Efficient Clinical Trials: Real-Time Oversight & Insights

To ensure successful outcomes for your clinical trial, partner with a team that understands the objectives of the study, enables data-led decision making, and provides trial oversight & incisive insights to keep the study on track to meet timelines and deliverables.

Having conducted 600+ clinical trials across 20+ therapeutic areas, Navitas Life Sciences has partnered with over 100 sponsors to deliver successful clinical trials. Timely and informed decision-making is critical when faced with the challenges of steering your study to success and Navitas Life Sciences is here to help you with just that. Navitas Life Sciences ensures adherence to study timelines and milestones through:

1. In-depth domain expertise
2. Vast experience in managing global studies
3. A robust medical and scientific talent pool
4. A best-practice driven project management and governance model
5. Adoption and use of proven technologies

All of our clinical trials services are powered by **OneClinical**® analytics, our source system, format agnostic, data driven, and ICH E6 R(2) compliant eClinical platform.

NAVITAS LIFE SCIENCES

Driving better outcomes through insights

CLINICAL

- **600+** Clinical Trials
- **1500+** BA/BE Studies
- **20+** Therapeutic Areas
- **40+** GCP/Non GCP Audits
- **120000+** Patients & Volunteers

REGULATORY

- **245000+** Regulatory submission
- **50+** Regulatory consulting
- **145000+** eCTD Submissions
- **35000+** NeES Submissions
- **65000+** Paper Submissions
- **250+** Regulatory experts
- **200+** Clients
- **130+** Countries
- **100+** Health Authorities

SAFETY

- **300+** Safety Consulting Engagements
- **100+** Global clients
- **30+** Years in Pharmacovigilance

NETS

- **9** unique, proprietary industry networks
- **110+** network members
- **20+** years of industry benchmark data

Navitas Life Sciences Provides an Integrated Approach by Leveraging Expertise Across Clinical, Regulatory and Safety to Deliver Improved Outcomes to Pharma and Biotech Clients

350+ Clients

Repeat Business From 90% of Clients with Multiple Years of Engagement

1000+ Professionals

Including Doctors, PhDs, Biostatisticians, Pharmacologists, etc.

Global Delivery Model

Combines Global Reach of Scientifically Skilled Professionals and Leading-edge Technologies Focused on Generating Measurable Business Value Outcomes for Our Clients with Seamless Execution

Increase the efficiency and effectiveness of your Clinical Trials

The operational success and the long-term impact of a clinical trial depends on the ability to deliver high-quality data, quickly and cost-effectively. This enables timely and informed decision making by the study teams and sponsors. In addition, it has become essential to leverage trial data using analytics to improve decision-making capabilities. Quality by design and a risk-based approach are imperative to the success of clinical trials. An effective clinical trial requires a deep understanding of how to identify and mitigate risks from start to finish, how to identify the right parameters to drive trial progress and stay patient-centric, and how to set up trial endpoints to ensure a meaningful study.

Navitas Life Sciences leverages 30+ years of clinical trial experience and a vast array of therapeutic area expertise, powered by the latest technology solutions, to deliver high-quality outcomes for your clinical trials. Our global workforce of domain experts is tuned to the latest industry trends, contributing significant subject matter expertise to develop appropriate clinical development strategies and guide your clinical trial effectively. This is bolstered by our audit-ready infrastructure, skilled and experienced global delivery teams, and industry-specific technology platforms that ensure compliance and data integrity, enhance efficiencies, reduce costs, minimize risks and maximize patient safety.

Give your trial the **Navitas Life Sciences edge!**	**Leveraging industry insights and agility for seamless execution** Driving the project objectives towards successful delivery with significant knowledge across end-to-end project support
	Extensive clinical and therapeutic area domain knowledge & talent Innovative models to reduce operational costs delivering improved outcomes to pharma and biotech clients
	Well-established governance Senior leadership commitment to support your ongoing projects ensuring successful outcomes
	Organization uniquely positioned to commit & deliver the end goal Valuable Partner with an understanding of your needs and providing co-created tailored solutions to meet your specific requirements

NAVITAS LIFE SCIENCES *Driving better outcomes through insights*

End-To-End Support across Clinical Development

Clinical Trial Operations | Medical Services | Regulatory | Pharmacovigilance | Clinical Data Sciences

