



In an increasingly complex clinical trial landscape, bringing a new therapeutic modality to market requires precise insight into patient health and outcomes. A critical success factor is selecting the right population for clinical trial execution. For "Top Pharma"—a leading pharmaceutical company with a vast product pipeline—the stakes are high: the accuracy of molecular RNA-level measurements is critical to selecting suitable populations for study recruitment and driving impactful outcomes. To achieve this, an exemplary biosample collection process, guaranteeing integrity throughout, is non-negotiable.

Top Pharma's existing internally developed solution was no longer fit for purpose. Manual processes led to slow trial enrollment, inefficiencies, and elevated risks to data integrity. With multiple clinical sites involved, standardization was lacking, putting the clinical trial success at risk. Top Pharma needed a modern solution to accommodate growing requirements, streamline sample management, and reduce inefficiencies while ensuring the highest level of compliance.

The increasing number of trials, evolving regulatory requirements, and the growing need for precision and speed have created an urgency for Top Pharma to overhaul their biosample collection process. Delays in patient enrollment, scalability challenges, and compliance risks could severely impact the timelines and success of their clinical trials. It was time to implement a scalable, automated, and compliant solution to meet these challenges head-on.

L7|ESP® was chosen as the ideal solution to transform Top Pharma's clinical trial biosample collection and management. With L7|ESP, Top Pharma was able to standardize processes, automate biosample tracking, and guarantee compliance—all while scaling to meet increased demand.

Challenge	L7 ESP - The Power of the Platform
Slow Trial Enrollment Process	<ul> <li>Accelerates enrollment through standardized sample registration processes at partner sites of choice.</li> <li>Manages the registration and receipt of samples from hundreds of clinical sites, ensuring a streamlined process from start to finish.</li> </ul>
Scaling Trial Management	<ul> <li>Automates data collection processes and assay assignments based on sample metadata, eliminating manual bottlenecks and potential errors.</li> <li>Increases throughput, boosts lab productivity, and enhances end-user experience, enabling clinical teams to focus on high-value tasks.</li> <li>Supports flexible data ingestion formats and accommodates changes while maintaining a robust overarching data model ensuring consistency and traceability.</li> <li>Removes the need for manual sample tracking and scales seamlessly to accommodate expanding process needs and sample and data throughput.</li> </ul>
Inefficient Resource Utilization	<ul> <li>Maximizes resource efficiency by fully integrating and managing all laboratory instruments, equipment, robotics, and supplies, thereby removing the need for manual tracking and optimizing resource utilization.</li> </ul>
Increased Data Integrity Risk	<ul> <li>Registers samples upon physical receipt in the lab, even managing edge cases to avoid any lapses in data.</li> <li>Assesses sample shipment conditions and ensures samples are stored appropriately.</li> <li>Requires electronic signature at critical process checkpoints or during updates to previously registered samples, maintaining compliance and improving data reporting and transparency.</li> <li>Maintains chain of custody for every sample, meticulously tracking metadata, collection protocol, storage location, and sample amount or concentration.</li> <li>Ensures all data is organized, accessible, and adheres to FAIR principles, laying the foundation for effective data utilization.</li> </ul>
Ensuring Data Compliance and Adherence to Privacy Regulations	<ul> <li>Operates in a fully regulated environment, safeguarding both data and patient privacy while meeting stringent regulatory standards.</li> <li>Provides a comprehensive audit trail for each entity involved—from sample collection to testing—combined with role-specific permissions to control access.</li> <li>Monitors and controls all field changes, reinforcing data accuracy and adherence to privacy regulations.</li> </ul>

L7|ESP transformed Top Pharma's biosample collection and management process, addressing the challenges faced at every step. By automating enrollment, sample collection, and data entry, Top Pharma was able to accelerate patient enrollment, increase sample throughput, and reduce human error—directly contributing to more efficient clinical trials.

With L7|ESP, Top Pharma now enjoys improved connectivity between teams, enhanced traceability, optimized resource utilization, and the highest standards of data compliance. All of these factors not only improve the efficiency and quality of clinical trials but ultimately ensure that new therapeutic modalities reach the market faster, benefiting patients worldwide.

