



Forschungsdock CRO GmbH

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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

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 TEAM



Dr. Margret I. Moré
Principal Medical Writer



Kirstin Steffen
Clinical Monitoring Manager



Christian Hilgenstock
Senior Quality Manager



Dr. Cornelia Breuer
Project & Quality Manager



Ritika Jain
Clinical Trial Assistant



Sebastian Liebender
IT Manager



Rüdiger Brandt
Office Manager



Our Services

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OUR FOCUS IS GOOD CLINICAL PRACTICE

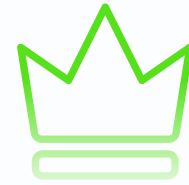


- Full Study Management
- Sponsor Oversight
- Quality Management
- Consulting
- GCP Training



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



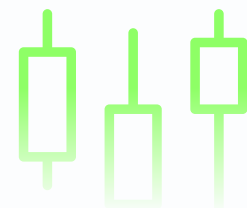
Senior project management to oversee your CRO—without additional headcount. We ensure you stay actively involved and make critical decisions.

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

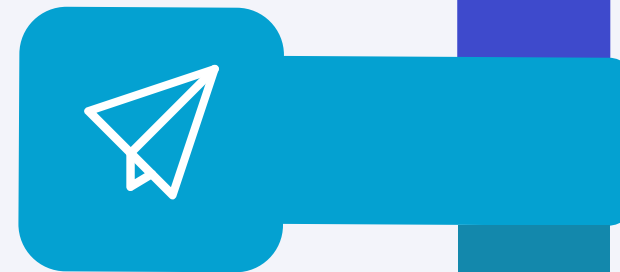
Clear Accountability

Single point of accountability



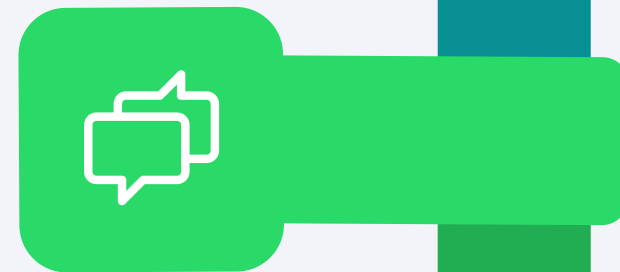
Seamless Execution

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



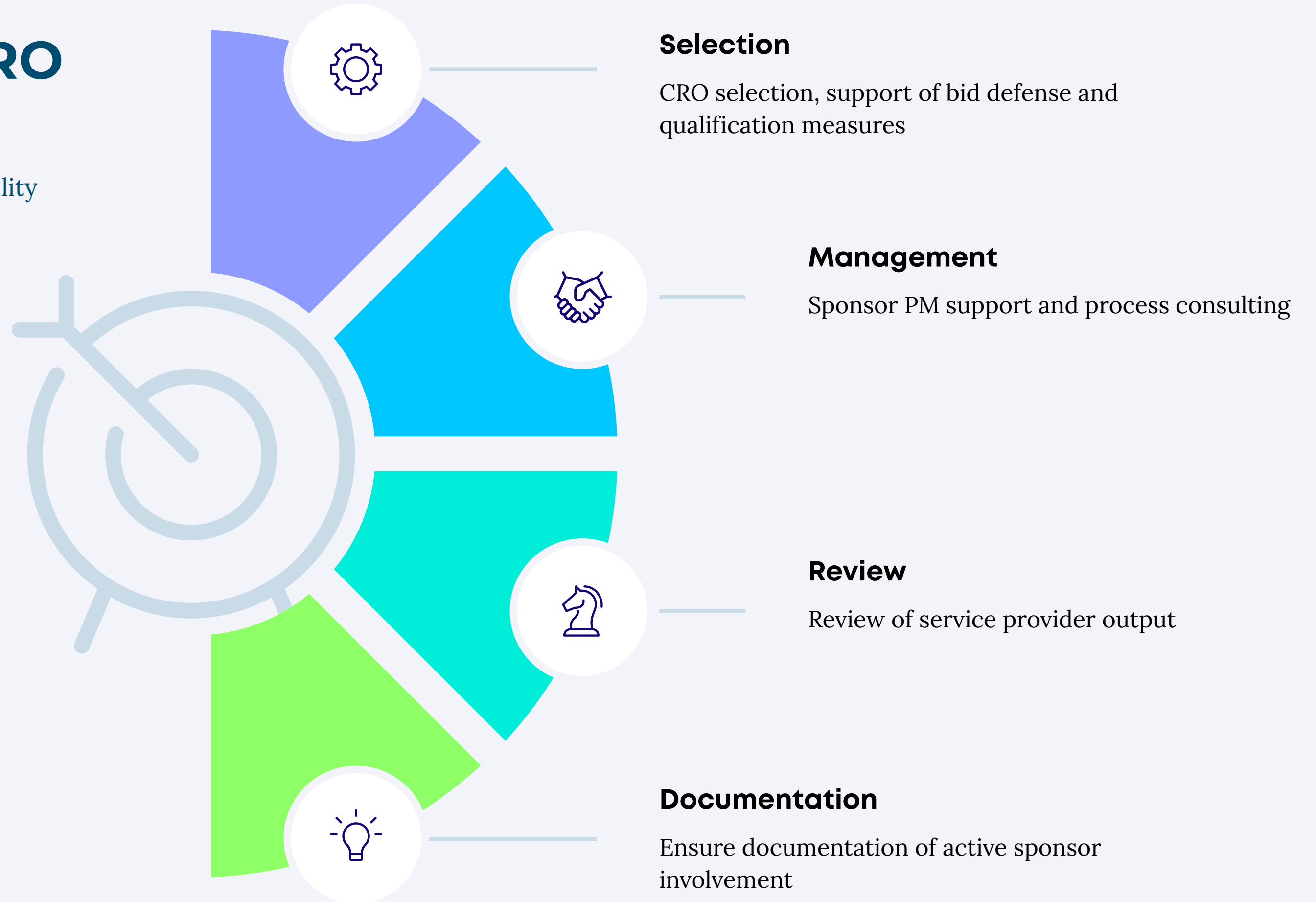
Oversight Without Overload

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.



