

## CLINICAL / REGULATED NGS PIPELINES

# Turn a working NGS pipeline into infrastructure your team can **release, test, and defend.**

For diagnostics, precision medicine, and regulated genomics teams preparing NGS pipelines for clinical use, customer deployment, or internal review.

## A prototype pipeline can produce useful results and still be a poor foundation for clinical operations.

The risks usually sit around the workflow: weak release discipline, brittle cloud architecture, inconsistent QC, sparse documentation, limited automated testing, or development and production environments that are too closely coupled. We help teams close that gap with the same scientific care they put into the assay itself. A full rebuild is not always required — sometimes the right answer is better testing, clearer release management, stronger documentation, or targeted architecture work.

### When teams call Fulcrum

- An NGS assay approaching clinical deployment
- A pipeline inherited from academic or early-stage R&D code
- Releases that are hard to trace, test, or explain
- Cloud workflows that are slow, expensive, or failure-prone
- QC metrics that vary across runs or environments
- Documentation too thin for clinical, regulatory, or partner review
- A need to separate development, staging, and production with confidence

### What we build

- Production workflow architecture and implementation
- Versioned release processes
- Automated unit, integration, regression, and end-to-end tests
- Dev / staging / production environment separation
- QC metric definition and standardization
- Cloud runtime and cost optimization
- Audit-supporting documentation
- Knowledge transfer and handoff to internal teams
- Optional maintenance and regression-testing support

# Proof in practice: Belay Diagnostics

Belay Diagnostics needed to bring its Summit™ cancer detection assay from promising error-corrected NGS technology to clinical testing for brain and spinal cancers. The science was strong, but clinical launch required more than a working analysis pipeline: production-grade workflows, auditable software releases, reproducible results, and cloud architecture that could support clinical operations. Fulcrum supported the Belay team across production pipeline development, comprehensive testing, cloud architecture optimization, and release infrastructure.

## What we delivered

- A production error-corrected sequencing pipeline developed for clinical deployment
- Runtime safety checks, unit tests, integration tests, and end-to-end tests added to protect performance
- Cloud dataflow redesigned to eliminate resource exhaustion and reduce costs
- Versioned release infrastructure established across development, staging, and production
- Workflows Belay can maintain, release, and use with confidence in clinical operations



*“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

## START HERE

If your NGS assay is approaching clinical use, partner deployment, or internal review, bring us the current pipeline, documentation, release process, and biggest operational concern.

→ [Read the Belay Diagnostics case study](#)

→ [Talk with Fulcrum](#)