

Information sheet

# Integrated Programs: Early Development

## Accelerating molecules through to Proof-of-Concept

### Simplify early development and accelerate to Proof-of-Concept

**Proof-of-Concept (POC) is a key milestone in the development of a new drug candidate. At Quotient Sciences, we understand the increasing pressures on R&D budgets, therefore the need to transition molecules through early development to POC needs to be fast and cost-effective.**

With fully integrated capabilities from First-in-Human testing to seamless drug product supply for patient trials, we simplify early development and accelerate molecules through to POC. Unparalleled in the pharmaceutical industry, our **Integrated Programs** get molecules to patients faster by dramatically shortening development timelines.

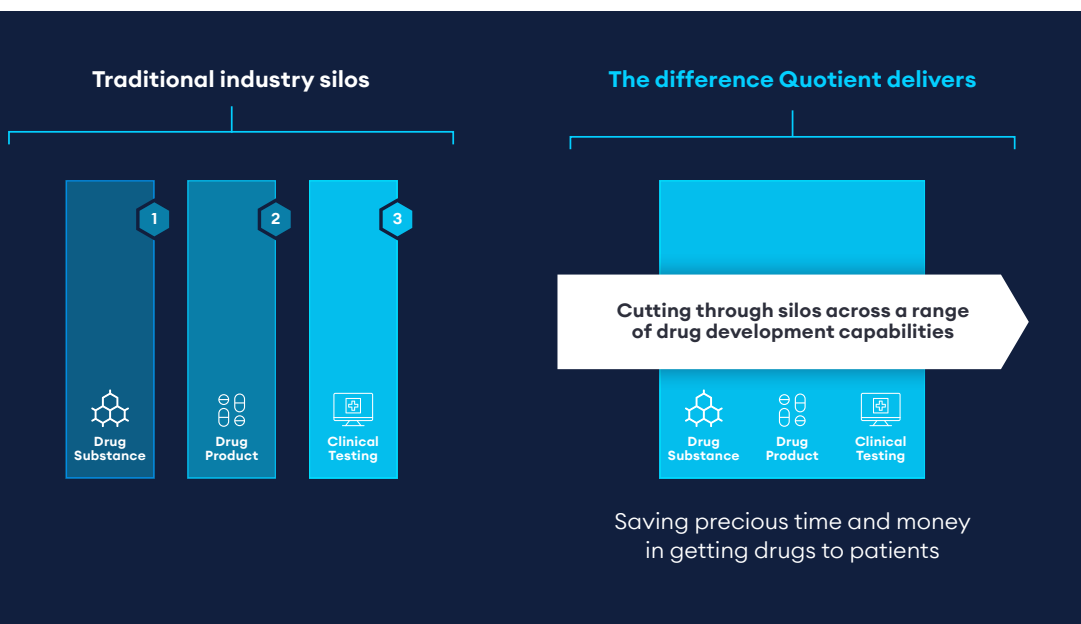
### The difference Quotient delivers

Our integrated approach brings together drug substance, drug product and clinical activities, supporting the expediting of lead molecules from FIH into POC trials. This integration, enabled by Translational Pharmaceuticals®, provides the fastest route to POC, shortening the drug development timeline by up to 18 months, saving valuable resources and budget.



