CMC services

With our CMC management, you can rely on our chemistry expertise to set up synthesis strategies, stability and quality controls, labeling methods, and ensure regulatory compliance — accelerating IMP manufacturing and aligning it seamlessly with your (clinical) development program.

Quality control

- Quality control method development and validation
- Quality assurance
- Design and execute stability studies of drug product, such as purity and binding properties
- Setup validation and qualification of quality control assays for release of drug product (HPLC, etc.)
- Stability testing of pharmaceutical products

Manufacturing of IMP

- CTM manufacturing (also known as IMP manufacturing)
- Small batch manufacturing (GLP and GMP)
- QP release of (radiolabeled) drug product for clinical trials
- CDMO selection and management for clinical trial material
- Fluorescence/Radiolabeling method development and validation
- (c)GMP/GLP/R&D grade manufacturing and release of (labeled) study drugs
  - Manufacturing of (radiolabeled) drug product (for human use)
- Radiosynthesis
  - GMP synthesis
  - Guidance in GLP and GMP synthesis of precursors for labeling

Regulatory & strategy

- CMC regulatory
- CMC roadmap to support (non-) clinical development
- Identify and write protocols for method development and validation
- CMC regulatory, technical and document preparation and review of IMPD/IND for Clinical Trial Application (CTA)
- Design and evaluation of stability studies

TRACER

To find out more, visit:
www.tracercro.com/services

Welcome at TRACER

Thank you for your interest in working with us. TRACER is characterized by flexibility and dedication. Our company goal is to bring new therapies faster from bench to bedside. This means we are fully committed to making your clinical trial a success. This starts with accessibility and communication. Do you have questions? Please feel free to contact us.

Hyper specialist

Clinical trials, preclinical research, CMC (Chemistry, Manufacturing, and Controls), and regulatory processes are complex fields. Adding labeling, synthesis and in-human imaging increases this complexity. TRACER is an imaging CRO, meaning we design and conduct (pre)clinical studies with imaging. Each study begins with CMC, ensuring compounds are labeled with imaging agents that provide reliable data without altering compound behavior.

As hyper specialists, we are happy to participate in the conversation. So don't hesitate to invite us to a meeting for advice from our expertise. Don't rely on assumptions, reach out for expert advice.

Talk to our experts

Maarten Brom, PhD
For CMC and nuclear imaging related questions.
Mail: maarten@tracercro.com
Chat on LinkedIn

Prof. Go van Dam, MD, PhD
For fluorescent imaging, physiological and disease related questions.
Mail: go@tracercro.com
Chat on LinkedIn

Famke Van Renesse-Brouwer, MSc
For business related questions.
Mail: famke@tracercro.com
Chat on LinkedIn

Jenny Haan
For clinical trial related questions.
Mail: jenny@tracercro.com
Chat on LinkedIn

Fastest in-human

Let’s get your compound in-human as fast as possible. As a full-service CRO we can simultaneously work on CMC, write necessary study documents, and obtain regulatory approval. First patient-in is possible in 6-9 months!

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