GOUYA INSIGHTS

CLINICAL DEVELOPMENT

Expert Clinical Consultancy and Operational Services for Innovative Solutions

www.gouya-insights.com

Welcome to GOUYA INSIGHTS

Your Strategic Clinical Development Partners

GOUYA INSIGHTS
Clinical Development

55+
CLIENTS

70+
PROJECTS

15+
COUNTRIES

Empowering your journey from concept to market with strategic guidance and innovative, tailored solutions.

OUR MISSION

Accelerating your success through expert consultancy and comprehensive services.

With deep industry knowledge and a proven track record, we are **your trusted partner** in navigating drug and device development complexities.

WHAT WE OFFER

From enhancing regulatory strategy and optimizing clinical trials to ensuring market access, **we support you every step of the way.**

Dedicated to delivering value and driving impactful results for our clients.

Who We Are

GOUYA INSIGHTS
Clinical Development

Established, Expert-Driven Clinical Development Consultancy

Offering extensive experience and deep domain expertise in guiding clients through complex clinical development and regulatory processes.

Deep Specialization

Specialized in regulatory strategy, early clinical development, and adaptive trial design, providing tailored solutions to meet the unique needs of our clients.

Serving Biotech, Pharmaceutical, and Medical Device Innovators

Partnering with a diverse range of industry leaders across Europe and beyond, helping to bridge the gap between scientific vision and regulatory execution.

Trusted Partner

Earning the trust of our clients through our unwavering commitment to delivering exceptional results and navigating the complexities of the regulatory landscape.

Clinical Development & Regulatory Expertise

GOUYA INSIGHTS

End-to-end clinical strategy development

Comprehensive approach to clinical trial planning and execution, from initial target product profile to regulatory submission

Target Product Profile (TPP) and Clinical Development Plans tailored to regulatory pathways

Customized strategies to navigate complex regulatory environments and accelerate development timelines

Strong track record with EMA, FDA, and national agencies (scientific advice, INDs, CTAs)

Proven expertise in engaging with global regulatory authorities to secure approvals and streamline the development process

Accelerated approval pathways: Fast Track, Breakthrough Designation, Orphan Drug support

We develop tailored strategies to efficiently navigate the development and approval process, optimizing timelines and increasing the chance for success

Positioned at the Heart of Biotechnology Innovation

Proven impact for clients transitioning from preclinical to clinical stages

- Supporting first-in-human, proof-of-concept, and accelerated development programs
- Strong reputation in high-growth therapeutic areas and innovative product classes (e.g., mAbs, personalized treatments)
- Proven impact for clients transitioning from preclinical to clinical stages

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Clinical Development

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12/2016

2017
Clinical development strategy and biostatistical support in study design

2018
Clinical and Regulatory Expertise
Medicinal Product and Medical Device

2019
Pharmacovigilance
Risk Management
Quality Management

2020
Data Management
Geographical expansion of clients in EU and US

2021
New office in 1190 Vienna
Automation in data review and data visualization

2022-2023
Growth in MD and IVD Expertise
Regulatory market access strategy for Biotechnology companies

2026
Continuous geographic market expansion

ACCELERATOR Program

Strategic partnerships with Innovation Hubs

GOUYA INSIGHTS: **Key Areas of Expertise**

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Clinical Development

Expertise supporting funding strategy

STRATEGIC CONSULTANCY

- Regulatory planning
- Milestone planning (Value points)
- Market access strategies

