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Charles River Navigator Services: Helping Chart the Path for Successful Drug Development

Broad Network of Resources

- Global network of preclinical facilities spanning North America, Europe and Asia
- Phase I clinical facilities in North America and Europe
- Full range of study types and multiple species meeting the highest level of health and genetic standards in the industry
- North American (Montreal & Navigator Services-U.S.) and European (Edinburgh) Strategic & Regulatory Consultation and Program Management services

Mission

- Collaborate with sponsors to achieve successful preclinical development programs
 - Expert scientific and regulatory consulting to address strategic and tactical issues
 - Individualized program management to facilitate communication and keep programs on track
 - Access to global network of Charles River scientists to provide specialized scientific and technical expertise



Navigator Services

Scientific and Regulatory Consulting

- Develop program strategy
- Customize study designs
- Review regulatory documents
- Resolve issues

Program Management

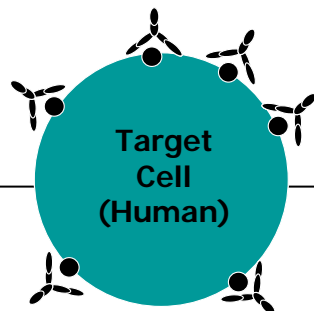
- Provide logistical support
- Plan programs
- Develop Gantt charts
- Lead regular team teleconferences
- Provide status reports
- Serve as link between client and operations
- Facilitate internal communications

Regulatory & Scientific Consulting

Areas of Expertise

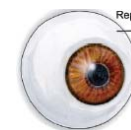
Product Types

- Small molecules
- Synthetic peptides
- Biologics
 - Monoclonal antibodies
 - Recombinant proteins
 - Cell, tissue, and gene therapy
 - Vaccines



Routes of Administration

- Oral
- Intravenous
- Subcutaneous
- Topical
 - Ocular
 - Dermal
- Specialty delivery



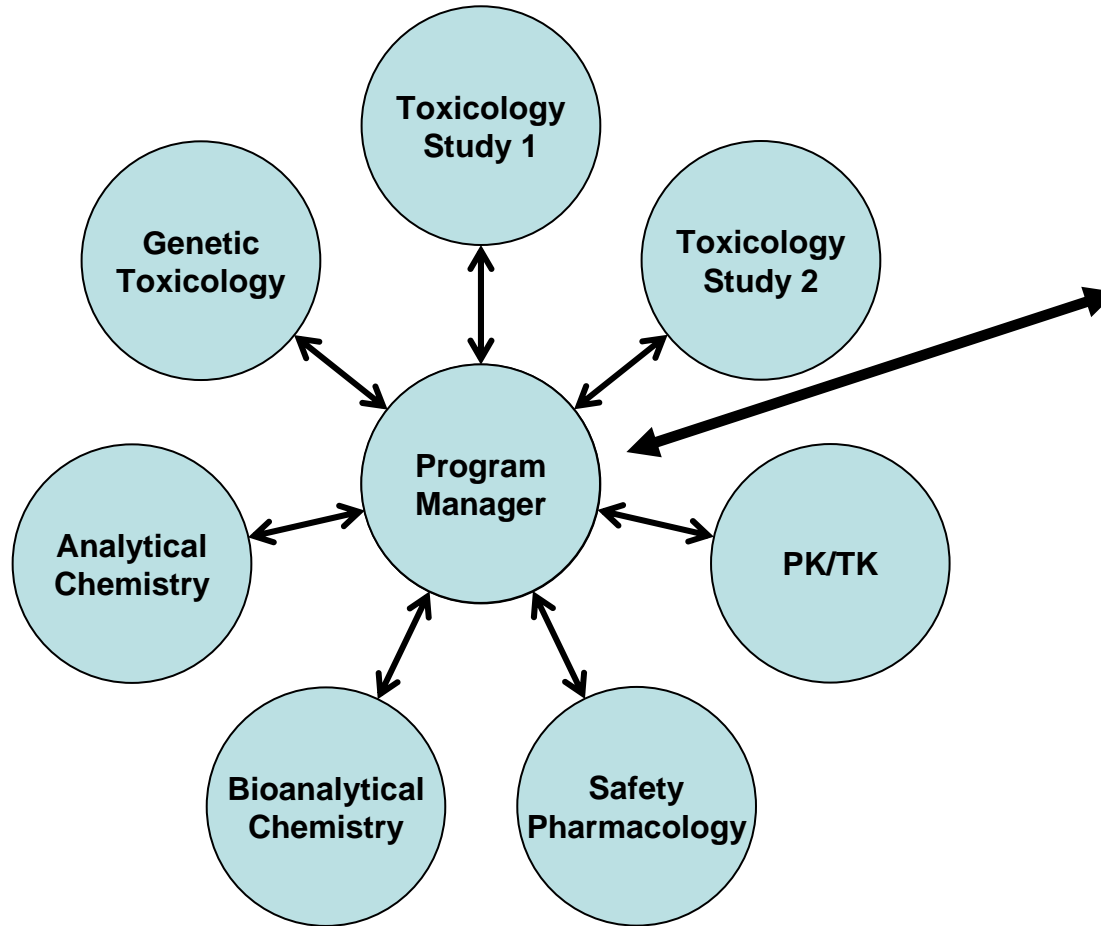
Regulatory & Scientific Consulting Activities

