

Forschungsdock CRO GmbH

WWW.FORSCHUNGSDOCK.COM

WHO WE ARE

A Contract Research Organisation (CRO) that helps

- Biotech,
- Medtech,
- Small Pharma and
- Sponsor-Investigators

plan, conduct and report their clinical studies.



Company History



2011

Founded in January

2017

FD GmbH

2021

BVMA Member

2023

FD CRO GmbH

2026

Continuing growth

OUR CORE TEAM

Sandra Woller
Senior Project Manager

Dr. Doris Greiling
Clinical Development Expert

Dr. Christoph Ortland
Founder & CEO

Dr. Antje Dahlen
Senior Quality Manager & GCP Auditor



Our Services



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OUR FOCUS IS GOOD CLINICAL PRACTICE

- Full Study Management
- Sponsor Oversight
- Quality Management
- Consulting
- GCP Training



Our Focus is GOOD CLINICAL PRACTICE

FULL STUDY MANAGEMENT



Complete trial management from protocol to CSR. We handle every operational step needed to set up, execute, and deliver your study.

SPONSOR OVERSIGHT



Senior project management to oversee your CRO—without additional headcount. We ensure you stay actively involved and make critical decisions.

QUALITY MANAGEMENT



Quality embedded from Day 1, not reactive issue fixing. Auditor-built systems that prevent findings instead of documenting them.

CONSULTING

Strategic advisory for vendor selection, quality systems, and operational planning. Pragmatic, hands-on guidance from experienced consultants when you need it.

GCP TRAINING



GCP and best practice training that builds competence, not just completion rates. Practical, role-specific training from auditors.

FULL STUDY MANAGEMENT

Complete Clinical Trial Management, End to End

We manage every stage of your clinical trial, from planning to close-out. Whether you're launching a pilot or running a multi-center study, we act as your operational backbone—so you can focus on strategy and science.



END-TO-END MANAGEMENT

From Planning to Closeout

Planning



Study design support, protocol development, vendor selection, timeline and budget development, risk assessment

Documentation



Protocol and ICF development, eTMF Set-up and maintenance, ISF and site documentation, operational plans

Submissions



Regulatory authority and ethics committee submissions, document preparation, RFI management, approval tracking

Coordination



Site identification & activation, clinical monitoring, investigator communication, vendor management, cross-functional alignment

END-TO-END MANAGEMENT

From Planning to Closeout

Data Management and Statistics

Planning, setup, management and analyses together with our established and experienced business partners

Alignment

Stakeholder communication, sponsor-site-CRO coordination, meeting facilitation, expectation management

Management

Ongoing study management, issue identification and resolution, timeline and budget tracking, clinical monitoring, reporting

Reporting

Reporting according to regulatory requirements, manuscript development, publication of study results

