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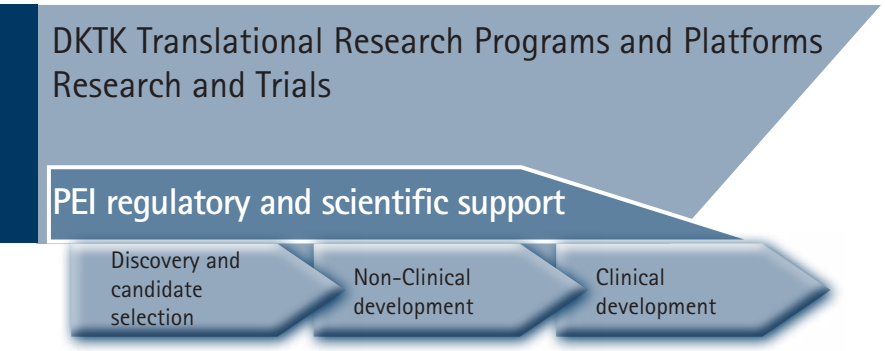
German Cancer Consortium
Core center Heidelberg

Paul-Ehrlich-Institut

SUPPORT OF DKTK WITH REGULATORY EXPERTISE

// SUPPORT FROM THE PAUL-EHRLICH-INSTITUT (PEI) TO FACILITATE TRANSLATION //



The Paul-Ehrlich-Institut (PEI) is the German Federal Institute for Vaccines and Biomedicines. As member of the DKTK Clinical Communication Platform, the PEI supports you as scientist and clinician associated / affiliated with the DKTK with expert regulatory guidance. With this flyer, we intend to inform you on the support that the PEI can provide with its Regulatory Service embedded in the DKTK.

// OFFICIAL DUTIES OF THE PEI - MEDICINAL PRODUCTS AND IVDs //

Products:

- Advanced therapies (cell therapies and gene therapies)
- Tissue preparations
- Sera and monoclonal antibodies
- Vaccines
- Blood preparations
- Bone marrow preparations
- Allergens

Authorisations:

- Clinical trials
- Tissue preparations
- Advanced therapies in hospital exemption
- Processing of applications for marketing authorisations

IVD:

- PEI-IVD: testing laboratory for in vitro diagnostic medical devices (IVDs)
- Verification of manufactured products (batch testing)
- Assessment and laboratory evaluation of „high risk" IVDs, e.g. blood screening IVDs
- Cooperation with notified bodies in the CE-marking process of IVDs

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// HOW THE PEI CAN SUPPORT DKTK //

- Classify development candidates: medicinal products and in vitro diagnostic medical devices (IVD)
- Advise on regulatory aspects
- Screen information for potential gaps
- Define critical translational paths via regulatory research
- Identify regulatory challenges associated with highly personalized therapies
- Provide support for distinct regulatory issues related to biological and cell therapies
- Provide link to BfArM, EMA
- Educate on regulatory topics

// WHAT THE PEI CANNOT DO //

- Define product specifications and release criteria
- Compile dossiers for Clinical Trial Authorisations (CTA)
- Engage in collaboration with pharmaceutical industry

// KEY ELEMENTS TO SUPPORT PRODUCT DEVELOPMENT //

Informal meeting (kick-off meeting) between PEI and DKTK / research team*°

- Informal introduction of a DKTK-topic to the PEI
- Ideally at an early stage, e.g. after identification of a development candidate
- Discussion of next steps and milestones

Scientific and regulatory advice by PEI°

- Meeting at the PEI for scientific and regulatory national advice

Regulatory workshops depending on DKTK needs*

Training workshops at the PEI on

- general regulatory issues
- specific product-related regulatory issues

Comment: In a first step we focus on development candidates within PEI responsibility

// YOUR CONTACT TO PEI //

- Phone: 06103-77 6162
- E-mail: dktk@pei.de

*provided free of charge

°for further information please see Flyer II (in German only)