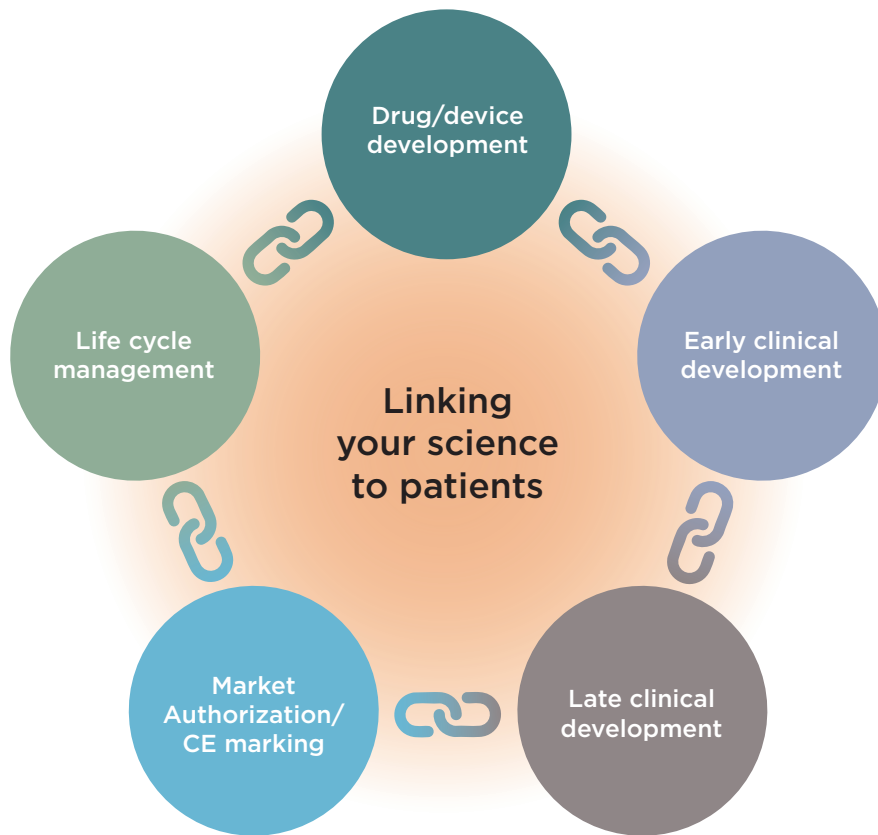




We always work backwards

Because you cannot afford to generate data you do not need - or beautiful answers to the wrong questions. We work backwards to move your project forward. Sustainably.

LINK
M E D I C A L



LINK Medical is with you all the way.
Always linking to the end.

Regulatory – start with the question you will be asked at the end

At the end of development, you will be stuck with a very simple question: *Is this enough?* Enough evidence for approval, for CE marking, for reimbursement, for further funding, or for the next clinical phase? By thoroughly digging into and defining the regulatory end goal (e.g. claims, approval pathway, clinical evidence requirements) from the start, and working backwards, your chances of a future “yes” to this simple question increases.

Working backwards makes regulatory interactions more effective. Scientific advice meetings, interactions with notified bodies and all documentation are planned around what you ultimately need to demonstrate. With 300+ ongoing projects within regulatory, we are reminded daily of the impact that the early choices have, across both drug and device development.

Clinical – start with the question

A clinical study can run perfectly and still answer the wrong question. Defining the claim the study must support might sound easy, yet it represents the main challenge. The right population, endpoints, the statistics foundations, aligned with regulatory and commercial expectations, are derived from that. Backwards planning also keeps patient safety, ethics, CMC, GMP manufacturing and scale-up integrated from the start, not managed retrospectively.

With our own clinical units in Turku and Helsinki, and the way we love to link expertise, clinical development becomes a continuation of development work rather than a handover. Regulatory, CMC, nonclinical, and clinical teams work together, linking phases and people so each study delivers data that answers – the right question.



A strong clinical study begins with a crystal-clear target, says Sharareh Elfversson (Director Clinical Operations), Tahmina Haider (Clinical Project Manager), Hanna Tolf (Group Manager Study Start-Up), and Matilda Knutsson (Senior CRA). Together, our project teams have supported more than 800 clinical trials, including over 100 Phase I and 30 medtech studies. Always linking to the end.





What this means for you;

Clear goals. Fewer surprises.
Linked expertise across phases.

When everything connects, from strategy to execution, you gain a development partner that helps you move forward - by thinking backwards.

Anders Göransson,
CEO of LINK Medical

Pre-clinical – start with clinical

You need to think of the first *clinical* human study, and the decisions after it, to define the *nonclinical* work that truly supports it. Starting from the clinical and regulatory needs, allow preclinical programs (e.g. toxicology, dose selection, pharmacology, PK/PD, formulation, biocompatibility) to be focused, relevant, and defensible.

This backwards logic helps avoid generating tons of data that looks great but cannot be used. It gives you confidence that preclinical evidence will stand up to scrutiny and directly support next steps, whether that is a first-in-human study, a clinical investigation, or a regulatory submission.

Welcome to LINK Medical. Linking your science to patients. Backwards.

LINK Medical is an end-to-end Nordic CRO, drug development, and regulatory partner for biotech, pharmaceutical, and medical device companies, as well as other CROs. Our comprehensive service offering, built on deep expertise and experience, spans early phase drug development through to post marketing support. Founded in 1995, LINK Medical has offices in all Nordic countries, clinical trial units in Finland, and a presence across Europe – linking science to patients. linkmedical.eu

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