

TrakCel in the wider Clinical Ecosystem: Accelerating Integration and Automation

Sharing information among Clinical systems can have a very positive effect on patient outcomes, regulatory compliance and the costs associated with clinical trials.

Integrating TrakCel's traceability and supply chain information into existing systems across your supply chain can deliver significant benefits, with a clear Return on Investment. +

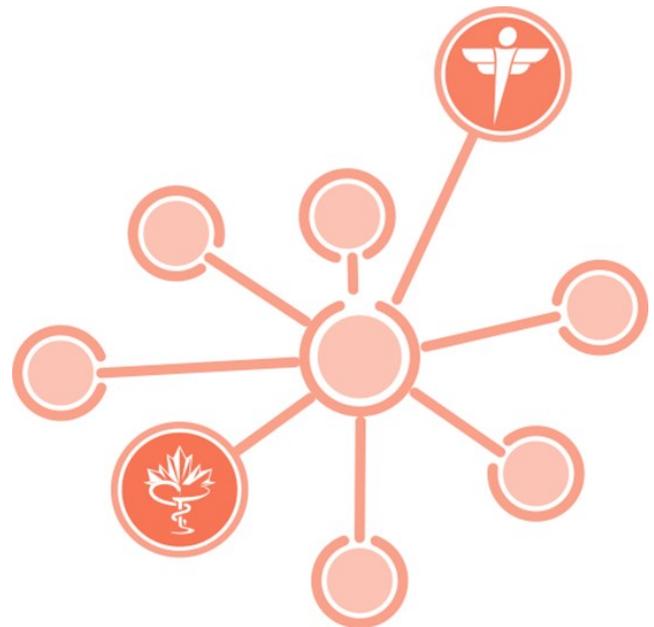
From one way data transfer to two-way real time exchange, an integrated supply chain with TrakCel can enable you to:

- Reduce data entry work and errors
- Strengthen compliance programs
- Enable better decision making
- Ensure synchronized data in multiple systems

Approaches to integration

TrakCel supports a number of powerful approaches to integration:

TrakCel API (Application Programming Interface) – TrakCel's APIs expose supply chain data and functionality to our customers and partners in a consumer friendly, secured and governed manner. When external systems' processes need to communicate with each other and maintain synchronisation, our API is the tool of choice. It controls data into and out of TrakCel for seamless integration. The TrakCel API supports both data integration and process integration enabling external systems to influence the process flow in the supply chain.



Middleware - Middleware is the critical substrate for data integration within TrakCel, providing portability and access to horizontal services such as LDAP, remote security and transactional support. TrakCel's support for middleware approach to integration simplifies connectivity by providing a unified experience to integrate across cloud, on premise and business-to-business.

SQL Database Views – When the need is simple one-way out data sharing, the most cost effective approach could use database views. This could typically involve sharing data such as inventory levels with your LIMS system. Database views create a one-way integration that allows you to easily share valuable data across systems.





> Application Programming Interface (API)

The TrakCel Application Programming Interface

The TrakCel Application Programming Interface provides clients with the ability to establish integration points with other enterprise software applications including ERP, LIMS, MES and BI or reporting tools.

The API is based on RESTful Web Services and is the fundamental data access interface for the platform. RESTful (Representational State Transfer) is an architectural style for networked applications that is primarily used to build services that are lightweight, maintainable, and scalable. It is agnostic to programming languages as all modern languages support HTTP and JSON and can create and consume RESTful messages using any third party middleware.

TrakCel API resources

TrakCel represents supply chain entities and activities in groups of accessible data services called resources. Subject to your process definitions and TrakCel's role within your organisation, these resources will provide access to recorded supply chain events, activities and manufacturing steps in the end-to-end cell therapy supply chain.

API resources examples include:

- The audit-events resource tracks the steps in the supply chain in terms of who did what and when, from the medical center through shipping, manufacturing and final therapy delivery
- The cellular-material resources contain information on the patient samples and derivative cellular materials
- The inventory-asset resource contains information on assets – equipment and inventory – applied and consumed in the supply chain.
- The shipment resource contains information on any cellular materials in transit. This includes shipment specifications, temperature trails, location information and excursion reports.

TrakFlow - the core of the TrakCel platform

TrakFlow, the core of the TrakCel process orchestration framework, is built on a light-weight workflow and Business Process Management (BPM) Platform. It is a super-fast and rock-solid process engine that can be deployed on a server or cluster and in a public, private or hybrid cloud environment.

TrakFlow is fully-compliant with BPMN 2.0 and its process models can be managed, versioned and shared as required. Optional Online analytics add-ons provide real-time insights into Clinical and business processes to highlight bottlenecks, identify process inefficiencies and support optimisation of critical Clinical supply chain processes.

TrakFlow's API and service oriented approach allows the creation and management of clinical and operational process and composite applications that exist independent of TrakCel's underlying technologies.

