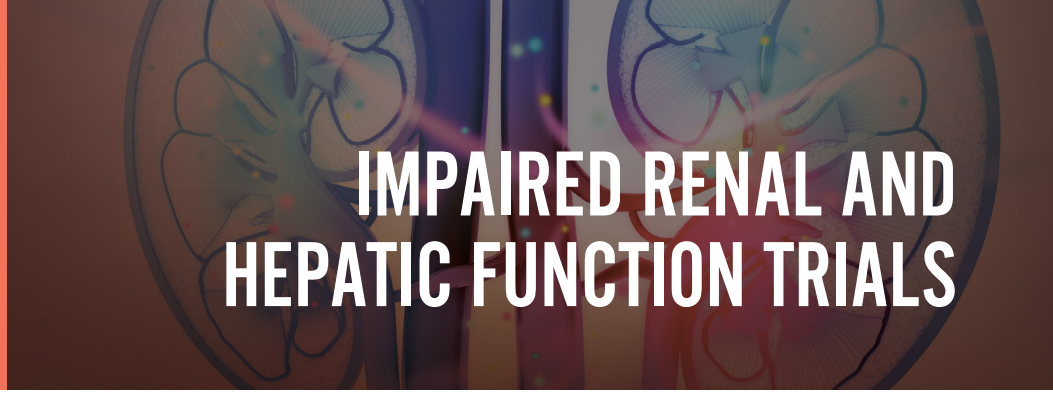
ALTASCIENCES
CLINICAL SERVICES



IMPAIRED RENAL AND HEPATIC FUNCTION TRIALS

Insights from renal and hepatic impairment studies play a key role in **guiding dosing strategies**, supporting both **patient safety** and **therapeutic effectiveness**. Regulatory agencies typically recommend at least one such study, depending on how the drug is cleared from the body.

WHY CHOOSE ALTASCIENCES FOR YOUR RENAL AND HEPATIC IMPAIRMENT TRIALS?

We utilize **three clinical pharmacology units** and an **extensive site network** to expertly assess specific impairment levels, alongside matched healthy populations.

- Completed 100+ studies across various routes of administration, including parenteral injections.
- Full- and two-stage adaptive integrated designs aligned with FDA (U.S.A.), Health Canada (Canada), and EMA (Europe) guidelines.
- Comprehensive support provided in:
  - Project and site management
  - Bioanalytical services
  - Data management
  - Biostatistics
  - Regulatory compliance
  - Report writing

Access to

145,000+

patients in our internal and external databases with varying degrees of hepatic and/or renal function impairment.

CLINICAL STUDY START-UP

We simplify **contract implementation, regulatory document preparation**, and **participant recruitment** to ensure efficiency and timely results. Altasciences' experienced project management and dedicated internal team work in close collaboration with sites and sponsors to significantly **reduce your start-up timelines**.

Our clinical pharmacology units, established site network, and co-located bioanalytical laboratories in the U.S.A. and Canada provide two regulatory pathways:

Investigational New Drug (IND)

Clinical Trial Application (CTA)

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FASTER, SMARTER RECRUITMENT SOLUTIONS

Enrollment timelines and study participant completion rates can directly impact the results of your renal and hepatic study and the reliability of your clinical data. It's why we have built a rapid, targeted, recruitment and retention strategy—customized for each project with defined enrollment thresholds to ensure efficient study implementation.

Our comprehensive site selection and screening methods enable precise identification of renal and hepatic impairment subpopulations, including assessment of severity and relevant medical history.

3 MONTHS

to enroll **eight patients** with severe, moderate and mild renal impairment.

KEY ADVANTAGES OF OUR RECRUITMENT STRATEGY

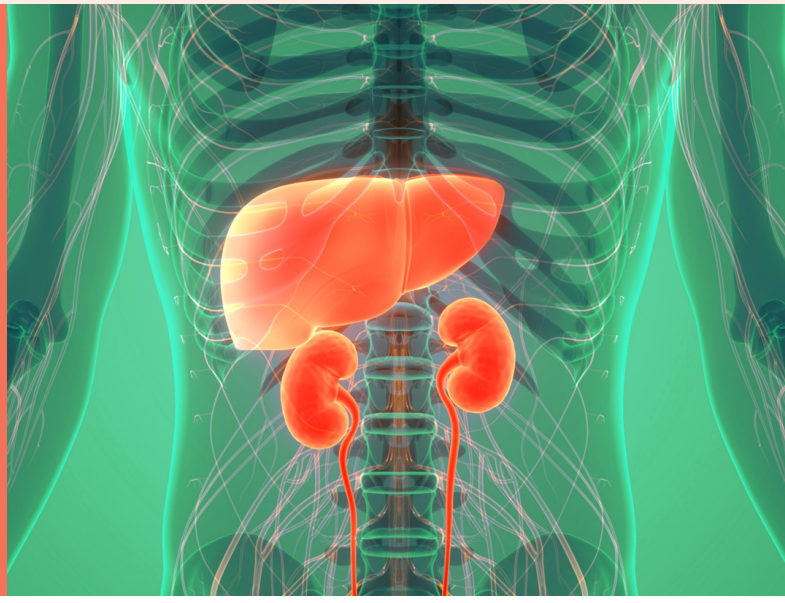
Our proven site selection methods and participant database make it possible to quickly and efficiently identify and enroll patients with renal or hepatic impairment to ensure on-time completion.

- Fast recruitment and enrollment of patients with renal or hepatic impairment, as well as healthy volunteers.
- Access to patients with mild, moderate, or severe renal or hepatic impairment through our proprietary database and partner site network—including hepatic impairment populations such as NASH and Child-Pugh A, B, and C, due to alcohol-related or other causes.
- Collaboration with dialysis centers and specialized investigators for end-stage renal disease (ESRD) studies.
- Ability to match healthy control subjects through a database of over 120,000 participants, 40,000 of which are active.
- Tailored inclusion/exclusion criteria to optimize safety, recruitment, and population diversity.
- Precision pharmacokinetic assessments to determine dosage adjustments in impaired populations.
- Defined enrollment targets and checkpoints to mitigate risk and meet recruitment goals.

TURNKEY SOLUTION FOR YOUR RENAL AND HEPATIC IMPAIRMENT STUDIES

Our highly experienced and dedicated early-phase team understands the complexities of conducting clinical trials with renal and hepatic impaired patients. This expertise drives effective trial design and implementation, and promotes strong engagement with patients.

We provide end-to-end clinical trial services specifically for your NDA-enabling clinical pharmacology trials.



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