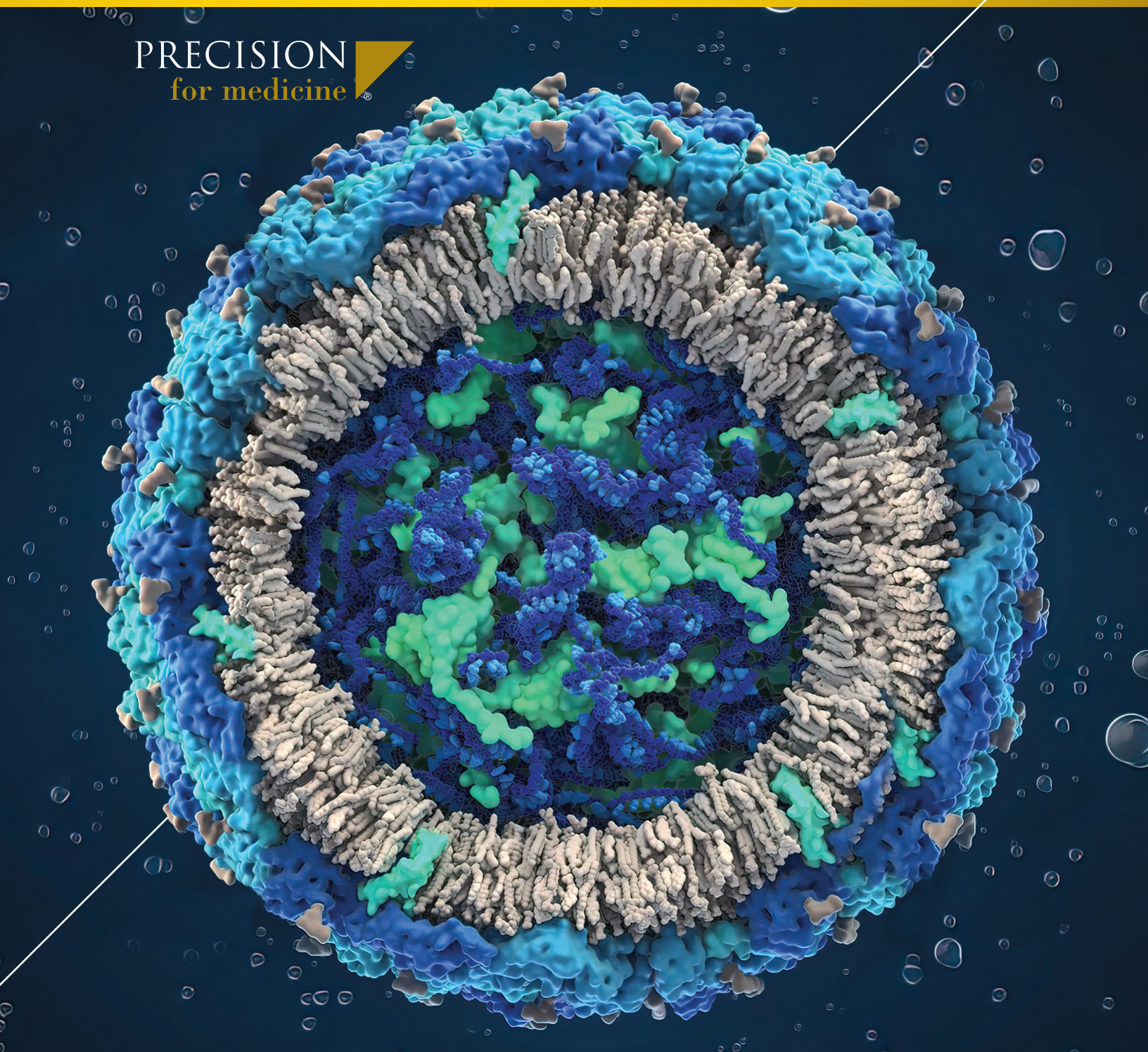
Guiding the Way for Novel Therapeutics in Complex Indications

PRECISION for medicine®



Life-changing Treatments Without a Lifetime of Development

Precision's Aligned Services:

Global CRO

Central Lab Services

Specialty Labs

Manufacturing

Data Intelligence

Biospecimens

Commercialization

Meet the needs of the most critically ill patients with expert execution of the most intricate clinical development and commercialization programs.

Equipped with comprehensive clinical and contract research organization (CRO) services, Precision for Medicine uncovers novel and differentiating pathways forward—solving challenges and impacting outcomes for your patients and your business.

Over the past 20 years, our industry-leading medical, operational, scientific, and regulatory experts have successfully applied novel clinical trial designs, formulated value-added biomarker solutions, and uncovered deep scientific insights that propelled medicine forward.

