Serialization: Great Value Beyond the Supply Chain

Life science companies and contract manufacturers have worked diligently over the years to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States in accordance to the Food and Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA). The system is based on uniquely serializing products and ultimately creating unit level traceability including aggregation throughout the supply chain.

While companies have focused on achieving the requirements and deadlines in the ten-year DSCSA Implementation Plan, many have overlooked the additional business value serialization offers. Benefits that not only impact the business, but also the providers and patients who prescribe and utilize the innovative, life-changing medications.

The following article provides a summary of how Covectra is leveraging its ControlTrack® Patient Medication Adherence Platform in an observational study with the Center for Pain Management at Brigham & Women's Hospital (BWH) for patients who have been prescribed opioid analgesics. While we initially chose to address one of the biggest challenges our country faces with opioid treatment, consider your own patients and market challenges that may be barriers to maximizing your commercial efforts.

ControlTrack® was designed with physicians to reduce treatment obstacles by extending the reach of the practice beyond its four walls, enhancing patient engagement, and increasing patient accountability. Challenges that are experienced across the healthcare system in many disease states and medications such as high-value drug manufacturers experiencing resistance from payors where a practical, enhanced patient adherence program could lead to better outcomes, improved formulary positions, or reductions in treatment administration.

Center for Pain Management Brigham & Women's Hospital Observational Study

"Patient engagement is a critical part of providing patient-centered care and reinforcing treatment goals and potential dangers. This is of particular importance as we balance the challenges of delivering patient care in the presence of COVID-19.", Edgar L. Ross, MD, Pain Management Center at the Brigham & Women's.

Treating patients with opioid analgesics is inherently challenging and the misuse/abuse of these medications have been described as a national epidemic with catastrophic effects. In 2018, the Substance Abuse Mental Health Services Administration (SAMHSA) National Survey on Drug Use and Health found that 86% of those who misuse/abuse opioid pain relievers obtain them from one doctor or get/buy/steal them from a family member or friend. In 2019, a Journal of American Medicine Association study reported that merely having opioids in your home increases the risk of a family member overdosing by 3-15 times depending on the strength of the dose, versus not having opioids in your home.

BWH Center for Pain Management clinicians are interested in enhancing its patient adherence monitoring processes, which already included random urine toxicology screens and pill counts that require patients to present their medications in person to verify they possess the correct amount. The new capabilities need to avoid creating burdensome tasks for the staff or be perceived as overly intrusive by the patients.

One of the primary concerns of their adherence monitoring processes was the integrity of pill counts due to the ease with which patients can share tablets to mislead the staff. Additionally, many of their patients are having difficulty managing their medications between appointments, so they also want a tool to help keep patients on track.

ControlTrack® provides the functionality the staff is seeking and implementing it into the standard treatment procedures within the clinic and pharmacy has shown to be uncomplicated. After enrolling in the program, a patient's opioids are dispensed in uniquely serialized blister packs that are associated to them in a cloud-based database; thus, linking specific drugs to specific patients. After taking each dose, the patient uses their smartphone and the ControlTrack® Patient App to capture an image of the blister pack. If a patient documents taking the medication sooner than the prescriber expects, an Early Dose Notification is forwarded to the staff alerting them of potential problems.
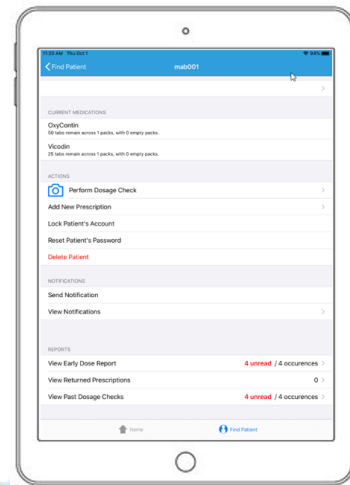
ControlTrack® Prescriber App

The uniquely serialized blister packs raise additional challenges for patients looking to share medications, which they believe will increase the integrity of the pill counts. Furthermore, traveling to the clinic will be unnecessary as staff can use telehealth resources, such as: Zoom or FaceTime to conduct virtual pill counts. This is of particular importance for patients with health challenges, limited mobility or have difficulty arranging transportation especially in the presence of COVID-19.

The ControlTrack® Patient App assists the patients by maintaining a record of their medication use, including how much time has passed since their last dose and how many pills they have remaining. This information will help the patient manage their opioids and make it easier to uncover situations when the patient is being victimized by trusted, but drug-seeking individuals.

Often reaching the patients outside of the clinic is a challenge. At the clinicians' request, a Notifications feature was added that enables the staff to send direct messages to the patient through the ControlTrack application. This enhanced capability affords them the opportunity to reach the patient to schedule appointments or send messages that reinforce the patient's personalized treatment goals.

ControlTrack® Patient App

Leveraging Serialization

The general supply chain benefits and applications of serialization are well known, such as: track-and-trace, knowledge of product flow, reverse logistics, recall compliance, new goods uptake, and even pricing integrity.

Neither implementing serialization within a manufacturing facility nor creating value added services utilizing those numbers should be looked upon as a Herculean effort. There are factors to consider that will decrease project complexity and increase the likelihood of success.

When considering a serialization partner, if the solution requires multiple companies to deliver a single solution, it is highly likely to increase cost and complexity. Multiple companies often result in multiple markups and accountability can sometimes be difficult when challenges arise. These types of hybrid relationships often also require customers to utilize proprietary equipment and software. These technology solutions limit options, increase implementation costs, and raise future switching costs should you be displeased with your level of service.

Finding a company that provides an end-to-end solution, which utilizes open source software will reduce the implementation complexity, project schedule and costs. The increased interoperability of these technologies will make it easier to integrate serialization across people, processes, data, and technologies both internally and externally.

Lastly, companies that provide fit-for-purpose solutions that are agile and can scale-up as your business needs grow is vital. Robust solutions can support manual, automated and hybrid packaging processes. They offer mobility and can be connected to different lines within a facility to minimize idle equipment and reduce your operating costs.

Finding the appropriate serialization partner and implementing interoperable solutions like these will ensure that you never pay for scale or functionality you do not require.

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