Enabled by **Technology**

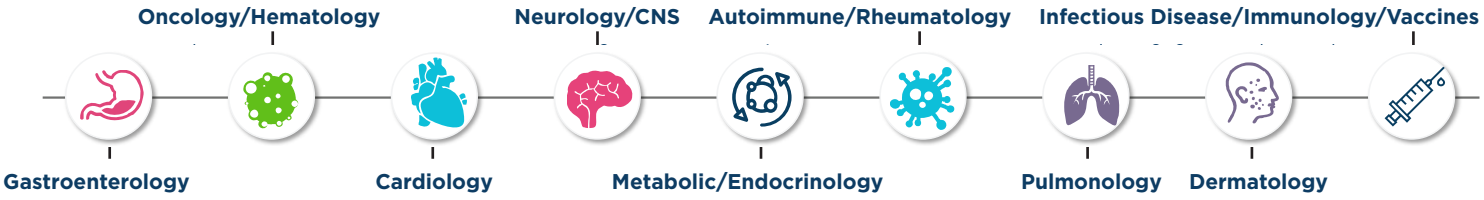
OneClinical® pharmaREADY traceREADY affiliateREADY safetyREADY

Leverage our Vast Expertise in Managing Full-Service Clinical Trials

In the digital health revolution age, Navitas Life Sciences serves as an integrated development partner for faster and more cost-effective management of Phase I-IV clinical trials. Right from study start-up, conduct, to closure, we leverage our extensive experience to support your global clinical trial requirements. Our clinical trials services include feasibility, start-up, project management, traditional monitoring, centralized statistical monitoring driven by concepts of risk-based monitoring, data management and biostatistics, medical & PV services, and publishing and submissions. Powered by **OneClinical® analytics**, our eClinical platform with organic analytics and insights, our clinical trials services deliver successful outcomes while maintaining the highest quality standards and regulatory compliance.

Deep expertise across multiple therapeutic areas

Explore Navitas Life Sciences' in-depth knowledge and expertise in therapeutic areas that you are focussed on. Hone your clinical trial strategies with insights from experts who understand the disease condition and are familiar with the necessary care and the markers of disease progress. Benefit from our comprehensive understanding across multiple therapeutic areas.



Strategic Partner with End-To-End Clinical Trial Capabilities with a Commitment to Seamless Execution

Navitas Life Sciences leverages its domain expertise, technology knowledge, and world-class systems & processes to support your needs. Our end-to-end clinical trials operations provide you support with Clinical program management, feasibility, site selection and activation, Patient recruitment, Site management and clinical monitoring (including Risk Based Monitoring (RBM), Central Monitoring (CM), Remote Monitoring (RM) & Adaptive monitoring).

Clinical Trial Operations

Power your clinical trials with the right expertise, experience, artificial intelligence and digital tools to avoid costly delays and gain a competitive edge. Access our global teams and get support from multiple geographic locations and patient populations to rapidly start your clinical trials with diversity and safety at the core.

Navitas Life Sciences blends domain knowledge and technology expertise to create immense value for your organization. Our clinical experts apply their extensive expertise and knowledge to guide sponsors to achieve their strategic objectives through best practices. Our efficient clinical trial operations adapt innovative technologies to deliver high quality outcomes.

- **Clinical Trial Management**
- **Clinical Monitoring**
- **Site Management**
- **Portfolio Management**

Medical Services

Our medical services include medical strategy and program design, and expert medical monitoring services that are delivered with a holistic approach and a customer-focused mindset with scientific guidance in alignment with regulatory prerequisites, and cost effectiveness. There is support for overall drug development strategy, including the target product profile (TPP), regulatory, non-clinical, and clinical development plans.

Proactive Approach to Medical Monitoring to Generate Greater Value

With a comprehensive academic standing, and rich experience in both industry and healthcare systems, our Subject Matter Experts (SMEs) for all major therapeutic areas provide Strategic KOL Engagement. Our Global medical monitoring experience (North America, EU, and Asia Pacific) and our comfort in delivering for major regulatory authorities (USFDA, EMA, MHRA, CDSCO, TGA, SFDA etc.)ensures that we are strategic partners for small, medium and large pharma.

Navitas Life Sciences aims at accelerating the movement of therapeutic agents from the lab to the market by efficient management of your clinical trials, with safety and efficiency in focus. Our Medical Monitors have vast therapeutic knowledge and clinical research experience to provide strategic and specific support throughout the clinical trial.

Regulatory Affairs

Optimize your Regulatory Processes, drive First-Time-Right Submissions, and enable Life Cycle Management with our regulatory services support. Our offerings include regulatory strategy, process consulting, technology solutions & services, end-to-end regulatory services and regulatory industry networks. In the ever evolving regulatory environment, there is increased emphasis on Patient Safety. We successfully partner with our clients to navigate the landscape and ensure Patient Safety. With a rich legacy of experience and expertise, we serve as trusted advisors and provide tailored solutions grounded in industry best practices.