Clinical stage enabling

OPERATIONAL CONSULTANCY

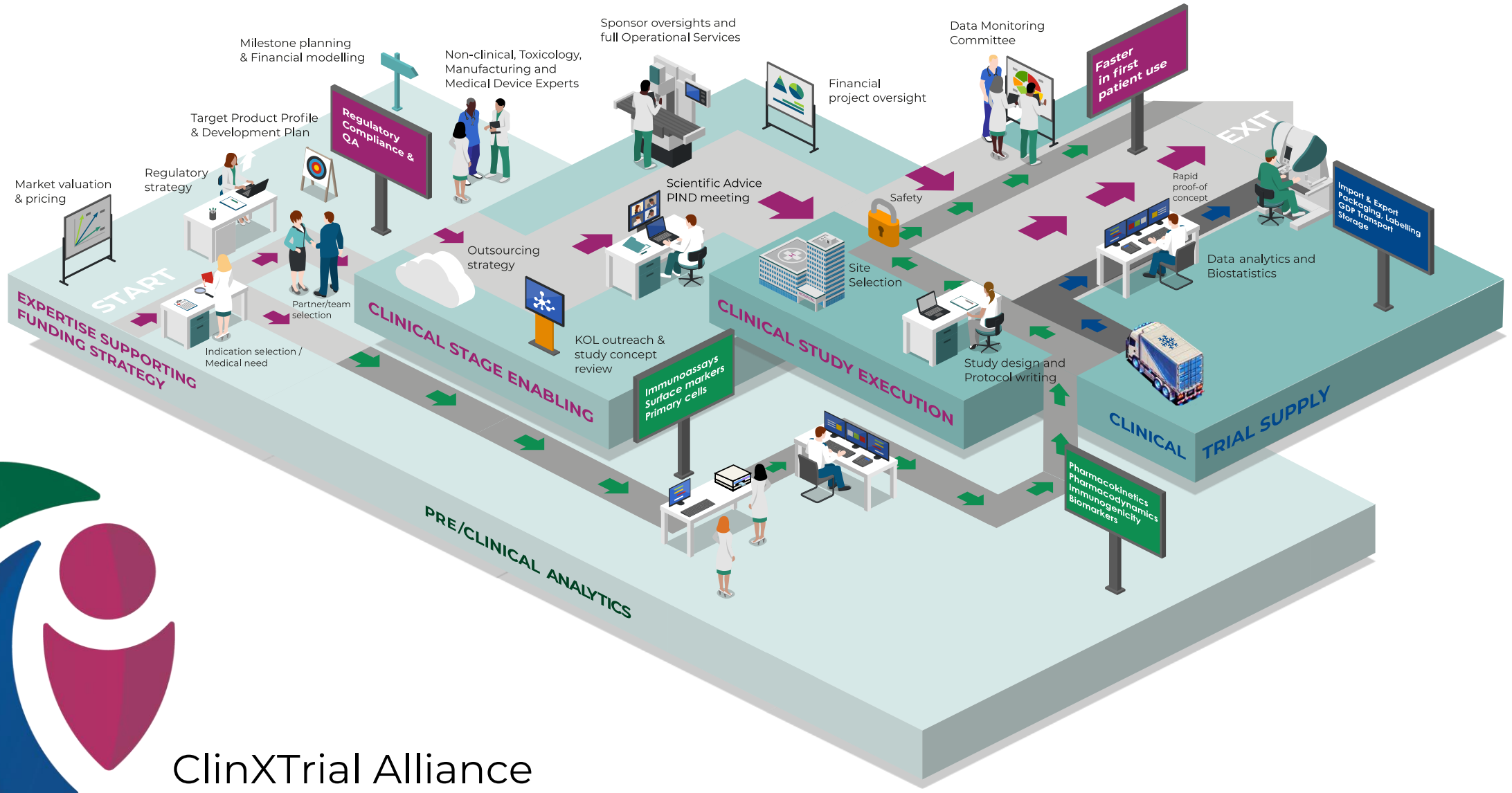
- Outsourcing strategies
- Scientific Advice/PIND meeting
- Advisory board/KOL outreach

Clinical study execution

OPERATIONAL SERVICES

- Full service CRO
- Safety oversight
- Data safety and monitoring board creation
- Quality assurance

Gouya Insights provides **comprehensive strategic and operational consultancy and services for drug and device development**, helping clients achieve their goals efficiently and effectively.