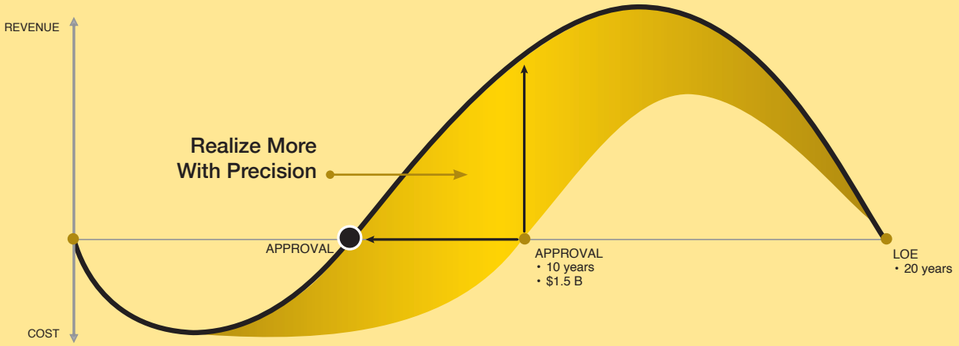
Creating Pathways for Pioneers

Bring the future forward

Clinical trials are growing more complex. In the face of evolving global regulations, challenging data environments, and a growing need for more patient-centric solutions, your program's success hinges upon your ability to navigate the ever-changing pathway to approval.

Selecting the right clinical research and commercialization partners protects your investment and enhances your potential with specialized expertise, value-generating technologies, and connected services that support you as your program grows.

Sophisticated clinical and commercial capabilities, best-in-class technologies, and global teams of experts allow us to strategically improve key milestones across the development life cycle to drive faster ROI and (most importantly) patient impacts.



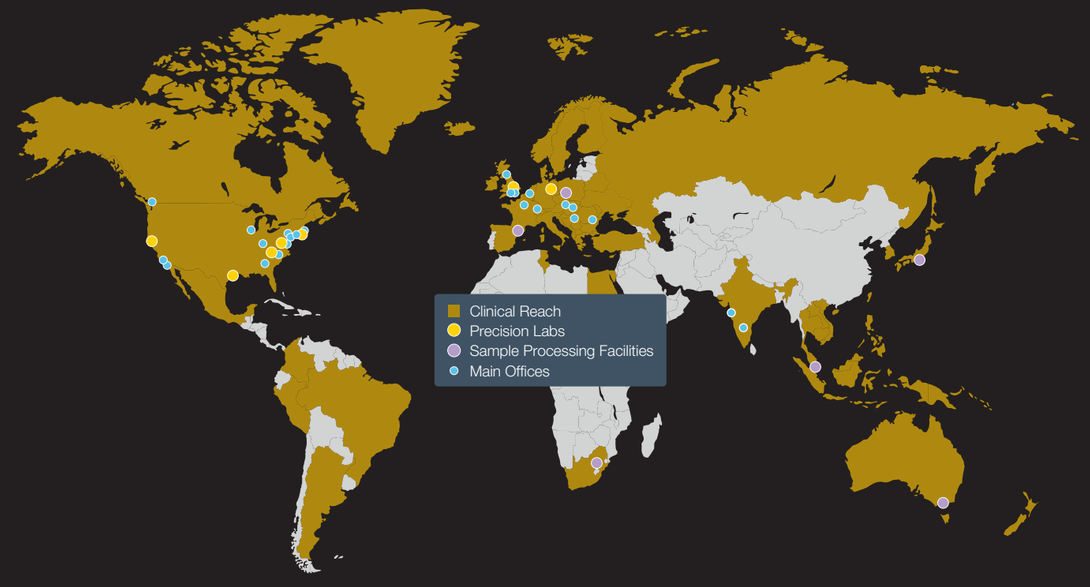
It can take 10 years to develop most new medicines—that is too long

Precision's integrated capabilities are helping life science innovators accelerate the development pathway, reduce the costs of research, increase the probability of approval, and quickly expand access to novel treatments.

Integrated and Specialized Services

End-to-end capabilities are only the beginning. Precision's global teams and proprietary technologies strategically enhance key milestones across the development life cycle.

Precision operate across 70 countries



3500+ Employees

12 Sample Processing Locations

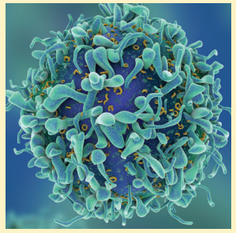
40+ Offices

Next-Generation CRO

Faster pathways to life-changing therapies

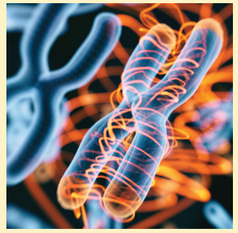
Purposefully built for advanced therapies, we are a next-generation CRO committed to innovation, adaptability, and excellence. At Precision, we redefine industry standards through reliable delivery, proactive solutions, and integrated teams. Your project's success is our priority.