Pharmacovigilance & Safety

Navitas Life Sciences has been at the forefront of new developments in Pharmacovigilance for more than 30 years. Our experts have defined and implemented PV processes, governance practices and even organizations.

Many of the top 100 biopharma companies are members of pvnet or pvconnect, our Safety Networks. They benefit from round-the-year insights on operational performance, compliance and the latest trends highlighted during our forums, and frequent interactions with our experts.

Pre-Study Activities

- Study Planning & Design
- Study Startup

Study Conduct

- Study Conduct & Monitoring
- Ongoing Management & reporting

Study Closeout

- Data Management & Analysis
- Medical / Safety Review
- Study Document & Submissions

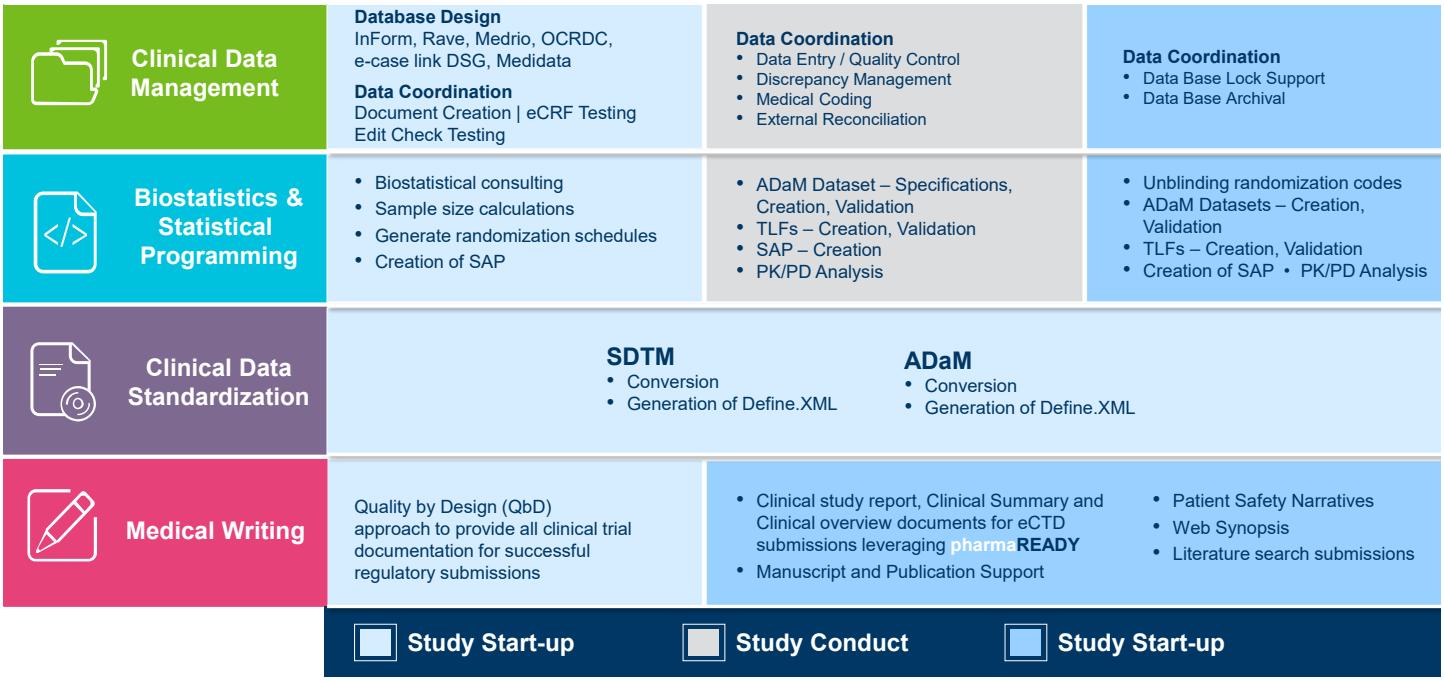
Clinical Data Sciences

Navitas Life Sciences provides the flexibility of either full-service or stand-alone Clinical Data Sciences, per your requirements. We have deep domain expertise through decades of working with world leading pharmaceutical and biotech companies. Our highly qualified teams of data managers, and programmers include numerous SMEs with multiple years of experience in leading data management platforms and SAS Programming.

Our services are backed by state-of-the-art technology, industry affiliations, years of experience, and qualified domain experts, who deliver cost-effective data management services to address increasingly complex clinical data sets while conforming to the regulatory requirements of CDISC submissions.

