Translational and Biomarker Sciences: Enabling Breakthroughs

PRECISION for medicine®

Enabling Breakthroughs by Solving the Most Complex Challenges in Development

Precision for Medicine is the first global, precision-medicine, biomarker-driven contract and clinical research organization, with expertise in today's most advanced techniques for deeply interrogating samples to better understand patient biology.

Our translational solutions begin with biospecimens, through a spectrum of laboratory services from biomarker identification, to clinical immune monitoring, to companion diagnostics development and more.

With teams of responsive industry veterans, we support you by solving complex challenges to fuel breakthroughs at every development stage.

Precision's Translational and Biomarker Sciences:

- Global Support for Innovation
- Central Lab Services
- Biospecimens
  - Characterized Biospecimens
  - Pathology Expertise
- Specialty Lab Services
  - Genomics Services
  - Tissue Biopsy Profiling
  - Flow Cytometry & Immune Monitoring
  - Protein & Cytokine Analysis
  - Bioanalytical Testing
  - Proprietary Technologies

Complementary Solutions:

- In Vitro Diagnostics and Companion Diagnostics Regulatory Consulting
- Clinical Trials
- Data Intelligence & Data Management

Transforming Science Into Solutions Through Integrated Services

Enhancing your research journey from lab to delivery

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

In addition to the ability to solve complex laboratory analysis challenges, today's environment of therapeutic and diagnostic development requires a connected understanding of each aspect of development, along with the experience and savvy to weave those aspects together effectively.

At Precision, we have built a specialized suite of services tailored to the requirements of precision medicine and biomarker-driven development, along with the expertise to customize and integrate those services for each program's unique needs. This approach allows us to support you and deliver more predictable outcomes, accelerate clinical development and in the end, help produce new life-changing treatments for patients around the globe.

Global Support for Innovation

12 Strategic sample processing locations worldwide

>11M Tissue, cellular, and biofluid specimens available

6 Specialty labs in North America, Europe

2500+ Programs supported

Central Lab Services

Foundations for discovery: setting the stage for breakthroughs

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.

Clinical Trial Supply

- 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

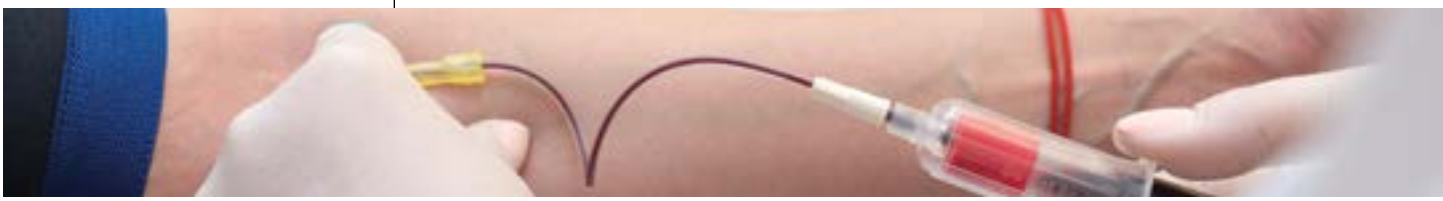
Precision Lab ePortal and vSIM

- Centralized data reporting and analytics
- Virtual sample inventory management (vSIM)
- Kit inventory reports
- Online location for kit reorder
- electronic Sample Requisition Form (eSRF)

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.

Generating data from clinical samples

Supporting assay development and validation

NGS-Characterized Biospecimens

Precision offers extensive clinical samples characterized via next-generation sequencing (NGS) to help researchers optimize biomarker and diagnostic development. These well-characterized, fit-for-purpose samples are essential for optimizing target identification, drug development, and patient selection.

Researchers can choose from Precision's NGS-characterized library, which includes FFPE tissue blocks and liquid biopsy biospecimens like tumor samples, normal and adjacent tissues, DNA/RNA, H&E images, and detailed data.