Therapeutic expertise to support the most complex development plans

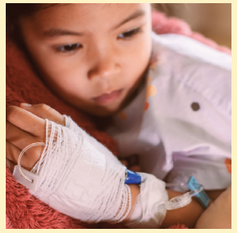


Oncology and Immuno-Oncology

Rare and Orphan Disease



Cell and Gene Therapies



Pediatrics

Maximize Your Program's Success with Comprehensive Support

- Clinical development planning and consulting
- Biomarker-driven strategy and execution
- Regulatory affairs strategy and consultancy
- Decentralized clinical trial solutions
- Advanced trial design experts (basket, seamless Phase 1/2 & 2/3, adaptive)
- Access key academic centers via Precision Site Network
- Integrated specialty and central lab services
- Data analytics and AI-driven insights
- Companion diagnostic development and GTM strategy

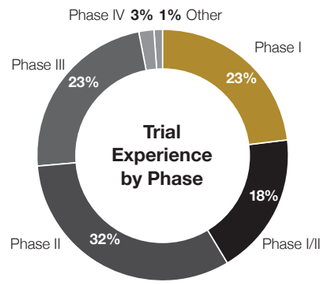
Executing and delivering trials at scale with excellence in biomarker science and clinical operations strategy

140+
Biomarker-driven Trials

600+
Projects

55%
International Studies

Maximize the potential of your clinical program at every phase



Recognized for excellence three years running

Partner with an award-winning Global CRO capable of integrating clinical trial execution with translational delivery.

Simplify your vendor strategy to achieve efficient and reliable delivery of your clinical program. Precision provides comprehensive expertise and solutions to propel your program to its full potential.

- Integrated teams and experts supporting clinical and translational strategy, execution, and delivery
- Consultation services for maximizing clinical development and commercialization strategies
- Data scientists and specialists to protect your data and maximize insights

CRO LEADERSHIP AWARDS 2024 CAPABILITIES
CRO LEADERSHIP AWARDS 2024 COMPATIBILITY
CRO LEADERSHIP AWARDS 2024 EXPERTISE
CRO LEADERSHIP AWARDS 2024 QUALITY
CRO LEADERSHIP AWARDS 2024 RELIABILITY

Diagnostic and regulatory solutions supporting development and commercialization

Precision medicine and advanced therapies often require in vitro diagnostic (IVD) and companion diagnostic (CDx) strategies to support clinical development and commercialization.

Precision's Regulatory Affairs experts provide guidance and assistance across the spectrum of diagnostic development to eliminate avoidable disruption:

- Regulatory strategy, roadmaps, agency interactions, and submissions
- Product development strategy and pathways for clinical trial assays and CDx
- Design of analytical and clinical studies

100+
IVD and CDx Presubmissions, Preclinical Trial Designs and Executions

55%
IVD and CDx Regulatory Filings in Countries Around the Globe

Your potential drives our passion

250+
IVD and CDx Submissions, 510(k)s, Special 510(k)s, EUAs, *de novos*

Scalable Clinical Solutions

Flexible Solutions for Complex Needs

At Precision for Medicine, we offer both full-service clinical trial execution and scalable functional service provider (FSP) support. Understanding that one size does not fit all in clinical research, our flexible approach ensures you have the right solutions to navigate today's dynamic clinical trial environment with precision and efficiency.

Custom FSP Models by Precision

Our FSP models are designed for adaptability, ensuring seamless integration and scalability at every step. By providing customer-facing, cost-effective solutions, we not only align with your current needs but also possess the flexibility to grow alongside you.

Staff Augmentation

Optimize your project outcomes with our FTE model for scalable support tailored to your program. Enhance your team's capabilities with a dedicated resource model or comprehensive global team.

Precision FSP

Ideal for single or multiple-function projects, this flexible model enhances your projects with expert functional teams, while you retain full control over project management.

Available FSP Services

- Clinical monitoring
- Clinical data management
- Drug safety & pharmacovigilance
- Biostatistics
- Statistical programming
- Medical writing

The Precision Difference

Integrating unique capabilities and insights

From early phase excellence to late phase success, we provide integrated solutions that accelerate development with the right tools and teams to deliver precise insights to propel your innovative therapies to the next stage of development and beyond.

From Early Phase Excellence to Late Phase Success

Precision provides a seamless transition from early to late-phase development. With comprehensive solutions optimized for every phase, we deliver precise insights and robust data to support your program.

Embrace end-to-end efficiency and excellence

An optimized approach to early phase development

- Transform ambitious trial designs into actionable plans with deep therapeutic and specialized expertise
- Compress early phase timelines and refine strategies with a suite of integrated solutions
- Expedite First-In-Human to Proof of Concept with efficiency, reliability, and precision

Late-phase development, delivered at scale

- Streamline success with strategic planning, patient recruitment, and operational efficiency
- Gain consistent quality across all study sites with our global footprint, integrated lab capabilities, and Precision 360 Intelligence
- Prepare for approval and commercialization with HEOR strategy, market access planning, and medical communications

Specialty Lab Services

Unlock your program's potential with services and solutions at every step

Integrate holistic solutions for the entirety of your clinical development across a broad range of sample types, modalities, and analytical techniques.

Leveraging established and proprietary technologies, we develop and validate biomarker assays and offer direct access to our experts, who created these value-added approaches.