Our Clinical Data Services Offer Flexible Engagement Models that can be Delivered Globally

We have skilled professionals to meet all your clinical data needs. No matter the size and phase of your study, our work is completed with the utmost precision and accuracy.



Significant Non-Interventional Experience across Therapeutic Areas and Geographies

Our services range from study setup, conduct, to closure, with a wide range of therapeutic areas covered, including Oncology and Neurology.

Custom Approach

- SOPs specifically designed for GPP NIS
- 'Lean' operational execution approach
- Simplified baseline processes
- NIS team specifically trained on NIS processes

Flexible & Scalable

- Flex and scale to adjust to PF standards
- Site selection
- Site management
- Regional PM/ Remote Monitoring / Oversight

Extensive Expertise

- 15+ Therapeutic areas including Oncology, Neurology,& Opthalmology
- National, Regional and Multi-national NIS projects in North America, APAC and Europe
- Integration of GCP experts if/as needed
- Experience with real world evidence & registries

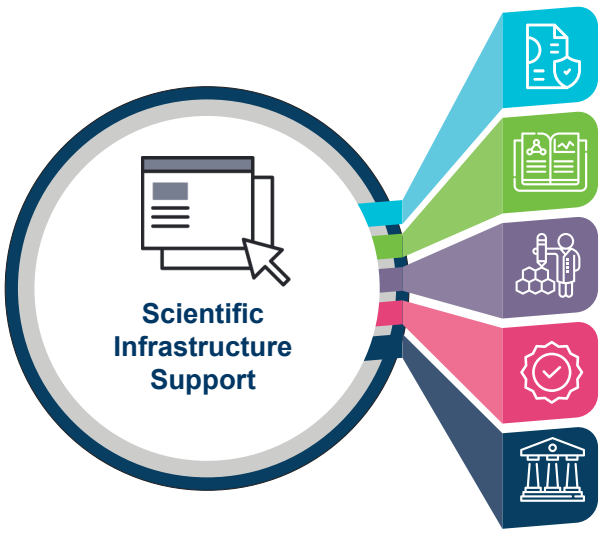
Extensive Expertise in Supporting Registries

We have over 30 years of expertise in managing early through late phase clinical trials and registries & other observational studies. Disease registries are observational, based on Real-World Evidence (RWE), and use patients' data from standard care, patient-reported outcomes, medical history, and other information. A registry can provide valuable insights for use in future clinical trial design, patient recruitment, care cost, and policy decisions.

We support your registry studies by:

- Alleviating data complexities, especially in patient trials
- Supporting first-time right regulatory submissions
- Providing robust, intuitive Registry and eSolutions offerings
- Reducing operating costs by providing predictable outcomes in key support areas, e.g. operational and regulatory support, Data Management, data analysis and visualization, privacy and information security.

Our Experts Enable Better DSMB and DMC Management



- Data Safety Monitoring Board (DSMB) Support
- Scientific portfolio database applications
- Risk assessment of Agency portfolio or individual projects
- Quality Assurance Reviews, including GXP, regulatory compliance, study and site audits/monitoring, eSolution audits, 21 CFR Part 11 compliance
- Training of academic investigators and government officials

We have 3 Decades of Experience Working with the US Federal Government

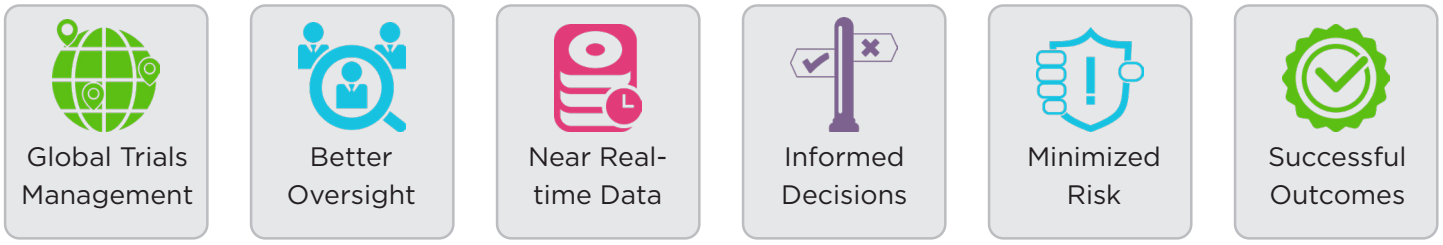
Navitas Life Sciences has supported several US Federal Agencies, including 10 National Institute of Health (NIH) Institutes, The Centers for Disease Control and Prevention (CDC), and The United States Department of Defense (DoD) for almost four decades with the coordination of hundreds of clinical trials and epidemiological studies covering a wide variety of therapeutic areas.