Precision's NGS-characterized specimen library contains

>13K
FFPE Tissue Blocks

H&E
Images of Every Biospecimen

20
Oncology Indications

In-house pathologists' support ensures precise digital pathology and optimal NGS biospecimen analysis, enhancing diagnostic accuracy

Pathology Expertise

Our group consists of highly qualified board-certified pathologists. They offer support in various areas of clinical research. This includes biomarker discovery and evaluation, companion diagnostics (CDx) development, and in vitro diagnostics (IVD) development. In addition to these, our pathologists aid with clinical trial work, regulatory support, and optimizations.

Pathology Services

With an integrated high-throughput histology laboratory, offering services such as pathologist review and annotation, Precision can support global clinical studies from early-phase discovery and IVD through late-phase studies.

Digital Pathology Solutions

Precision offers digital pathology solutions to enable simpler storage, sharing, and retrieval of whole slide images (WSIs)—for real-time collaboration across laboratories.

Additionally, we have created an archive of digital images from our specimen library. These H&E-stained images can be delivered securely through the cloud and are a powerful tool for quantitative pathology, development of predictive artificial intelligence (AI) models, or other digital pathology uses.

Specialty Lab Services

Overview

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.

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

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+

Therapeutic, diagnostic, and CDx programs supported

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)
- Western blotting – traditional and automated (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

Genomics

Helping you unlock the molecular blueprint

Tailored cutting-edge genomic solutions for your unique project requirements. Leveraging our expertise, we deliver unparalleled results across various sample types, guiding you from assay development through to clinical validation.

NGS & Single-Cell Analysis

Next-Generation Sequencing (NGS) & Single-Cell Analysis

- RNA Sequencing (RNASeq)
- Single-cell sequencing via 10x Genomics Chromium and Illumina NGS
- TruSight Oncology 500 (TSO500) - TMB (tumor mutational burden) and MSI (microsatellite instability)
- Oncomine assays (Oncomine Precision Assay, Oncomine Comprehensive Assay v3, Oncomine Myeloid Assay, TCR sequencing)
- Whole exome sequencing (WES), whole genome sequencing (WGS)
- Custom panels

qPCR/ddPCR

Droplet Digital™ PCR (ddPCR) and qPCR

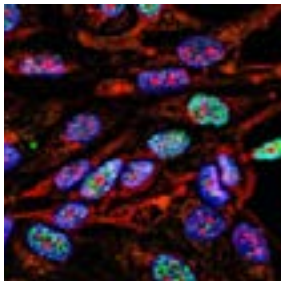
- Biodistribution and shedding of the test article
- Quantification of CAR T cells or other cell therapy products
- Mutation detection/copy number variation (CNV) determination
- Genotyping
- RT-PCR/ddPCR: gene expression, transgene expression
- therascreen® PCR assays

nanoString nCounter®

NanoString nCounter® Technology

- Gene expression panels
- Common panels: PanCancer IO 360™ panel, human immunology v2 panel, CAR-T characterization panel
- Custom CodeSet Plus available

FISH/ISH



Gene expression panels

- FISH: genetic alteration – amplification, insertion, deletion, translocation. HER2 amplification, ALK Break Apart FISH assays
- ISH - RNAscope® assay: in situ RNA detection, preserve spatial information and morphological context

Tissue Biopsy Profiling

Tailored analysis: uncovering each sample's untold story

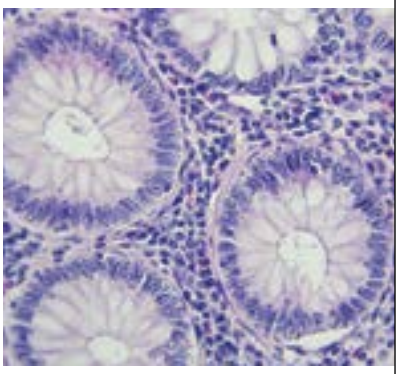
Our tissue biomarker analysis capabilities involve leveraging solutions that provide rich biomarker data – including spatial analysis of cells within and surrounding a tissue or tumor biopsy, as well as our proprietary ApoStream® technology for capturing and enriching rare circulating tumor cells (CTCs) from liquid biopsies.

