Life-changing Therapies Without a Lifetime of Development

Guiding the Way for Novel Therapeutics in Complex Indications

PRECISION for medicine®

Specialized Capabilities for Every Stage of Development

- **Global CRO**
- **Central Lab Services**
- **Specialty Labs**
- **Regulatory Expertise**
- **Data Intelligence**
- **Biospecimens**
- **Commercialization**

76%
of our trials are in oncology

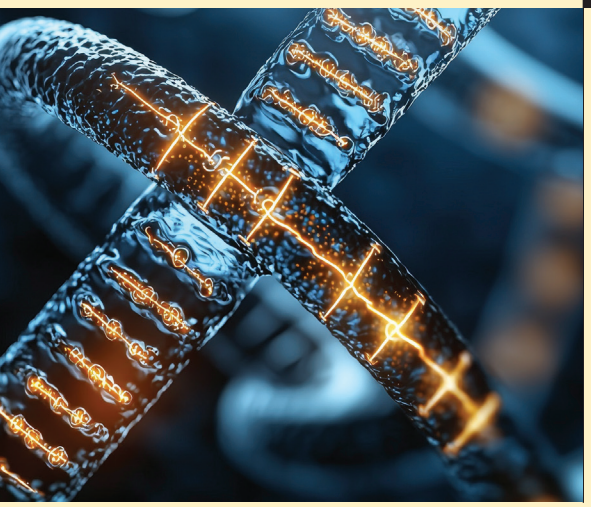
68%
of our trials involve rare diseases

Bringing a novel therapy to market demands excellence at every milestone. For sponsor teams developing next-generation therapies, every choice has downstream impact on time, capital, and trust.

Precision for Medicine was built for this exact environment—where complexity spans not just clinical trials, but lab operations, regulatory strategy, and commercialization planning. Our integrated model combines global CRO services with world-class laboratory expertise to enable faster execution, fewer handoffs, and smarter decisions across the development lifecycle.

For over 20 years, our medical, operational, scientific, and regulatory experts have supported the advancement of breakthrough therapies through innovative trial design, value-added biomarker solutions, and deep scientific insight.

Precision for Medicine delivers the infrastructure and insight of an integrated CRO and lab partner—with the flexibility, responsiveness, and focus of a specialty organization.

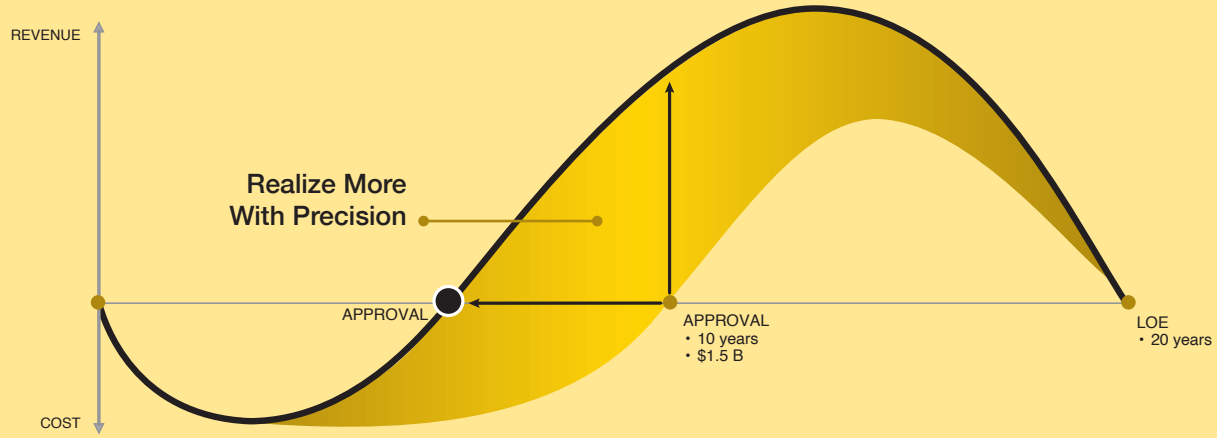


Where Scientific Complexity Meets Commercial Urgency

Bringing a novel therapy to market is a race against time. With pharmaceutical patents typically lasting 20 years and the average drug development process taking a decade, every month lost can reduce opportunity—and increase risk.

$10B

in funding secured for sponsors in 2023 and 2024.



Precision's integrated model is designed to move science forward faster.

By streamlining development, reducing handoffs, and aligning cross-functional execution, we help sponsors accelerate timelines and make smarter, earlier decisions. These gains are amplified by our investment in proprietary technology platforms and AI-powered tools—enriching every stage of the development journey with greater visibility, automation, and insight. In today's capital-sensitive environment, we also bridge science and valuation—aligning milestones with investor expectations to support growth and unlock funding.

