

How Fulcrum Helped Belay Diagnostics Implement Their Cancer Detection Assay Pipelines for Clinical Testing

Fulcrum Genomics partnered with Belay Diagnostics to bring their Summit™ cancer detection assay to market with production-grade infrastructure, experience-based workflow development best practices, and audit-ready systems.

The Challenge

Belay Diagnostics needed to launch their Summit™ test leveraging a promising error-corrected NGS technology to inform treatment and management of brain and spinal cancers. As a young startup translating academic research to clinical diagnostics, Belay faced a critical challenge: they needed to have pipelines that passed CAP/CLIA standards to deploy clinically.

To do this required:

- Clinical-grade pipelines capable of meeting regulatory scrutiny
- Auditable software releases with proper version control
- Development processes that could support growth and compliance

The Results

- Summit™ liquid biopsy diagnostic brought to market with high variant detection accuracy
- Reproducible, auditable workflows meeting regulatory standards
- Optimized cloud architecture reducing costs and preventing resource exhaustion
- Comprehensive testing framework protecting against regressions



"Fulcrum has been an essential partner in shaping our clinical-grade workflows and processes. Their support across software development processes, scalable workflow architecture, molecular assay validation, and compliance was invaluable for a small start up with a big vision, high quality standards, and aggressive timelines. This partnership has empowered our ability to deliver patients reliable, high-quality results with confidence."

**Kyle Hernandez, Ph.D., Sr. Director of
Translational Informatics, Belay Diagnostics**

Fulcrum's Approach



Specialized Bioinformatics Team

Fulcrum staffed the engagement with two bioinformatics scientists, Zach Norgaard and Erin McAuley, allowing Belay to tackle regulated clinical readiness from multiple angles at once: pipeline reliability and validation, release auditability, and day-to-day delivery operations.



Operational Improvements

Jira-based project management was streamlined with automations to reduce administrative work and improve coordination during growth.



Production Pipeline Development

An error-corrected sequencing pipeline for Summit™ was taken from a prototype to clinical deployment in approximately one year, achieving high variant detection accuracy with clinical-grade quality metrics and validation.



Comprehensive Testing

Runtime safety checks, unit tests, integration tests, and full end-to-end pipeline tests were implemented to lock in baseline performance and prevent regressions, which are essential in CAP/CLIA environments.



Auditable Release Infrastructure

Version control, automated testing and deployment, and clear separation of development, staging, and production environments were established to ensure traceable, reliable releases.



Solving Critical Architecture Problems

Belay's initial architecture triggered thousands of cloud jobs per sample sheet, causing resource exhaustion and timeouts. A redesigned dataflow for cloud deployment optimized runtime while reducing cloud costs.

Why Fulcrum Genomics

While most bioinformatics consultants specialize in either pipeline development or DevOps, Fulcrum has specifically cultivated a broad set of expertise. Fulcrum operates at the intersection of software engineering, bioinformatics, and biology, which is the combination required when both compliance and time-to-market are critical.

Next Steps

If you saw something that made you think “we need that level of analysis”, we'd love to explore how the Fulcrum team can help.



Bioinformatics expertise trusted by scientists who demand accuracy, reproducibility, and speed.