- ApoStream® – CTC and Rare Cell Capture for Liquid Biopsy
- CTC/cfDNA/ Exosome Analysis
- Multiplex Immunofluorescence (mIF)
- Immunohistochemistry (IHC)
- Fluorescence in Situ Hybridization (FISH)/ISH
- Single-Cell Analysis – 10x Genomics

Utilizing multiplex immunofluorescence and advanced software to gain a deep understanding of tumor and tissue biology

- **Spatial analysis:** quantify proximity of cell types of interest and identify nearest neighbor
- **Infiltration analysis:** define tumor margin and quantify immune cell infiltration
- **Analyze cells & tissues:** quantitate biomarkers in enriched cells such as circulating tumor cells (CTCs)
- **Single-cell detection and phenotyping:** single-cell intensity and spatial coordinates to study single cells or entire subpopulations and the importance of their location within the tumor microenvironment
- **Classifier analysis:** AI algorithms that can be used to classify different tissue regions or structures to have them analyzed separately

Globally integrated IHC solutions



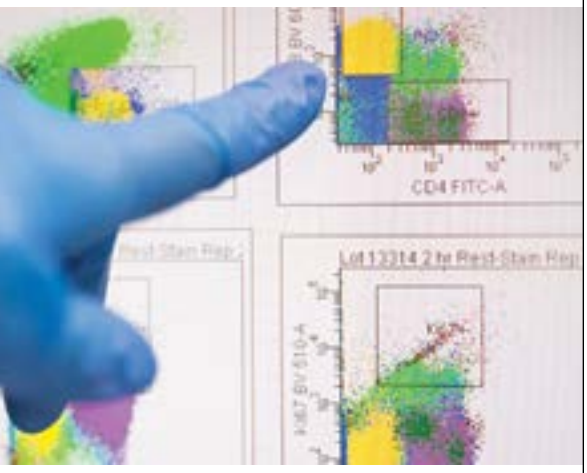
Immunohistochemistry

From biomarker identification to tissue cross-reactivity testing, to development of companion diagnostics, Precision excels in the use of immunohistochemistry in therapeutic and diagnostic development.

- **Global Laboratories:** Our services span across three international labs, equipped with advanced, redundant instruments to guarantee accuracy and reduce variability.
- **Expert Analysis:** Our staff pathologists deliver detailed and reliable interpretations, supported by our comprehensive FFPE tissue repository.
- **Innovation in CDx:** Our capabilities for the development of IHC-based companion diagnostics underscores our dedication to pioneering solutions that meet the evolving needs of researchers.

Flow Cytometry and Immune Monitoring

Unraveling the complexities of immunity: precision techniques for detailed insights



Precision provides an industry-leading array of comprehensive immune monitoring services and solutions, from the development of customized assays for early clinical studies to managing the logistical and immune monitoring testing needs of global, multisite studies.

We leverage multiple technology platforms on a global scale, including proprietary innovations like Epiontis ID®.

Flow Cytometry

We offer a range of advanced multiparameter standard and spectral flow cytometry assays using cutting-edge equipment, including up to 64-color instruments and clinical grade cytometers:

- Immunophenotyping
- Intracellular cytokine staining (ICS)
- Real-time whole blood analysis
- Receptor occupancy (RO) assays
- Phospho-flow analysis
- Tumor microenvironment analysis (MDSC/TIL)
- Cell therapy analysis
- Antigen-specific analysis
- Fluorescence-activated cell sorting (FACS)

Epiontis ID® – Optimized Immune Profiling

Within our suite of immune monitoring services, Epiontis ID® proprietary technology stands out by offering an epigenetic approach to cell profiling.

This innovative technology enhances our robust immune analysis by targeting cell type-specific epigenetic markers, delivering automated, precise results.

Epiontis ID® streamlines your study by:

- Minimizing sample processing
- Simplifying logistics
- Ensuring comparability across global trials
- Providing over 35 validated assays

ELISpot and FluoroSpot

Sensitive assays for the enumeration of cytokine-secreting cells at the single-cell level. Both ELISpot and FluoroSpot assays are offered to support global preclinical and clinical projects, providing prevalidation and validation services using standard and custom assays.