YOUR STUDY ADVANTAGE

Accountability, Clarity, Results

Clear Accountability

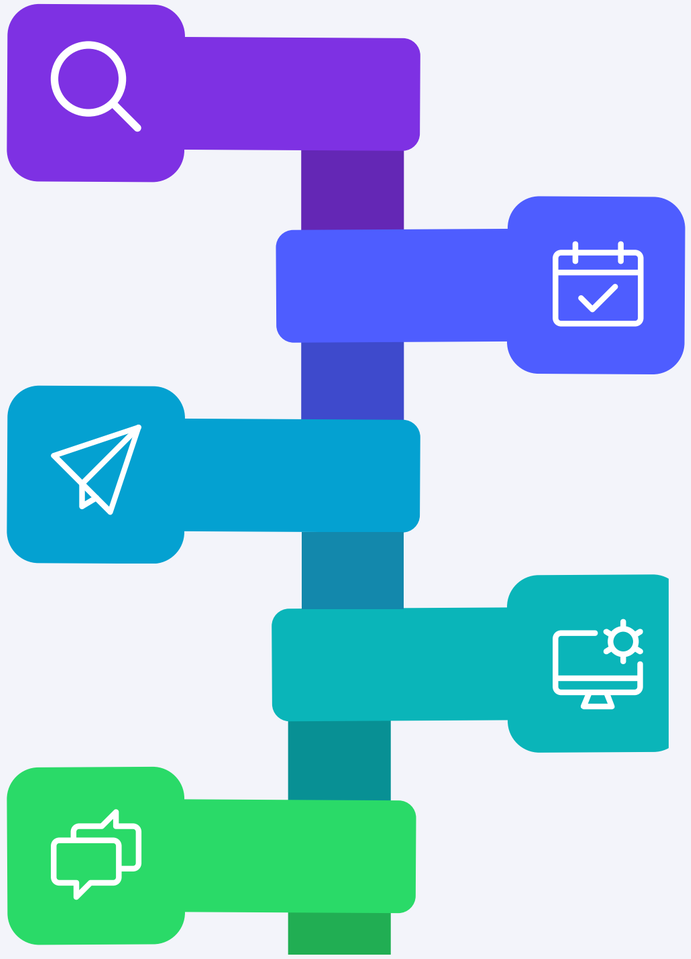
Single point of accountability

Seamless Execution

Seamless coordination across functions

Real Compliance

Real-world GCP enforcement—not just box-checking



Full Visibility

Full transparency, structured reporting

Dual Expertise

Team with CRO and Sponsor-side experience

SPONSOR OVERSIGHT

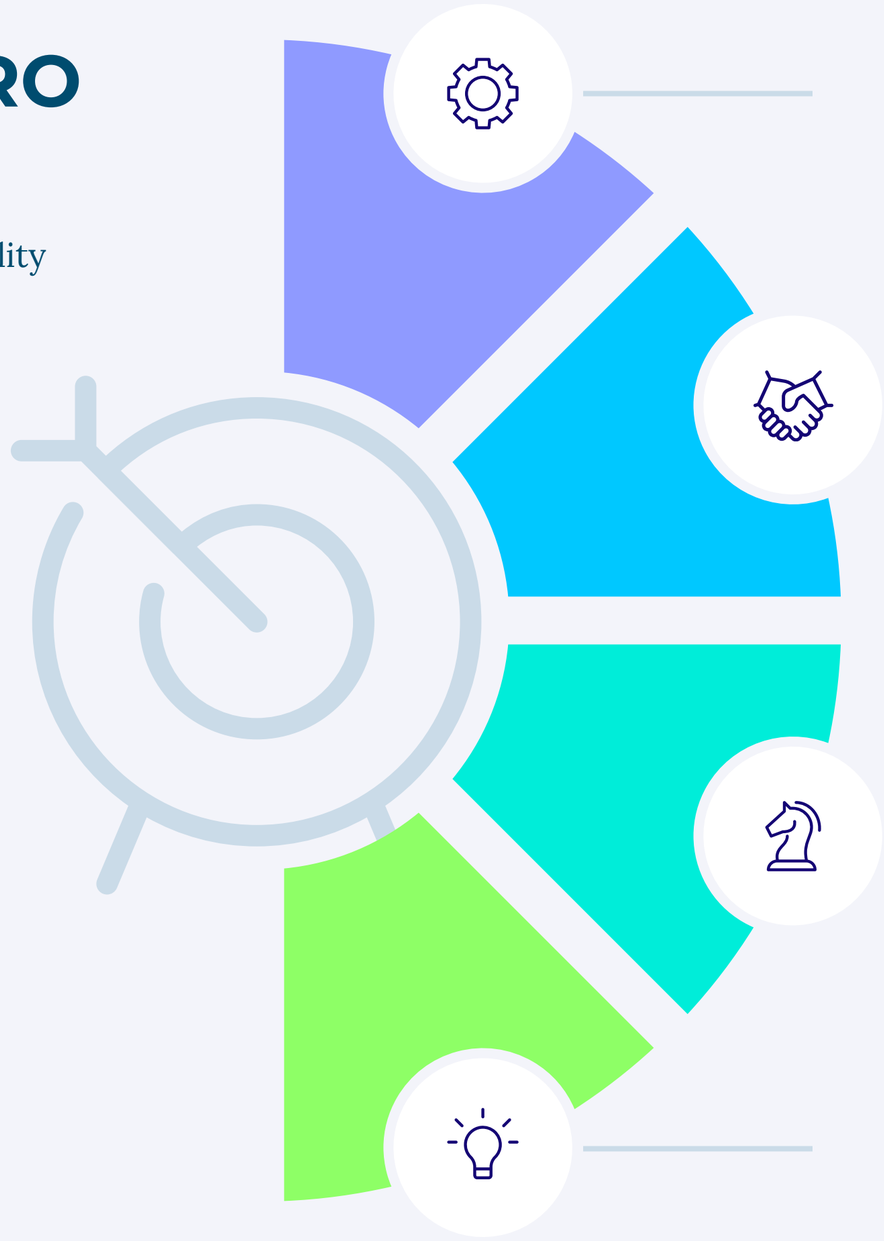
Oversight Without Overload

We help lean sponsor teams maintain true oversight over large CROs in local and global trials. From KPIs to escalation paths, we ensure you meet regulatory expectations and stay in control.



