

Module: Translational Medicine

Module coordinator: Ulrich Kalinke

Module outline:

The focus of this module is the transfer of knowledge in translational medicine in infectious disease and early phase clinical research with specific focus on vaccine development. This module will address the classification of the three major classes of medicines, small molecules, biologicals, and medicinal devices. State of the art preclinical test systems will be introduced, including animal experimentation, with a focus on systems that are particularly suited to predict effects in humans. Key principles to be considered to prepare for application of clinical trial authorization at the competent authorities will be discussed. Finally, relevant infrastructure and measures necessary in order to carry out first-in-human clinical trials will be addressed.

Topics:

- The three major classes of therapeutics: natural compounds, biologicals, devices
- Coding and noncoding RNA
- Monoclonal antibodies and innovative antibody formats
- Vaccines
- Combination therapies
- Preclinical testing: Animal experiments vs. assays based on primary human cells
- Regulatory framework for clinical trial application in the EU
- Phase I clinical trials and translational medicine

Students will gain knowledge about all relevant steps towards clinical development of innovative therapies after a new therapeutic strategy has been envisioned.

After successfully completing the module the students are able

- to understand how a new medicine is clinically developed in a phase I trial,
 - to discuss the specific characteristics of vaccine development,
 - to understand novel approaches in drug development (e.g. telomerase modulation)
 - understand the importance of animal phenotyping during drug development,
 - get an overview about bioinformatics tools in drug development,
- perform key experiments in RNA biology (detection, quantification of RNA molecules).

Learning: 5 ECTS

Lectures: 28h

Seminars: 28h

Practical work: 14h

Independent work: 80h

Assessment:

100% Written exam

Ungraded course work: Oral presentation (scientific paper)

Practical work (including written report)

Short lab project (including oral presentation)