Trusted by Multiple Federal Agencies

NIH 9 Institutes
National Institutes of Health

Navitas Life Sciences's Performance Assessment Report from National Institute of Health (NIH)

OneClinical® analytics analytics for Near Real Time High-Quality Data Insights



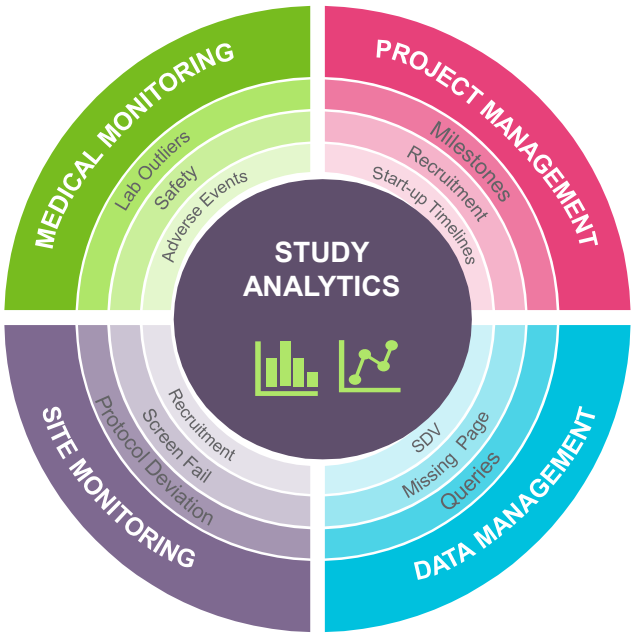
Our intelligent, cloud-enabled, **OneClinical® analytics** platform is proven to deliver near real time, high-quality data for delivering better insights and enabling proactive decision making, resulting in successful outcomes. Designed for, and delivered via, cloud, and in compliance with regulatory and data privacy requirements, our eClinical platform enables end to end clinical trial data management, data visualization, analytics, monitoring and submission services. Proven across a variety of global trials, the platform offers short setup time with low fixed costs, and provides global accessibility with near real-time data analytics and visualizations.

Powered by modern technology architectures, **OneClinical® analytics** provides quality by design, effective oversight of trials and actionable insights through comprehensive data visualization. **OneClinical® analytics** reduces source data verification through industry standards driven central, remote and risk based monitoring, and enables data review, query reconciliation and management through a configurable workflow based solution.

Our optimized eClinical and Analytics platform offers comprehensive trial oversight and enables informed decision making in a timely manner

Partner with us to be at the forefront of technology! Your clinical trial will benefit immensely from our intelligent, cloud-enabled, clinical analytics platform which is proven to deliver near real time, high-quality data. This can be used to deliver better insights and to enable proactive decision making, with your clinical trials resulting in successful outcomes.

Robust Approach utilizing Analytics as the core for Monitoring and Executing different methodology for Clinical Operations, Clinical Monitoring, Data Management, Site and Patient-level Medical Reviews



Navitas Life Sciences is your reliable partner for clinical development and beyond

The bio/pharma industry is at the cusp of a data revolution, and as end-to-end patners, we can help you adapt to the new way of functioning and to stay ahead of competition with our scientific insights to unlock operational efficiencies for faster and efficient trials.

Our compelling value proposition

Value | Experience | Innovation

NAVITAS LIFE SCIENCES

About Navitas Life Sciences

Navitas Life Sciences delivers platform-driven full-service Clinical, Regulatory and Safety solutions and services. Navitas Life Sciences operates across North America, Europe, Asia pacific and Latin America. Navitas Life Sciences combines the knowledge and experience of our legacy brands – Ecron Acunova, Navitas, DataCeutics, KAI Research, and Intelent. Thus, Navitas brings together the capabilities of a full-service CRO, a technology-led life sciences services provider, and expertise in analytics and data sciences to address critical challenges and drive outcomes for life sciences. Navitas Life Sciences has over 30 years of rich experience across 600+ phase I-IV clinical trials, 20+ therapeutic areas, 1500+ BA/BE studies and 40+ successful GCP/non- GCP audits. Our trial expertise is augmented by OneClinical® Analytics, a platform that delivers trial oversight, analytics, and insights to drive successful study outcomes.

For more information

Americas **+1 609 720 1002** Europe **+44 (0) 2392 268133** APAC **+91 44 4590 9000**

contact@navitaslifesciences.com **www.navitaslifesciences.com** **/company/navitas-life-sciences**