Strategic CRO Oversight

Control, Metrics, Accountability



Selection

CRO selection, support of bid defense and qualification measures

Management

Sponsor PM support and process consulting

Review

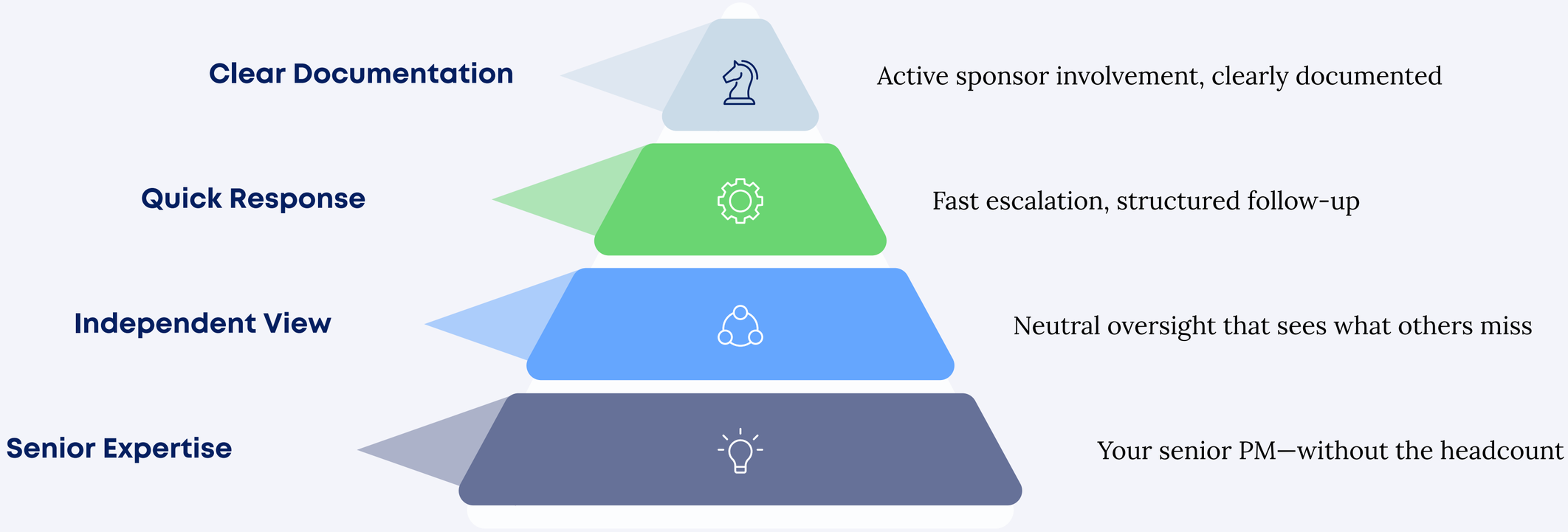
Review of service provider output

Documentation

Ensure documentation of active sponsor involvement

YOUR OVERSIGHT ADVANTAGE

Control, Insight, Management



QUALITY MANAGEMENT

Quality That Starts Before the Audit or Inspection

We embed quality into your organization and your clinical study from Day 1. Our approach ensures compliance without chaos—so you're always inspection-ready, not inspection-worried.



