RESOURCES



Scaling Compliance: How Phase 3 Reata Pharmaceuticals (Acquired by Biogen) Partnered with TraceLink and NNIT to Meet U.S. & EU Regulations

Laying the Groundwork for Serialization Success

Reata Pharmaceuticals, a Phase 3 biopharmaceutical company acquired by Biogen in 2023, was in the critical phase of transitioning to commercialization with the launch of SKYCLARYS, a treatment for the inherited neurodegenerative disorder Friedreich's ataxia. Moving from clinical development to commercialization presents unique challenges, requiring companies to rapidly scale operations, navigate complex regulatory landscapes—such as the U.S. Drug Supply Chain Security Act (DSCSA) and the EU Falsified Medicines Directive (EU FMD)—and establish serialization and supply chain integration. Any missteps in this transition can lead to delayed product launches, financial setbacks, and, most importantly, restricted patient access to essential therapies.

Challenges in Compliance and an Evolving Commercialization Timeline

To successfully launch SKYCLARYS in the U.S., Reata needed to comply with DSCSA regulations. With the support of TraceLink and strategic advisory & IT consultancy NNIT, the company implemented TraceLink's suite of serialization and traceability

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solutions, ensuring regulatory compliance and supply chain readiness.

Building on this track-and-trace digitalization foundation, Reata prepared for the European launch of SKYCLARYS. The expansion required compliance with EU FMD regulations and country-specific mandates while ensuring seamless integration with contract manufacturing organizations (CMOs). However, without an internal track-and-trace team, Reata had to rely heavily on NNIT for Business Process Engineering, Quality & Regulatory Expertise, Technical Implementation, and Program Sustainability.

Reata's launch timeline for SKYCLARYS was uncertain. Before its acquisition by Biogen, the company faced delays, only to encounter an accelerated schedule post-acquisition—adding complexity to serialization planning. Shifting launch timelines can create major challenges, impacting serialization efforts, regulatory compliance, and overall commercialization strategy.

Additionally, Reata needed an experienced partner like NNIT to collaborate with their existing Supply Chain, IT, Trade, and Quality teams, ensuring compliance across both U.S. and EU markets while maintaining efficiency in market entry.

A Scalable and Future-Ready Serialization Approach

To address these challenges, Reata required a serialization and compliance solution that:

- Supported Reata's DSCSA requirement in the U.S.
- Adheres to EU FMD compliance requirements and any other country requiring a compliance solution.
- Adapted to shifting product launch timelines.

Establishing this foundation not only ensured compliance for SKYCLARYS but also positioned Reata for seamless future product launches in both regions, enhancing

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scalability and regulatory agility.

Achieving Compliance and Market Readiness with Precision

Despite the evolving commercialization timeline, Reata successfully met all regulatory requirements and launched SKYCLARYS on schedule. In its first year of commercialization, the company recorded just three serialization alerts—significantly less than industry averages —from the EMVO system. The low number of alerts is a reflection of NNIT's meticulous approach to master data management and data quality before configuring TraceLink.

The partnership between NNIT and TraceLink proved instrumental in achieving regulatory compliance while minimizing operational disruptions. Reata also successfully streamlined the onboarding of external CMOs, making the integration process more efficient and reducing potential roadblocks.

Key Factors for Seamless Integration and Compliance

Reata's ability to navigate complex regulatory requirements was driven by several key factors:

- **Leveraging an established serialization framework**: With TraceLink's solution already in place for U.S. compliance, extending the same platform for EU FMD compliance was a logical and efficient decision.
- **Relying on expert partners**: TraceLink and NNIT played a crucial role in managing both U.S. and EU compliance requirements, ensuring consistency and integration across markets.
- **Bridging internal resource gaps**: Without a dedicated serialization team, Reata relied on NNIT's operational and advisory expertise to navigate regulatory complexities and ensure smooth implementation.

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Best Practices for Future Serialization Success

Through this experience, Reata identified several best practices for future product launches:

- **Start compliance preparation early**: Regulatory readiness should begin 18 to 24 months before a planned launch to avoid delays.
- **Engage executive leadership**: Early involvement of leadership helps expedite approvals and critical decision-making.
- **Work with a single global compliance provider**: A unified serialization framework simplifies international expansion, reduces operational complexities, and ensures data accuracy.
- **Minimize integration challenges**: Partnering with organizations that understand the unique challenges and time-to-market constraints of Phase 3 organizations helps accelerate commercialization with fewer disruptions.

By implementing these best practices, Reata successfully launched SKYCLARYS while laying a strong foundation for future commercialization efforts. With a scalable, compliance-ready serialization approach, the company is well-positioned to navigate evolving regulatory landscapes and bring life-changing therapies to patients worldwide.

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