Whether you're navigating complex clinical trials or preparing for market entry, Precision offers the agility, expertise, and integration needed to guide your therapy from concept to commercialization—with greater speed and confidence.

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

Next-Generation Clinical CRO

160+
biomarker-driven trials

600+
projects

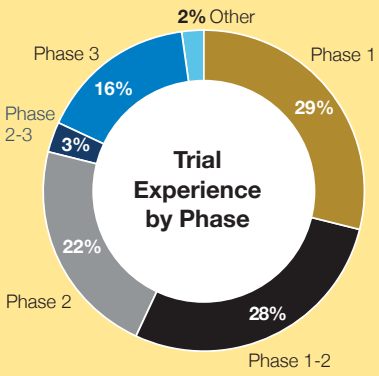
55%
linternational studies

Faster pathways to life-changing therapies

Purposefully built for emerging innovations, we combine global CRO capabilities with the agility, responsiveness, and personalized attention you need to accelerate development and optimize capital.

Expertise in advanced therapies and specialized patient populations

- Oncology and Immuno-Oncology
- Rare and Orphan Disease
- Cell and Gene Therapies
- Pediatrics



Maximize the potential of your clinical program at every phase

- Clinical development planning and consulting
- Biomarker-driven strategy and execution
- Regulatory affairs strategy and consultancy
- Decentralized clinical trial solutions
- Advanced trial design experts (basket, adaptive, seamless Phase 1/2 & 2/3)
- Access to 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

Partner with an award-winning Global CRO designed for the unique needs of small and mid-sized innovators

Simplify your vendor strategy to achieve efficient and reliable delivery while preserving capital. Our integrated approach reduces the management burden on lean teams while providing access to sophisticated capabilities typically reserved for larger organizations.

- Strategic guidance to reach value inflection points that attract additional investment
- Consultation services tailored to companies with limited in-house regulatory and clinical expertise
- Data solutions that deliver investor-ready insights without requiring extensive internal infrastructure
- Flexible engagement models that scale with your funding stages and development needs

FSP Models, Your Resource-Efficient Solution

We offer flexible engagement models that align with your funding stages and evolving needs—preserving capital while ensuring access to world-class expertise.

CRO LEADERSHIP AWARDS2024 CAPABILITIES

CRO LEADERSHIP AWARDS2024 COMPATIBILITY

CRO LEADERSHIP AWARDS2024 EXPERTISE

CRO LEADERSHIP AWARDS2024 QUALITY

CRO LEADERSHIP AWARDS2024 RELIABILITY

Customizable engagement models:

Staff Augmentation

- Enhance your in-house capabilities with dedicated experts
- Scale resources up or down based on development phase
- Maintain consistency while optimizing spend
- Ideal for companies with established teams, needing targeted expertise

Precision FSP

- Access specialized functional teams while maintaining project control
- Eliminate overhead costs of full-time specialized staff
- Flexible, outcome-focused model ideal for milestone-driven development
- Perfect for companies with limited internal resources

Available FSP services

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

Specialty Lab Services

6
specialty labs across
North America & Europe

2500+
programs supported

- Proprietary technology platforms purpose-built for precision medicine
- Experts across immunology, oncology, and rare disease
- Regulatory-ready infrastructure and GLP/GCP-compliant systems

Purpose-Built Support for Biomarker-Driven Development

With a comprehensive range of capabilities—including assay development, molecular profiling, flow cytometry, histology, and digital pathology—Precision specialty lab services are designed to meet your program's distinct scientific and operational needs. This enables more predictable outcomes, faster development timelines, and ultimately, the delivery of transformative treatments to patients.

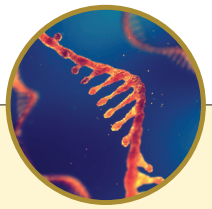
Proprietary Technologies

- Epiontis ID® – Immune cell phenotyping and monitoring via epigenetic markers
- ApoStream® – Proprietary platform for isolating circulating tumor cells (CTCs)
- QuartzBio® – Biomarker data integration platform linking assay results to clinical and molecular data
- XpressWay™ – Curated database of over 2,300 gene and protein expression profiles for rapid target discovery

DNA

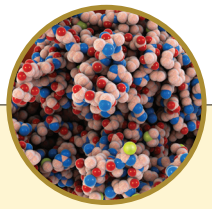
- PCR – ddPCR, qPCR
- Immunophenotyping via proprietary epigenetic platform
- Sequencing – whole genome, whole exome, targeted sequencing

RNA



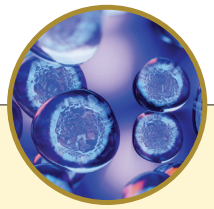
- Gene expression profiling – NanoString
- Bulk and single-cell RNASeq
- RT-PCR and RT-ddPCR
- Spatial transcriptomics

Protein



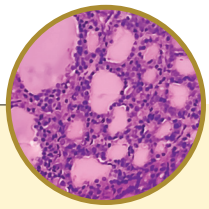
- Comprehensive large-molecule bioanalysis – PK, ADA, NAb, TAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays – ELISA, MSD, Olink®
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)
- Western blotting – traditional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

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

Tissue



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

Central Lab Services

Setting the stage for breakthroughs in 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.