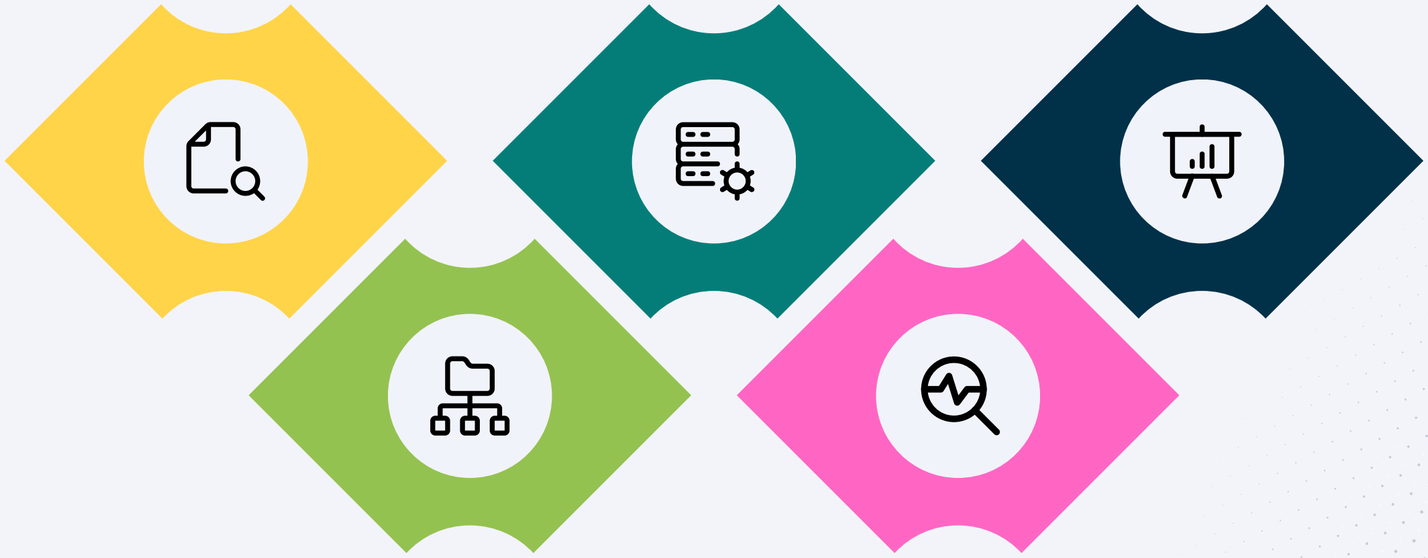
PROACTIVE QUALITY SYSTEMS

Prevention Over Documentation

Quality oversight plans and documentation

TMF readiness checks and QC support

Risk-based quality reviews



Service Provider and site quality assessments

Audit preparation, conduct, reporting and CAPA tracking

YOUR QUALITY ADVANTAGE

Compliance, Confidence, Readiness

Audit Confidence

Inspection-ready before the notice arrives.

Early Detection

Systems aligned to ICH E6(R3), Reg (EU) No. 536/2014, ISO 14155, Reg. (EU) 2017/745, ISO 13485

Early Detection

External perspective that sees the gaps early

Scalable Systems

Practical, scalable quality systems

CONSULTING

Expert Guidance When You Need It

Strategic advisory and hands-on support without long-term commitments. From vendor selection to quality system design to GCP training—we provide on-demand expertise to solve your specific operational challenges.



Strategic Advisory for Critical Decisions

Expertise, Flexibility, Results



Vendor Selection & Management

CRO evaluation and selection support, proposal assessment, vendor qualification frameworks, oversight planning

Quality Management Systems

QMS gap analysis, SOP development roadmaps, audit preparation, inspection readiness reviews

Risk Management & Planning

Risk assessment frameworks, risk-based monitoring plans, study feasibility reviews, contingency planning

GCP Training & Development

Role-specific GCP training, practical scenario-based sessions, auditor-led workshops for sponsors and sites