ClinXTrial Alliance

an end-to-end solution for biotechnology companies

Partnering for Success

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Clinical Development

BIOTECHNOLOGY COMPANY

MEDICAL DEVICE/ IVD COMPANY

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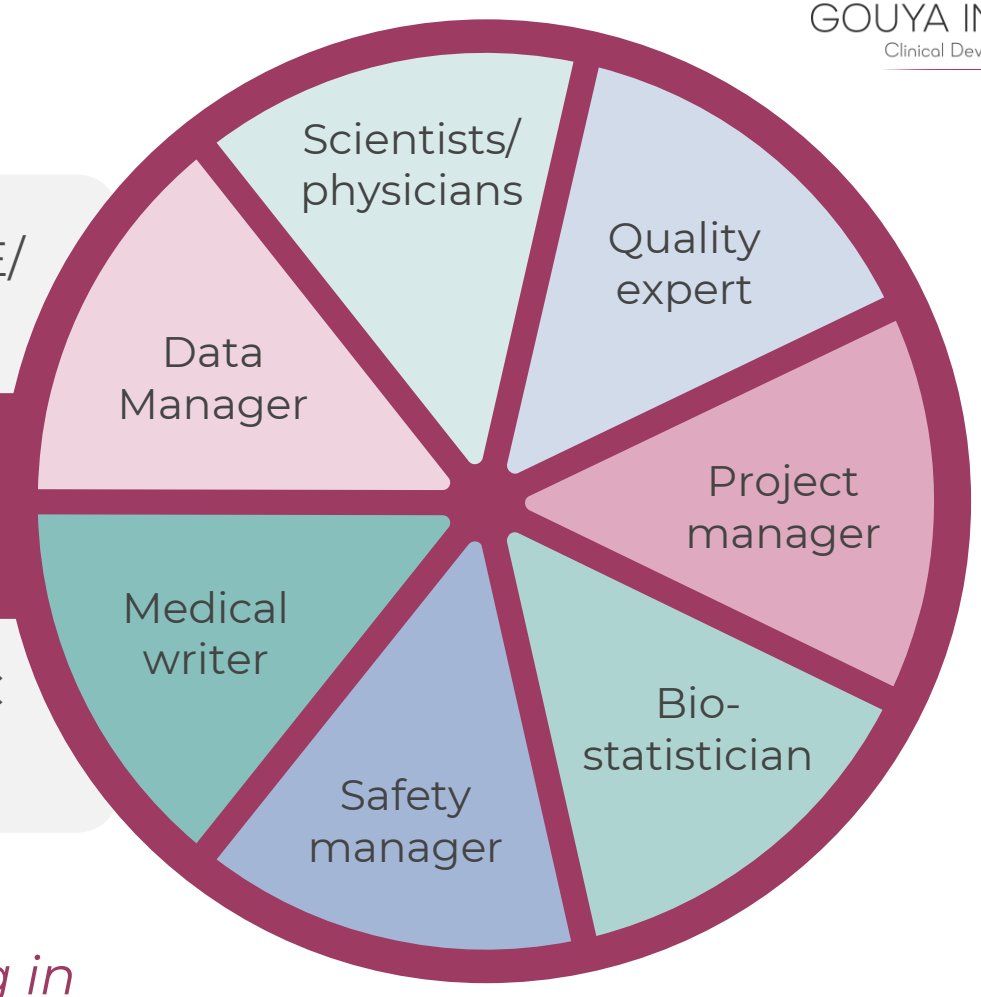
ACADEMIC START-UP

PHARMACEUTIC COMPANY



Gouya Insights stands out for its strategic consulting and operational services to bring in fact-driven strategic solutions.