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.

Customized Clinical Kitting

- Custom trial- and visit-specific kits
- Multiple sample type kitting
- Collection-specific QA plans
- Logistics, courier, and supply chain management

Biospecimen Management

- Sample processing in 5 continents
- Biorepository and storage under controlled conditions and all temperatures
- Inbound/outbound sample management
- Same-day PBMC isolations

Biospecimen Data Services

- 21 CFR part 11 and Annex 11 compliant
- Discrepancy reporting management
- BSI complete specimen management
- Precision LIMS

Precision Lab ePortal

- Centralized data reporting and analytics
- Kit inventory reports
- Online location for kit reorder

3M+
PBMC, DNA, and RNA Isolations

55+
countries with active sample logistics

12
strategic sample processing locations

35M+
specimens managed

Regulatory Expertise That Moves Science Forward

Our regulatory teams help sponsors navigate evolving global requirements, minimize delays, and keep programs aligned with scientific and commercial goals. From early engagement strategies to global submission management, we offer practical, real-world support grounded in decades of experience.

Clinical Regulatory Capabilities

- Pre-IND and CTA Planning
- Agency Meeting Support (FDA, EMA, other global authorities)
- Fast Track, Orphan, PRIME, and Pediatric Designations
- Regulatory Strategy Input for Protocol Development
- Multi-Regional Submission Coordination
- Ongoing Regulatory Intelligence & Guidance

Precision provides strategic regulatory support across clinical development planning, designation strategies, and complex pathways—guiding sponsors through critical interactions and submissions across North America, Europe, and key global regions.

Regulatory Impact in the Past 5 Years

Clinical Trial Submissions:

- 24 IND Applications (FDA)
- >40 CTA submissions (EU CTR via CTIS)
- >40 CTA submissions (Non-CTR EU)
- 11 Pre-IND Meeting Requests (FDA)

Accelerated & Special Designations:

- 3 Orphan Drug Designation requests
- 2 Fast Track Designation requests

Whether you're preparing for early-phase engagement or managing multi-regional submissions, we deliver the clarity, coordination, and expertise to move your program forward—faster, smarter, and fully compliant.

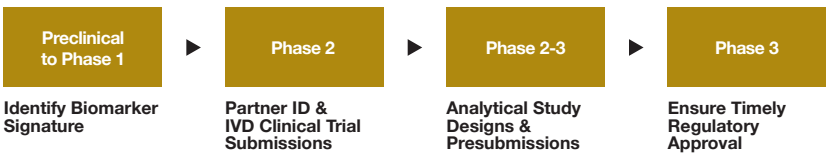
IVD & CDx Regulatory Consulting and Services

With over 350 global IVD and CDx submissions and registrations, Precision delivers comprehensive regulatory guidance that transforms promising diagnostic technologies into approved, market-ready solutions.

- 200+ IVD & CDx presubmissions, IDEs, ITAs, and Annex XIV submissions
- 50+ 510(k), special 510(k)s, EUAs, De Novos, PMAs, and PMA supplements
- 100+ Global IVD and CDx registrations

Our seasoned regulatory team anticipates challenges to efficiently guide you forward, delivering results across global markets.

- Diagnostic testing strategy for patient stratification; LDT/CTA to CDx
- Global CDx regulatory strategy to maximize therapeutic success
- Significant risk determination for clinical trial assays
- CLIA vs CLSI validation of CTA/CDx
- Tx/diagnostic partnering strategy, identification, and support
- Global submission and technical documentation file development and support



Precision Delivers Comprehensive Regulatory Expertise Across Your Development Journey

Development strategy

- Regulatory pathway identification
- Indications and claims development
- Product design considerations
- Diagnostic/CDx partner dentification

Regulatory Submissions

- Q-submissions and agency meetings
- IDE, 510(k), De Novo, PMA submissions
- EUA applications and transitions
- Breakthrough device designations

Global Compliance

- EU IVDR technical documentation
- UKCA mark approvals
- CE mark transitions
- Multi-regional submission strategy

Specialized Expertise

- Companion diagnostic co-development
- Gene therapy diagnostics
- Digital/software assessment
- COVID-19 and viral panel assays

Quality & Lifecycle Management

- QMS mock audits and certification
- Post-market surveillance
- Product updates and supplementary filings
- Risk management and determination

Sample and Biomarker Intelligence

Transforming the way precision medicine teams work with 360° intelligence

Our QuartzBio® Precision AI Agent Platform empowers clinical and research teams with autonomous data ingestion, workflow management, and real-time insights—all with no technical expertise required.