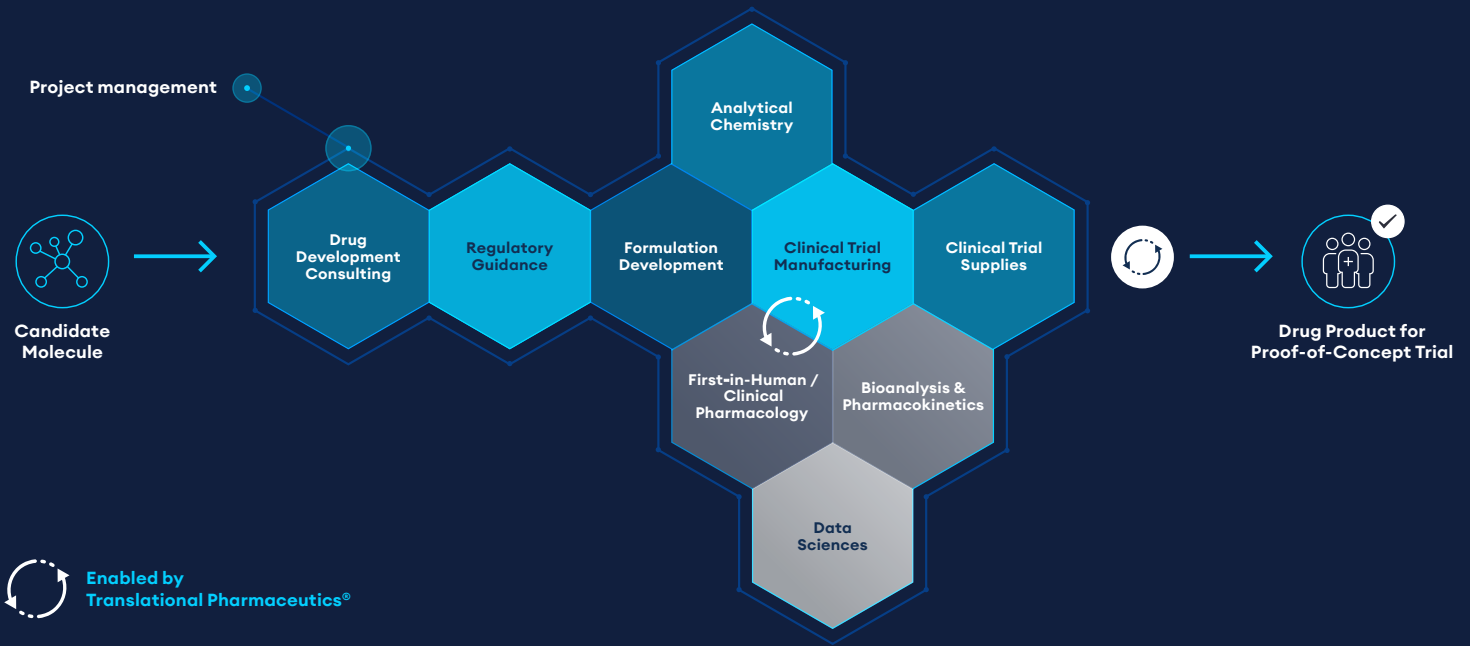
### Key benefits of an integrated approach

- > The fastest route to proof-of-concept
- > Shortens timelines by up to 18 months
- > Clinical data drives dosage form design
- > More effective decision making
- > Seamless drug product supply
- > Streamlined outsourcing



Integrating formulation development, drug product manufacturing and clinical testing enables clinical data to help guide dosage form design, ensuring better decision making; and supporting a more streamlined approach to outsourcing by avoiding the complex problems associated with multiple vendor management, found in traditional drug development programs.

## Integrated Early development programs



### Case study

## Accelerating through FIH to POC



### Molecule overview

- > US biotech<sup>1</sup> developing a new chemical entity (NCE)
- > Hereditary angioedema (orphan indication)



### Project scope

- > Integrated healthy volunteer study & real time adaptive manufacturing to support POC trials



### Development & Manufacturing

- > Capsule formulation manufactured by Quotient for healthy volunteer phase
- > POC product manufactured “on demand” as patients enrolled with 14-day lead time



### Outcome

- > Project initiation to positive POC in 18 months

### Real-time manufacturing



Single ascending dose



Multiple ascending dose



HAE patients



<sup>1</sup>BioCryst - A comprehensive approach to a rare disease case study, Dr Phil Collis, Vice President of Clinical Development, BioCryst Pharmaceuticals

## One Business, One Experience

We are committed to delivering “one business, one experience” to our customers, irrespective of where a project is performed.

The integration of our sites, capabilities and project teams is designed to deliver an exceptional service for our customers.

## End-to-End Project Management

With expertise in end-to end Project Management and integrated Project Teams, we make drug development easier for our customers and dramatically reduce the time and cost of getting new medicines to patients. Our Project Managers are agile and adaptive to ensure project needs are met. They have broad expertise from Early Phase Development through to Commercial Manufacture and will support you at any stage along your development pathway. Our Project Managers will provide end-to-end support from concept and project scoping, to project delivery, to making recommendations for the next stage in development; and where projects transition across our sites, or intersect with other service providers, we'll make the process seamless for you. Together we will build your program.



## What makes us different? Science, Agility, Culture

Science, agility and culture are the three core components that define who we are, that allow us to do what we do in the way that we do it.

### Science

This is our non-negotiable foundation, uncompromised scientific integrity committed to turning ideas into solutions, molecules into cures.

### Agility

Speed is of the essence. Speed which does not compromise scientific integrity. Cutting through silos. Eliminating obstacles. Saving time.

### Culture

A culture of supportive teamwork with people who work hard together and enjoy it. People who respect each other's abilities. People who know that ideas need to become solutions, molecules need to become cures, fast.

## About Quotient Sciences

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, molecules need to become cures, fast. Because humanity needs solutions, fast.

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UK +44 (0)115 974 9000 USA +1-800-769-3518  
Email [info@quotientsciences.com](mailto:info@quotientsciences.com) Visit [www.quotientsciences.com](http://www.quotientsciences.com)



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