Proprietary technologies

- **Epiontis ID®**—Immune-cell phenotyping and monitoring via epigenetics
- **ApoStream®**—Isolate circulating tumor cells (CTCs)
- **QuartzBio®** Biomarker Data Management—Link assay results to sample and clinical data
- **XpressWay™**—Profiles Database containing profiles for over 2300 genes, enabling access to robust data for your target(s) of interest

6
NA & EU Specialty Labs

2000+
Programs

Tissue

- Multiplex IHC with centralized pathology reading
- Quantitative IF – up to 9 concurrent markers
- FISH, ISH, sequencing
- GLP tissue cross-reactivity (TCR)

Cell

- Flow cytometry – standard and spectral flow up to 64 color panels
- Functional assays – eg, ELISpot/FluoroSpot, T-cell activation, ADCC
- Single-cell quantitative image analysis
- Proprietary cell separation technology for CTCs
- cfDNA

Protein

- Comprehensive large-molecule bioanalysis – PK, ADA, NAb, TAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays – ELISA, MSD, Olink®
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)
- Automated Western blotting – Jess

RNA

- Gene expression profiling – NanoString
- Bulk and single-cell RNASeq
- RT-PCR and RT-ddPCR
- Spatial transcriptomics

DNA

- PCR – ddPCR, qPCR
- Immunophenotyping via proprietary epigenetic platform
- Sequencing – whole genome, whole exome, targeted sequencing

Central Lab Services

Conquering the complexity of biomarker-driven trials

Biomarker data present unique challenges to precision medicine clinical trials, compounding the inherent complexities of kit development, logistics, sample management, and data collection.

Translating science into success

To simplify clinical trial management, Precision developed a robust, systematic solution for translational central lab services. This harmonized approach is rooted in a deep understanding of the needs of both early-phase trials and those with complex biomarker designs.

Clinical Trial Supply

- Kitting
- Logistics
- Courier and supply chain

Biospecimen Management

- Inbound/outbound
- Sample processing
- Storage
- Shipment/tracking

Biospecimen Data Services

- Database setup
- 21 CFR Part 11
- Discrepancy reporting

Precision Lab e-Portal

- Centralized reporting
- Inventory reports
- Kit reorder
- eSRF creation

3M
PBMC, DNA, and RNA Isolations

55+
Countries With Active Sample Logistics

12
Sample Processing Locations

35M
Specimens Managed

Manufacturing Solutions

Pioneers in complex biologics, advanced therapies, and novel modalities

Advancing technical operations from ideation to commercialization

Precision has a proven track record of planning, building, and maintaining manufacturing facilities and technical operations for novel modalities and complex biologics.

We are optimizing the manufacturing of 100+ lifesaving therapies across biologics, cell and gene therapies, mRNA-based medicines, radioligands, oligonucleotides, and other novel modalities.

Services

- Strategy
- Owner's representative and project leadership
- Project scheduling and controls
- Capital project, facility builds, and tech transfers
- Commissioning, qualification, and validation
- Quality, regulatory, and compliance
- Automation and controls
- Supply chain
- Operational readiness
- Facilities management and operations

Proceed with Precision

Whether you are considering in-house or contract manufacturing, our team will help you determine the best strategy for your organization. We've scaled technical operations and manufacturing facilities from 5000 to more than 500,000 square feet, utilizing every form of technology, equipment, and software used in the development of biologics and transformative medicines.

30+

Manufacturing strategy initiatives led

Experts in Cell and Gene Therapies

Experts in delivering advanced therapies

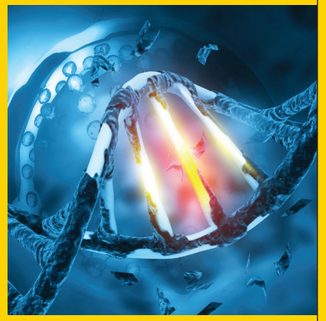
To address the complex challenges of developing advanced therapies, we've brought together our market-leading experts in early development, biologic manufacturing, and commercialization strategies in a cell and gene therapy collective.

With interconnected services and immersed teams, Precision is uniquely equipped to support and protect the uninterrupted advance of your therapy.

50+

research and clinical development projects supported in the last two years

- Design and execution of cell and gene therapy studies
- Specialty laboratory services, including assay development
- Companion diagnostic development and commercial strategy
- Biomarker and translational intelligence with proprietary technology



70%+

of approved cell and gene therapies commercially launched

- Evidence-based solutions and value demonstration
- Strategies for pricing, access, payment, and distribution
- Engagement solutions, communication, and promotion
- Economic modeling based on real-world evidence

60+

facility builds and capital expansions with $6B+ in investments over the past four years

- Technical operations strategy
- Manufacturing execution
- Program management
- Engineering and compliance

