

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, or 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 stand-alone diagnostics (IVD). Precision's team excels at supporting co-development of a CDx and its 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



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	<ul style="list-style-type: none"> • AAV2 • AAV rh.10 • AAV5 • AAV8
TAbs	<ul style="list-style-type: none"> • AAV2.7m8 • AAV5 • AAV8

COVID-19 and viral panel assays

Chaperone the transition from EUA to global registrations



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 (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, BMDCs, 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

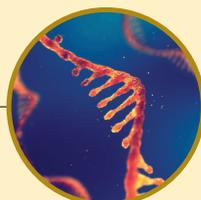
Globally recognized innovators in biomarker-driven development. Comprehensive suite of technologies, capabilities, and proprietary approaches to interrogate any sample type.

DNA



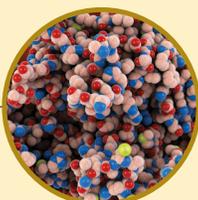
- PCR—ddPCR, qPCR
- NGS—whole-exome and targeted resequencing

RNA



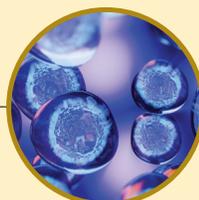
- Gene expression profiling—NanoString
- CAR T and virus (ie, gene therapy) biodistribution
- rtPCR
- MicroRNA analysis

Protein



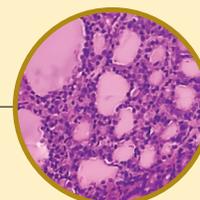
- Comprehensive large molecule bioanalysis—PK, ADA, NAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays—ELISA, MSD, Biacore
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling)

Cell



- Flow cytometry—up to 31 color panels, ICS, phosphoflow, receptor occupancy
- Functional assays—eg, T-cell activation, ADCC, ELISpot
- Single-cell quantitative image analysis
- Proprietary cell separation technology for CTCs and cfDNA
- Immunophenotyping via proprietary epigenetic platform

Tissue



- Multiplex IHC with centralized pathology reading
- Quantitative IF—up to 9 concurrent markers
- FISH, ISH, sequencing

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



7.5

MILLION LIQUID BIOSPECIMENS

3.5

MILLION TISSUE BIOSPECIMENS

7

LABS ACROSS NORTH AMERICA AND EUROPE

90+

MEDICAL CONDITIONS FOR PROSPECTIVE COLLECTIONS

350+

IVD AND CDx SUBMISSIONS AND GLOBAL REGISTRATIONS

Providing End-to-End Solutions for IVD and CDx Development



Biospecimens



Clinical Trial Support



Kitting & Logistics



Lab Services



Regulatory Consulting



Download your digital copy

precisionformedicine.com/diagnostics

© 2023. All rights reserved.
Rev. 02

PRECISION
for medicine®