Clinical Operational Efficiency

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Therapeutic Areas

Autoimmune Diseases – Oncology - Cardiovascular - Dermatology – Neurology - Gynecology – Vaccines – Gastroenterology – Ophthalmology - Viral diseases - others

Product Types

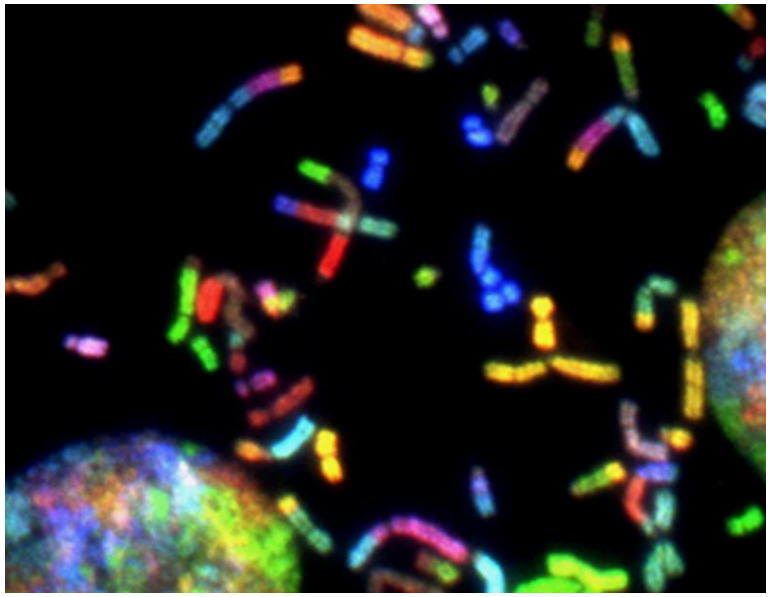
Small molecule, biologics, personalized therapies, ATMPs, medical device including implantable, software and substance-based MD, in-vitro diagnostics (IVD), systemic and topical applications

Our clinical research experience covers a wide range of therapeutic areas, product types, and studies, and our in-house experienced team is well-equipped to handle complex projects.

Gouya Insights Operational Services

GOUYA INSIGHTS

GCP and ISO 14155 Compliant Operational Services in Drug and Device Development



Sponsor

Sponsor Oversight

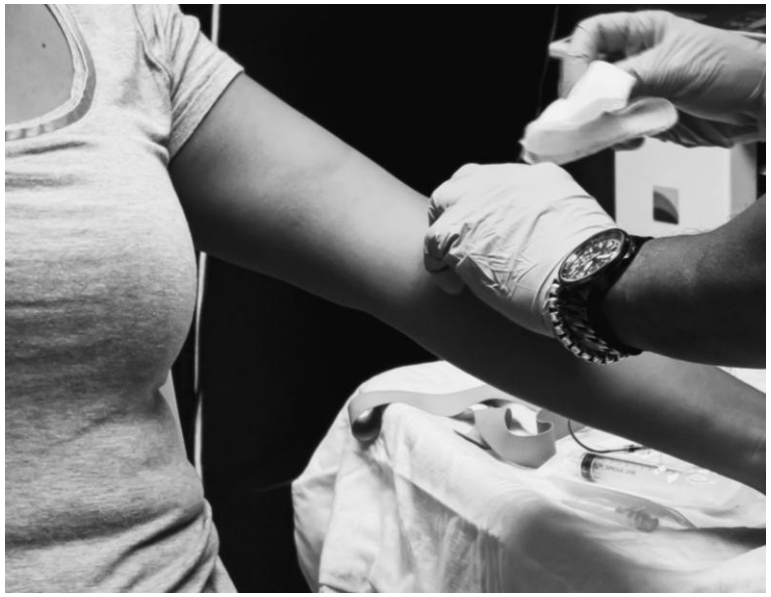
Quality and Risk Management

KOL engagement

Monitor

Gouya Insights Full Service in Clinical Operations

Project management, Medical Writing, Monitoring, Vigilance, Datamanagement, Biostatistics



Investigators

Site selection and Feasibility exercise

Site training

Optimizing Site set - up

Regulatory Documentation & Submission Excellence

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CTIS and IND submission leadership for clinical trials application

Demonstrated expertise in managing the complex regulatory landscape for clinical trial submissions in the US and EU, ensuring seamless and compliant processes.