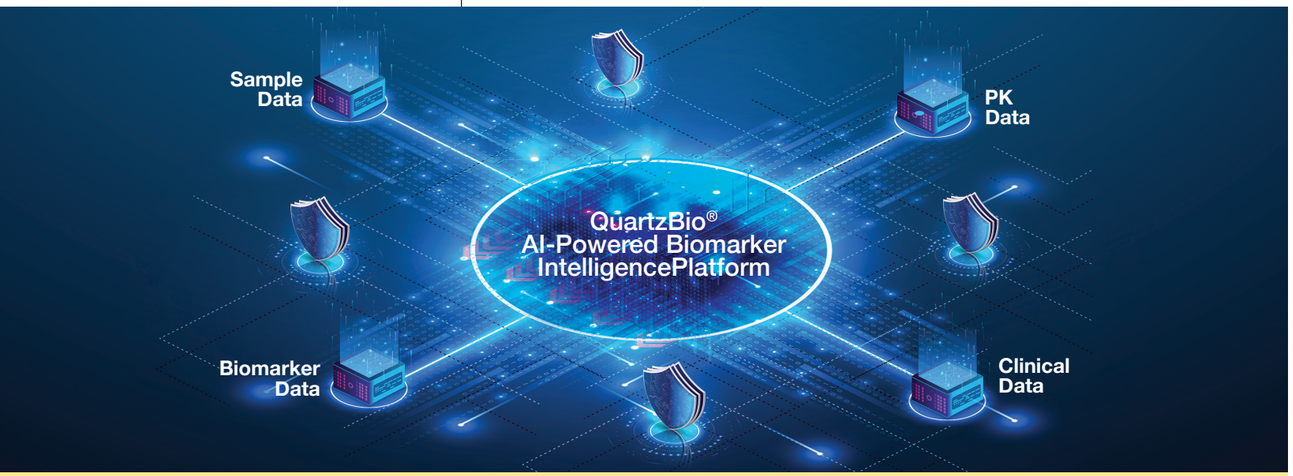
We anticipate likely obstacles and make the necessary preparations to successfully bring your cell or gene therapy to market.

Biomarker Intelligence

AI-powered products that create a connected ecosystem for the full precision medicine lifecycle

Overcome the challenges of disconnected technology and data inherent in modern drug development with a suite of fully connected SaaS solutions that transforms the way precision medicine development teams access, interact with, and gather insights from sample and biomarker data across clinical programs.

Powered by the first ensemble of precision medicine large language models (LLMs), our Biomarker Intelligence Platform and products use the power of conversation to drive biomarker-informed decisions for biospecimen/biomarker operations, translational research, and data science teams.



Precision QuartzBio's AI-powered Biomarker Intelligence Platform is the first fully integrated platform linking sample and biomarker data, connected to clinical annotations, creating a data ecosystem that supports collaborative decision-making across the precision medicine lifecycle.

virtual Sample Inventory Management (vSIM)

Gain a 360° view of clinical trial samples across their lifecycle - from collection to long-term storage, across multiple sites, labs, and biorepositories.

- Reduce operational and compliance risks by quickly identifying patterns of non-compliance at clinical sites, enabling timely course corrections
- Increase flexibility and speed of deployment by alleviating time spent on data wrangling and manually identifying discrepancies
- Collaborate more effectively with centralized visibility into informed consent, sample collection, processing, and storage status across siloed source systems

enterprise Biomarker Data Management (eBDM)

Gain a 360° view of biomarker data across their lifecycle – from data acquisition to QC to indexing and mapping, including exploratory data, preclinical data, and public repositories, connected to sample and clinical data.

- Explore and visualize biomarker trends across cohorts, subjects, and timepoints and perform exploratory analyses to surface signals of interest
- Improve accuracy and efficiency by eliminating manual data ingestion, quality control, and processing workflows
- Generate visualizations and connect cleaned, annotated data to existing tools to improve cross-team collaboration

AI Virtual Assistant

Talk with your sample and biomarker data ecosystem with our conversational AI Virtual Assistant, harnessing precision medicine AI models to generate insights in seconds.

- Enable data storytelling by interrogating a connected sample and biomarker data ecosystem using natural language
- Leverage prescriptive AI to predict anomalies and known study tendencies
- Generate insights at the speed of decision-making

Reporting, analysis, and collaboration

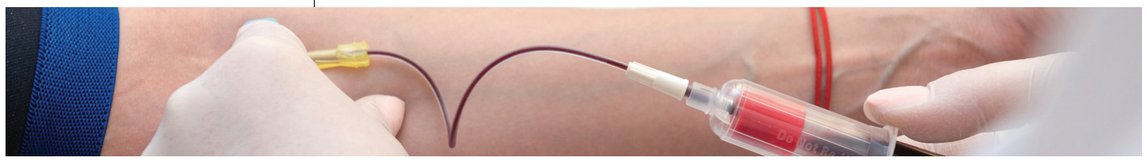
Our suite of analytics, visualization, and reporting tools can be layered on top of any solution. These tools include:

- Connectors to a variety of visualization tools (eg, SpotFire, Prism, Plot.ly)
- General visualization suite (eg, line plots, clustering, dimensionality reduction)
- Biomarker-specific visualization suite (eg, flow cytometry, genomics, imaging)
- On-study configurations

Biospecimens

Quality science begins with quality biospecimens

Thousands of Institutional Review Board (IRB)-approved, clinically annotated biospecimens ready to ship the same day to your lab



Blood, Biofluids, and Derivatives

- Diseased/healthy
- Blood/plasma
- Serum
- CSF
- Stool
- Ascitic fluid
- Saliva
- Urine

Tissues

- Fresh/frozen/fixed
- Healthy/diseased
- FFPE tissues
- Tissue microarrays
- Pathologist verified

Viable Cells

- PBMCs
- BMMCs
- Leukopaks
  - Research grade
  - GMP
- Mobilized leukopaks
- Dissociated tumor cells
- Purified cell subsets (eg, CD34+)
- HLA typed

Custom Biospecimen Collections

- Global clinical network
- Regulatory approved, ready to enroll
- Study specimen collection kits

7M
Liquid Biospecimens

3M
Tissue Biospecimens

Precision, with its comprehensive biobank and sample collection network, is well equipped to support a wide range of research programs, including assay development, bench research, and R&D studies.

