The US Food and Drug Administration (FDA)'s Center for Drug Evaluation and Research (CDER) has provided a guidance document on the qualification process for biomarker (titled "Draft Guidance for Industry: Qualification Process for Drug Development Tools"). Requirements set in this document make clear that the qualification process for a biomarker has many parallels to drug discovery and development, starting with biomarker identification and validation, followed by assay development and optimization, and finally followed by validation in clinical trials. In the preclinical oncology research departments from most pharmaceutical and biotech companies, the translational research has now become an integrative part of the development.

TR needs:

- Large panels of patient-derived tumor models (in vitro and in vivo) representing the heterogeneity of the disease
- Extensive data on the characteristics of these tumor models (gene and protein expression, gene amplifications, mutations, epigenetics, miRNA expression, histology, reference drug sensitivity, and corresponding databases containing all this information and tools allowing bioinformatic analyses)
- Orthotopic models, metastasizing models, and imaging models

This type of research is now frequently performed in academia-industry partnership.

5 Mouse and Rat Strains for Preclinical Oncology Research

Cancer research at bench side has been conducted by the use of animal models for decades. The transplantation of rodent tumor cells into laboratory mice or rats (syngeneic models) has been a widely spread approach for sensitivity testing, biomarker identification, and pharmacokinetic or metastasis studies from the early twentieth century till now. Some of the rodent tumors have been induced by exposure to carcinogens, which led to the development of several specific carcinogen-induced tumor models, i.e., the nitroso-methyl urea (NMU) rat breast cancer model (Shull 2007). For these models, a panel of mice or rat inbred strains have been developed (Table 1).

The observation that athymic nude mice have an impaired immune system, lacking functional T-cells, led to the development of xenotransplantation models. These models allowed for the first time the in vivo growth and passage of human tumors in a laboratory animal (Morton and Houghton 2007). The success of the nude mouse models has intensified the search for further immunodeficient mutations. The discovery of the SCID mutation in mice and crossbreeding with mice bearing the NOD or BEIGE mutation led to the development of further immunodeficient mice with T- and B-cell defects. These mice develop a severe immune deficiency and improved the xenotransplantations. These mice require