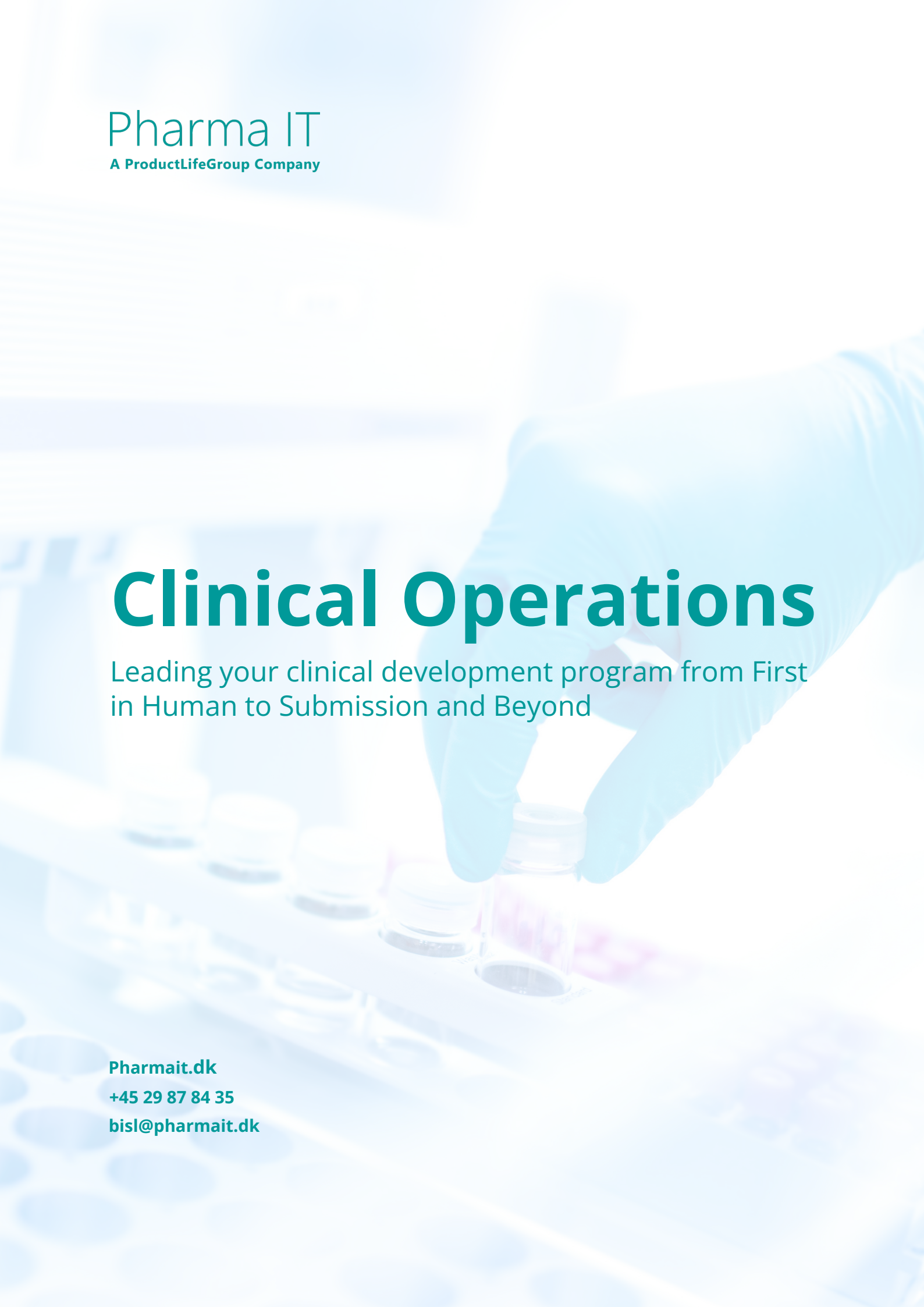
Pharma IT
A ProductLifeGroup Company

Clinical Operations

Leading your clinical development program from First in Human to Submission and Beyond



