Pharma IT
A ProductLifeGroup Company

Clinical Operations & Medical Writing Services

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

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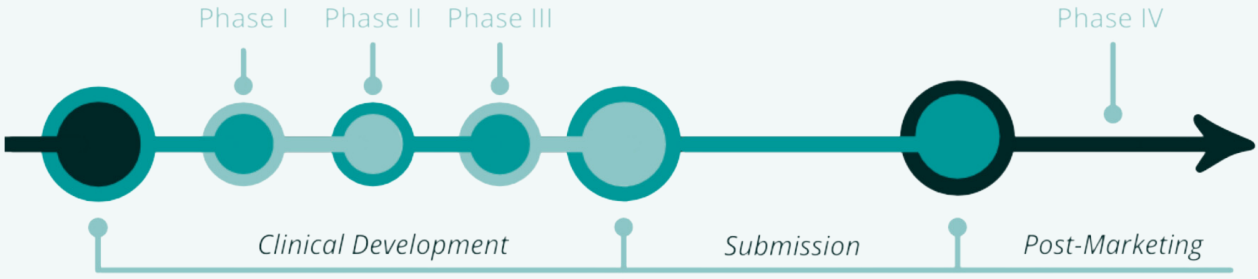
bisl@pharmait.dk

Birgitte Sloth, MSc, PhD, PdDip
CSO Drug Development

We are experts in clinical development

Pharma IT can assist you in shaping 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.

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



Pharma IT has over 100 customers of all sizes. We value all types of assignments from small projects to large enterprise solutions.

You can find an excerpt of our customer roster below

EVAXION · Inphena · Genmab · ALK

ZEVRA THERAPEUTICS · ascendis pharma · LEO · CONTERA PHARMA

Clinical Operations Consulting Offerings

Below you will find a list outlining an excerpt of the services that Pharma IT's Clinical Operations department offers. If you need assistance with any of these tasks, or other clinical-related work, do not hesitate to reach out.
We can create a tailored solution to meet your needs.

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

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

Medical Writing Services

Our proficient Medical Writers boast extensive expertise with authoring clinical trial documents such as:

- CTD Submission Documents
- HA Meeting Packages and Communication
- Clinical Study Reports
- Clinical Trial Protocols, and related documents
- Investigators Brochure
- Scientific Publication
- Aggregated Safety Reports

Our Medical Writers are experienced in taking the leadership for submission projects, and aligning stakeholder's input to various documents

Looking for a service that isn't listed? Or for cross-functional support?

This list is non-exhaustive. Reach out to our team about any additional needs, or support services.

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Clinical Project Managers

Birgitte Sloth, MSc, PhD, PdDip

VP of Clinical Operations and Principal Pharma Consultant with more than 20 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 17 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 14 years of experience as a global trial manager, working with phase I, II, III and IV studies from protocol development to finalization of the clinical study report.
Maria has worked as a project manager, providing strategic input to implementation of EU Clinical Trial Regulation. She collaborated across departments to pinpoint crucial decisions and milestones, facilitated updates to existing processes, and provided training to Subject Matter Experts.

Mette Bredal Kristensen, MSc, PhD

Principal Pharma Consultant with 20 years of experience with clinical research in academia, the pharmaceutical and medical device industry working with projects from idea generation to publication of results. Experienced with all phases of clinical trials, including clinical pharmacology trials. Solid experience with CRO oversight, KOL, and ad Board engagement, as well as clinical strategy development and scientific and medical writing.

Trine Stougaard, MSc

Principal Pharma Consultant with over 17 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 22 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 12 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, MSc, PhD

Principal Pharma Consultant with over 21 years' experience in the pharma industry and academia, both as a scientist and medical writer. Experienced in providing clear written and oral scientific communication. 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. Experienced in collaboration across skill-areas. Utilizes IT tools for efficient writing and data interpretation.

Lena Brahe, MSc, PhD

Principal Consultant with more than 10 years' experience in the pharma 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 20+ 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.

Rasmus Høigaard Nielsen, MSc, PhD

Principal Pharma Consultant with 12 years' experience in the pharma industry, including CRO Research and Clinical Development. Specializes in Regulatory and Safety Medical Writing. Brings experience from two complete BLAs/MAAs, including Clinical Summaries/Overviews, pre-approval Q&A, Briefing Books, and FDA Advisory Committee meetings. Expertise in phase III and IV Clinical Study Reports, Investigator's Brochures, protocols, layman summaries, and other clinical lifecycle 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
- Regulatory Affairs
- Data Management services

Looking for a profile that isn't featured? Or for cross-functional support?

This list is non-exhaustive, and does not include our extensive freelancer network. Reach out to our team about any additional needs, or support services.

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Want to get in touch?

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