

Practical aspects of implementation of translational research studies in an OTP

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Translational Research within OTP

- ▶ Translational research studies usually have multiple components
 - ▶ Questionnaires
 - ▶ Blood drawing
 - ▶ Invasive or noninvasive procedures
- ▶ Pharmacokinetic studies require blood drawing at specific times.
- ▶ Requirements for sample processing
 - ▶ Centrifugation
 - ▶ Rapid freezing at -80°C
- ▶ Invasive procedures can be difficult

Patient perspective on translational studies

- ▶ Translational research studies may not have easily identified benefit as clinical studies.
 - ▶ MeDiCALF vs PCORI
- ▶ Multiple components that may be time consuming
- ▶ Potentially more risk than clinical studies.
- ▶ Issue of overcoming stigma

Analogy to Studies to End HIV

- ▶ Barriers to implementation of HIV vaccine studies
- ▶ Studies to end HIV

Institutional perspective

- ▶ Cost
- ▶ Resources
 - ▶ Personnel
 - ▶ Space
- ▶ Patient flow
- ▶ Infrastructure

MeDiCALF-Lessons learned

- ▶ Transient elastography procedure
 - ▶ Time to conduct a valid measurement
- ▶ Patient methadone dosing
 - ▶ Required trough methadone levels.
 - ▶ Patients can become anxious if not dosed on time.
- ▶ Patient involvement in the planning and implementation of the study.
- ▶ Issue of sufficient numbers of HIV/HCV co-infected patients
 - ▶ Many have been treated for HCV
- ▶ Adequate space with in the OTP