- Custom collection of specimens is carried out at FDA-registered facilities according to your specifications, ensuring optimal cell yield, viability, and quality.
- Through robust study kit design, distribution, and tracking capabilities, enrollment is simplified, specimen insights are maximized, and data quality is elevated.
- Our repository houses over 3 million FFPE tissue samples and several million histology slides spanning a wide range of oncologic and medical diseases, with quality control by our on-site pathologists.

Commercialization

Empowering access to life-changing medicine for all

Precision AQ architects the way novel treatments get to market.

As a group of life-science experts, advisors, and creatives, we partner with leading biotech and pharmaceutical companies, large and small, to widen access to life-changing medicine—helping ensure patients get access to the therapies they need. Together, our analytic and creative capabilities cover the full spectrum of the healthcare journey and bring the added value of multiple perspectives.

- **40+** years of experience
- **300+** successful launches and label expansions

Our integrated approach combines expertise, data, and cutting-edge technology to transform patient lives

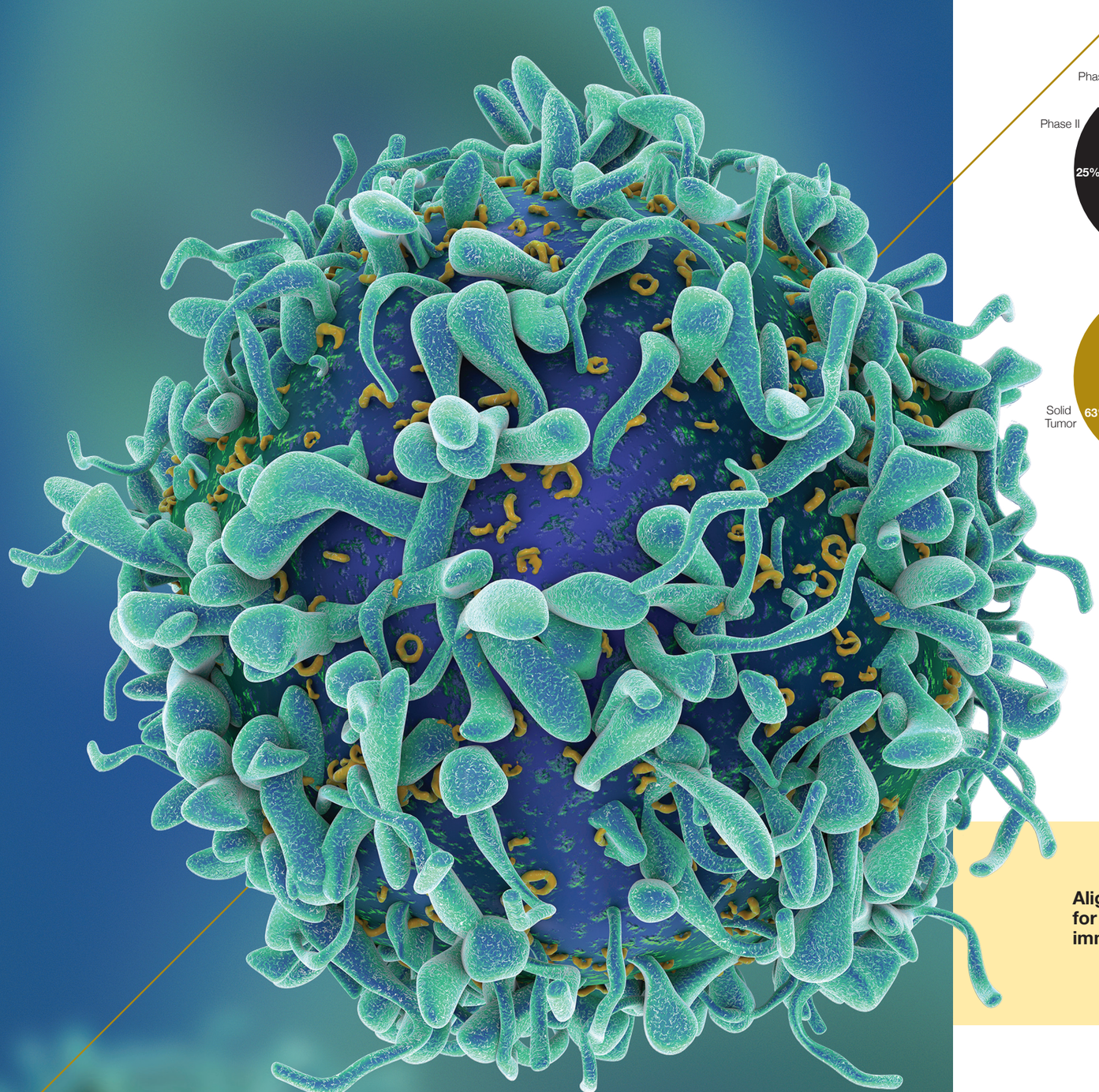
Our ambition is clear, and our method is unique: widening access to life-changing medicine for all.

