Experience that matters in successful impairment studies

The depth of experience and combined capabilities you need to determine if, when and how to design and conduct the impairment studies demanded by regulators for labeling packages.

Anticipating and meeting regulatory scrutiny with robust impairment plans

As drug development progresses, regulators require a clear picture of how products are metabolized in the human body, and the risks associated with compounds that may linger in critical organs of the body.

Fortrea has over 25 years of global hAME leadership and deep scientific expertise in impairment studies. As hAME studies reveal the metabolization of a drug, they can provide guidance as to both the need for and the level of rigor likely to be demanded by regulators for associated impairment studies.

Such impairment studies are complex and demand a scientific rigor, an established site network and the experience needed to assess, consult, conduct and submit high-quality impairment studies, supporting ongoing clinical trials and as part of a wider set of final label studies in anticipation of marketing authorization.

140+

Phase 1 impairment studies conducted

40

Hepatic impairment

45

Renal impairment

Global Phase 1 impairment study sites with active master CDA in place

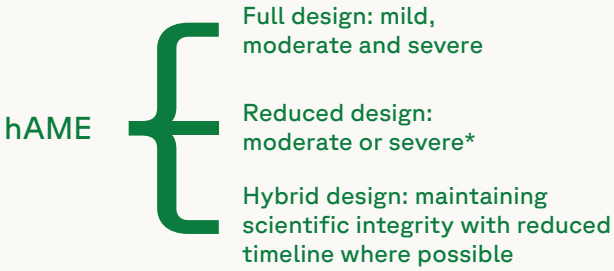
Fortrea

Navigating and conducting the studies you need. And only the studies you need

Fortrea's clinical pharmacology services provide the answers and guidance you need to make informed decisions along your drug development pathway.

Our experience with global regulatory bodies, and our experience at interpreting hAME study outcomes, means we can anticipate and design the impairment studies needed to support the ongoing development of your drug.

And with each of the 140+ impairment studies we have conducted, we hone our expertise, helping you determine the approach you need to move your drug through its development.



** Hepatic reduced design takes place in moderate subjects first; Renal reduced design takes place in severe subjects first*

An integrated suite of labeling package studies available to support your NDA

- hAME with DMPK labs in proximity offering real-time radioanalysis
- Impairment studies
- Food effect studies
- QTc studies
- Drug-drug interaction studies
- Bioequivalence studies

LEARN MORE at fortrea.com

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