

Do you need a manager...

- ... with team leadership competency? ?*
- ... able to manage the team without solid-line authority? ?*
- ... able to build and implement a communication plan? ?*
- ... able to manage the quality of project deliverables? ?*
- ... skilled in risk identification and analysis? ?*
- ... skilled in negotiation and conflict management? ?*

We take care that your projects...

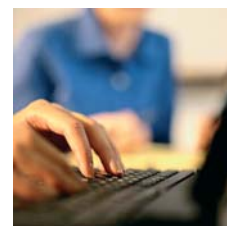
- ... comply with good clinical practice and international regulations*
- ... follow project-specific operating procedures*
- ... remain within your budget*
- ... keep to your timelines*
- ... maintain the highest quality*

As your single port of call, the Accovion project manager will enable you to streamline your work and reduce your own management workload. You can rely on the project manager to take care of all issues arising throughout the project, to supervise and manage the team, and to ensure optimal conduct and closure of the project. With your needs in focus, the project manager will maintain quality within the framework of your project plan and budget. Our regular project status reports allow you to monitor our work and assess project progress.

Our team training, not only at project start-up but also throughout the project's life cycle will ensure that new regulations and guidelines will be promptly taken on board.

Our project managers and study coordinators have extensive experience of large multinational project teams in all major therapeutic areas. Many possess higher qualifications as MDs, PhDs and MScs, and have worked in the research-based pharmaceutical industry as well as in the CRO environment.

**Our project managers
are backed up by
ACCOVION clinical teams
that include our highly
experienced study
coordinators.**



Our services include

- ✓ Project planning and tracking
- ✓ Resource management
- ✓ Quality management
- ✓ Time and budget management
- ✓ Resolution of time and resource conflicts
- ✓ Contingency planning and problem resolution
- ✓ Documentation of all activities, responsibilities, issues arising and actions taken
- ✓ Project status reports
- ✓ Development and implementation of project policies and procedures
- ✓ Team training

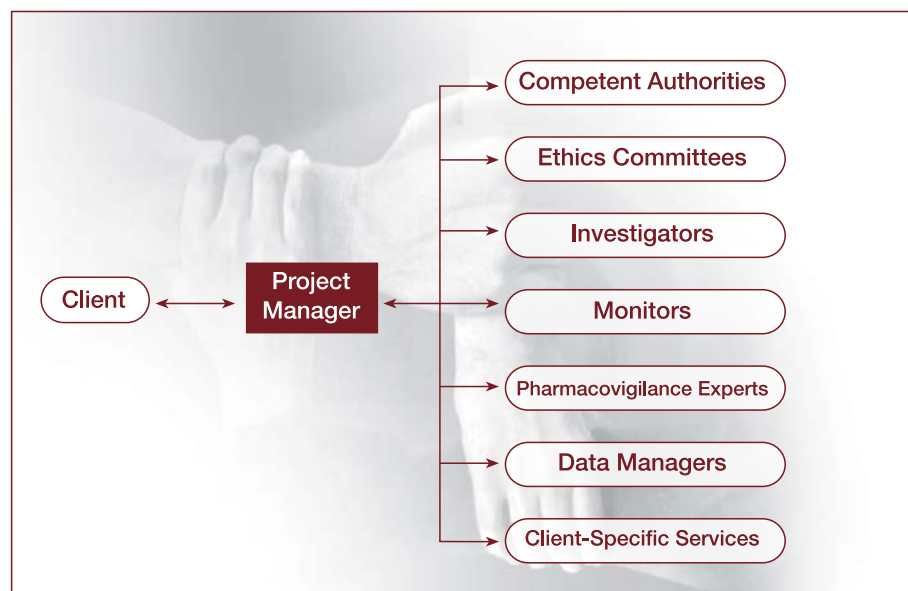
With up to thirty years of experience in clinical development, our project managers and study coordinators will accompany the project from start to finish, ensuring:

- ✓ Development of study start-up documents
- ✓ Coordinated submissions to regulatory authorities, ethics committees and institutional review boards
- ✓ Maintenance of the trial master file
- ✓ Availability and distribution of study drugs and other study materials
- ✓ Organization of central laboratories
- ✓ Application of randomization procedures
- ✓ Set-up of independent data monitoring committees, data safety monitoring boards and other committees
- ✓ Regular medical review
- ✓ Quality monitoring
- ✓ Ongoing team training
- ✓ Organization and conduct of investigator, monitor and team meetings

We use state-of-the art project management techniques, tools and databases:

- ✓ Clintrial® and Oracle Clinical® for data management reports
- ✓ Impact® and other project management tools
- ✓ Trial master file database
- ✓ Monitor database
- ✓ Investigator database
- ✓ Investigator payment database

Our teams ensure state-of-the-art knowledge and optimum quality across projects.



Our ACCOVION expert teams assure that we comply with all regulatory requirements, providing baseline process definitions and operating procedures that the project team can adapt to project-specific requirements



Regulatory affairs expert team

- ✓ European guidelines and regulations
- ✓ US guidelines and requirements
- ✓ Other country-specific guidelines and requirements
- ✓ Our European Door Opener service*

Trial master file expert team

- ✓ General filing plan and study-specific filing plan
- ✓ ACCOVION's trial master file database
- ✓ Documentation check list and guide

Study coordination team

- ✓ Drug supplies
- ✓ Central laboratories
- ✓ Project tracking

OUR SERVICES

- ✓ Project Management
- ✓ Study Operations
- ✓ Clinical Monitoring
- ✓ OSMO – Oncology Site Management Organisation
- ✓ Pharmacovigilance
- ✓ Health Outcomes Research
- ✓ Medical Writing
- ✓ Document Management
- ✓ Electronic Publishing
- ✓ Biostatistics
- ✓ Statistical Programming
- ✓ Data Management
- ✓ Information Technology
- ✓ Quality Assurance



* The ACCOVION EUROPEAN DOOR OPENER is a modular service designed to support small and medium-sized pharmaceutical and biotech companies when preparing and planning their European clinical trials. For further information, you can contact our specialists at europeandooropener@accovion.com

Contact us to learn more about our Clinical Project Management!

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