The platform integrates biomarker, sample, and clinical data into a unified ecosystem, streamlining trial operations and enabling faster decision-making.

Experience faster, smarter data-driven decision-making.

Accelerate Study Close and Time-to-Market

It's never been easier to enhance operational efficiency, ensure data quality, and accelerate drug development timelines to bring treatments to patients faster.

- Autonomous Data Management: AI-driven integration of clinical, sample, and biomarker data
- Faster Insights: Domain-specific analytics and visualizations accelerate decision-making
- Unified Data Ecosystem: Eliminates siloed systems, creating a connected precision medicine data value chain
- Natural Language Interface: Easily converse with your data with your own Precision Medicine Virtual Assistant
- Drive Study Compliance and Efficiency: Security and guardrails for 21 CFR part 11, GDPR compliance; GxP-ready

Biospecimens

Quality science begins with quality biospecimens

Our 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.

Thousands of IRB-approved, clinically annotated biospecimens ready to ship the same day to your lab.

Blood, biofluids, and derivatives:
Diseased and healthy human blood, plasma, serum, CSF, stool, ascites fluid, saliva, urine, and more.

Viable cells:
HLA-typed cellular products including PBMCs, BMMCs, DTCs, and more.

Liquid biopsy:
Comprehensive services, including kitting, collection, processing, and profiling from your patients or ours.

Tissues:
Pathologist-verified, fresh, frozen, and fixed tissue specimens from healthy and diseased human subjects.

Custom biospecimen collections:
Global clinical network, regulatory approved, and ready to enroll.

- 13,000+ NGS-characterized FFPE tissue blocks with matched data and digital H&E images
- Expert pathologist oversight for every tissue sample—ensuring clinical relevance and diagnostic-grade quality
- Digital pathology infrastructure for high-resolution slide sharing and AI-ready applications

Whether you're developing an assay, validating a biomarker, or powering an AI model, Precision provides the biospecimens—and scientific confidence—you need to move forward faster.

7.5M+
liquid biospecimens

3.5M+
tissue samples

90+
indications for custom collections

PRECISION AQ™

1200+

specialists in commercialization who empower access for patients and drive growth for sponsors

Commercialization

Empowering Access to Life-Changing Medicine for All

We transform scientific innovation into patient access. In 2023 alone, 57% of all FDA-approved drugs were brought to market with Precision's commercial team support. With over 300 successful commercial launches and label expansions, we understand what it takes to bring breakthrough therapies to patients who need them most.

End-to-End Commercialization Solutions

Commercial Consulting

- Navigate category complexities and develop early market strategies that maximize your therapy's value and position

Investor Relations & External Communications

- Facilitate engagement with the financial community and reach financing goals through compelling scientific and commercial narratives

HEOR (Health Economics & Outcomes Research)

- Generate evidence quantifying the value of healthcare interventions to support pricing, access, and adoption

Medical Communications

- Craft clear, impactful messages from complex medical science for peer-to-peer audiences and KOLs that drive understanding and action

Market Access Marketing

- Optimize commercial success through payer marketing strategies that overcome access barriers and demonstrate value

Marketing, Branding & PR

- Build your brand identity and enhance market presence with HCPs and patients through integrated, insight-driven campaigns

Precision 360° Intelligence

AI analytics and data intelligence that reveal insights in every direction. Powered by proprietary programs and technologies, plus paradigm-shifting partnerships

Sample and Biomarker Intelligence

Precision Medicine AI Agent Platform
Transform the way precision medicine teams work, with 360° sample and biomarker intelligence

Clinical Trial Intelligence

Metavate
Metadata-driven, data transformation platform that accelerates regulatory submissions

Clinscope
Clinical data intelligence and risk-based quality management suite

Assay Intelligence

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

ApoStream™
Isolate circulating tumor cells (CTCs)

Epiontis ID℠
Phenotype and monitor immune cells

Access Intelligence

EHR Connect Prescreen site EHR for eligible patients

OncoGenius
Oncology treatment pathway and drug management insights

Target Oncology with Precision

Our Impact in Oncology

76%
of our trial portfolio is in oncology

150+
oncology trials conducted in the past 5 years

Precision for Medicine is a specialized oncology CRO that is deeply embedded in the science, strategy, and execution of modern cancer research. From solid tumors to hematologic malignancies, we bring proven experience, therapeutic fluency, and real-time integration between clinical execution and biomarker intelligence.

For emerging innovators, that means faster enrollment, cleaner data, and fewer handoffs—so your programs move forward with clarity and confidence.