Breakthrough Designation & CE Marking achievements for clients

Guided clients through the successful acquisition of Breakthrough and other fast track regulatory paths accelerating their product development and market access.

Seamless preparation of Investigator Brochures, Risk Management Plans, Briefing Books

Streamlined the development of essential regulatory documentation, ensuring completeness, quality, and timely submission to regulatory authorities.

Systematic literature reviews

Conducted comprehensive literature reviews and integrated scientific evidence to strengthen regulatory submissions and support product claims.

Our team's expertise in regulatory documentation and submission excellence has been a driving force in helping clients navigate the complex regulatory landscape, achieve regulatory milestones.

Full-Spectrum Services Across the Development Lifecycle

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Clinical Development Planning & Adaptive Study Design

Comprehensive strategy and design for clinical trials, incorporating adaptive elements to enhance efficiency and responsiveness

Medical Writing: Protocols, IBs, CSRs, Regulatory Dossiers

Crafting high-quality regulatory documentation, including clinical trial protocols, investigator's brochures, clinical study reports, and submission dossiers

Regulatory Submissions: EMA, FDA, Notified Bodies

End-to-end support for regulatory filings, navigating the requirements of key authorities such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and Notified Bodies

Data Management, Biostatistics, and Technology-Enabled Operations

Robust data management practices, advanced biostatistical analysis, and the integration of innovative technologies to streamline operations

Risk-Based Monitoring & Pharmacovigilance Oversight

Proactive risk management strategies and comprehensive pharmacovigilance programs to ensure patient safety and regulatory compliance

Strong and Comprehensive Clinical Project Management

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Sponsor Oversight

- Oversight Project Plan
- Budget Monitoring
- Risk Management
- Quality Assurance TMF
- Report Reviews
- Regulatory Affairs
- Deviation Management
- Communication
- Progress Updates

Project Oversight

- Project Plan
- Responsibility Matrix
- Risk Management
- Trainings
- Deviation Management
- Monitoring
- Quality Management
- Vigilance Overview
- Communication
- Progress Updates

Vendor Oversight

- Oversight Vendor Qualification
- Communication Plan
- Supply Management Co-ordination
- Sample Management
- Co-ordination

Ensuring Compliance with all Applicable National and International Guidelines (ICH E6, E8, Q9, CTR, AMG, Declaration of Helsinki and Taipei)

Operational Services

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Seamless operational services—from planning to close-out—ensure high-quality data, regulatory compliance, and timely delivery of study results.

Operational Services: Clinical Data Management

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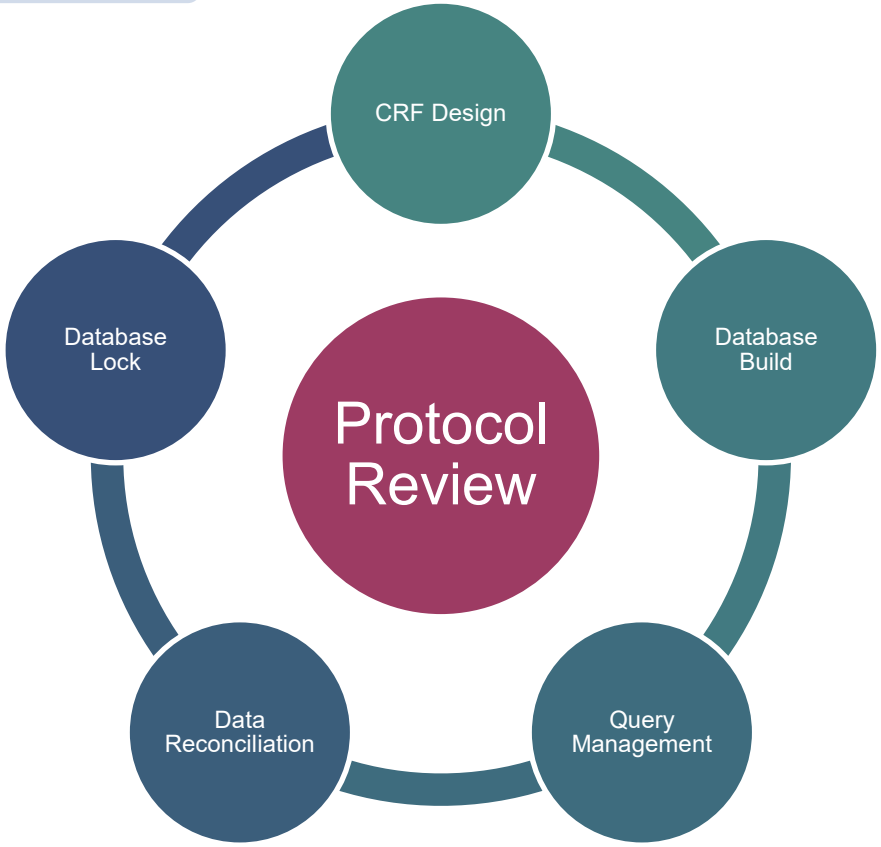
Ensuring Clean, Reliable and Real-time Data

