

Project Management

Study Operations

OSMO – Oncology Site Management Organisation

Pharmacovigilance

Health Outcomes Research

Medical Writing

Document Management

Electronic Publishing

Biostatistics

Statistical Programming

Data Management

Information Technology

Quality Assurance

CLINICAL MONITORING

- ✓ **Verifying rights and well-being of study subjects**
- ✓ **Committed to your protocol, GCP and regulatory requirements**
- ✓ **Focused on your enrollment rates and timelines**
- ✓ **Dedicated to the timely collection of accurate data**

ACCOVION

Do you need...

- *experienced and well-trained clinical monitors with excellent communication and reporting skills* ?
- *quality-committed clinical monitors paying conscious attention to securing the value of clinical and safety data* ?
- *reliable and responsible clinical monitors and study managers supervising subject recruitment and study conduct* ?
- *access to a worldwide-wide distributed monitoring network coordinated by highly-qualified study managers* ?
- *access to qualified and motivated investigational sites dedicated to recruitment and study requirements* ?



ACCOVION has a core team of clinical monitors that provides both clinical monitoring and study management services. Members of the core monitoring team are medical documentation specialists, graduates in the natural sciences or medical doctors. They have many years of proven clinical experience and have worked on many trials from small, national phase I trials to international phase II-IV megatrials in various indications. Their experience in study coordination and data cleaning facilitates cooperation and workflow with study sites and within the whole study team.

The ACCOVION core team is supported by a well-selected and controlled network of partner CROs and freelancers.

ACCOVION's access to thousands of clinical physicians worldwide guarantees fast feasibility results and selection of the most appropriate investigational sites committed to study-specific enrollment rates.

✓ The ACCOVION Approach to Clinical Monitoring

ACCOVION clinical monitors are subject to a well-defined selection process considering personal and language skills, background, experience and training records.

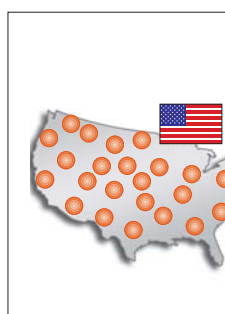
ACCOVION's **extensive training program** ensures adherence to

- ✓ Declaration of Helsinki
- ✓ Good clinical practice (GCP)
- ✓ Country-specific regulatory requirements
- ✓ Study-specific requirements (protocol, standard operating procedures (SOPs), indication etc)

Study managers provide comprehensive guidance and support to clinical monitors and perform **ongoing quality control steps**. ACCOVION guarantees highest standards of quality by

- ✓ Following communication lines within the study team
- ✓ Reviewing incoming essential documents, monitoring reports and CRFs
- ✓ Closely monitoring subject recruitment, study conduct and adverse event reporting
- ✓ Controlling adherence to protocol, SOPs, guidelines and regulations
- ✓ Promptly and properly reporting study status and issues to the sponsor