Specialized Capabilities for Emerging Innovators

- Biomarker-driven patient selection strategies to enhance response rates
- Advanced trial designs including adaptive, basket, and umbrella approaches
- Experience with novel endpoints and surrogate markers
- Seamless integration with specialty labs for real-time biomarker analysis

Empower your program with the Precision Site Network

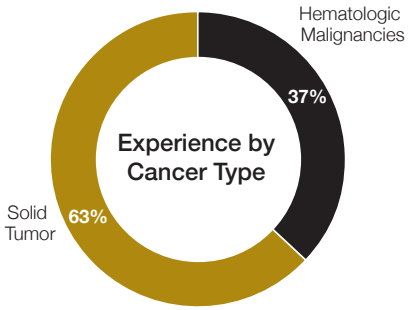
With 3500+ investigators in 100+ sites in 15 countries our site network streamlines every aspect of the clinical trial process, from site selection to patient recruitment.

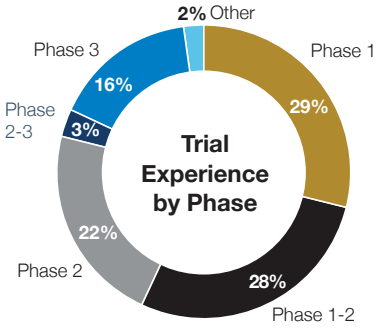
- Curated network of pre-vetted sites to expedite selection
- 6% faster to IRB/EC approval & 12% faster to achieve FPI versus non-PSN sites
- Access broad and diverse patient populations to efficiently achieve recruitment goals

Deep Therapeutic Fluency

In oncology, time is measured in milestones—and missed opportunities. Precision was designed to bring speed, clarity, and scientific rigor across every phase of development.

Whether you're advancing a targeted therapy, immunotherapy, or next-generation cell therapy, our integrated CRO and lab teams work as one—eliminating silos and enabling real-time alignment between trial operations and scientific decision-making.

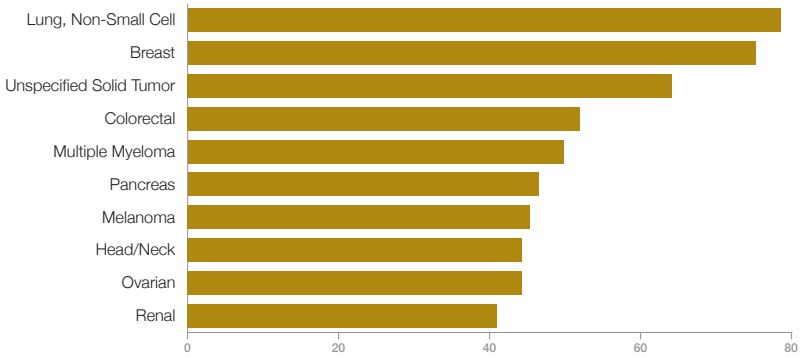




Aligned services for oncology and immuno-oncology

- ApoStreamTM for CTCs
- Epiontis IDSM for immune cell phenotyping
- QuartzBio platform for Biomarker DM & vSIM
- Centralized monitoring
- Diverse oncology biospecimens with genomic characterizations
- Commercialization services
- OncoGenius market insights

