



Don't Let Diagnostic Regulation Become Your Clinical Trial Bottleneck

Align your regulatory pathway with your biomarker strategy and clinical execution from the beginning.

Biomarker-driven trials must conform to diagnostic-specific regulatory requirements before testing can begin. Without the right approach, this process can delay trial initiation while you await submission review and approval.

CellCarta connects regulatory strategy, assay development, and global laboratory execution from day one to help therapeutic developers reduce regulatory hurdles and meet global requirements, advancing programs toward approval and enrollment assays toward CDx commercialization if needed.

NEW REAL-WORLD EVIDENCE: DIAGNOSTIC APPROVAL CAN STALL CLINICAL TRIAL PROGRESS

CellCarta contributed de-identified operational data on PSA and EC submissions to the peer-reviewed analysis of clinical trials across Europe¹.

RESULTS SUMMARIZED

132

PSA and EC submissions
investigated

129 DAYS

Mean combined approval time for
PSA and EC submissions

32–346 DAYS

Observed range for combined
submission timelines

76 – 175 DAYS

Mean country-level timelines in the
EU for combined approval

1. Hersey, Sarah, et al. "Diagnostic regulatory pathways are an underrecognized bottleneck in precision oncology clinical trials: Real-world evidence across Europe." *European Journal of Cancer*, vol. 246, Oct. 2026, p. 117009, <https://doi.org/10.1016/j.ejca.2026.117009>.

Legend: EC – Ethics Committee, EU – European Union, PSA – Clinical Performance Study Application

HOW CELLCARTA HELPS

SYNC REGULATORY AND SCIENTIFIC STRATEGY

Align biomarker strategy, assay development, validation and regulatory path early, including for central, local or hybrid testing.

NAVIGATE GLOBAL REQUIREMENTS

Custom solutions to help teams navigate country-specific requirements, prepare regulatory submissions, and coordinate diagnostic pathways across Europe, the U.S., China and key global markets.

BUILD THE PATH TO CDx WHEN NEEDED

Connect clinical trial assay development and validation with IVD/CDx approval and commercial deployment.

IDENTIFY THE RIGHT PATHWAY FOR CLINICAL TESTING

Based on your trial stage and goals, choose the right submission path to minimize time from assay validation to clinical testing initiation.

For certain EU trials, CellCarta can develop and deploy an in-house IVD under the IVDR's Health Institution Exemption, which can reduce the time between assay validation and sample testing by up to 9 months.

WHAT SETS CELLCARTA APART

Proven regulatory experience integrated with laboratory execution.

190+

IVDR
submissions

37+

PSA packages
assisted across 27
EU countries

150+

PMA projects
supported

30+

CDx projects
supported

Legend: CDx – Companion Diagnostic, EU – European Union, IVDR – In Vitro Diagnostic Regulation, PMA – Premarket Approval, PSA – Clinical Performance Study Application



SET YOUR TRIAL UP FOR SUCCESS BY ENGAGING CELLCARTA EARLY.

Build the diagnostic regulatory path alongside the clinical development plan, not after it.

Biomarker
Strategy

Assay Development
and Validation

Regulatory Submission
and Approval

Sample Management
& Logistics

Clinical Sample
Testing

Data
Analytics

CDx
Development



Benefit from our multi-omic capabilities, scientific depth, and global reach.

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