Gene Expression Profiling of Biopsies

Precision leverages advanced technologies to decode target expression and both adaptive and innate immune responses at the gene expression level. Our expertise unlocks deep insights into the immune status of tumor and tissue biopsies, and facilitates the analysis of rare circulating tumor cells through liquid biopsy.

Protein and Cytokine Analysis

Decoding proteins: paving the pathway to progress

From cytokine profiling to advanced Western blotting and Olink® analysis, we align our expertise to your unique research needs with multiple advanced platforms.

ELISA Assays

- Multiple platforms (colorimetric, fluorescent, luminescent)
- All regulatory levels
- Ideal for single analytes that do not multiplex well

Olink® Proteomics

- Multiplexing up to 92 targets
- Minimal clinical sample volume
- Exceptional sensitivity and specificity
- Broad dynamic range
- A wide range of sample types

Meso Scale Discovery (MSD)

- Panels of 10-131 analytes
- V-plex, S-plex, U-plex, R-plex, and T-plex assay formats
- Lower sample volume
- Less matrix interference

Automated Western Blotting—Jess

- Minimal clinical sample volume
- Reproducible data with intra-assay CVs <15%
- High throughput with minimal hands-on time
- Quantitative and versatile

Luminex® Assays

- xMAP technology and R&D systems
- Multiplex up to 50 analytes
- Rapid analysis; up to 4800 results per plate
- Wide dynamic range with high sensitivity

Sensitivity and multiplex capabilities of Precision's platforms:

	ELISA	MSD	Olink® Proteomics	Luminex®	Jess Automated Western Blotting
Sensitivity	ng/mL-pg/mL	ng/mL-fg/mL	pg/mL	pg/mL	pg/mL
Dynamic Range	2 logs	>4 logs	3-4 logs	>4 logs	3-4 logs
Multiplex Capabilities	1	10	45/92	50	1-3
Sample Volume	50-100 µL	25 µL	1 µL	50 µL	3 µL
Use	All stages	All stages	All stages	Early stages	All stages

Bioanalytical Testing

Deep-dive bioanalysis: translating biodata into insights

Guided by your bioanalytical needs, we provide comprehensive support for large molecule drugs. This includes areas of pharmacokinetics and immunogenicity/immune response, and extends to complex biologics such as PEG, bispecifics, ADC, gene therapy, and cell therapies (including CAR T-cell and other types of cell therapy).

Immunogenicity Testing

Precision specializes in challenging immunogenicity projects, such as the evaluation of multidomain proteins, PEGylated proteins, antibody drug conjugate (ADC), and development of gene therapy antidrug antibody (ADA) assays in multiple AAV serotypes.

Assays

- ADA Assays
- Neutralizing antibody (NAb) assays
- Specialty techniques (acid dissociation, SPEAD)
- Specialty assays (eg, complement)
- Fully compliant (CLIA) cell-based NAb assays

Unique Offerings

- Specialty assays (eg, functional IgE, anti-PEG IgG, and IgM assays)
- Detection of circulating B lymphocytes producing ADA
- Detection of drug-specific immune complexes and complement activation
- Binding of ADA to aggregated drug

Neutralizing Antibody (NAb) and Total Antibody (TAb) Assays

We support preclinical through post-market studies with ADA assays for biologic, biosimilar, gene therapy, and companion diagnostic development.

Precision's ADA assays are generally conducted using ELISA or Meso Scale Discovery (MSD) technologies.

Integrated services going full circle: qualified biospecimens with in-house pathology services

Pharmacokinetic (PK) Assays

We offer assay development, validation, and implementation to support the following PK analyses:

- Nonclinical (GLP and non-GLP)
- Clinical (from first-in-human to late-stage pivotal)

GLP-Compliant Tissue Cross-Reactivity Testing

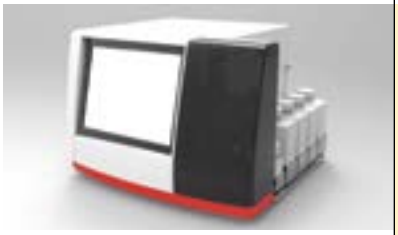
The unique combination of research services and tissue procurement capabilities forms the pillars of our TCR services.