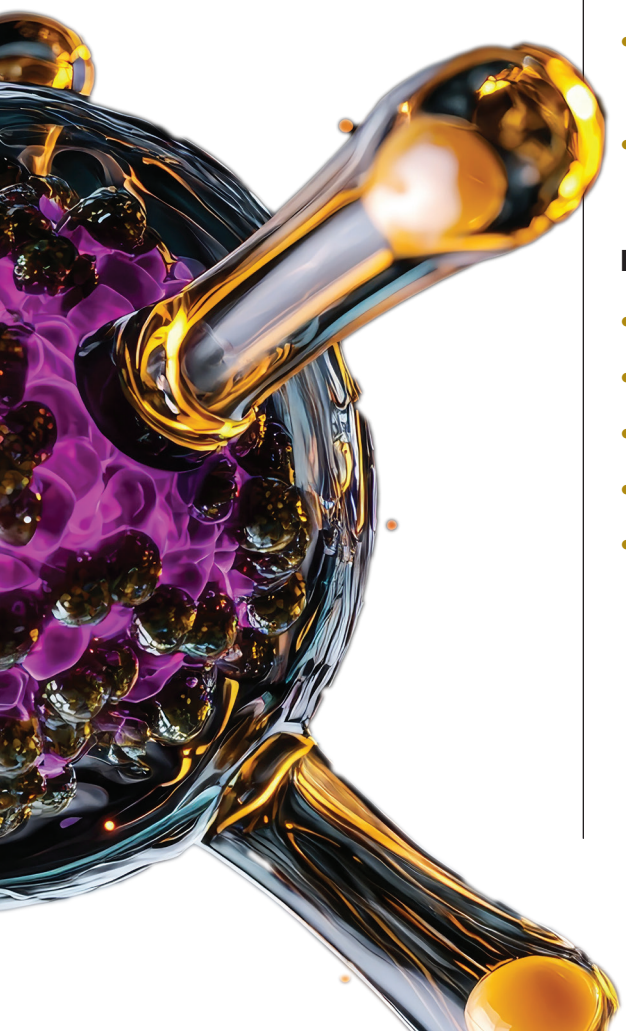
Top Indications at a Glance*



*Additional indications of >15 historical clinical trials include: Non-Hodgkin's Lymphoma, Bladder, Gastric, Prostate, Esophageal, Acute Myelogenous Leukemia, Pain (nociceptive), Pulmonary Hypertension, Neuroendocrine, Soft Tissue Sarcoma, Liver, Myelodysplastic Syndrome, Bile Duct (Cholangiocarcinoma), Cervical, Endometrial, Small Cell Lung, Glioblastoma, Primary Peritoneal, Fallopian Tube.

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



Specialized Expertise for Advanced Therapies

Accelerating Development for Cell Therapy Innovations

For biotech and emerging pharma companies developing cell therapies, Precision provides the specialized expertise needed to navigate unique challenges from concept to approval.

Our Cell Therapy Capabilities

- **Immune Monitoring:** Comprehensive assessment of cellular therapy activity and immune response
- **Flow Cytometry:** Advanced multi-parameter analysis for cell characterization and functionality
- **Digital PCR:** Sensitive detection of genetic modifications and vector persistence
- **Biomarker-Driven Trial Design:** Enhanced patient selection and response monitoring strategies
- **Regulatory Navigation:** Expert guidance through evolving frameworks for cellular approaches
- **Logistics Coordination:** Secure management of chain of custody and chain of identity

Proven Cell Therapy Experience

- 35+ cell therapy trials across autologous and allogeneic platforms
- Expertise spanning CAR-T, TIL, NK, and stem cell approaches
- Purpose-built laboratory capabilities for cellular characterization
- Specialized sample handling protocols for sensitive cellular materials
- Experience working with academic innovators and commercial sponsors

Precision Strategies for Gene Therapies

The path from promising genetic technology to approved therapy requires a partner with deep understanding of the scientific and regulatory complexities unique to gene therapy development.

Our Gene Therapy Capabilities

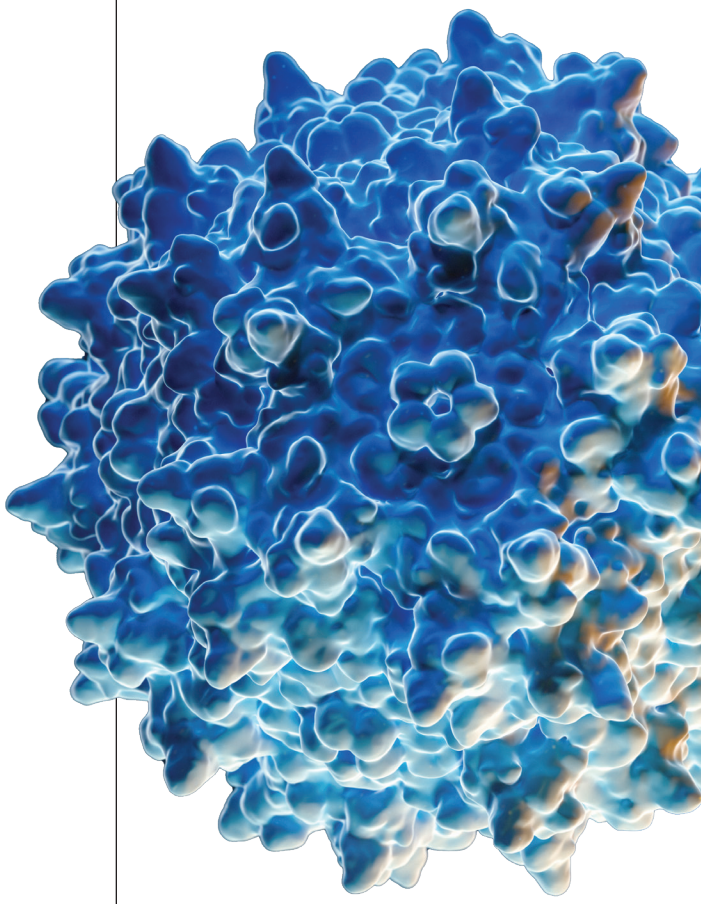
- **Immunogenicity Assay Development and Validation:** Expertise in NAb, TAb, and ELISpot assays across AAV serotypes; development of assays into CDx
- **Vector Analysis:** Comprehensive characterization and detection methodologies
- **Transgene Expression:** Specialized assays to monitor therapeutic efficacy
- **Patient Identification:** Advanced analytics to locate eligible rare disease patients
- **Biomarker Strategy:** Customized approaches for measuring therapeutic effect
- **Integrated Regulatory Support:** Navigation for evolving guidance for novel genetic modalities

