IVD Regulatory Consulting

PRECISION for medicine®

IVD & CDx regulatory consulting to accelerate commercialization

Bringing a product from development to market can be challenging to navigate, which is why it is crucial to have a team of experts who know the ins and outs of the development life cycle for your diagnostic or companion diagnostic (CDx). Our team of In Vitro Diagnostic (IVD) Regulatory Affairs experts are ready to walk you step-by-step through these processes and guarantee to streamline the path to success for your IVD product.

200+

IVD & CDx PRESUBMISSIONS, IDEs, ITAs, AND ANNEX XIV SUBMISSIONS

250+

510(K), SPECIAL 510(K)s, EUAs, DE NOVOS, PMAs, PMA SUPPLEMENTS FOR IVD & CDx SUBMISSIONS IN THE US

100+

IVD & CDx GLOBAL REGISTRATIONS

Precision for Medicine provides expertise and support across IVD development, offering comprehensive regulatory strategy, early agency interactions, design of analytical validation studies, clinical trial designs, and global regulatory submissions. No matter where you are seeking approval, we can help you work with the FDA, EMA, MHRA, NMPA, PMDA, IVDR-designated Notified Bodies, EU Competent Authorities, and design a regulatory solution.

Global IVD regulatory support across all therapeutic areas and technologies

Comprehensive IVD & CDx regulatory services

Development of Product Technology

- Regulatory Strategy Development & Regulatory Pathway Identification (eg., FDA/LDT, product class/IVDR)
- Indications & Claims Development
- POC vs Laboratory vs Home Use
- Product Design Considerations
- Diagnostic/CDx Partner Identification

Product Development, Preclinical Submissions, and Evidence Collection

- Analytical & Clinical Study Designs
- Diagnostic Protocol Design & IRB Submissions
- Annex XIV Submissions
- Q-submissions & Meetings With FDA
- Study Risk Determinations for Clinical Trial Assay (CTA)

Timely Regulatory Approval

- IDE, 510(k), Special 510(k), EUA, De Novo, and PMA Submissions
- IVDR Technical Documentation File Development for EU
- Global Registration Filings
- Breakthrough Device Designations
- CLIA Classification/ CLIA Waiver
- Compliance With UK MDR 2022 and UKCA Mark Approvals

Commercialization Planning

- Labeling/Advertising/ Promotion
- QMS Mock Audits
- Registration & Listing

Product Launch & In-Market Support

- Postmarket Surveillance
- QMS Certification
- Product Life Cycle Management
- Product Updates and Supplementary Filings

Global companion diagnostics (CDx) regulatory expertise

The development of companion diagnostics can carry challenges beyond the development of a stand-alone diagnostics (IVD). Precision's team excels at supporting co-development of a CDx and it is therapeutic, from early phase biomarker development through therapeutic and CDx market authorizations.

- 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

Preclinical to Phase 1	Phase 2	Phase 2/3	Phase 3
Identify Biomarker Signature	Partner ID & IVD Clinical Trial Submissions	Analytical Study Designs & Pre-Submissions	Ensure Timely Regulatory Approval

Gene therapy CDx regulatory support

Precision for Medicine has supported over 18 AAV-focused gene therapy companies and their projects for customized assay development. Our regulatory team provides comprehensive support at each critical step of the development timeline from advising on requirements and design through analytical and clinical protocol development and execution. In parallel, Precision for Medicine will draft the required regulatory documentation (SRD, IDE, Annex XIV, ITA) to support clinical trials and final commercialization (PMA, CE Mark, UKCA Mark) while communicating with the regulatory bodies to ensure compliance and streamlined review of submissions.