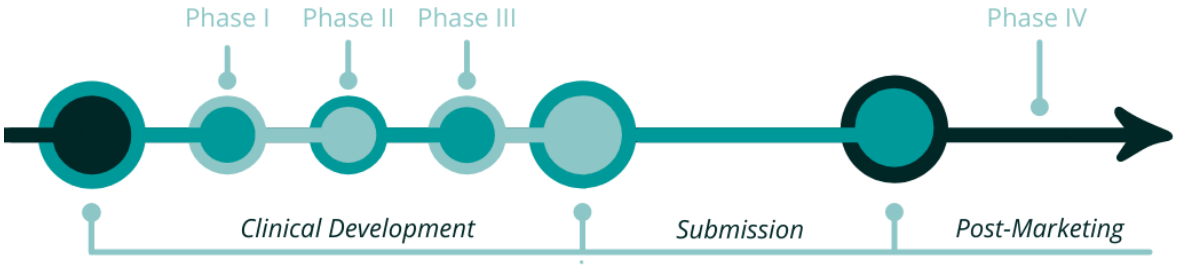
Pharmait.dk
+45 29 87 84 35
bisl@pharmait.dk

We are experts in clinical development

Pharma IT can assist you in leading your clinical development program and global clinical trial conduct - whether your company has chosen an in-house or a partly or fully outsourced solution. Because of our vast experience, we are in a unique position to contribute with specialist perspectives, experience, and advice on your project - all this while ensuring that the tasks at hand get solved and milestones are met.

Birgitte Sloth, MSc, PhD, PdDip
VP of Clinical Operations

At Pharma IT, we are highly experienced in leading and assisting clinical development projects through phase I to IV:



Our services span all phases of clinical drug development from First-in-Man to Post-Marketing:

- Development of Clinical Investigational Plans
- Development of Translational Medicine strategies
- Core Team Support
- Global Clinical Trial Management
- Sponsor Oversight, CRO & Vendor Management
- Development of Clinical Trial Protocols & other Trial Documents

We also offer Functional Support, including cross functional work with other Pharma IT consultants in the following areas:

- Trial Master File set-up and maintenance
- Audit/Inspection preparation
- Drug Safety
- Clinical SOP development
- Medical Writing services
- Data Management services

If you need our assistance, please reach out and let us discuss how we can support your project.

bisl@pharmait.dk

+45 29 87 84 35

Clinical Project Managers

Birgitte Sloth, MSc, PhD, PdDip
VP of Clinical Operations and Principal Pharma Consultant with more than 13 years of experience with Clinical Science and Global Trial Management (Ph I-III) both as Clinical Scientist, Global Trial Manager, Clinical Project Manager and People lead. Experience with multiple different indications and solid experience with early phase clinical development, translational medicine and rare disease indication and regulatory strategy.

Heidi Vestergaard Nielsen, MSc
Principal Pharma Consultant with over 15 years of experience in the global study management. Experience from international studies and teams. Solid experience planning, running, and managing phase I, II, III, and IV clinical trials in multiple indications. This includes protocol development, finalization of the clinical study report and reporting of results, protocol authoring, presenting at investigator meetings, sponsor oversight and management of study teams, vendors and stakeholders.

Louise Davidsen, MSc
Principal Pharma Consultant with 14 years of experience in the pharmaceutical industry working with Clinical Pharmacology trials and late phase trials (II-IV) of different types within numerous indications and populations. Experience from headquarter, affiliates and CROs mainly within Trial Management, but also as a CRA. Solid experience with protocol writing, operational excellence, vendor and trial team management.

Maria Iversen, MSc
Principal Pharma Consultant with 11 years of experience as global trial manager, working with phase I, II, III and IV studies from protocol development to finalization of the clinical study report. Subject matter expert in Lab set up and collaboration, Sponsorship transfer, vendor management and clinical study reports. Experience with multiple indications with key disease areas being oncology and metabolism.

