Phase 1 Clinical Trials and Strategic Development Services

Building upon its expertise in research and discovery, preclinical drug development, and investigational product manufacture, SRI Biosciences offers Phase 1 clinical trial services and strategic development support for biotechnology and device companies, university investigators, and other clients and partners.

Particularly for small or virtual biotechnology companies, SRI’s Phase 1 Clinical Trial and Strategic Development Services fill a need that is not prioritized by large contract research organizations. The Phase 1 Clinical Trials unit leverages SRI’s core competencies and relationships to provide an agile, top-tier development organization with the capacity to carry programs from concept to clinic.

In addition to executing clinical trials, the unit provides early strategic guidance in the refinement of efficient, scientifically sound development plans leading to a future drug product or device that addresses a well-defined, unmet medical need, and that will be well positioned for significant market share given the evolving competition. Early and adequate attention to key strategic elements increases the strength of funding pitches and maximizes the likelihood of FDA acceptance and successful development.

Clinical trial execution and strategic guidance for biotech companies, university investigators, and start-ups.

The 13-bed, 3-infusion chair, state-of-the-art Phase 1 clinical trial facility is situated at the Michigan Life Science and Innovation Center in Plymouth, Michigan, centrally located near academic medical centers in Ann Arbor, Detroit, and Royal Oak and within 20 minutes of the Detroit International Airport.

Integrated Support

- **Clinical strategy**: leveraging decades of experience in clinical development and translational medicine in the biotechnology, biopharmaceutical and nonprofit sectors, in addition to the strength of a network of clinical experts spanning many therapeutic areas

- **Phase 1 clinical research and operations**: enabling single-dose and multiple-dose Phase 1 clinical studies in patients and healthy volunteers, as well as integrated single and multiple ascending dose studies, food-effect and drug-drug interaction studies. Access to SRI’s existing strength in biomarker development will facilitate the conduct of Phase 1b studies in patients with translational biomarker endpoints that serve to mitigate the risk of late-stage clinical development failure.

SRI Biosciences offers:

- State-of-the-art Phase 1 clinical trial facility
- Staff trained in advanced cardiac life support
- Strategic clinical development support and innovative trial design
- Expertise in biomarker development and PK-PD modeling
- Dosage form development and cGMP manufacture of investigational products
- Regulatory, and, through its partners, full biometrics, and pharmacovigilance support

Experienced Leadership

Spearheading the organization is David Sahner, MD, senior director of clinical translation in SRI Biosciences. Dr. Sahner is a board certified internist and infectious diseases expert with 15 years of chiefly industry-based experience in the research and development of drugs, biologics, and devices, superimposed upon a background of nearly 10 years of clinical practice following his fellowship training at Brown University. His research career subtends every point on the continuum from idea through post-licensure studies, across multiple therapeutic areas including infectious diseases, vaccines, oncology, neuroscience, pain, and medical countermeasures. He was the clinical lead responsible for the Sustiva supplemental New Drug Application, which led to significant revised
labeling pursuant to the conclusion of 168 weeks of follow-up in a Phase 3 study, and he assisted the development team in their preparations for a successful Advisory Committee meeting which subsequently culminated in the approval of Reyataz. Previously Dr. Sahner has held clinical positions of progressively increasing responsibility and leadership at Chiron, Bristol-Myers Squibb, Pfizer, Vical, and Nektar Therapeutics where he served as Vice President of Clinical Development.

Dr. Sahner has a history of repeatedly successful interactions with regulatory agencies, experience with numerous types of submissions and meeting formats, as well as deep expertise in executional, tactical and strategic elements of R&D. He has consulted for over half a dozen biotechnology/biopharmaceutical companies and the private equity space.

Dr. Sahner, who will serve as medical monitor, is joined by a Michigan-based SRI physician investigator, sub-investigator, study coordinator, Director of Clinical Operations, study nurses and pharmacist, phlebotomy and laboratory sample processing staff, regulatory compliance specialist, local study monitor (CRA), and administrative support.

Key Services

Drug Development and Formulation
- IND-enabling preclinical studies evaluating drug safety, as well as pharmacokinetic, toxicity, and animal efficacy model data
- Dosage form development and cGMP manufacture of investigational products
- Biomarker discovery, development and validation from preclinical to clinical studies

High-Quality Strategic Development Support
- Creation/refinement of target product profiles
- Integrated clinical development plan
- Analysis of existing and looming competition

Clinical Trial Services
- High-quality design and execution of clinical trials
- Preparation of clinical protocols, informed consent forms and other key study documents
- Operational oversight by a highly experienced director of clinical operations
- 24-hour medical monitoring and site physician availability
- Electronic data capture
- Human sample analysis
- PK-PD analysis
- Top-line clinical study report

Administrative and Regulatory Support
- Coordination of Institutional Review Board (IRB) review of studies
- Arrangement, planning and management of Pre-IND meetings
- Preparation of IND submission documents

About SRI Biosciences

SRI International Biosciences teams with pharmaceutical and biotechnology companies, academia, foundations, and government agencies to solve important problems in global health. SRI Biosciences conducts basic research, drug discovery, and drug development, including contract research. SRI has all of the resources necessary to take R&D programs from “Idea to IND and Beyond™—from initial discovery to investigational new drug applications to start human clinical trials—and specializes in cancer, immunology and inflammation, infectious disease, and neuroscience research.

To date, SRI has helped advance more than 100 drugs into clinical trials, including a number of its own discoveries, several of which have reached the market. SRI is also working at the nexus of science and technology to create new technology platforms for the next generation of drug discovery and development in areas such as diagnostics, drug delivery, medical devices, and systems biology.

For More Information

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