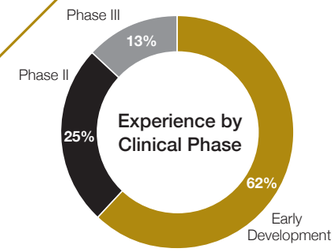
Access over 1,200 experts, from Principal Statisticians to Creative Designers. Infuse a wealth of knowledge and experience to every project with comprehensive capabilities and a suite of solutions that span the entire commercialization journey.

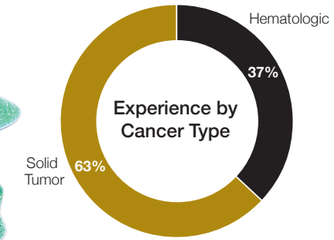
- **Research, strategy, and product development:** Navigate market complexities and develop early-stage strategies.
- **Marketing, branding, and PR:** Establish a strong brand identity and enhance market presence.
- **HEOR:** Generate robust evidence to quantify the value of healthcare interventions.
- **Medical communications:** Deliver clear, impactful messages from complex medical science.
- **Market access:** Optimize commercial success through strategic payer marketing.
- **Investor relations:** Engage with the financial community to achieve financing goals.
- **Data and technology:** Enrich brand marketing strategies with market-leading technology, relevant data, and unmatched insights.

In 2023 alone, **57%** of all FDA-approved drugs were launched with our expertise.

Oncology and Immuno-Oncology

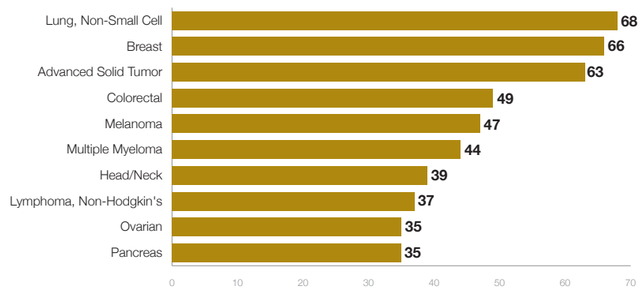






In the cancer arena, our suite of aligned services combines world-class teams and technologies to support your research and development requirements.

Top Indications at a Glance*



*Additional indications of >15 clinical trials include: Renal, Gastric, Acute Myelogenous Leukemia, Bladder, Prostate, Glioblastoma, Myelodysplastic Syndrome, Soft Tissue Sarcoma, Esophageal, and Small-cell Lung.