Your Consulting Advantage

Expertise, Independence, Flexibility

Flexible Engagement

On-demand support without full-service commitments or long-term contracts

Senior Expertise

180+ years combined experience with sponsor-side and CRO-side perspectives

Practical Solutions

Advice grounded in operational reality, not theoretical compliance

Independent Perspective

Objective guidance on vendor selection and operational decisions





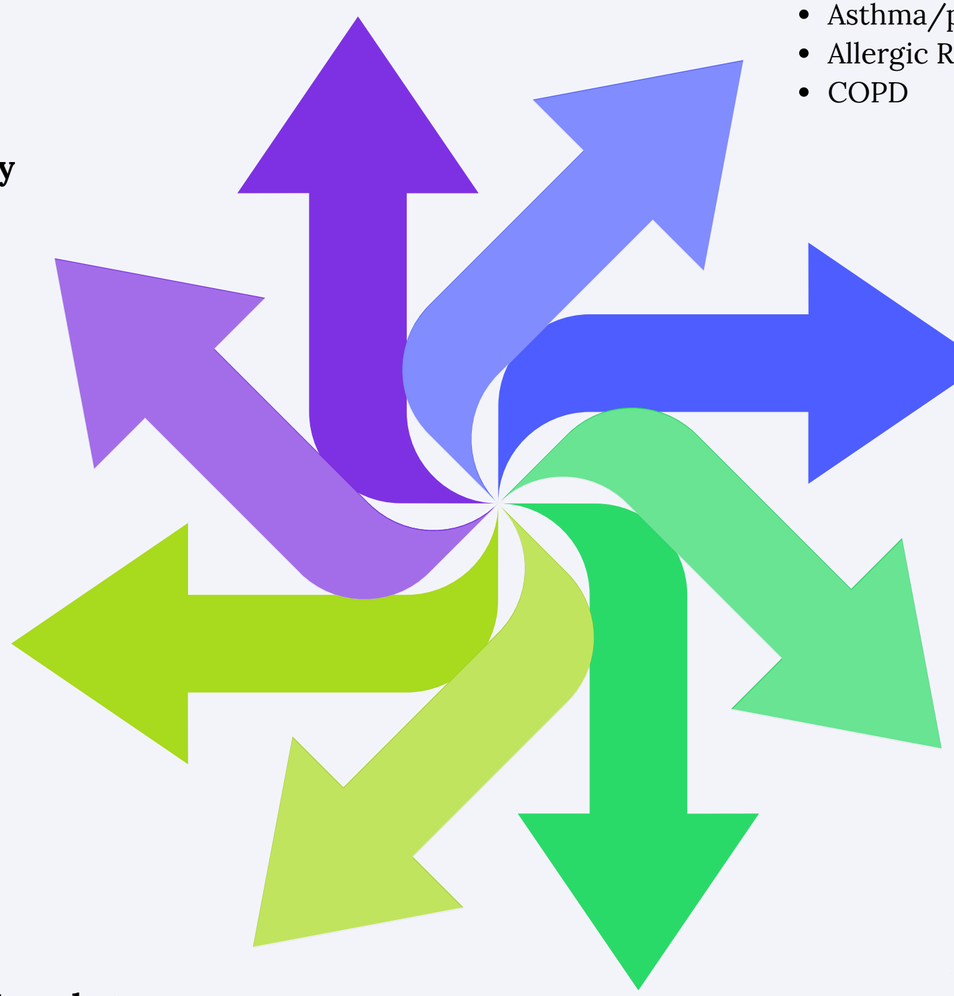
Our Experience

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Ophthalmology
- Macula degeneration

Respiratory
- Asthma/paediatric Asthma
- Allergic Rhinitis
- COPD

Lymphology and Phlebology
- Lymphoedema
- Lipoedema
- DVT Prophylaxis
- Wound management
- Ulcus cruris



Dermatology
- Psoriasis
- NMSC (AK, BCC)
- Acne vulgaris
- Atopic dermatitis
- Rosacea

Oncology
- Mamma carcinoma
- Non-small lung cancer (NMSC)
- Glioblastoma

ENT
- Acute hearing loss

Neurology
- Alzheimer
- Neuropathic pain
- Depression

Diabetes



Thank you

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