Strategic Outsourcing:

The Advantages of Clinical Development in Canada

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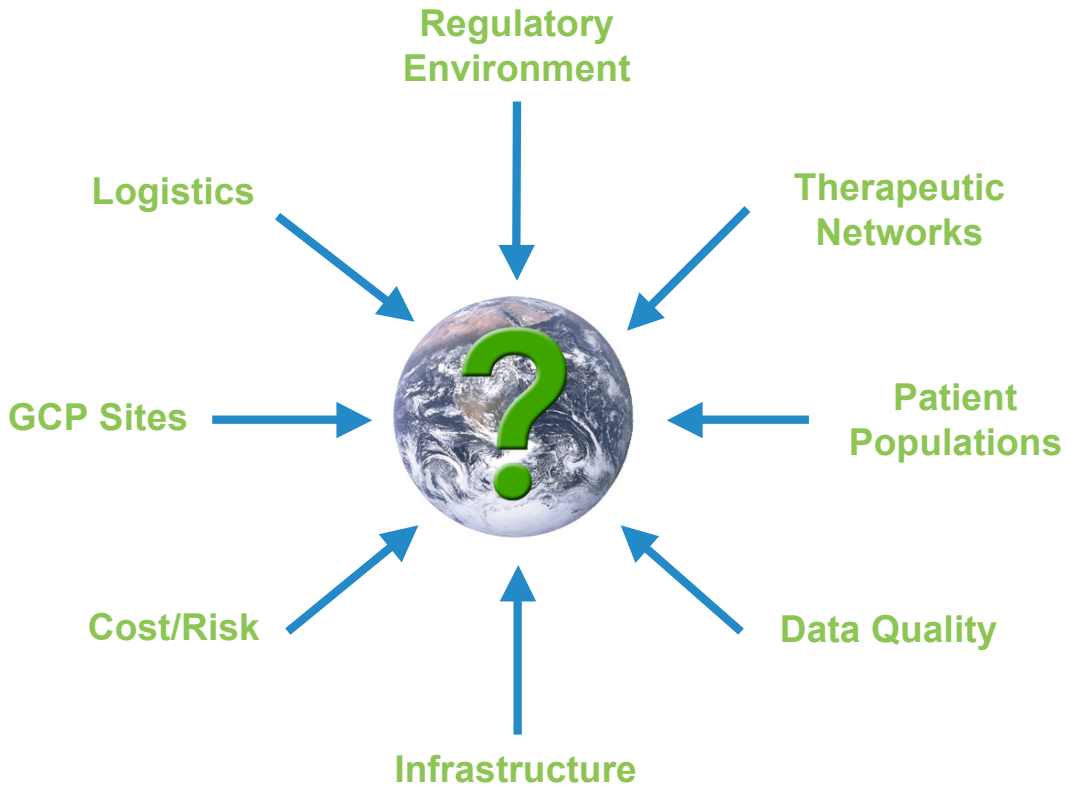
ALLPHASE® CLINICAL RESEARCH

Exceeding Your Expectations®

Factors Affecting Global Trial Decisions



The Clinical Benefits of Canada

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- Many international trials are conducted in Canada to strategically reinforce global development capacities

- Why do so many companies conduct trials in Canada?

  - Cost effectiveness
  - Regulatory initiatives
  - High clinical quality standards and Health Care System
  - Well-characterized/diverse patient populations
  - Regulatory synergies with US FDA
  - Extensive patent protection timeframes
  - Therapeutic networks and centres of excellence

ALLPHASE allows our international clients to realize these advantages

World Leading Cost-Effectiveness

- SR&ED Incentives
  - Highest tax-based support system in the world (4 times US)
  - Can be applicable to Canadian and foreign-controlled companies performing R&D in Canada.
  - Applies to R&D expenditures including salaries, material, contracts and incremental overhead
  - Up to 35% credit of the first $3M in R&D expenditures

- Provincial R&D Incentives
  - Additional 10-15% above the Federal incentives
  - Potential combined credit in Ontario = approx 44%

