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

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Basic concept of Translational Research

T1 “Bench to Bedside”
- Translating basic science observations into the human setting
  - Basic science methodology

T2 - Practice change
- Translating clinical studies into clinical practice
  - Clinical science
  - Health care

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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