Key Responsibilities

- Database Design
- Data Validation Planning & Edit Checks
- Query Management & Resolution
- SAE Reconciliation
- Data Review Meetings
- Interim & Final Data Cleaning
- Database Lock and Archival

Tools & Outputs

- EDC System Clinspire® by DATAMEDRIX
- Power BI Dashboards
- Outputs: Clean Dataset ➔ ready for Biostatistics
- Focus: Timelines, Quality, Compliance



Operational Services: Pharmacovigilance

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Comprehensive Safety and Medical Oversight

- Vigilance services for Investigational Medicinal Products (IMPs)
- Development of study-specific Safety Management Plans (SMPs) and templates
- End-to-end safety case handling: SAE, SUSAR, pregnancy reports
- Narrative writing and sponsor-level medical assessment
- Medical Monitoring support: review of medical data, ongoing safety oversight, and medical guidance on emerging issues
- Support for regulatory compliance and site safety support
- DSUR preparation in accordance with ICH E2F and EU CTR 536/2014
- Aligned with ICH E2A/E2B/E6 and applicable Good Pharmacovigilance Practive (GVP) modules

Safety is not a checkbox - it’s a culture embedded in every step of your study

Operational Services: Biostatistics

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Turning Data into Decisions

Key Responsibilities

- Development of the Statistical Analysis Plan (SAP)
- Sample size & power calculations
- Randomization schema generation
- Support for protocol and CRF development
- Interim and final analysis
- Statistical input for CSR, DSUR, and publications

Value Contribution

- Ensures methodological rigor
- Supports regulatory submissions
- Drives data-driven decisions
- Enables transparency and reproducibility

Tools Used

- SAS / R / Python for data analysis
- CDISC standards (SDTM, ADaM)

