CellCarta

CellCarta May Provide EU Clinical Trial Testing Under Article 5(5) of the IVDR

What Does This Mean for Your Program?

For eligible clinical trials running in the European Union (EU), CellCarta can perform in-house *In Vitro* Diagnostics (IVD) testing. This pathway can reduce time and costs without compromising quality.

Based on updates to FAMHP's "Q&A on the Belgian and European rules for in-house IVDs", certain clinical trial activities at CellCarta may, where applicable and subject to compliance with all relevant requirements, be performed using in-house IVDs within the scope of IVDR Art 5(5). This update applies to both our Antwerp and Gosselies laboratories, spanning histopathology, genomics, immunology, and proteomics assay capabilities, creating a more streamlined path from assay validation to clinical trial sample testing.

POTENTIAL BENEFITS FOR YOUR CLINICAL TRIAL IN THE EU:

1. **Uncompromised quality:** The same high-quality assay design and development processes as before, compliant with the General Safety and Performance Requirements (GSPR)
2. **Accelerated timelines:** Can reduce the timeline between assay validation and first sample testing by up to nine months
3. **Less regulatory complexity:** Can reduce regulatory documentation traditionally associated with IVDR clinical performance study approval
4. **Reduced costs:** Submission fees may no longer apply and total regulatory work decreases
5. **Greater flexibility:** Follow the testing pathway that best supports your program

WHAT CELLCARTA CAN PROVIDE OVER TRADITIONAL HEALTH INSTITUTIONS:

- ✓ Assay development and testing occurs within a high-quality framework, supported by a strong IVD expertise
- ✓ Reduced operational complexity, with one central partner the entire way to ensure data consistency
- ✓ Dedicated scientific expertise in assay development, validation, and implementation of in-house IVDs

POSSIBLE PATHWAYS FOR CLINICAL TRIAL TESTING

1 Existing CE-marked assay

Use an existing, CE-marked commercial assay for its intended purpose (on-label).

The benefit:
No further regulatory action is needed, and the assay can be rapidly implemented following validation.

Best used when:
The assay already exists and meets study requirements.

2 Clinical Performance Study for custom assays and off-label use

Develop a custom assay and submit a Clinical Performance Study in every EU country where samples are collected, **typically taking 5 – 10 months** before sample testing begins.

The benefit:
Delivers data ready for CE-marking of your assay built for long-term, multi-site use across the EU and beyond.

Best used when:
Supporting a future CDx filing, or running registrational clinical trials.

3 In-house IVD now available at CellCarta under IVDR Article 5(5)

Run an in-house IVD when eligible, **possibly reducing the wait between assay validation and sample testing by up to 9 months.**

The benefit:
Major time and cost savings without compromising on high standards of quality.

Best used when:
Supporting non-registrational or early-stage studies and where the data is not intended to support an immediate CDx/IVD filing.

We offer a new pathway that accelerates clinical trial testing and biomarker studies for EU programs.

IDENTIFY THE RIGHT CLINICAL TRIAL TESTING PATHWAY FOR YOUR PROGRAM IN THE EU.

Discuss with your CellCarta representative to assess eligibility, timing, and alignment with your downstream regulatory and commercialization strategy.

CellCarta

ABOUT CELLCARTA
CellCarta is a global CRO supporting biopharma with reliable, regulatory-ready biomarker data from translational research to CDx. With fully owned and harmonized laboratory operations across North America, Europe, Australia, and China, CellCarta delivers integrated capabilities spanning immunology, histopathology, proteomics, and genomics, supported by comprehensive sample management and logistics solutions.

www.cellcarta.com

@CellCarta