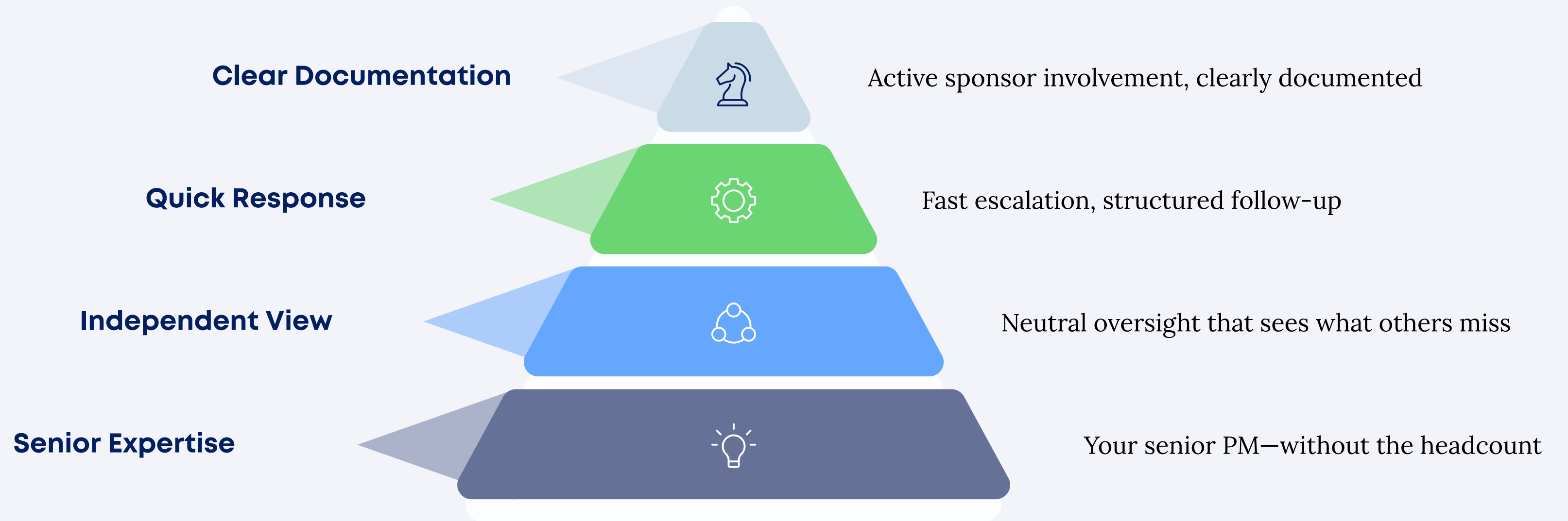
Strategic CRO Oversight

Control, Metrics, Accountability



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

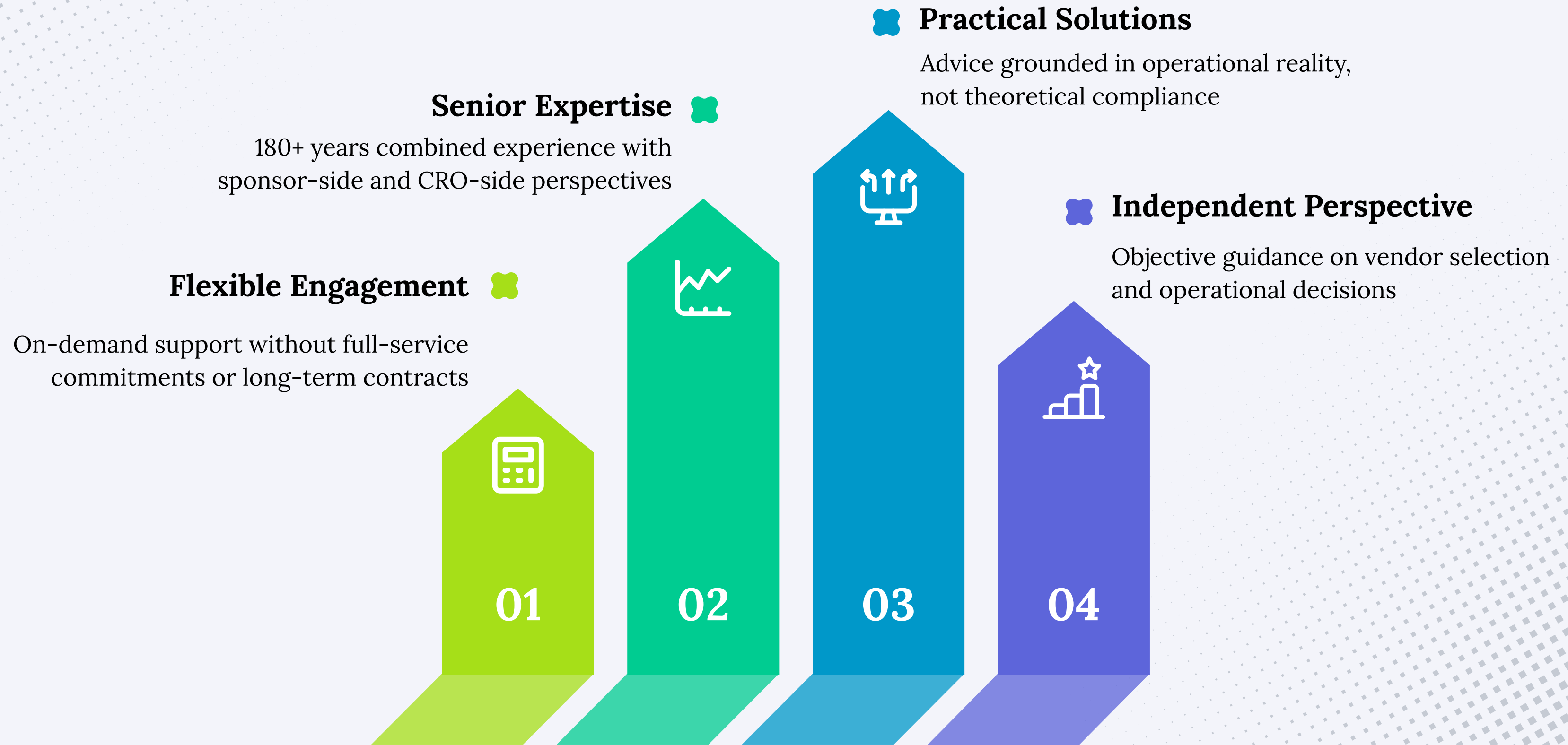
GCP Training & Development

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



Your Consulting Advantage

Expertise, Independence, Flexibility