- Confirmation of tissue antigenicity
- TCR screening using frozen tissue microarrays (TMA) for rapid data delivery prior to fully GLP-compliant studies
- GLP tissue cross-reactivity studies utilizing all 36 required human tissue types

Proprietary Technologies for Liquid Biopsy and Immune Monitoring

Innovation at the forefront: unique technologies advancing research

At Precision, we are dedicated to pioneering advancements that empower researchers with precise, actionable insights. Our proprietary technologies, ApoStream® and Epiontis ID®, exemplify this commitment, offering sophisticated solutions for liquid biopsy and immune cell profiling.



ApoStream® - Novel Approach To Rare Cell Enrichment

Precision's complete solution for CTC liquid biopsy is enabled via ApoStream®, a device that isolates and enriches CTCs, facilitating any type of downstream analysis, such as multiplex quantitative immunofluorescence or FISH/ISH.

ApoStream® can also be used to collect other rare cell types, such as stem, progenitor, and differentiated immune cells, including CAR T cells and other difficult-to-identify immune cell populations for immuno-oncology applications.

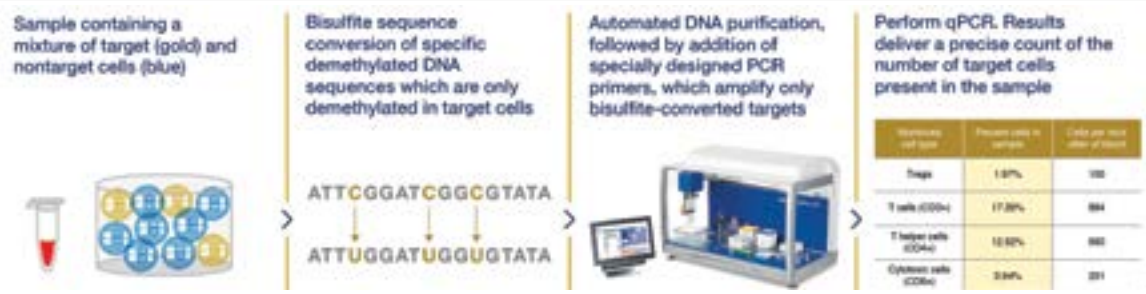
Some benefits of ApoStream® include:

- Antibody-independent rare cell capture
- Enriches rare cells present in low frequencies from biofluids
- Small starting volume
- No binding with target cells during processing
- Minimal cell loss during processing steps
- Compatible with multiple downstream
- biomarker assays (NGS, ddPCR, quantitative mIF, FISH/ISH, etc.) Parameters to control high recovery and high purity