Operational Services: Medical Writing

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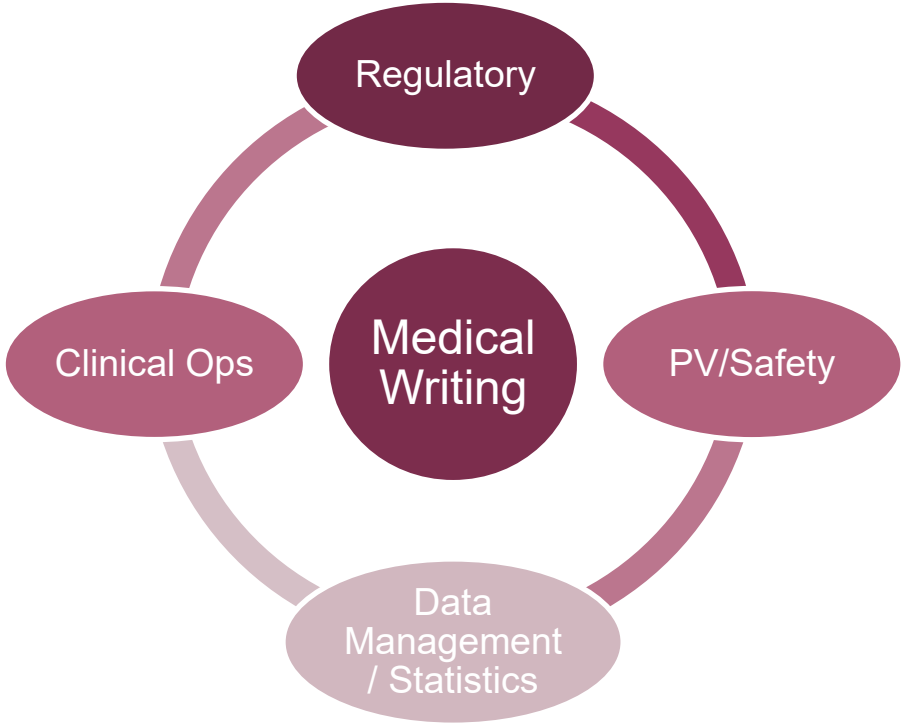
High-Quality Medical/Scientific Writing

- Creating Target Product Profiles (TPPs) and comprehensive clinical development plans.
- Data-driven development of study designs.
- Development of all essential clinical documents: Clinical Study Protocols, Investigator's Brochure, Informed Consent Forma, and Clinical Study Reports.
- Briefing packages for scientific advice.
- Scientifically sound content that supports informed decision-making and aligns with applicable regulatory frameworks (e.g. ICH GCP (E3/E6/E8), EU CTR 536/2014)
- Reference Safety Information (RSI) developed and integrated seamlessly into IB and safety documents



Close collaboration across functional teams to ensure consistency and accuracy

Scientific integrity, clarity of messaging and stakeholder alignment

Quality Management

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Quality Management System
ICH E8; ICH E6 annex I, 3.10, 3.11

- ✓ Robust Quality Management System
- ✓ Administrative processes
- ✓ QA and QC measures implemented in every aspect of the study conduct

Risk Management
ICH Q9; ICH E6 annex I, 3.10/3.10.1

- ✓ Early on Risk Management
- ✓ Risk Management Plan
- ✓ Risk Log and mitigation strategies

Non-compliance and CAPA Management
ICH E6 annex I, 3.12

- ✓ Identification and follow-up of non-compliances
- ✓ Implementation and effectiveness check of corrective or preventive actions
- ✓ Reporting procedure

Audit and Inspection Readiness
ICH E6 annex I, 3.11.2

- ✓ Conducting site and vendor audits on behalf of the sponsor
- ✓ Supporting site and sponsor in achieving inspection readiness

Quality by Design
(ICH E8)

"If you think compliance is expensive, try non-compliance."
(Paul J. McNulty)

At Gouya Insights, our unique combination of deep scientific expertise and hands-on operational excellence makes us the ideal partner for you!

We don’t just advise — we deliver strategic, evidence-based solutions that accelerate development and drive success.

Key Differentiator

GOUYA INSIGHTS

We find the fastest route to your pivotal trial — designing smart, streamlined studies that unite multiple objectives in one powerful protocol and can even eliminate an extra trial where possible.

Connecting science, regulation, and strategy — that's where meaningful progress starts

De-risking the development path

Not only consulting- but delivering high quality services

We're not just consultants — we're committed members of your team

We take ownership

Clients feedback

GOUYA INSIGHTS

"You can connect the dots between CMC, Toxicology, and Regulatory — understanding their impact on timelines in the clinical development and flagging risks to enable the most efficient decision-making"

„The level of ownership and quality of your deliverables are outstanding"

„You are our clinical development and clinical operations team"

„ Your deep knowledge regulatory processes, your ability to foresee the right regulatory pathway for our product, and your alignment with business strategy were spot-on"

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Clinical Development

Let's chat!

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