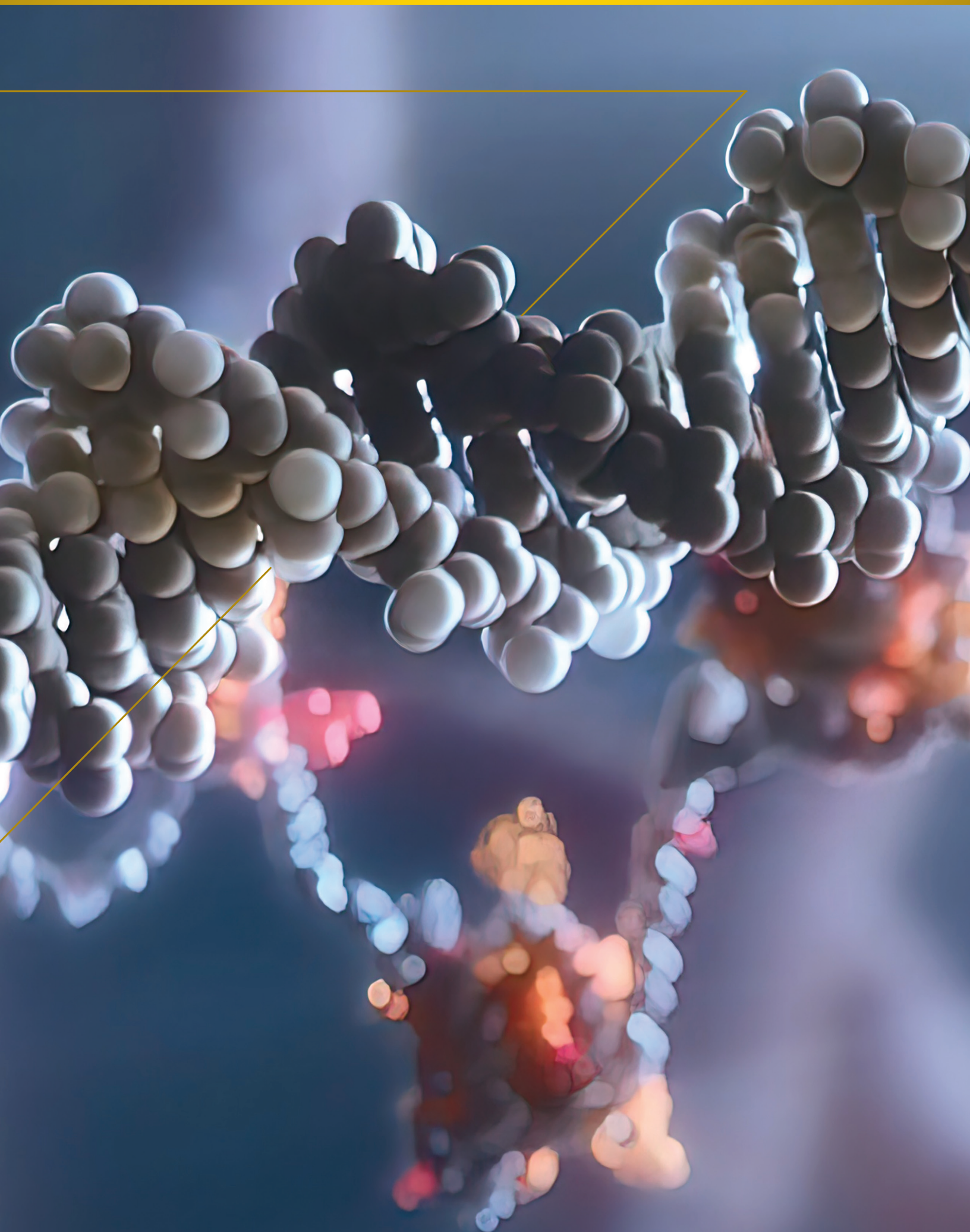
Proven Gene Therapy Experience

- 30+ gene therapy trials across multiple delivery systems
- Expertise with AAV, lentiviral, and non-viral delivery systems
- Experience across numerous rare genetic diseases and oncology
- Specialized expertise in CNS-targeted gene therapies
- Purpose-built laboratory capabilities for gene therapy bioanalysis

30+

gene therapy trials across multiple delivery systems





Rare Disease Expertise, Realized

300+ rare disease trials across nearly 100 rare indications

Rare and orphan disease clinical trials come with an urgency and responsibility to extract meaningful, high-quality insights from each precious patient and data point. Our specialized capabilities overcome the unique challenges of rare disease development, obtaining the most elusive information to answer the most complex questions.

