

# Accelerating PK Noncompartmental Analysis to Protect Regulatory Timelines

How Spaulding Clinical, in Partnership with  
Aplos Analytics, Cut PK Analysis Timelines  
by Two Weeks for Alume Biosciences



# Client Overview

**Sponsor: Alume Biosciences**

**Study:** ALM-488 Phase 1 Thorough  
QT (TQT) Study

**Focus Area:** Pharmacokinetics –  
Noncompartmental Analysis (NCA)

**Clinical Partner:** Spaulding Clinical

**PK Technology Partner:** Aplos  
Analytics (Aplos® NCA)

**Outcome:** PK NCA completed in 5  
calendar days, reducing timelines  
by ~2 weeks





## The Challenge: PK Analysis on the Critical Path to Submission

As part of the ALM-488 Phase 1 program, Alume Biosciences required rapid, high-quality PK noncompartmental analysis (NCA) to support integrated clinical interpretation and final regulatory reporting.

The overall program—from protocol development through final Clinical Study Report (CSR)—was constrained to six months to meet a fixed regulatory submission deadline. Within this compressed schedule, PK analysis represented a critical path activity.

Under traditional industry workflows, PK NCA typically requires about three weeks due to manual data preparation, sequential analysis and QC steps, and limited automation in legacy PK software. For Alume, a conventional PK timeline would have placed downstream analysis and CSR preparation at risk.

## The Approach: A Modern PK Workflow Powered by Aplos Analytics

To eliminate PK analysis as a timeline bottleneck, Spaulding Clinical leveraged its biometrics expertise and partnered with Aplos Analytics, integrating Aplos Analytics into its early-phase PK workflow.

Since 2007, Spaulding Clinical has built its reputation as a full-service Phase 1 clinical pharmacology unit focused on speed, quality, and regulatory rigor. As sponsor timelines have continued to compress, Spaulding has invested in modern technologies and strategic partnerships that accelerate decision-making while maintaining data integrity.

Aplos Analytics was selected as a third-party partner because it enables:

-  Rapid, intuitive study setup, reducing upfront preparation time
-  Standardized, automated NCA calculations, minimizing manual handling and variability
-  Built-in quality checks and traceability, supporting regulatory confidence
-  Automated exports to SAS, streamlining downstream statistical workflows

By embedding Aplos Analytics directly into its biometrics operations, Spaulding Clinical was able to initiate PK analysis immediately upon data availability—without delays caused by reformatting, tool limitations, or iterative setup.



## The Result: PK NCA Completed in 5 Days Instead of 3 Weeks

Using this modern PK workflow, Spaulding Clinical completed PK noncompartmental analysis for ALM-488 in:

- 5 calendar days from data availability to finalized outputs

This represented a timeline reduction of up to 66% compared to traditional PK approaches.

By recovering approximately two weeks on the overall study timeline, Spaulding Clinical:

- Reduced pressure on downstream analysis and CSR authoring
- Ensured PK results were available early for integrated clinical interpretation
- Helped Alume Biosciences remain on track for its regulatory submission

In a program where every day mattered, faster PK delivery proved critical to maintaining momentum.