Strategic Outsourcing

- Challenges in the industry are driving new trends in outsourcing
  - High rate of product failures - Fewer blockbusters
  - Products coming off patent – Generics
  - Downsizing and investment limitations
- Clinical trials are increasing in complexity
- Functional vs Full Service vs Strategic Outsourcing
- Why are most companies outsourcing?
  - Cost savings
  - Efficient utilization of resources
  - High quality outcomes
  - Obtain experience and strategic input
  - Risk Sharing

Strategic Outsourcing in Canada

- ALLPHASE facilitates realization of the multitude of R&D advantages in Canada
- Access to North American market
- ALLPHASE provides strategic and regulatory support throughout the entire clinical development lifecycle

ALLPHASE is eligible for project-related tax incentives that are transferred back to our international clients translating into significant cost savings for clinical R&D

Advantages of Early Involvement

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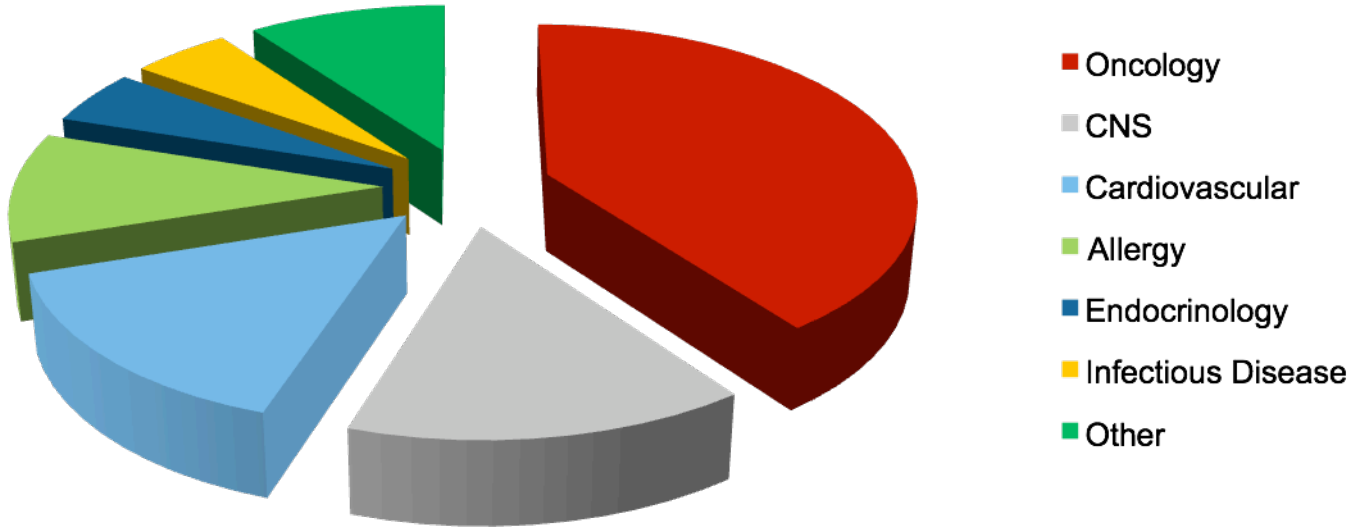
- Many emerging technologies are focussed on novel indications that present unique regulatory challenges
- Early strategic input requires sophisticated scientific and regulatory staff to:
  - Provide input on regulatory landscape
  - Identify challenges
  - Evaluate development options to help build a framework for the overall development plan
  - Outline the greatest value path to market
- Early stage input facilitates the assembly of the entire scope of required trials (preclinical, clinical, CMC) required for registration

Evolving Therapeutic Indications



- Development programs are becoming more specialized
- CROs must adapt to be able to provide niche expertise and service
- Therapeutic expertise AND drug class expertise

