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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

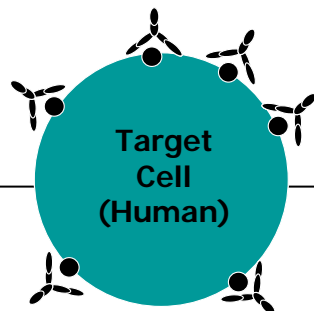
- Provide logistical support
- Plan programs
- Develop Gantt charts
- Lead regular team teleconferences
- Provide status reports
- Serve as link between client and operations
- Facilitate internal communications

# Regulatory & Scientific Consulting

## Areas of Expertise

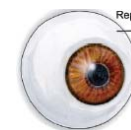
### Product Types

- 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



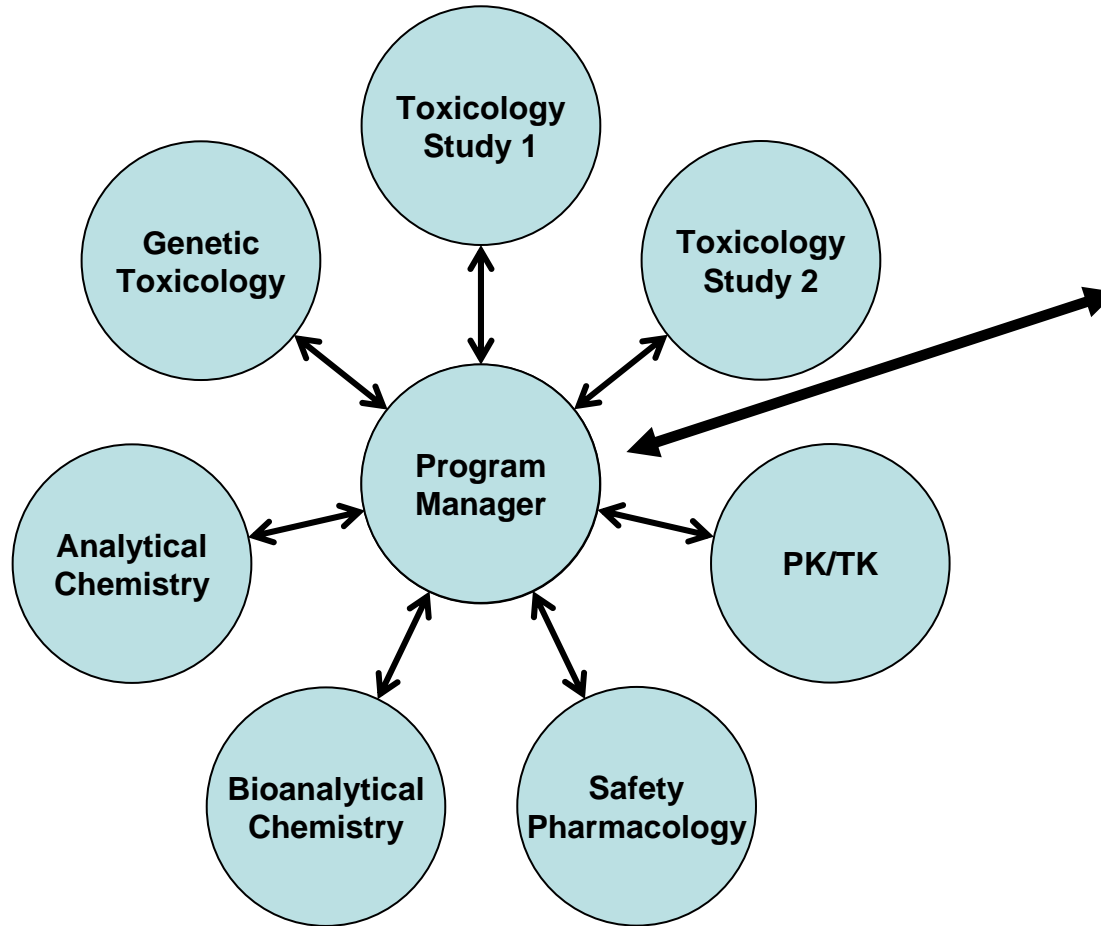
# Regulatory & Scientific Consulting Activities