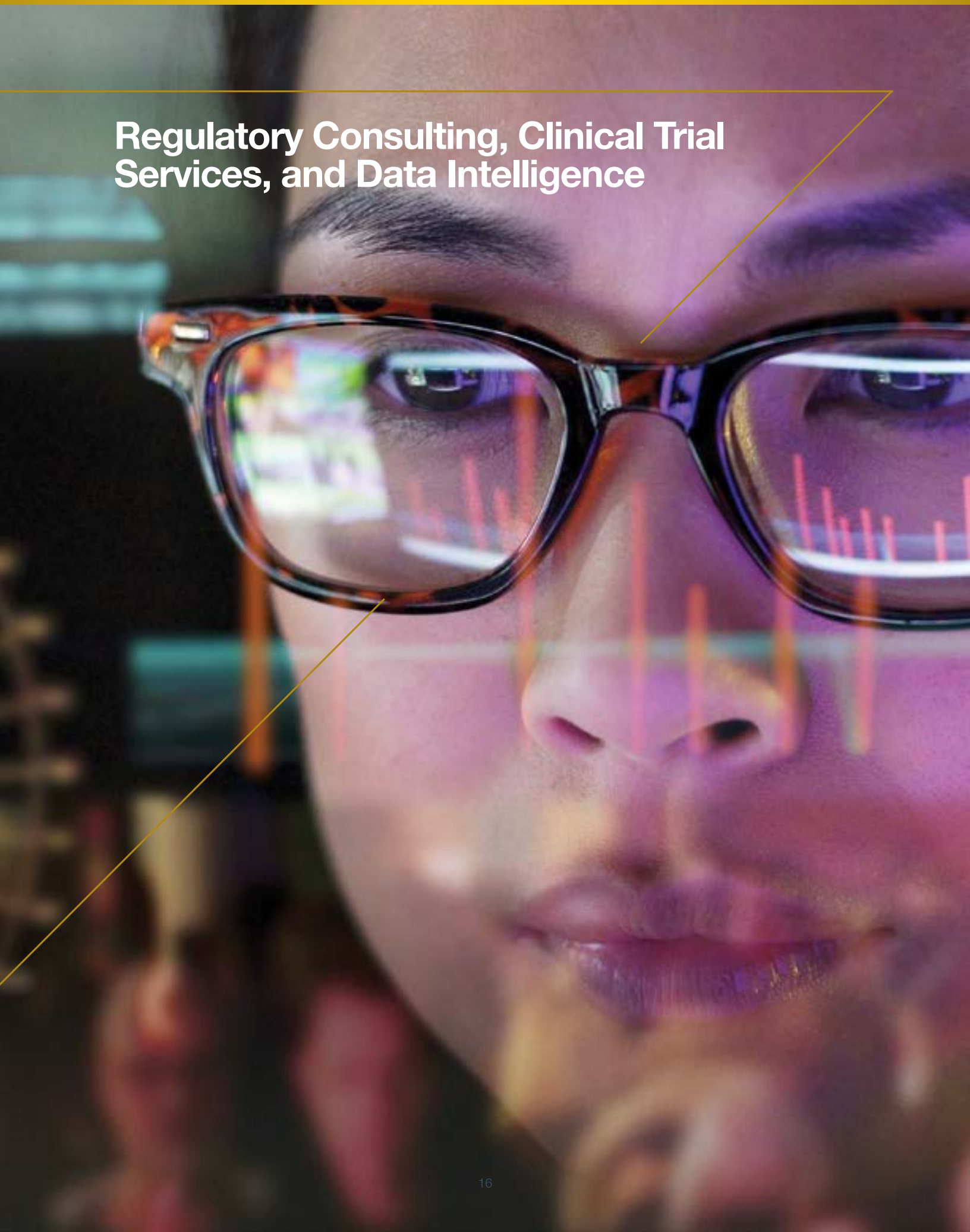
Epiontis ID® – Unique Approach To Immune Monitoring

Precision's Epiontis ID® technology with its unique approach to cell phenotyping, is a robust, adaptable, and cost-effective solution for immune cell profiling. Epiontis ID® uses unique methylation patterns to distinguish cell types, as all cells have the same DNA but differ in gene expression. This approach amplifies demethylated DNA regions in specific cells using a custom process and qPCR primers, allowing precise cell count in any sample.

- Simplified Logistics: no need for complex sample preparation or rushed shipments
- Wide Range of Sample Types: monitor immune cells in whole blood, tissue, and many other biological samples
- Precise and Reproducible Results: excellent comparability of results within and across studies
- Proven Clinical Utility: routinely used in clinical studies, including as a secondary outcome measure



Regulatory Consulting, Clinical Trial Services, and Data Intelligence



IVD and CDx Regulatory Consulting

Global IVD regulatory support across all therapeutic areas and technologies

Precision for Medicine's IVD Regulatory Team provides end-to-end regulatory support to ensure commercialization success and beyond. Expert guidance is essential for the challenging journey of bringing a diagnostic or CDx from development to market.

Our team of IVD regulatory experts is ready to walk you step-by-step through these processes and guarantees to streamline the path to success for your IVD product.

Empowering treatment decisions: comprehensive CDx solutions

The development of CDx can carry challenges beyond the development of a stand-alone IVD, including the need to coordinate the CDx development with its therapeutic, IVD-specific regulatory submissions for clinical trial testing and registrations to align parallel approvals of the therapeutic and CDx.

Precision's IVD regulatory team excels at supporting co-development for CDx, from early-phase biomarker development through therapeutic and CDx market authorizations.