www.accovion.com



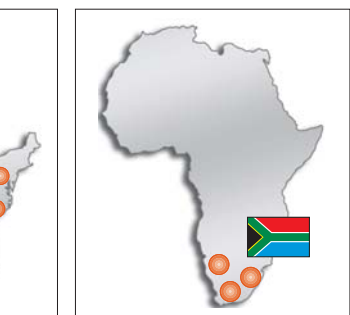
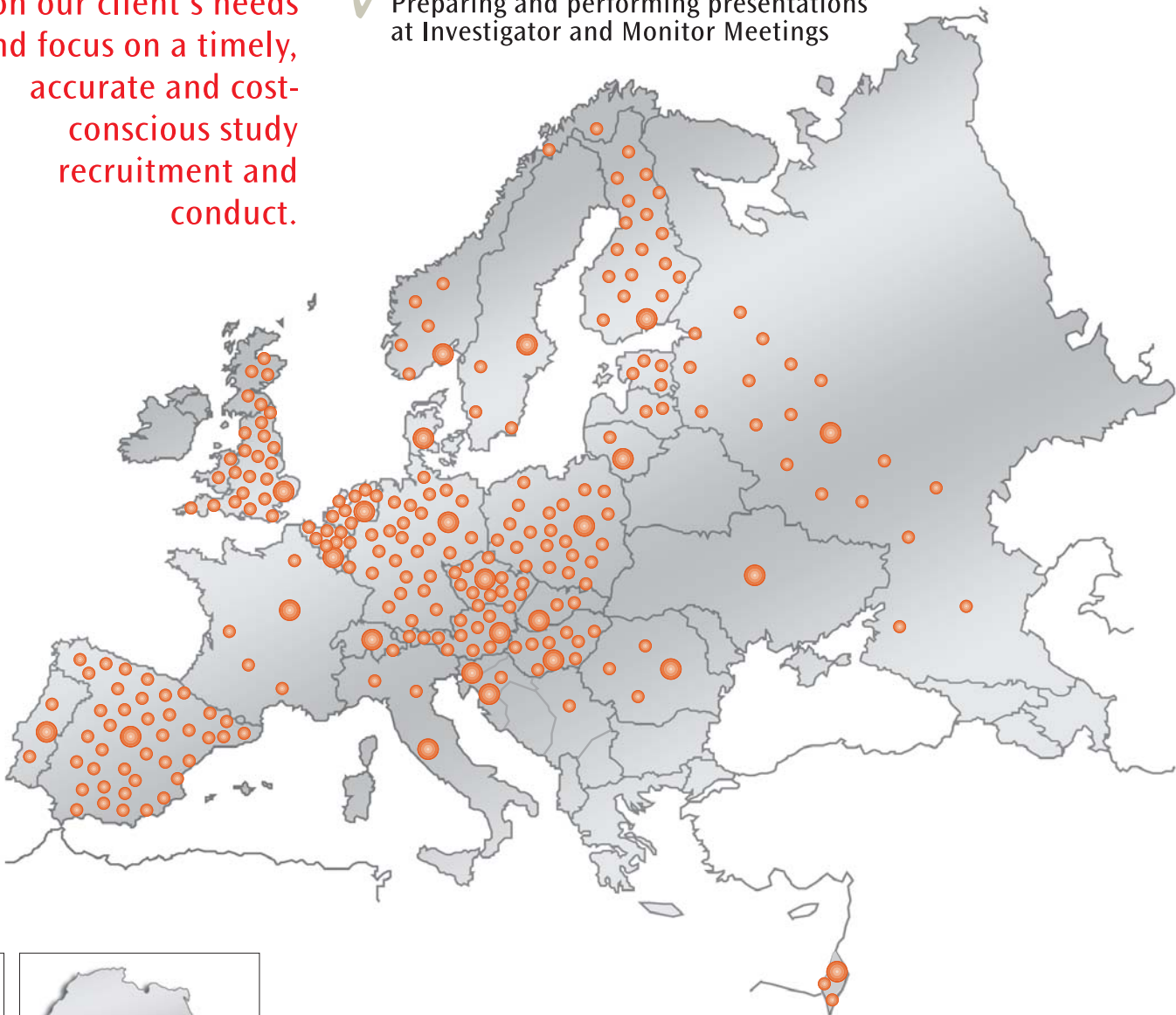
✓ ACCOVION Clinical Monitoring Services

- ✓ Feasibility studies
- ✓ Site identification and investigator recruitment
- ✓ Collection of essential and regulatory documents
- ✓ Ethics committee and regulatory authority submissions
- ✓ Investigator Site File compilation and review
- ✓ Translation of study-specific documents including quality check
- ✓ On-site visits according to GCP
- ✓ Site Management (telephone monitoring)
- ✓ Supporting study logistics
- ✓ Coordination of on-site audits and inspections
- ✓ Preparing and performing presentations at Investigator and Monitor Meetings

*Pre-study visits
Initiation visits
Monitoring visits
Close-out visits
Co-monitoring visits*



ACCOVION's clinical monitors and study managers concentrate on our client's needs and focus on a timely, accurate and cost-conscious study recruitment and conduct.



ACCOVION has a core team of clinical monitors in Germany, France and Poland and offers an extended monitoring network of well-selected partner CROs and more than 200 freelancers encompassing 31 countries worldwide. ACCOVION's dedicated professionals are located in Western, Central and Eastern Europe, USA, Israel, and South Africa.



We understand that strong interactive skills such as clarification of information, mediating disputes, problem solving and gaining trust of third parties can make an important difference to the results achieved in a clinical trial.

One central “window person” is appointed as the main contact for the sponsor and guarantees smooth integration of the ACCOVION study team into the sponsor’s team structure.

In addition, ACCOVION offers local or overall project management services with people highly experienced in defining, coordinating and supervising the cross-functional study team and study processes.

ACCOVION’s integrated approach ensures local knowledge and presence for a smooth study start-up, well-controlled subject recruitment and proper study conduct, while adherence to proven processes and SOPs facilitates the collection of clean data according to the sponsor’s requirements and timelines.



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

Contact us and find out how we can support you with clinical monitoring services.

ACCOVION GmbH
 Helfmann-Park 10
 D-65760 Eschborn
 Germany
 Phone: + 49 6196 7709-0
 Fax: + 49 6196 7709-120

ACCOVION. Global reach. Personal touch.

www.accovion.com

Visit us to learn more about our services.

ACCOVION