Navigating a medical product over complex scientific and regulatory hurdles on the way to human clinical trials can often end in failure. Having an experienced partner who can guide you through this difficult process can greatly enhance your success while decreasing development time and cost.

SRI International offers you expert assistance in planning and implementing the development of your lead candidate from early discovery activities through the initiation of Phase I clinical trials. Our Regulatory Services team complies with the U.S. Food and Drug Administration (FDA) regulations and protocols to guide your process to a successful Investigational New Drug (IND) application. We work with pharmaceutical and biotechnology companies, universities, and the U.S. Federal Government to prepare for Phase I- enabling studies and to develop, review, deliver, and follow the progress of documentation required for a Sponsor’s pre-IND and IND submissions.

Learn more
Preclinical Development Planning

SRI-designed preclinical development plans support Phase I clinical studies. They balance cost, schedule, and risks to optimize your prospects for a successful program. We can help you to:

1. Refine preclinical program objectives
2. Develop a regulatory strategy
3. Review data and perform gap analyses
4. Design preclinical development testing to support an IND application
5. Design a risk management and contingency plan

SRI can create a Preclinical Development Plan (PDP) that defines a specific strategy and the study outlines to advance your lead candidate from the discovery stage to IND submission and initiation of Phase I clinical trials.

Benefits of a PDP include:
- A planning and budgeting tool
- Fundraising
- An introduction to regulatory requirements
- Milestones for go/no-go decisions
- Documentation useful for future licensing efforts or potential scientific collaborations

Contents of a PDP include:
- Proposed Target Product Profile
- Outlines for pharmacokinetics, genetic toxicology, and safety/toxicity studies
- Bulk manufacturing overview
- Plans for production of Clinical Trial Material for Phase I Drug Product
- Regulatory information
- Cost estimates
- Preclinical schedules
Pre-IND and IND Support

SRI can assist the developer of a new drug by providing resources to navigate the burdensome FDA approval process for INDs.

The IND application requests FDA authorization to administer an investigational drug or biologic to humans. An IND typically includes structure and composition of the candidate, manufacturing specifications, analytical evaluations, proposed safety studies, and clinical study approach. SRI can assist in preparing and assembling the entire IND data package provided by you or your representatives for an IND submission.

Before initiating time-consuming nonclinical studies and establishing a clinical trial design, SRI recommends that you discuss plans with the FDA in a pre-IND meeting. This meeting gives you an opportunity to obtain FDA advice regarding studies proposed for the IND and to discuss questions concerning early development data. SRI can help you arrange the pre-IND meeting and prepare a pre-IND document package.

IN PARTICULAR, WE CAN:

- Help you prepare and submit all necessary documents to request a pre-IND meeting and assemble the required informational briefing package for FDA review before the meeting.

- Obtain, review, edit, and assemble the necessary IND information as required in the Code of Federal Regulations, Title 21 Section 312.23.

- Help you to prepare or update the clinical Investigator’s Brochure (IB).

- Assist as needed in the writing and assembly of a Master File.

- Assemble the IND study protocol and provide information related to the four basic clinical sections—clinical protocol, investigator data, facility data, and Institutional Review Board data.

- Obtain authorization for cross-filing of information and lot release, protocols, and required IBs prepared by the appropriate organization.

- Participate in discussions with the FDA during pre-IND and IND meetings.

- Help you to respond to FDA meeting reviews and comments.
About SRI International Biosciences
SRI Biosciences carries out basic research, drug discovery and drug development, and provides contract services. SRI has all of the resources necessary to take R&D from Idea to IND—\textsuperscript{\textregistered}—from initial discovery to the start of human clinical trials—and specializes in cancer, immunology and inflammation, infectious disease, and neuroscience. SRI’s product pipeline has yielded marketed drugs, therapeutics currently in clinical trials, and additional programs in earlier stages. In its CRO business, SRI has helped government and other clients and partners advance well over 100 drugs into patient testing. SRI is also working to create the next generation of technologies in areas such as diagnostics, drug delivery, medical devices, and systems biology.

About SRI International
Silicon Valley-based SRI International is one of the world’s leading independent research and technology development organizations. SRI, which was founded by Stanford University as Stanford Research Institute in 1946 and became independent in 1970, has been meeting the strategic needs of clients and partners for more than 60 years.

Perhaps best known for its invention of the computer mouse and interactive computing, SRI has also been responsible for major advances in drug discovery and development, networking and communications, robotics, advanced materials, atmospheric research, education research, economic development, national security, and more. The nonprofit institute performs client-sponsored research and development for government agencies, businesses, and foundations. SRI also licenses its technologies, forms strategic alliances, and creates spin-off companies.