- Global regulatory strategy development and regulatory pathway identification
- GAP Analyses for reagents, software, and hardware (CLIA vs CLSI)
- Therapeutic/diagnostic partnering strategy and support
- Diagnostic testing strategy and protocol designs for biomarker-based patient selection clinical trials and IRB/EC submissions
- Clinical trial enabling IVD regulatory submissions (eg, SRD, pre-IDE, Q-submission, IDE, Annex XIV, local ethics committee, and ITA)
- Clinical trial assay analytical validation study plans and execution; CLIA and CLSI guidelines
- IVDR and UKCA mark technical documentation file development
- US 510(k), Special 510(k), EUA, de novo, and PMA development and submissions
- Labeling, advertising, and promotion
- Postmarket surveillance, product life-cycle management, product updates, and supplemental filings

350+

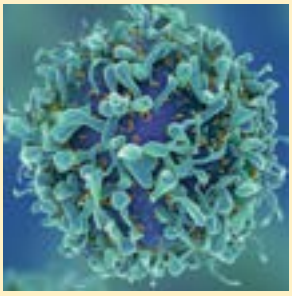
IVD and CDx Global Regulatory Submissions and Registrations

Global Clinical Trial Services

Complexity is our playground and research is our passion

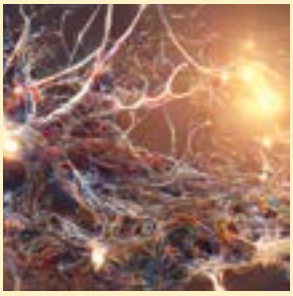
Precision is purposefully built to support the unique and complex demands of advanced therapies and the continued evolution of next-generation medicine. With a focus on delivery, service, and efficiency, your project's success is our top priority.

Therapeutic expertise to support the most complex development plans

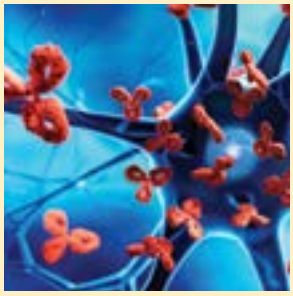


Oncology and Immuno-oncology

Rare and Orphan Disease



CNS and Neuroscience



Autoimmune

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

- Clinical development planning and consulting
- Biomarker-driven clinical trial strategy and execution
- Companion diagnostic development and go-to-market strategy
- Regulatory affairs strategy and consultancy
- Decentralized clinical trial solutions
- Complex basket, master protocol, and umbrella trial management
- Relationships with key academic centers via the Precision Site Network

140+
Biomarker-Driven Trials

600+
Projects

55%
International Studies

Data Intelligence

Harness sample and biomarker intelligence with QuartzBio® SaaS products

Overcome the data chaos inherent in modern drug development with a suite of fully connected SaaS solutions for clinical operations, biomarker operations, and translational teams.

Built on the first AI Biomarker Intelligence platform that supports the entire precision medicine development lifecycle, QuartzBio® products enable clients to avoid costly delays or discrepancies, improve collaboration, generate insights faster, and make more accurate and informed decisions.

QuartzBio's AI-enabled Biomarker Intelligence platform shortens the time from data to insights. To build a high-quality data asset, QuartzBio's Data Management tools automatically ingest data, map to a standardized data model, and check data to surface anomalies. The platform's Business Intelligence tooling deliver capabilities for data exploration and reporting.

virtual Sample Inventory Management (vSIM)	Gain AI-powered insights into biospecimen status and consent across multiple sites, labs, and repositories, over the entire sample lifecycle.
enterprise Biomarker Data Management (eBDM)	Acquire, QC, and transform all your biomarker data, including exploratory data, preclinical data, and public repositories—connected to sample and clinical data—across your enterprise.
Analytics, reporting, and AI-powered insights	Enhanced Biomarker Intelligence capabilities provide advanced analytics, reporting, and conversational AI-powered insights to vSIM and eBDM products. Along with access to our AI-powered Virtual Assistant, enhanced capabilities offer advanced on-study and portfolio-wide reporting and visualization for complex data.

Solving the most complex challenges in biomarker-driven and precision therapeutic development

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For more information please visit us at: precisionformedicine.com

Rev. 02

PRECISION for medicine®