- Provide value-added strategic and/or regulatory advice as part of programs conducted at Charles River
- Provide billable consulting to companies conducting studies outside of Charles River
- Lecture at continuing education courses
- Participate in FDA workshops
- Network with colleagues within and outside of FDA

Program Management

- Serves as central point of contact within Charles River throughout the program
- Facilitates communication within Charles River and between Charles River and the sponsor
 - Work closely with operational departments to coordinate the multi-disciplinary and cross-site activities
 - Lead team meetings and teleconferences
 - Maintain meeting minutes and follow up on action items
 - Use web-based portal to provide ready access to data and study documents
- Facilitates transition to Charles River Phase I
- Provides customized services as needed

Program Management Central Point of Contact

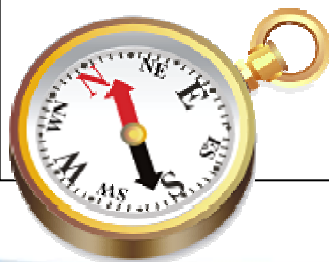


Program Management Facilitating Partnership



Charles River Navigators

- **The Navigator Services at Charles River help accelerate drug development throughout the discovery, preclinical, and clinical phases:**
 - Assist with program and study designs
 - Provide solutions for study-related issues
 - Oversee and facilitate program conduct – “single point of contact”
 - Facilitate smooth transition into clinical studies
 - Provide drug and biologics development training
 - Review and prepare regulatory documents



Navigator Services

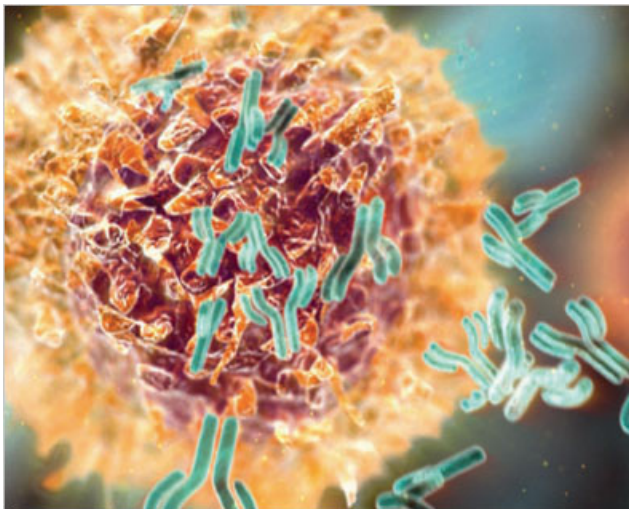
- Possess know-how spanning the drug development process
- Form customized collaborative relationships with pharmaceutical companies
- Reduce time and cost to accelerate drug development

Case Example I

Management of an Ex-US Program

Background

- A Pacific Rim company with primarily small molecule expertise developing a monoclonal antibody



Goals

- Submit a successful IND to the US FDA
- Continue drug development beyond Phase 1

Challenges

- Relative lack of experience in developing a monoclonal antibody
- Managing a preclinical program being conducted at multiple sites in the United States

