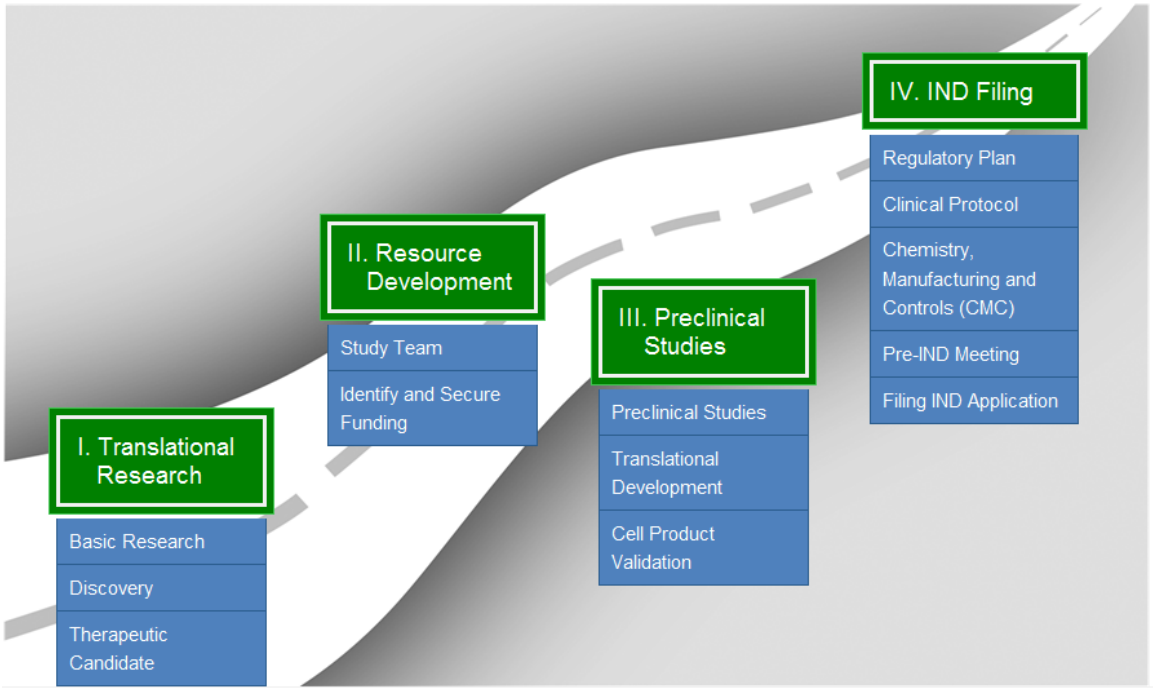
Cellular Therapy Clinical Research Roadmap



What is it and why do we need it?

- Developed by PACT's cell processing facilities
- A resource for researchers new to the field of cellular therapy.
- To provide a high-level overview that will assist researchers in the identification of the critical areas that need to be considered when developing a cellular therapy intended for evaluation in human clinical studies under an IND.

Roadmap Categories

- Roadmap Category I - Translational Research
- Roadmap Category II - Resource Development
- Roadmap Category III - Pre-Clinical Studies
- Roadmap Category IV - IND Filing

Speaker Objectives

- *Roadmap Category I - Translational Research*
  - Identify steps in determining when a therapeutic candidate is ready to enter the translational phase.
  - Speaker: **Catherine Matsumoto**
- *Roadmap Category II - Resource Development*
  - Learn to develop a study team to coordinate the planning and initiation of preclinical and clinical research studies aimed at bringing the therapeutic candidate to the clinic.
  - Speaker: **Dr. David H. McKenna, Jr.**
- *Roadmap Category III - Pre-Clinical Studies*
  - Develop an understanding of implementing translational development and cell product validation processes to refine and optimize the early preclinical assays and models used during the discovery phase as the therapeutic candidate moves through product lifecycle.
  - Speaker: **Dr. Adrian Gee**
- *Roadmap Category IV - IND Filing*
  - Describe the benefits to and identify the elements used in developing a regulatory plan early on to facilitate the IND development and submission process.
  - Speaker: **John Centanni**