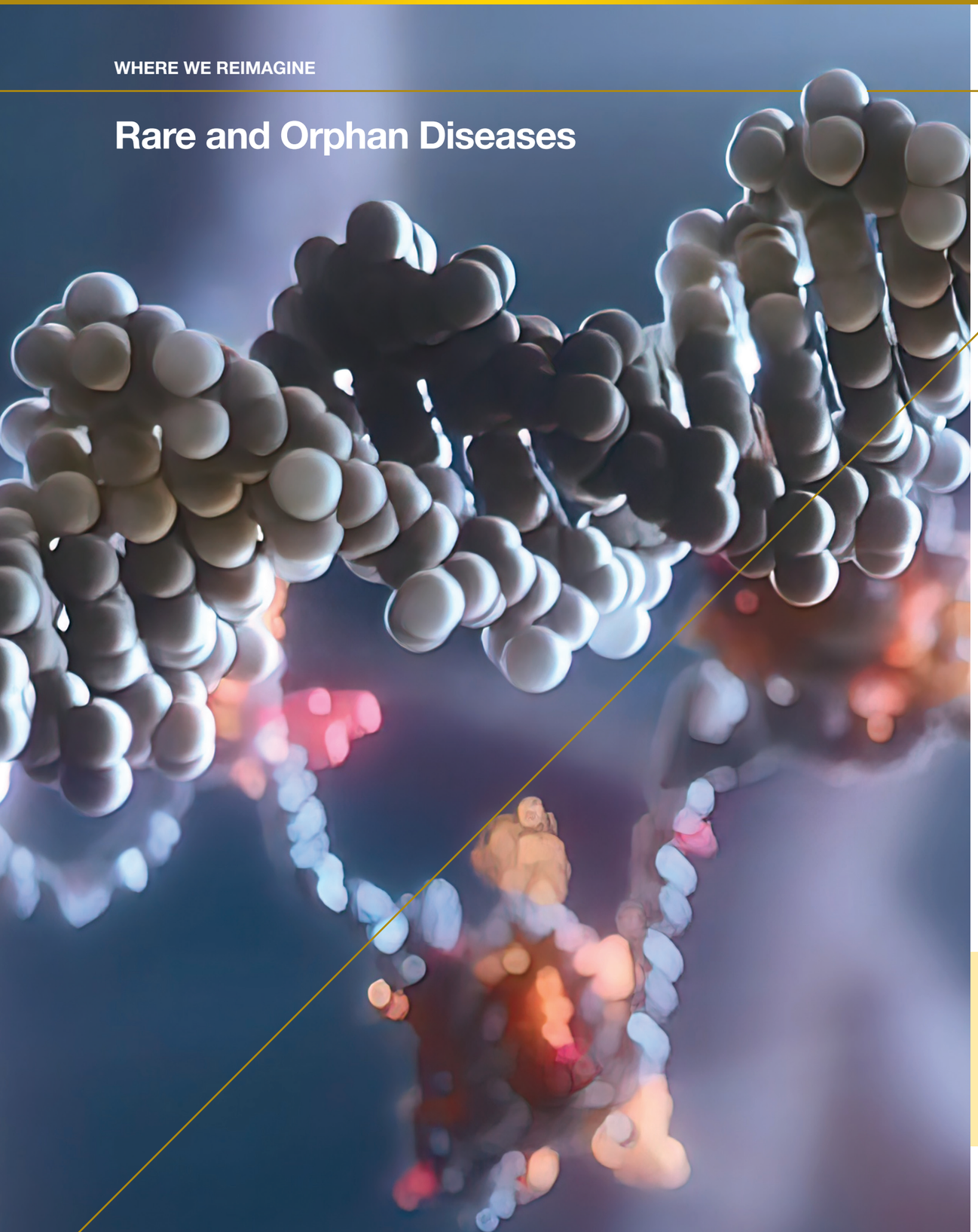
Broad therapeutic class expertise

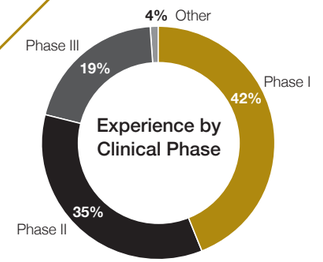
- Cell therapies (CAR-T, TCR, etc)
- Checkpoint inhibitor studies
- Cytokine and chemokines
- DNA repair modulators
- Epigenetic modulators
- Gene therapy, RNAi
- Hormonal modulators
- Kinase inhibitors
- Monoclonal and bifunctional antibodies
- Peptides
- Proteasome inhibitors
- Oncolytic viruses
- Radiopharmaceuticals
- Vascular disrupting agents

Aligned services for oncology and immuno-oncology

- ApoStream™ for CTCs
- Epiontis ID℠ for immune cell phenotyping
- QuartzBio® platform for Biomarker DM & vSIM
- Clinical Science Analytics & Insights
- Diverse oncology biospecimens with genomic characterizations
- Commercialization services
- OncoGenius market insights
- Advanced tumor profiling
- Comprehensive immune-monitoring

Rare and Orphan Diseases





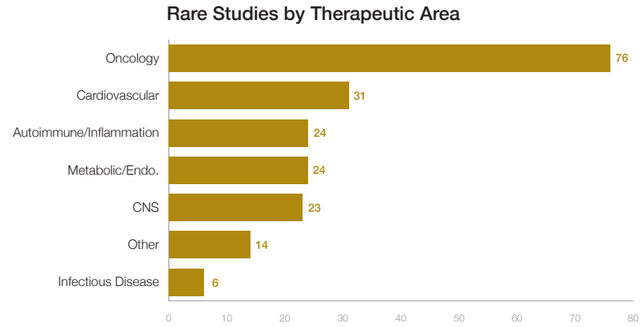
Rarefied Thinking

Nearly 200 rare disease trials across 100+ rare indications

Rare and orphan disease clinical trials come with an urgency and responsibility to extract meaningful, high-quality data from each precious patient and data point. As experts in running rare disease clinical programs, we have the tools, experience, and patient recruitment expertise required to build the bridge to a successful trial.

Obtaining the most elusive information to answer the most complex questions

From ultra-rare and pediatrics to cell and gene therapy, our expertise can enhance your proof points. Our extensive experience running rare disease clinical trials shows that no two studies are the same, opening the door for personalized solutions from research to realization.



Aligned services for rare disease:

- IVD and CDx strategies
- Virtual Sample Inventory Management for rare sample protection
- HEOR consulting
- Orphan regulatory strategy
- Biomanufacturing consulting
- Biomarker data management
- Natural history solutions

Innovation is in our DNA

At Precision, we continue to invest in technology to elevate our ability to add value to sponsors and speed therapies for patients.

Proprietary programs and technologies, plus paradigm-shifting partnerships

MetaVate
Seamless data transformation and standardization

Epiontis ID[SM]
Phenotype and monitor immune cells

OncoGenius
Oncology treatment pathway and drug management insights

EHR Connect
Prescreen site EHR for eligible patients

ApoStream™
Isolate circulating tumor cells (CTCs)

Biomarker Data Management
Integrate, analyze, and unlock your biomarker data

Virtual Sample Inventory Management
Enhance sample visibility and maximize data generation

Clarity
Clinical data intelligence and study performance suite

Shared Principles and a Shared Passion for Patients

Client Service
Purpose
Accountability
Mutual Respect
Collaboration

Proceed with Precision

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Rev. 03

PRECISION for medicine®