- 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

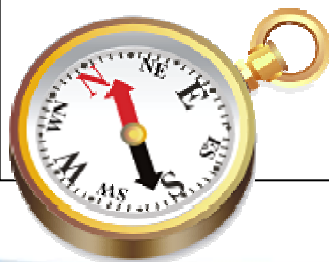


# Program Management Facilitating Partnership



# 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

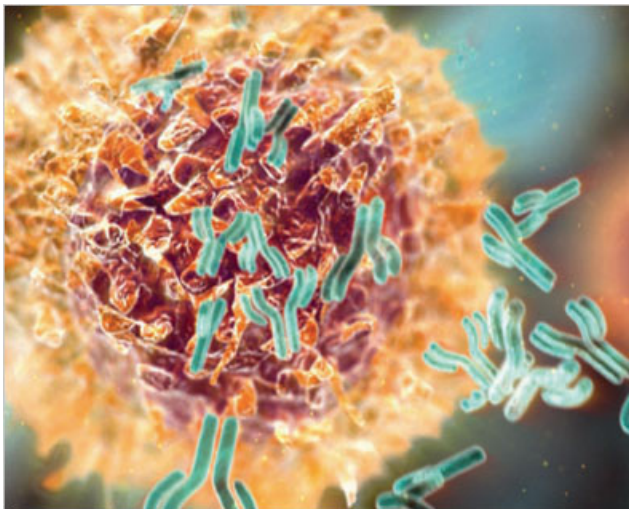
- Possess know-how spanning the drug development process
- Form customized collaborative relationships with pharmaceutical companies
- Reduce time and cost to accelerate drug development

# 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

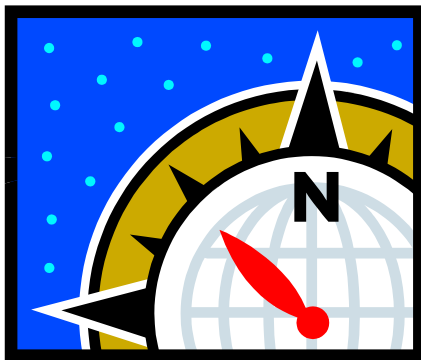
- Maintained channels of communication throughout the development process, facilitating decision-making
- Pre-IND meeting with FDA confirmed that the appropriate studies had been conducted
- Clinical trials initiated following successful submission of IND to FDA

# 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

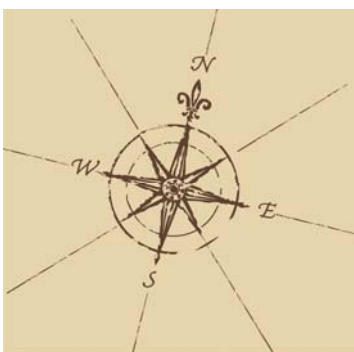
- Company able to consider external input when making decisions
- Participating in the advisory board enhances the partnership between the company and Charles River

# 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

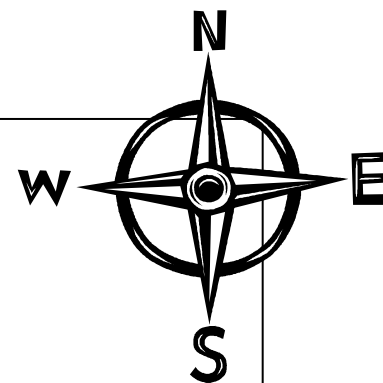
- Program Manager coordinated communication for all individuals involved in the preclinical program
- Senior Scientific Advisor and others participated as needed to address issues
- Ensured seamless transition from preclinical to clinical

### 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**