

Regulatory Guidance and Diagnostic Development

End-to-end submission strategy and support, from the only CRO purpose-built for precision.

Regulatory Services

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.

- Regulatory strategy development and regulatory pathway identification (eg, FDA/LDT, product class/IVDR)
- Diagnostic protocol designs and IRB submissions
- IDE, 510(k), Special 510(k), EUA, *De Novo*, and PMA submissions
- ANNEX XIV submissions and IVDR technical documentation file development for EU
- Global registration filings

Companion Diagnostics Regulatory Expertise

The development of companion diagnostics (CDx) can carry challenges beyond the development of a stand-alone diagnostic, including the need to coordinate the CDx development with its therapeutic to align parallel approvals.

Precision regulatory experts excel at supporting co-development, from early phase biomarker development through therapeutic and CDx market authorizations.

- Global CDx regulatory strategies and submissions to ensure successful CDx and therapeutic approvals
- Diagnostic clinical trial testing strategy for patient selection; central lab vs multiple LDTs
- Clinical trial assay analytical validation study plans and execution; CLIA vs CLSI Guidelines
- Diagnostics clinical protocol development and IRB approvals
- Clinical trial enabling IVD regulatory submissions globally (SRD, Q-Sub, IDE, Annex XIV, ITA)
- Therapeutic/diagnostic partnering strategy, identification, and support

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

100+

IVD & CDx GLOBAL REGISTRATIONS



Translational Research Services and Capabilities

**A uniquely
comprehensive
resource of
biospecimens &
biomarker services
from the only CRO
purpose-built
for precision.**

Therapeutic Breadth

- Oncology
- Cardiovascular
- CNS
- Dermatology
- Gastroenterology
- Immunology & Rheumatology
- Infectious
- Metabolic
- Ophthalmology
- Rare & Orphan
- Reproductive
- Respiratory

Delivering Value Throughout the Development Lifecycle



Global CRO



**Central & Specialty
Lab Services**



Biospecimens



**Data
Intelligence**



**Regulatory
Expertise**



Commercialization



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