setting.
Main Message: Researchers should be aware that priority must always be given to patient diagnosis. In the UK, all human tissue from operative specimens may only be released with agreement of the pathologist, so as not to prejudice its use for diagnosis. Tissue banks that collect material in the routine clinical setting therefore do not have control over all aspects of tissue management. Ethically, the patient's operation must be the same whether he/she has agreed to donate material excess to that used for diagnosis to a tissue bank or not. It is therefore important to put in place measures for QA post collection. H&E sections should be taken from each frozen block and paraffin embedded and stored digitally. A pathology audit revealed that frozen blocks taken from 80% of samples breast and head and neck cases contained more than 80% tumour epithelium. This figure rose to 90% in colon and renal cancer cases. In prostate, 60% of blocks contained less than 20% tumour epithelium. The percentage of tumour epithelium present may affect the sensitivity of some molecular biological tests (e.g. mutation analysis). Molecular biology QA was carried out in a total of 266 frozen tumour blocks from breast, head and neck, renal and colon cancer. In 86% of cases, RNA with an Agilent RNA Integrity Number (RIN) of >7 was extracted. This percentage varied among individual tumour types – head and neck and prostate most reliably producing high quality RNA. High quality (>10 kb) DNA was obtained in all cases using the WCB SOPs. Although extracted RNA may not always reach the QA required for Affymetrix arrays, it may still be useful for studies using RT-PCR. In a recent study conducted for the Chernobyl Tissue Bank, which compared RT-PCR for different sized amplimers of the housekeeping gene PBGD, amplimers of 942 kb were still present 74% of samples with a RIN of less than 5.5.