



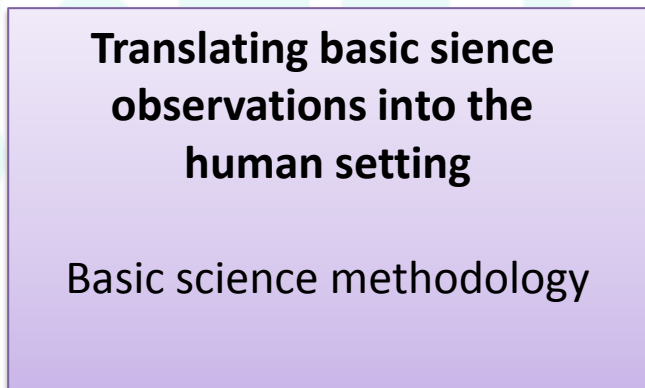
**The ESSO Clinical Research Committee:
Basic guidelines on Implementing
Translational Research in Clinical Trials**

**Presented by Patrick Starlinger MD, PhD
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Center of Translational Research**

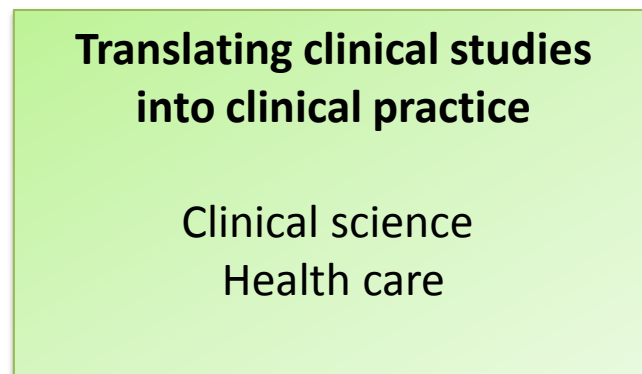
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Basic concept of Translational Research

T1 “Bench to Bedside”



T2- Practice change



Role of Surgeons

Choosing your endpoints

- The incidence of your outcome variable will substantially affect the power of your analysis. Consider a more frequent or a more clinically relevant endpoint to assure sufficient statistical power.
- Focus on methods to reduce variability.
- In an exploratory study with multiple molecules to be evaluated, be sure to include a statistical correction for multiple testing. Consult a statistician early during protocol preparation.

Methodology

- Identify long term storage requirements for your samples.
- Identify processing requirements relevant for your sample and molecules of interest.
- Team up with a basic science laboratory.
- Seek advise from TR experts.
- Pay attention to quality assurance every step of the way.

Validation

- Look out for opportunities to be involved in multicenter prospective trials to validate your research.
- TR projects this setting must be discussed early in protocol development to determine:
 - Endpoints
 - Timing of sample collection
 - Need for local or central biobanking
 - Shipping of samples
 - Tracking of samples
 - Quality assurance requirements
 - Funding required
 - Consent needed from patients

Funding

- Look out for multiple sources of funding.
- Sample collection/biobanking is usually inexpensive.
- Sample processing and analysis can be expensive.
- Apply for grants early in the project development.
- Collaboration with experienced teams can help in securing grants.

Resources needed for a TR project

Define area of interest, define your team
(mentor, research associates, basic science team)

Literature search, precise definition of research questions
(including statistics) and methodology (biobanking)

Writing proposal (including submission to grants and ethics)

Start sample recruitment

Data analysis and
manuscript preparation

1
year

1-2
years

6
months

To discuss your ideas, please contact:

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