Assay Type	Capsid	
NAb	• AAV2 • AAV rh.10 • AAV5	• AAV8 • AAV9 • AAV2.7m8
TAb	• AAV2.7m8 • AAV5	• AAV8 • AAV9
ELISpot	• AAV1 • AAV2.7m8 • AAV5	• AAV8 • AAV rh.10 • Proprietary

COVID-19 and viral panel assays

Chaperone the transition from EUA to global registrations

GAP ANALYSIS

Conduct a GAP analysis from EUA assay to CLSI-compliant analytical and clinical validation performance studies/data as well as other FDA-required performance metrics, such as sample stability studies

SOFTWARE ASSESSMENT

Evaluate the software package for the assay and instrument or mobile phone app to ensure compliance to FDA requirements for a 510(k) or de novo

REGULATORY STRATEGY

Develop a robust regulatory strategy and transition implementation plan that evaluates regulatory pathway (submission type), intended use, final assay configuration, repurposing previously collected data, and determining additional data requirements for the premarket submission

SAMPLE SOURCING AND STUDY EXECUTION

Determine your sample needs: Precision for Medicine clinics and a biobank of specimens are study ready to support all validation and submission requirements and assess impact of vaccinated patients on cohort

Design and conduct your clinical and usability studies

QUALITY MANAGEMENT SYSTEMS

Conduct a gap assessment to help transition the assay and instrument from research phase to documentation under design control and manufacture to GMP requirements

PRESUBMISSION / DE NOVO OR 510(K) / CE MARK

Draft a presubmission that includes an analytical and clinical validation plan to facilitate discussions with the agency to close the gaps for analytical and clinical validation performance studies. Begin drafting the premarket submission with the data you do have: 510(k) or de novo

EU and UK Regulatory Expertise

Traditional & advanced IVD regulatory affairs consulting services across Europe

CE Mark to IVDR

The In Vitro Diagnostic Regulation (IVDR) adopted by the European Union seeks to enhance transparency, quality, and safety in the manufacture of IVD medical devices, including CDx. Meeting IVDR requirements may be challenging, particularly for first-time manufacturers or those who have a broad IVD portfolio. Precision for Medicine understands the spectrum of changes and both premarket and postmarket requirements for obtaining your CE mark.

UKCA Mark

Manufacturers in the United Kingdom need to obtain UK Conformity Assessment marks (UKCA) marks to legally market their IVD in England, Scotland, and Wales. Precision for Medicine has experience with the UKCA mark and can provide a variety of regulatory service offerings to streamline your path to market.

Regulatory Service Offerings

EU

- Regulatory strategy
- Gap assessments from IVDD to IVDR documentation file
- Submission to the competent authorities and ethics committees for clinical trial assay (CTA)
- Product risk classification and conformity assessment routes
- Labeling (CE mark)
- Technical documentation file development for compliance to IVDR CE marking
- Notified Body ID and communications

UK

- Regulatory strategy
- Notification to the UK Medicines and Healthcare products Regulatory Agency (MHRA) and ethics committee for a CTA
- Conformity assessment routes
- Essential requirements
- Labeling (UKCA marking)
- Device registration submission to MHRA
- Notified Body ID and communications

Translational science solutions to support IVD development

Biospecimens

Quality science begins with quality biospecimens. Thousands of IRB-approved, clinically annotated biospecimens ready to ship the same day to your lab.

Blood, biofluids, and derivatives

Disease-state and healthy human blood, plasma, serum, CSF, stool, ascites fluid, saliva, urine, and more

Viable cells

HLA-typed cellular products, including PBMCs, BMMCs, leukopaks, 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 disease-state human subjects

Custom biospecimen collections

Global clinical network, regulatory approved, and ready to enroll

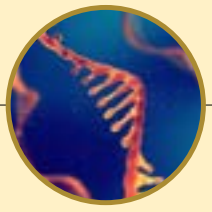
Specialty Lab Services

Globally recognized innovators in biomarker-driven development. Comprehensive suite of technologies, capabilities, and proprietary approaches to interrogate any sample type

DNA

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

RNA

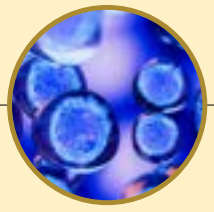


- Gene expression profiling – NanoString
- Bulk and single-cell RNASeq
- RT-PCR and RT-ddPCR
- Spatial transcriptomics

Protein

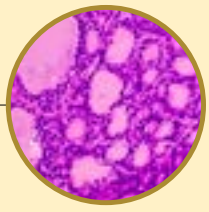
- Comprehensive large-molecule bioanalysis – PK, ADA, NAb, TAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays – ELISA, MSD, Olink®
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)
- Western blotting – traditional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

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

Download your digital copy

For more information please visit us at: precisionformedicine.com

Rev. 02

PRECISION for medicine®