Mette Bredal Kristensen, MSc, PhD
Principal Pharma Consultant with 15 years of experience with clinical research in academia, the pharmaceutical and medical device industry working with projects from idea generation to publication of results. Solid experience with clinical pharmacology trials including first in man studies, CRO oversight, KOL ad board engagement, scientific and medical writing and clinical strategy development.

bisl@pharmait.dk

+45 29 87 84 35

Trine Stougaard, MSc
Principal Pharma Consultant with 15 years of experience with the operational aspects of planning and conducting global clinical phase II-IV trials and non-interventional studies (from idea to publications incl. planning and conduct of Global Expert Panels). Extensive experience with outsourced clinical trials (from contracting to publications), CRO collaboration including CRO oversight, project management and stakeholder management.

Medical Writing

Anne Romstad, Msc, PhD
Principal Pharma Consultant with over 20 years' experience within the pharma industry, working within medical writing, project management, clinical transparency, and safety. Experience from international projects. Strong stakeholder and project management skills. Experience in clinical transparency (HC PRCI, EU CTR, EMA Policy 0043), and in preparing high-quality clinical documents such as clinical study reports, submission documents (for MAA and NDA), AdComm briefing book, and replies to questions from authorities. Experience with safety, both in writing of safety summary documents and as safety surveillance advisor.

Johanna Welch, MSc, PhD
Principal Pharma Consultant with 10 years' experience in Pharma as both a Medical Writer and a Clinical Pharmacology Scientist. Experience in coordinating and preparing high-quality clinical documents such as clinical study reports, submission documents (e.g. MAA/ NDA) and AdComm material. Experienced with early phase clinical trials including protocol authoring, CRO collaboration, oversight and management of study teams, vendors and stakeholders as well as interactions with Health Authorities.

Katja Heinemeier
Principal Pharma Consultant with over 19 years' experience in scientific communication in the pharma industry and academia, both as a scientist and medical writer. Experienced in providing clear written and oral scientific communication and has a solid scientific background within health and medical sciences. Experience in writing both scientific publications and regulatory documents including CTD submission documents, Investigator's Brochures, bridging reports, and clinical study reports. Experience in interpreting, visualising, and presenting scientific data and has a flair for collaboration with people across skill-areas. Experience and focus on use of IT tools for efficient writing and data interpretation.

bisl@pharmait.dk

+45 29 87 84 35

Lena Brahe, MSc, PhD
Principal Consultant with more than 10 years' experience in the pharmaceutical industry and academia working with Medical Writing, Clinical Science and Project Management. Experience with clinical development programmes and regulatory processes. Has driven clinical documents including Clinical Study Protocols, Participant Information/ Informed Consent forms, Investigator's Brochures, Clinical Study Reports, Health Authority Meeting Packages, and CTD Submission Documents, in addition to Scientific Papers.

Lene Sørensen Schmidt, MSc, PhD
Principal Pharma Consultant with over 10 years' experience in the pharma industry, biotech and academia working with clinical reporting, medical communication, and project management. Experienced medical writer with a demonstrated flair for medical communication and leadership on submissions projects. This includes authoring of CSRs, clinical overviews, summary documents, briefing packages for advisory committee meetings, protocols, Investigator's brochures & Health Authority interactions.

CRA and TMF Assistance

Christina Hendrup Obad, MSc
Senior Pharma Consultant with 8 years of experience in the pharma industry working with clinical development and pharmacovigilance. She has administrative and operational experience in planning, conducting and archiving early phase clinical trials including TMF filing and maintenance, trial budget and trial contracting activities and assistance in trial operational oversight and creation of trial related documents. She is also experienced in safety data entry and safety evaluating of clinical and post-marketing serious adverse events cases. Christina has experience from international projects and teams and has strong administrative and operational oversight skills.

Do you want to get in touch?

Call **Birgitte Sloth** at **+45 29 87 84 35**

or write an email to ***bisl@pharmait.dk***

We look forward to hearing from you!

Pharma IT
A ProductLifeGroup Company