

# IVD Verification & Clinical Decision Support Services

## DESIGNED WITH YOUR LAB IN MIND

NGS testing has become a cornerstone of advanced clinical care over the past decade. Yet many clinical laboratories still face challenges in scaling effective NGS diagnostic programs. Many labs choose IVDs for their convenience, benefiting from faster launch times and streamlined processes supported by FDA oversight.

Velsera operates seamlessly in both the LDT and IVD world, with our IVD-grade software being included in approved diagnostic tests such as Illumina's TruSight™ Oncology Comprehensive Assay. Backed by clinical, regulatory, and bioinformatics experts, we can help your lab ensure a quick launch of your IVD of choice.

We support labs seeking to take your in-house assays through regulatory approval, supported by robust IVD-grade software for secondary and tertiary analytics, and powered by our best-in-class Knowledgebase.

## RIGHT-SIZED PACKAGES FOR YOUR NEEDS

### Our Verification & Clinical Decision Support (CDS) Services may include:

- Verification plan and run structure
- Comprehensive verification report
- Clinical manifest
- Clinical sample best practices and decision support
- Blind case review guidance CDS assessment report

### Optional add-on services:

- Revenue Cycle Management
- Somatic and Germline Variant Interpretation Service



## The Limits of IVD Reporting

Choosing from a menu of IVDs or developing your own often comes with restrictions. FDA regulations limit the content displayed in IVD reports, which can make it difficult for labs to access all the information needed to support confident treatment decisions.

## Where Velsera Fits In

With Velsera, you don't have to compromise. Your standard IVD report can be seamlessly combined with Clinical Genomics Workspace Expanded Reporting, giving your lab a differentiated offering. This approach ensures you receive the comprehensive content required to make the best decisions for your patients, while still enjoying the benefits of a streamlined IVD workflow.



## TRUSTED BY LEADING LABORATORIES

"I knew that with the resources we had, there was no way to create something that would rival a system like Clinical Genomics Workspace. As we've set up reflex testing in various cancer types, we have been well supported to scale the massive undertaking."

Medical Director, Academic Medical Center.



## **VERIFY WITH CERTAINTY.** **SUPPORT DECISIONS WITH CLARITY.**

Want to see how our services approach can support your lab?  
Contact us today at [www.velsera.com](http://www.velsera.com) and discover how we help you deliver reliable, compliant results that improve patient care.