



1 A Value chain for drug development; from left to right © Fraunhofer IME | Andreas Ernst, Daniel Merck, Susanne Schiffmann, Natasja de Bruin.

WORKSHOP TRANSLATIONAL MEDICINE

Workshop Topics

You want to know how new drugs are developed?

You are interested in practical advice on the phases through which drug candidates have to pass before they are approved by the regulatory authorities like the Food and Drug Administration (FDA) or European Medicine Agency (EMA)?

Perhaps you would like to gain insight into specific aspects of compound testing, preclinical validation or pharmaceutical formulation?

Then you should apply for this Fraunhofer IME Master Class Workshop.

In the workshop „Translational Medicine“ we shall provide an overview of most of the main areas of preclinical research and clinical trials.

We shall focus on the following topics:

- From target to clinic: a brief overview
- Identification of a target enzyme
- Validation of hit compounds
- Detection of drugs and biomarkers using LC-MS/MS
- Generation of biologicals
- Pharmaceutical drug formulations
- Proof-of-concept studies in animal models and in humans
- Epigenetic modifications as new biomarkers
- Planning of clinical studies
- Immunogenicity

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A brief overview of the process from target to clinic will summarize the necessary steps to identify new targets, generate compounds (small molecules, biologicals) acting on the target and to perform preclinical studies as a prerequisite for translation of new drug candidates to clinical trials.

The initial challenge at the start of most new drug development projects is the identification of a target molecule, such as an enzyme.

This molecule should undergo a specific change during the course of the investigated disease and its modulation should lead to amelioration of symptoms in an animal model of the disease.

Subsequently, modulators of the target molecule are identified, usually by using medium and high throughput assays or protein engineering.

The identified hit compounds are validated by testing in further confirmatory assays.

Hit compounds are not necessarily small molecules, but can also be proteins, antibodies or peptides that are suitably active on the target molecule.

Generation of biologicals often involves extensive genetic modification to optimise the product and to create suitably stable conditions for its subsequent production.

Pharmaceutical drug formulations are utilised to improve the bioavailability and prolong the half-life of the lead compound.

A prerequisite for preclinical development (safety testing and upscaling) is that the drug, in a relevant formulation, is first tested for therapeutic activity in animal models.

Following successful preclinical development, the candidate compound can enter clinical trials, during which biomarkers of activity and additional safety tests (e.g. immunogenicity) that have been validated during preclinical studies are introduced.

Facts and Figures

Date: 16.10.2019

Time: 09:00 to 16:00 (CET)

Location:

Branch for Translational Medicine and Pharmacology of the Fraunhofer IME, Carl-von-Noorden Platz 9, 60596 Frankfurt am Main, Germany
Room: Conference Room

Structure: 10 talks with the above mentioned topics

Language: text on the slides is in English, the presentation language will be English or German depending on the preferences of the participants

Application: via email to Susanne Schiffmann including the following information: full name / university / study program / name of Master thesis supervisor