Case Study – Introduction to North America

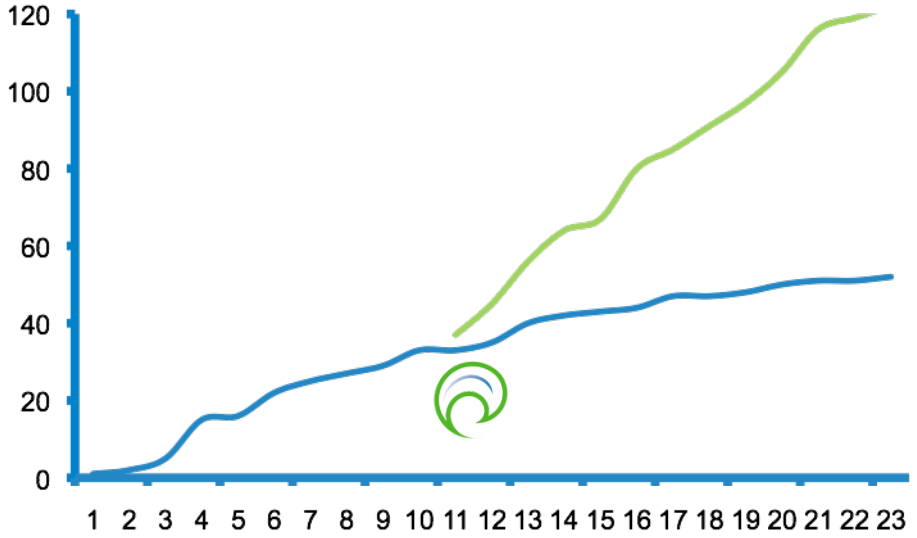
Oncology study – 140 patients

- Allphase coordinated Pre CTA/IND meetings ensuring regulatory expectations, fast approval, and FDA acceptance
- Access to key opinion leaders and therapeutic networks
- Defined patient population
- Client realized cost benefits of conducting research in Canada
- 100% repeat business

Case Study - Rescues

Immunology Study

- Biologic trial being conducted outside of Canada
- Recruitment behind schedule
- Fast Canadian start-up
- Access to high quality GCP sites and defined patient population
- Successful recruitment strategies
- Allphase awarded other studies to rescue



Case Study – Biomarker Program

Study I: Disease Target Validation

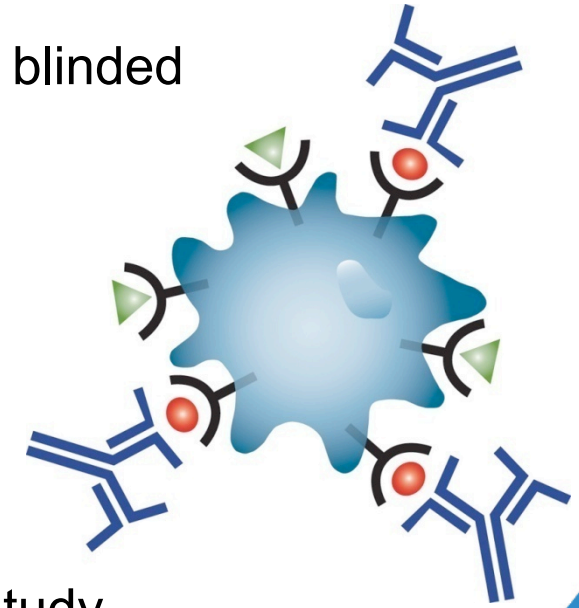
- Biomarker present in tumor tissues during progressive disease
- Initial EU patient population was limited
- Validation of diagnostic capabilities in Canadian blinded trial using diverse patient populations

Study II: Response Prediction

- Post-hoc analysis of drug-responses from a phase II study

Study III: Global Adaptive Design

- Use of biomarker for patient selection and mid-study decisions – serve as basis for Phase III



Global Perspective

- Canada is a central country to many clinical development programs
- Canada's contribution to Global R&D is significantly large
  - More clinical trials per capita than US or EU*
- Goal of Allphase is to facilitate the development of safe and effective medicines that not only benefit Canadian patients, but can be translated to the Global market
- Allphase provides trial management services that allow for our international partners to realize the advantages of conducting clinical research in North America

*Centerwatch.com data 2008 by number of active trials; Clinicaltrials.gov

More Information?

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