Case Example I

Management of an Ex-US Program

Navigator's Solutions

- Senior Program Advisor assigned to assist with program design and coordinating communication across multiple time zones
- Input obtained as needed from Senior Scientific Advisor with prior FDA experience with biologics



End Result

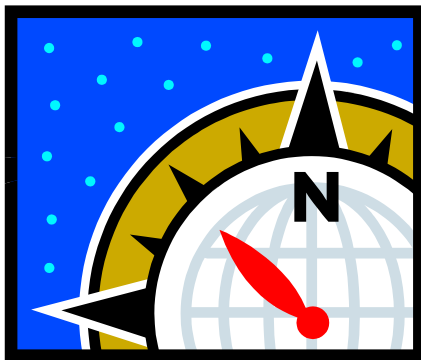
- Maintained channels of communication throughout the development process, facilitating decision-making
- Pre-IND meeting with FDA confirmed that the appropriate studies had been conducted
- Clinical trials initiated following successful submission of IND to FDA

Case Example II

Alliance Management for Large Companies

Background

- A large pharmaceutical company with multiple compounds in varying stages of preclinical development has outsourced preclinical development to Charles River



Goals

- Manage timelines
- Maintain consistency across Charles River sites to meet expectations (e.g. peer review for pathology)

Challenges

- Addressing goals with multiple people involved
- Focus on individual studies and overall alliance

Case Example II

Alliance Management for Large Companies

Navigator's Solutions

- Established working teams
- Issue resolution
- Implement resolutions that can be broadly applied to all studies to the extent possible

End Result

- Rapid timeline for filing regulatory submission
- Collaborative input to resolve scientific and regulatory issues



Case Example III

Scientific and Regulatory Consulting for a Large Pharmaceutical Company

Background

- A large US pharmaceutical company, which conducts preclinical studies for small molecules and biologics at Charles River, convenes an advisory board to obtain scientific and regulatory input on their programs



Goals

- Maintain a balanced pipeline by prioritizing compounds to facilitate drug development
- Meet challenges in scientifically sound, expeditious manner

Challenges

- Addressing scientific and regulatory challenges for multiple compounds in varying stages of development

Case Example III

Scientific and Regulatory Consulting for a Large Pharmaceutical Company

Navigator's Solutions

- Participate in regularly convened scientific advisory board meetings
- Fee for service discounted based on volume of preclinical studies conducted at Charles River



End Result

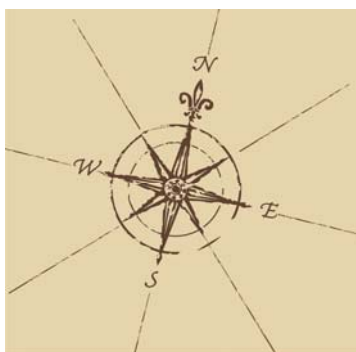
- Company able to consider external input when making decisions
- Participating in the advisory board enhances the partnership between the company and Charles River

Case Example IV

Management for a US-Based Small Company

Background

- A small US-based company (2 employees) developing its first compound, a small molecule intended to treat a chronic indication, used Charles River for its preclinical program and their Phase 1 clinical trial



Goals

- Complete preclinical IND-enabling program
- Initiate Phase 1 clinical trials
- Secure a partner for further development

Challenges

- Managing a preclinical program being conducted in the US and Canada
- Addressing scientific and regulatory issues
- Communication among multiple parties

Case Example IV

Management for a US-Based Small Company

Navigator's Solutions

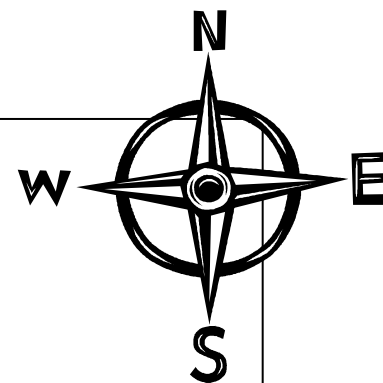
- Program Manager coordinated communication for all individuals involved in the preclinical program
- Senior Scientific Advisor and others participated as needed to address issues
- Ensured seamless transition from preclinical to clinical

End Result

- Establishment of partnership with company
- Timely communication across several organizations
- Successful IND submission achieved



Summary



Navigator Services:

- Scientific and Regulatory Consulting
- Program Management

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accelerating drug development. exactly