Paul Ehrlich Institut's scientific advice on oncology products provided to the German Cancer Consortium

Important progress has been made in cancer research over the past two decades. Cancer research has improved the understanding of the mechanisms and physiological pathways underlying cancer development. However, the translation of research results relevant for therapy into the clinical setting requires close collaboration between cancer researchers and clinicians as well as special regulatory and scientific expertise. The German Cancer Consortium - Deutsches Konsortium für Translationale Krebsforschung (DKTK) is a national network involving the German Cancer Research Center (DKFZ) and seven university sites with the main goal to achieve substantial improvements for cancer patients in various areas of cancer diagnosis and therapy

Advancing new research developments into a first clinical trial is a critical step towards improving cancer treatment of patients. Before initiating a clinical trial in Germany, a clinical trial authorization by one of the two federal medicines institutes, either the Federal Institute for Drugs and Medical Devices (BfArM) or the Paul-Ehrlich-Institut (PEI), and a positive appraisal of the relevant ethics committee are required. As part of the DKTK the Paul-Ehrlich-Institut supports the DKTK by expert regulatory guidance to promote efficient translation of basic research findings into new treatment approaches and applications for the diagnosis, prevention and treatment of oncological and hematological malignancies.

The Paul-Ehrlich-Institut supports DKTK in the following areas:

- Classification of development candidate products: medicinal products and in vitro diagnostic medical devices (IVD)
- Advice on regulatory aspects
- Screening information for potential gaps in product development
- Defining critical translational paths via regulatory research
- Identifying regulatory challenges associated with personalized therapies
- Providing support for distinct regulatory issues related to biologicals including cell and gene therapies
- Providing a link to BfArM, EMA and other regulatory bodies
- Educating on regulatory topics

Contact

Dr. Martina Schüßler-Lenz, Priv.-Doz. Dr. Matthias Renner
Telefon / Phone +49 (0) 6103 77 6162
E-Mail dktk@pei.de