RAREFIED THINKING

When every patient matters, rare study challenges require rarefied solutions

Maximizing Access to Limited Patient Populations

- Advanced approaches to identifying hard-to-find patient populations
- Decentralized trial solutions to reducing patient burden
- Natural history studies and registry development
- Engagement with patient advocacy groups and key opinion leaders

Regulatory and Development Strategy

- Experience with accelerated approval pathways
- Expertise in innovative trial designs for small patient populations
- Specialized biomarker strategies for surrogate endpoints
- Integrated regulatory and clinical strategy to maximize limited resources

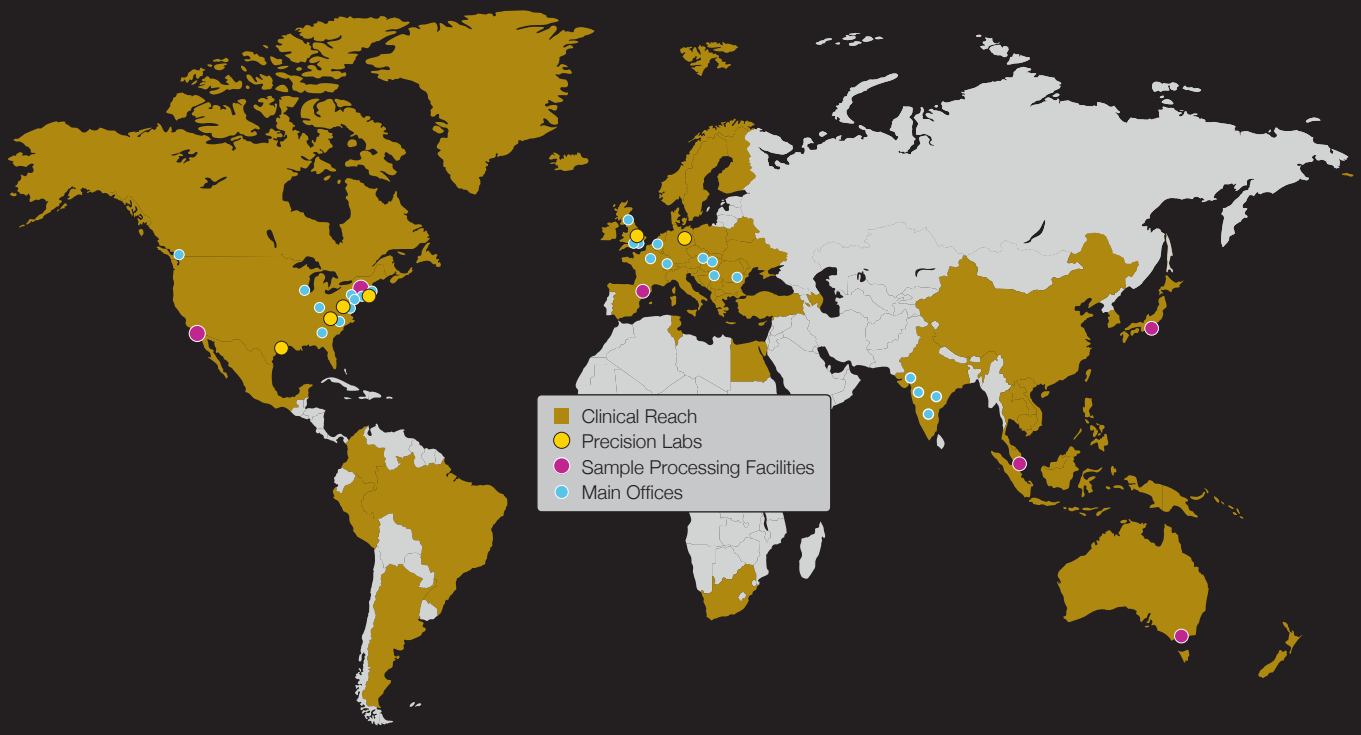
Our rare disease portfolio spans nearly 100 indications across neurological, metabolic, immunological, and genetic disorders, with specialized capabilities to support both pediatric and adult populations.

Integrated and Specialized Services

From promising molecule to next-generation therapy

Built to support innovations from molecule to market, the interconnected breadth and depth of services Precision offers is unparalleled. Precision's global teams and proprietary technologies strategically enhance key milestones across each stage of the development life cycle.

Precision Operates Across 70 Countries



3500+ Employees

12 Sample Processing Locations

55+ countries with active sample logistics

6 specialty labs

40+ Offices

Shared Principles and a Shared Passion for Patients

Client Service

Purpose

Accountability

Mutual Respect

Collaboration

Proceed with Precision

This company was based on an educated hunch that healthcare and especially medicine would become increasingly "personalized" and that the developers of new "precision" medicines would need more innovative, flexible and data savvy partners to both develop and commercialize these bold new treatments."

—Mark Clein, Co-founder of Precision Medicine Group

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Rev. 04

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