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CASE STUDY

The Swiss Army Knife of Compliance: How LENZ Therapeutics Built a Unified Foundation for Commercial Scale

How a U.S.-based late-stage biotech consolidated Quality, Regulatory, and TMF archive management, eliminated recurring CRO costs, and increased operational velocity ahead of commercialization.

As LENZ Therapeutics advanced from Phase III clinical trials toward commercialization, fragmented systems and CRO dependency became a structural risk. Manual quality processes, limited real-time visibility, and ongoing TMF hosting fees created operational drag for a lean organization under increasing regulatory scrutiny.

LENZ chose Ennov to unify Quality, Regulatory, and TMF archive management on a single data model, reducing cost and cognitive load while enabling continuous inspection readiness without additional headcount.

3-in-1
Unified Platform

$0
Recurring CRO Hosting Fees

1.5 FTE
Redirected to High-Value Work

Industry:	Pharmaceutical Development
Company Type:	Pharmaceutical company
Headquarters:	United States
Regulatory Scope:	FDA, GxP
Strategic Context:	Phase III completion, NDA preparation, commercialization

"We couldn't afford the risk of managing 30 different logins and disconnected data sources. Ennov is the Swiss Army Knife that allows our team to get the job done across Quality, Regulatory, and Clinical."

- **Eric Bonfadini,** *Director of Quality,* LENZ Therapeutics

The Challenge: The Friction of Fragmentation

During early development, LENZ relied on CRO-managed systems and manual tracking. While this supported initial speed, it created a "dependency trap" as they approached commercial scale:

› The "Paper Drag":
Manual workflows & Excel-based tracking (CAPAs/Deviations) limited scalability.

› Hidden Costs:
Ongoing monthly fees to host completed Trial Master Files (TMF) with vendors created a financial leak.

› Cognitive Load:
Managing disconnected data sources slowed decision-making and increased the burden on a small team wearing multiple hats.

The Solution: Strategic Consolidation

LENZ rejected the idea that "all eggs in one basket" was a risk. Instead, they realized that for an SMB, the true risk was fragmentation. They chose Ennov to unify Quality, Regulatory, and Clinical operations on a single data model.

Key Success Drivers:

1. **Internal Data Ownership:** Migrating completed studies to Ennov's TMF archive, ending the cycle of recurring vendor hosting fees.
2. **The Unified Approach:** A single environment where a user can manage a Quality Change Control while viewing related Regulatory specifications side-by-side.
3. **Process Fit with Fast Adoption:** Configuration supported LENZ's existing workflows, giving the team a practical, scalable system they could adopt quickly.

From System Sprawl to a Unified Ecosystem

PHASE 1:
Validation-Ready Infrastructure
Core Model Deployment

›

PHASE 2:
Cross-Domain Visibility
Quality, Reg, & TMF Archive Sync

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PHASE 3:
Strategic Ownership
TMF In-Sourcing & Archiving

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RESULT:
100% Data Sovereignty & Inspection-Ready Scale

› More than 450 Life Sciences companies around the world are powered by **Ennov**

The Results: Operational Velocity

By replacing "system sprawl" with a unified ecosystem, LENZ has transformed compliance from a hurdle into an accelerator.

AUDIT PRIDE, NOT AUDIT PANIC

By linking evidence across documents and processes, LENZ moved to a state of "inspection readiness by default." Instead of frantic spreadsheet reconciliation, the team uses live "Navigators" to provide instant visibility into open actions and ownership.

THE ECONOMIC IMPACT

By bringing the TMF in-house and automating manual quality workflows, LENZ eliminated monthly CRO access fees (typically $2,000-$5,000 per study) and avoided the equivalent of 1.5 full-time administrative hires. This allows their lean team to focus on strategic growth rather than paperwork.

A FOUNDATION FOR SCALE

The platform was configured to reflect existing LENZ processes, ensuring that non-frequent users in CMC and Clinical teams could "pick it up and run with it" with minimal training.

The Lean Biotech Blueprint: Why Infrastructure Must Precede Scale

The LENZ journey highlights a critical Life Sciences strategy: unification is a risk-mitigation tool. For lean teams, a unified platform is a force multiplier. It's the difference between being buried in admin work and having the agility to meet enterprise-level standards without the enterprise-level headcount.

- **Consolidation is the antidote to cognitive load:**
  By reducing system sprawl, teams accelerate decision-making when regulatory pressure is highest.
- **Ownership is a fiscal strategy:**
  Internal control of the compliance stack improves access and stops vendor "cost creep" before it compounds.
- **Infrastructure is the prerequisite for growth:**
  Establishing a validated, unified foundation before commercialization prevents reactive (and expensive) system replacements that can occur during inspections.
- **Built for Global Ambition:**
  A single, GxP-validated foundation ensures compliance across multiple jurisdictions, such as the FDA and EMA, allowing lean teams to enter new markets without the friction of regional system silos.

Future-Ready Growth

LENZ now operates on a unified foundation that supports commercialization and long-term expansion without the need for new systems or validation complexity. They have proven that for a modern biotech, internal ownership and a single source of truth are the ultimate competitive advantages.

THE UNIVERSAL TRUTH OF COMPLIANCE

Whether a startup of 15 or a global leader of 15,000, the challenge remains the same: Silos create risk, and fragmentation limits innovation. A unified compliance platform removes the friction.

By prioritizing internal ownership and cross-functional visibility today, organizations of all sizes gain the operational reach of a global enterprise with the agility of a startup.

Ready to build an inspection-ready foundation?

Learn how Ennov's Unified Compliance Platform powers the next generation of Life Sciences at

Connect with Ennov's experts today. **ennov.com**

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