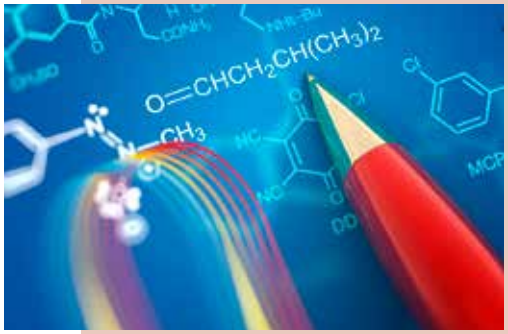
Drug/Device Development and Regulatory Support

In partnership with the North Carolina Translational & Clinical Sciences (NC TraCS) Institute, RTI International is helping to expand regulatory services to help researchers translate novel discoveries into new therapies. This new RTI-based NC TraCS service provides preclinical expertise, including guidance on good laboratory practice (GLP) studies and good manufacturing practice (GMP) drug substance and drug product manufacturing requirements for clinical studies.



Overview

Translating laboratory discoveries into therapies is a complex and expensive process. Developing a strategic plan is critical to the success of a drug or device development program. Regulatory guidance is important in both preclinical and clinical stages of drug or device development to ensure efficiency and cost effectiveness. The RTI-based Drug/Device Development and Regulatory Support Service can provide scientific and tactical experience to help navigate the drug or device development process. RTI has worked extensively with investigators, not-for-profit organizations, and small businesses to provide strategic preclinical development guidance and regulatory consultation.

Services

The Drug/Device Development and Regulatory Support Service provides a variety of services according to individual investigator needs:

- Preclinical consultation
  - Develop project gap analysis
  - Outline a plan to advance a product to Investigational New Drug (IND) or Investigational Device Exemption (IDE) submission
- Preclinical study support
  - Protocol design and report writing
  - Evaluation of pharmacology/toxicology and vendors
  - Scientific and regulatory advice
- Regulatory writing and consulting
  - Preparation of regulatory documents and U.S. Food and Drug Administration (FDA) communications
  - FDA meeting support
  - Pre-IND or pre-IDE briefing packages
  - IND and IDE preparation and submission
  - Orphan drug applications (ODAs)
  - Regulatory due diligence

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Tier 1: Consultation and Initial Planning (2–10 hours)

Tier 1 services are designed to make an initial determination of the need for drug or device development and regulatory support services and the likelihood of success. Team members will meet with interested investigators to discuss the project and the clinical endpoints and to review the currently available supporting data. The UNC Regulatory Specialist is also available to assist in the preparation and submission of the IND or IDE application (e.g., for publication-driven research). The goal of Tier 1 services is to determine whether there is sufficient interest and potential to move a drug or device development program forward.

Tier 2: Strategic Planning and Development (10–40 hours)

Tier 2 services aim to provide more targeted support to potential projects for which there is a clear justification and for which success is potentially achievable. Team members will work with interested investigators to develop a strategic preclinical plan, including a literature review if needed, and limited regulatory document writing or communications to FDA (i.e., pre-IND or pre-IDE briefing package). Services may also include consultation on GLP studies or drug substance/drug product manufacturing. The team will support and assist in meetings among investigators and other stakeholders as needed to facilitate project advancement. At the conclusion of Tier 2, investigators who wish to have Tier 3 support will need to prepare a business and research proposal.

Tier 3: Comprehensive Regulatory Support for Advancement of a Preclinical Program into the Clinic (TBD)

Tier 3 services provide extensive regulatory support, including the submission of multiple documents to FDA such as pre-IND or pre-IDE briefing packages, ODAs, INDs, and IDEs. Tier 3 services could also include guidance and monitoring of GLP studies and manufacturing of drug substance, drug device, or drug product activities to support an IND or IDE submission and clinical studies. A maximum of one to two Tier 3 projects will be supported in any given year. Progression to Tier 3 is usually contingent on approval from the Translational Sciences Advisory Board or support by the 4D Strategic Initiative.

Leadership Team

Diana Severynse-Stevens, PhD

Diana Severynse-Stevens is the Director of Drug Development within the Center for Global Health at RTI and the Director of the Drug/Device Development and Regulatory Support Service.

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Greg Gatto is the Regulatory Project Leader in the Drug Development Group within the Center for Global Health at RTI.

More Information

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