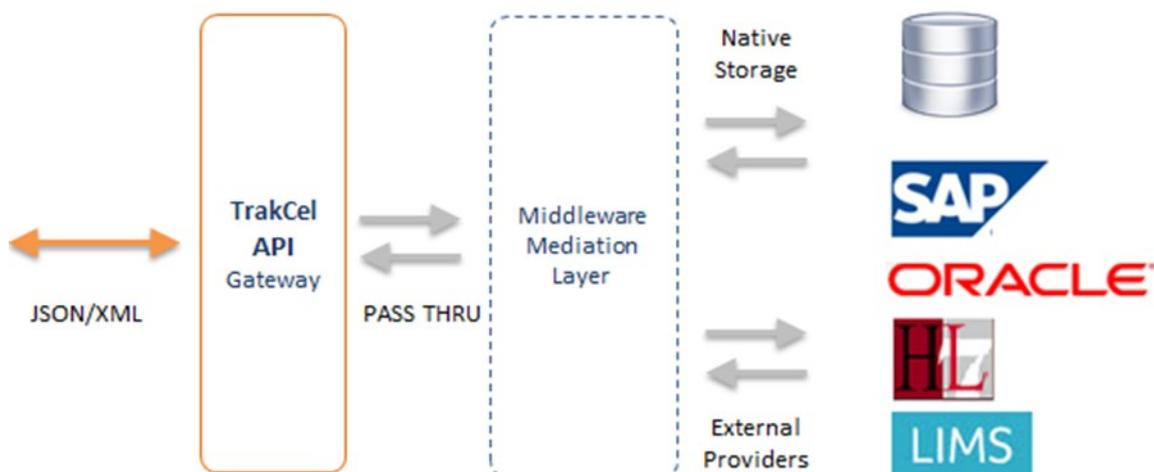




> Integration with Middleware Technology

TrakCel Data integration

The following illustrates the combination of TrakCel's API gateway and off-the-shelf middleware technology to effect communication with external data providers. These interactions can be anything from high-volume, high-performance batch loads to event-driven, trickle-feed integration processes. TrakCel's SOA architecture enables integrations built by combining loosely



coupled and interoperable services. This architecture can support integration and consolidation activities within complex clinical enterprise systems environments but does not specify or provide a methodology or framework for documenting capabilities or services. Reuse is promoted at the macro (service) level rather than micro (classes) level and simplifies interconnection to, and usage of, existing clinical and operational IT assets independently of development technologies and platforms.

Benefits

The key benefits of this SOA-based middleware approach to TrakCel's clients include:

- Allow external systems to communicate through a standardized approach
- Reduction in complexity and knowledge needed to connect systems
- Systems can be added or replaced without having to rewire existing connections
- Integration of data and systems more rapidly to respond to clinical and operational needs





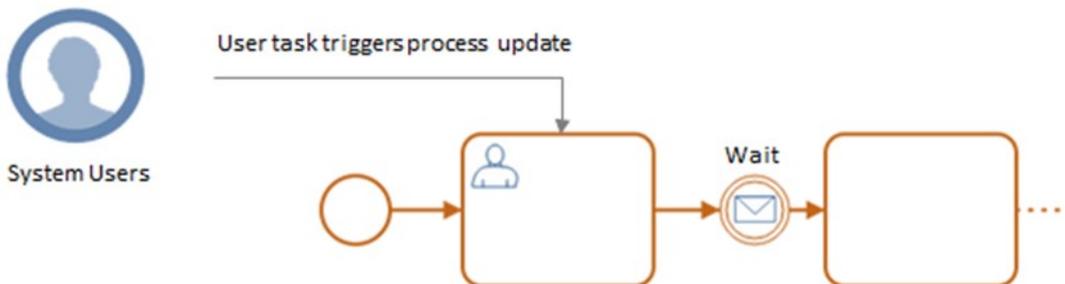
TrakCel Process Integration

TrakFlow plays the major role in managing all of TrakCel’s processes in the cell therapy supply chain. TrakFlow is a SOA-based solution and utilises a common technology for describing and executing business processes. Any interaction with a user or a system results in a call to a Web service representing the business process. On that basis, external systems can automate such supply chain tasks as customer scheduling, courier provisioning, financial recordkeeping, auditing, archiving and many others.

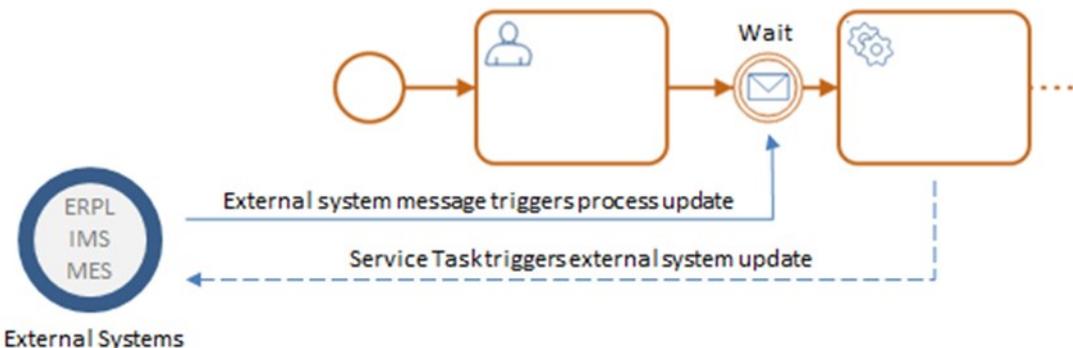
Process interaction via user tasks

In a TrakCel managed supply chain process, user interactions and external system interactions can be powerfully combined to synchronise data and manage the process flow.

1. User tasks (via TrakWeb or TrakPad activities) interact and update the TrakFlow clinical process.



2. The TrakCel managed process waits for receipt of an externally managed event. An external system (e.g. ERP, LIMS, MES ...) is enabled via the TrakCel API to send a message to manage the progress of the process from the wait-state.



3. A TrakFlow service task is able to initiate communication with an external system. Messages via a service task are fully automated and designed to initiate a specific action or set of actions in the external system to synchronise data or trigger an externally managed process.

TrakCel

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