Quotient Sciences

Molecule to cure. Fast.™

Translational Pharmaceutics® for first-in-human studies

A novel way to do drug development: Quotient Sciences' Translational Pharmaceutics® platform

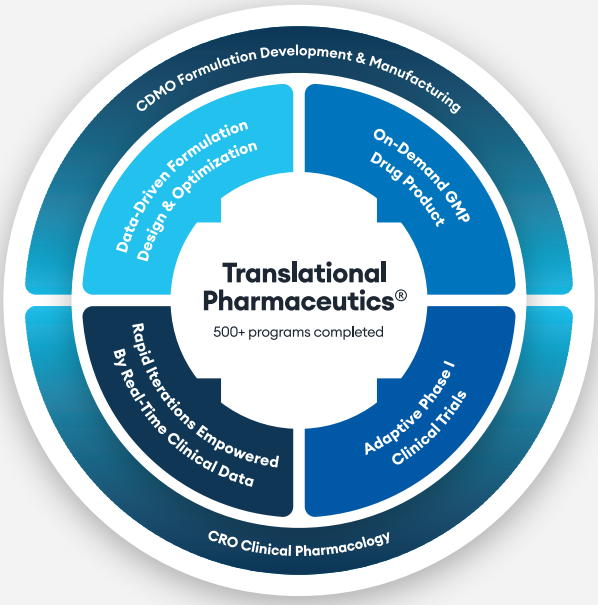
Quotient Sciences' Translational Pharmaceutics® platform enables First-in-Human (FIH) studies by re-engineering the transition of your drug molecule into clinical development and optimizing the timeline to Proof-of-Concept (POC). Translational Pharmaceutics® is applicable to all drug molecules, routes of delivery, and formulations.

What can Quotient Sciences do for me?

- ✓ Review your biopharmaceutics data package
- ✓ Develop formulations suitable for FIH and beyond
- ✓ Use in-silico modeling and simulation to predict human dose and pharmacokinetics (PK)
- ✓ Generate and compile the regulatory data package

Re-engineering the pathway into clinical development

Conventionally, to achieve the shortest timeline to first-subject-first-dose (FSFD), formulation development and clinical drug product manufacture are conducted prior to completion of pivotal toxicology studies. With Translational Pharmaceutics®, key pharmaceutical development activities and costs can be deferred until after completion of toxicology studies, with no negative impact on FSFD date.



Improving clinical conduct

On demand cGMP manufacturing gives drug developers more flexibility and control–without compromising safety, tolerability, or pharmacokinetic assessments. Decisions about the dose and formulation are guided by emerging clinical data, and dose escalations typically occur every 14 to 21 days.

Manufacturing the exact dosage strengths needed improves the accuracy of the study, and different formulation approaches can be tested and compared within the same clinical protocol. This approach also helps lower the risk of ending a program early due to poor drug exposure.

Shortening the timeline to POC

After screening and testing different formulations during FIH studies, the most suitable drug product can be selected earlier and manufactured quickly for use in multiple dose and proof-of-concept (POC) studies. Whether the POC study takes place at Quotient Sciences or elsewhere, we continue to supply the product directly to patients, avoiding delays that generally come with transferring manufacturing to a different third-party.

In some cases, timelines can be shortened by combining healthy volunteer and POC phases into one multi-part study protocol, requiring only a single regulatory submission. This approach has helped many clients generate POC data in under 12 months and has been used across a variety of therapeutic areas.

Benefits of FIH studies enabled by Translational Pharmaceutics®

	Conventional	TP Enabled
Pharmaceutical development	- 6 months	1 - 3 months
Stability program	> 3 months	< 7 days
Dose strengths	Multiple, pre-determined	Determined in real-time
Dose units	> 5000	< 500
API consumed	Kilos	100s grams
Formulation flexibility	No	Yes
Vendor management	Multiple	Single

For a list of our locations visit:
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