

**Information sheet**

# Clinical Pharmacology Human ADME studies

## Metabolism data for regulatory submission

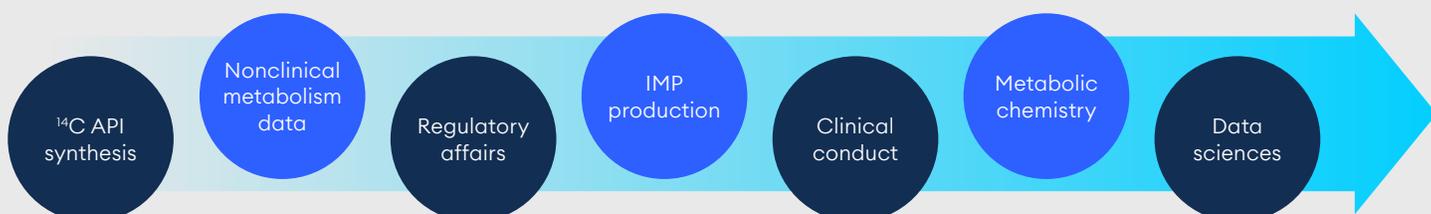
Whatever your requirements, Quotient Sciences can support you in the generation of clinical metabolism data for your drug development program and for NDA, MAA and global regulatory filings.

### Center of excellence for human metabolism investigations

- > World class medical and science teams
- > Expertise in reviewing clinical and non-clinical data and designing the human investigation
- > Effective study delivery from a combined experience of >300 human ADME studies
- > Scientific analysis and interpretation of clinical metabolism data

Facilitated by Synthesis-to-Clinic®, a unique service from Quotient Sciences delivering top quality human ADME data from a single program of work.

### Facilitated by Synthesis-to-Clinic®



## Human ADME studies

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### On-site pharmaceutical sciences facilities for the development, real-time GMP manufacture and QP release of <sup>14</sup>C drug products

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- > Supply of oral and parenteral formulations for ADME studies
  - > GMP manufacture of <sup>14</sup>C drug product in the same building as clinical dosing
  - > Real-time adaptive manufacturing to support ADME studies in patients at specialist clinics
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### Modern, comfortable and spacious clinical facilities

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- > Purpose-built, self-contained human ADME ward and laboratory
  - > Experienced volunteers who understand the rigors of human ADME studies
  - > Excellent volunteer recruitment, retention and completion
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### Real-time mass balance data output with cutting edge metabolite profiling and identification capabilities

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- > Rapid quantitative radiochemical analysis and low level (TopCount) radioactivity counting
  - > Dedicated metabolite identification and characterization using the latest instrumentation (LTQ Orbitrap XL™ and Q Exactive™)
  - > Extensive experience in utilising AMS technology to incorporate assessments of absolute bioavailability and for total radioactivity and metabolite profiling at lower assay sensitivity levels
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## Who is 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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