

# Human ADME Studies

Human metabolism data  
for regulatory submission



**Quotient Sciences is a leading provider of human ADME studies, offering extensive scientific expertise, operational knowledge, and a proven track record in conducting these studies for over 30 years.**

With a combined experience of over 300 human ADME studies, we leverage our insight to design comprehensive human ADME studies that align with your program's objectives, from the human ADME conduct to the scientific analysis and interpretation of clinical metabolism data.

Our team of medical and scientific experts has extensive experience in reviewing both clinical and non-clinical data. We routinely conduct ADME as either stand-alone protocols, or in combination with ivMicrotracer to fully understand the routes and rates of elimination from the body.

## Integrated human ADME studies facilitated by Synthesis-to-Clinic®

Our Synthesis-to-Clinic® integrated ADME studies are enabled by applying Translational Pharmaceutics® to create a program of work to deliver human ADME studies. All aspects to conduct a comprehensive human ADME program—from the radiosynthesis of the <sup>14</sup>C-labeled drug substance, to the clinical testing, and the final clinical report—combine in a program of work that is overseen and managed by Quotient Sciences team.

Whether you're looking to meet requirements for a New Drug Applications (NDA) or running in parallel with proof-of-concept studies, Synthesis-to-Clinic® ADME studies are a streamlined approach to meet your goals.





## Enabling excellence in Human ADME delivery

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

- ✓ Supply of oral and parenteral formulations for ADME studies
- ✓ GMP manufacture of <sup>14</sup>C drug product immediately followed by clinical dosing
- ✓ Real-time drug product manufacturing to support ADME studies in patients at specialist clinics

### Modern, comfortable, and spacious clinical facilities

- ✓ Purpose-built, self-contained human ADME ward and laboratory
- ✓ Experienced volunteers who understand the rigors of human ADME studies
- ✓ Excellent volunteer recruitment, retention, and study completion

### Real-time mass balance data output with cutting edge metabolite profiling and identification capabilities

- ✓ Rapid quantitative radiochemical analysis and low level (TopCount) radioactivity counting
- ✓ Dedicated metabolite identification and characterization using the latest instrumentation (LTQ Orbitrap XL™, Q Exactive™, Orbitrap Exploris 240/120, Vion IMS Q-ToF)
- ✓ Extensive experience in utilizing AMS technology to incorporate assessments of absolute bioavailability and for total radioactivity and metabolite profiling at lower assay sensitivity levels

### What our customers are saying:

“We conducted a <sup>14</sup>C human ADME study with Quotient Sciences... We were extremely satisfied with all aspects of the study, including project management, formulation development, manufacture, clinical conduct, and reporting. We would use Quotient Sciences again for this type of study.”

**Kadmon, a Sanofi Company**