charles river

SAFETY ASSESSMENT

Scientific Advisory Services

Market pressures continue to change the focus and structure of the drug development industry, with a heavy emphasis on accelerating early phases of development in order to create late-stage pipeline growth. Given these increasing pressures and a changed business model, the design and management of successful, lean and robust nonclinical programs is becoming increasingly important.

Our Scientific Advisory Services brings together a team of industry-proven professionals to guide clients through the ever-changing landscape of drug development. Our collaborative approach and deep understanding of regulatory expectations helps us shape the best strategy to advance novel therapies into and through clinical trials, and design custom studies and programs that reduce risk and accelerate timelines. With access to the industry's most comprehensive portfolio – from early discovery to safety assessment through manufacturing support – our scientific advisors are exceptionally qualified to navigate each client's unique journey.

Scientific Advisory Services:

- Regulatory guidance
- Strategic advice
- Customized program design
- Customized study design
- Fully integrated nonclinical programs from discovery to market
- Dedicated scientific leadership
- Risk mitigation strategies

EVERY STEP OF THE WAY

Regulatory Guidance

Many obstacles can prevent a drug from reaching its full market potential, including lack of specificity, inactivity or safety concerns. Additionally, preparing a translational nonclinical program has its challenges, such as selecting human-predictive animal species, settling on a dose regimen or selecting appropriate biomarkers. Admittedly, it is a long road from discovery to the clinic, but the lure of taking shortcuts to expedite regulatory submission, and thus not capturing critical information, can cause unexpected delays in achieving the critical first-in-human trials. We conduct more than 150 IND programs each year, and have seen great success getting products to key milestones and to market. Our Scientific Advisory Services group comprises scientific and technical experts who have worked in the pharmaceutical and biotechnology industries, universities and the FDA – many of whom have worked in drug development for over 20 years. Because of our broad experience, our scientists are often sought out by pharmaceutical and government consortiums to advise them on animal welfare refinements and drug evaluation practice – our everyday work.

Strategic Advice

From the initial inquiry stages, we collaborate with clients to tailor research around their drug, its chemistry and target, and the clinical objectives of their program. Our staff discuss research options and identify strategic and critical path issues that may arise during the development process. By assessing the preclinical development program at its start, we provide clients with assurance as to the relevance and applicability of the program to its future use. A core team of discovery, bioanalytical, toxicology and regulatory experts is established early in the process. The team is optimized and evolves as each stage of development is reached.

Customized Program Design

We work with clients to customize a specific nonclinical program based upon the type of drug, its intended route of administration, anticipated mode of action, clinical indication, regulatory and commercial strategy. We apply our expertise to every stage of a product's development, from hit identification and lead candidate selection to IND-enabling and chronic studies, all the way through to marketing authorization. The success of a program relies as much upon the planning as the execution; each program is assigned to an experienced Scientific Advisor and carried out by experienced scientific teams. This streamlined approach facilitates a smooth transition between key milestones.

Customized Study Design

Our Scientific Advisors use their personal experience and the full depth and breadth of scientific expertise within Charles River to design each individual study. With comprehensive offerings from access to state-of-the-art equipment to novel study designs and state-of-the-art equipment, Charles River's well-stocked toolbox fosters continuous innovation.

Fully Integrated Nonclinical Programs from Discovery to Market

Charles River offers an unparalleled range of nonclinical services, from target ID to pivotal GLP safety studies. The Scientific Advisor pulls all of these services into a coherent, seamless package, and provides advice on critical scientific decisions, such as dose selection and interpretation of study findings. At earlier stages of development, we advise clients through the development of their target product profile and lead candidate selection to support swift and timely transition from discovery into formal preclinical development studies.

Dedicated Scientific Leadership

The Scientific Advisor acts as the single scientific point of contact for the full program of studies conducted at Charles River, collating all critical information and communicating with clients in a concise format and timely manner. This person acts as an extension of the client's team within Charles River, providing everyone with regular status reports, joining team teleconferences and presenting at in-house meetings. The Scientific Advisor adds significant value with an ability to guide activities, interpret results and advise on the potential impact of findings on program progression, based on a thorough scientific understanding of the client's product. As a product reaches key development milestones, the Scientific Advisor can help review nonclinical modules of regulatory submission documents and participate in regulatory meetings, if required. The Scientific Advisor is also available to assist with preparing timely responses to nonclinical questions from the regulatory authorities.

Accelerated Program Timelines

In designing a program, the Scientific Advisor uses best practices based on previous experience to compress overall program timelines, with a focus on the most effective scheduling of individual studies. This can include a determination of where studies can be run in parallel; adoption of strategies to speed decision-making (based on availability of early data); short stagger periods between rodent and nonrodent studies; streamlined report review; critical path analysis, and other factors.

Convenient Data Access and Reporting

Our client portal provides access to near real-time data in a fully customizable format, enabling quick decision making. We have also completed the validation of our SEND suite to produce SEND data for all in-scope studies conducted using our global data capture system, facilitating streamlined reporting when required by the US FDA.

Risk Mitigation Strategies

Charles River's Scientific Advisors bring valuable experience to the table, having managed nonclinical discovery and development programs in both industry and CROs. Their diverse knowledge of a range of molecule classes across a spectrum of nonclinical studies, combined with a sound scientific understanding of a client's product, prepares them to predict likely issues before they arise and develop risk mitigation strategies to avoid problems or minimize their impact. Of course, history has shown that sometimes development plans just don't go as expected. While the Scientific Advisor strives to anticipate and mitigate risks, not all challenges can be foreseen. Should the unexpected happen, our people have the skill and background to identify that which has a critical impact on product development, and prepare a scientific justification for proceeding as planned. If moving forward is not possible, we can suggest what further studies should be conducted to provide evidence to facilitate a decision on whether development can continue.

Proven Track Record

The cumulative experience of the Scientific Advisory Services group is over 210 years (excluding postdoctoral experience). Our Scientific Advisors have spent, on average, 20 years working in the biotechnology or pharmaceutical industries.

The innovative therapies we've helped to develop include:

- Small molecules, including cytotoxics
- Proteins/Peptides
  - enzymes
  - clotting factors
  - cytokines
  - hormones
  - vaccines
- Antibodies/Antibody-like
  - mAbs
  - Fab
  - scFv
  - bi-specific
  - ADC
  - fusion proteins
- Nucleic acid-based therapeutics
  - antisense
  - siRNA
  - microRNA
  - mRNA
- Gene therapy
  - viral vectors
  - non-viral delivery
- Cell therapy
  - autologous
  - allogeneic
  - xenogeneic
  - CAR-T
- Engineered bacteria
- Viruses
  - oncolytic
  - vaccine
- Novel excipients
  - nanoparticles
  - specialty delivery
  - implants