Our Experience

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Ophthalmology

- Macula degeneration

Respiratory

- Asthma/paediatic 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

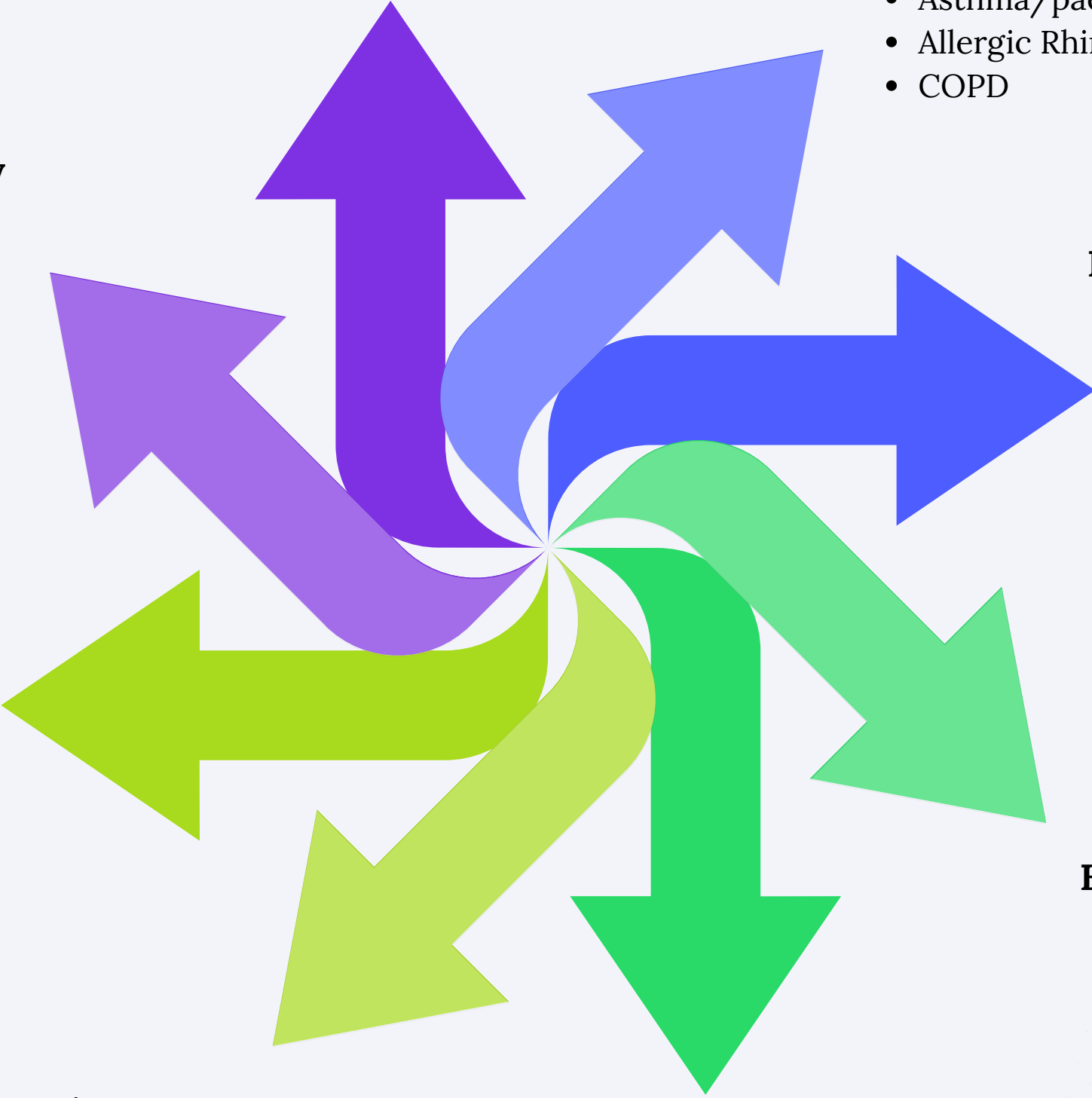
ENT

- Acute hearing loss

Neurology

- Alzheimer
- Neuropathic pain
- Depression

Diabetes



A group of five business professionals (three men and two women) are gathered around a table, engaged in a meeting. They are looking at a laptop and some papers. The scene is overlaid with a semi-transparent blue grid pattern. The text 'Thank you' is prominently displayed in the center.

Thank you

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