TrakCel

Visibility. Control. Scale

Integrating the Cell Therapy Supply chain

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Introduction

Who are TrakCel

Our people strategy

TrakCel
James Rudolf
Chief Operating Officer
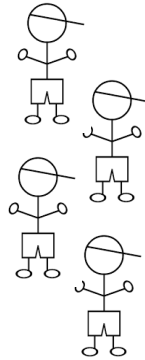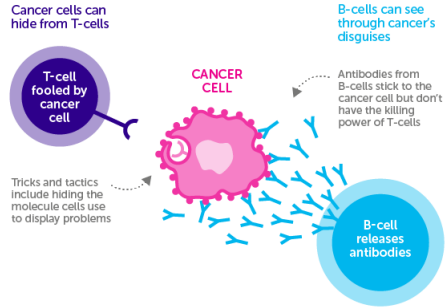
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Integrate your Cell Therapy Supply Chain

"To travel is to live."
Hans Christian Andersen

UNIVERSITY OF EXETER

Life Sciences

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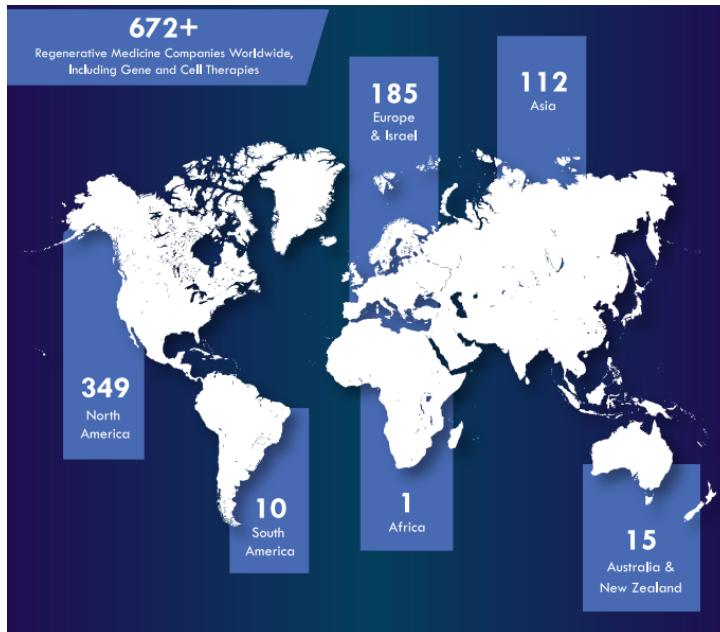
Our market

Therapy Owner

Therapy Owners and Trial Sponsors and Licence holders can design, integrate and report on the entire global supply chain with exacting detail.

Medical Centre

TrakCel has everything that Medical Centre professionals need to capture and record data, schedule collections, generate labels, schedule treatments and follow-up patient monitoring visits.

Manufacturing

Configurable workflows, capacity scheduling and inventory management are some of the many features that enable manufacturers to retain control of the production processes during scale up.

Distribution & Logistics

Reduce distribution and logistics risk with real-time monitoring of shipping including excursion reporting and real-time alerting.

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Medical Centre, Distribution & Clinical Logistics, Cell therapy manufacturing

Patient Biometrics
Capture and record essential patient data with optional safety features including patient biometrics.

Collection Kits and Consumables
Schedule delivery of Collection kits and consumables in line with treatment needs.

Automated Collection Notifications
Automated notifications from supply chain partners including Clinicians and Manufacturers allow alignment of resources.

Automated Labelling
Automated label generation, based on pre-configured data, at the Medical centre and Manufacturer save time and ensure consistency.

Step-by-step Clinical SOPs
Integrated process guides, driven by the process design, direct clinicians and ensure standardisation as you scale out.

Barcode and label creation
Create and print ISBT 128-compliant and site-specific bar code labels and supports read / write of RFID labels.

Real-time temperature reports
Real-time temperature monitors capture and report in-transit temperature data.

Real-time location reports
Real-time location tracking monitors capture and report in-transit locations worldwide.

Conditional workflows
Create workflows with conditional logic to ensure that your users perform and stay compliant with MAA approved procedures.

Automated Supply Chain Notifications
TrakCel generates automated notifications to supply chain partners to align their resources as needed. E.g logistics, manufacturers.

Tamper Alerts
Integrated light and humidity sensors can detect when a shipment is opened in transit or a route deviation occurs and report immediately.

Geo-fence notifications
TrakCel can automatically update supply chain service partners when shipments reach pre-defined locations.

Inventory and asset tracking
Identify and track products, collection kits, supplies, reagents, lab and logistics equipment and more.

Deviation Management
As each process step is progressed, TrakCel records all updates and transactions centrally for real-time reporting.

Conditional workflows
Create workflows with conditional logic to ensure that your users perform and stay compliant within product's approved process.

Deviation Management
Schedule sample collection and infusion in line with inventory, staff availability and clean room capacity.

Inventory & Asset Management
Identify and track products, collection kits, supplies, reagents, lab and logistics equipment and more.

Notifications to service partners
TrakCel generates automated notifications to supply chain partners to align their resources as needed.

Step-by-step Manufacturing SOPs
Integrated process guides, driven by the process design, direct clinicians and ensure standardisation as you scale out.

JIT Labelling and Barcoding
Create and print ISBT 128-compliant and site-specific bar code labels and supports read / write of RFID labels.

Electronic document generation
Perform document and record reviews electronically, including processing data, supplies, reagent consumption and more.
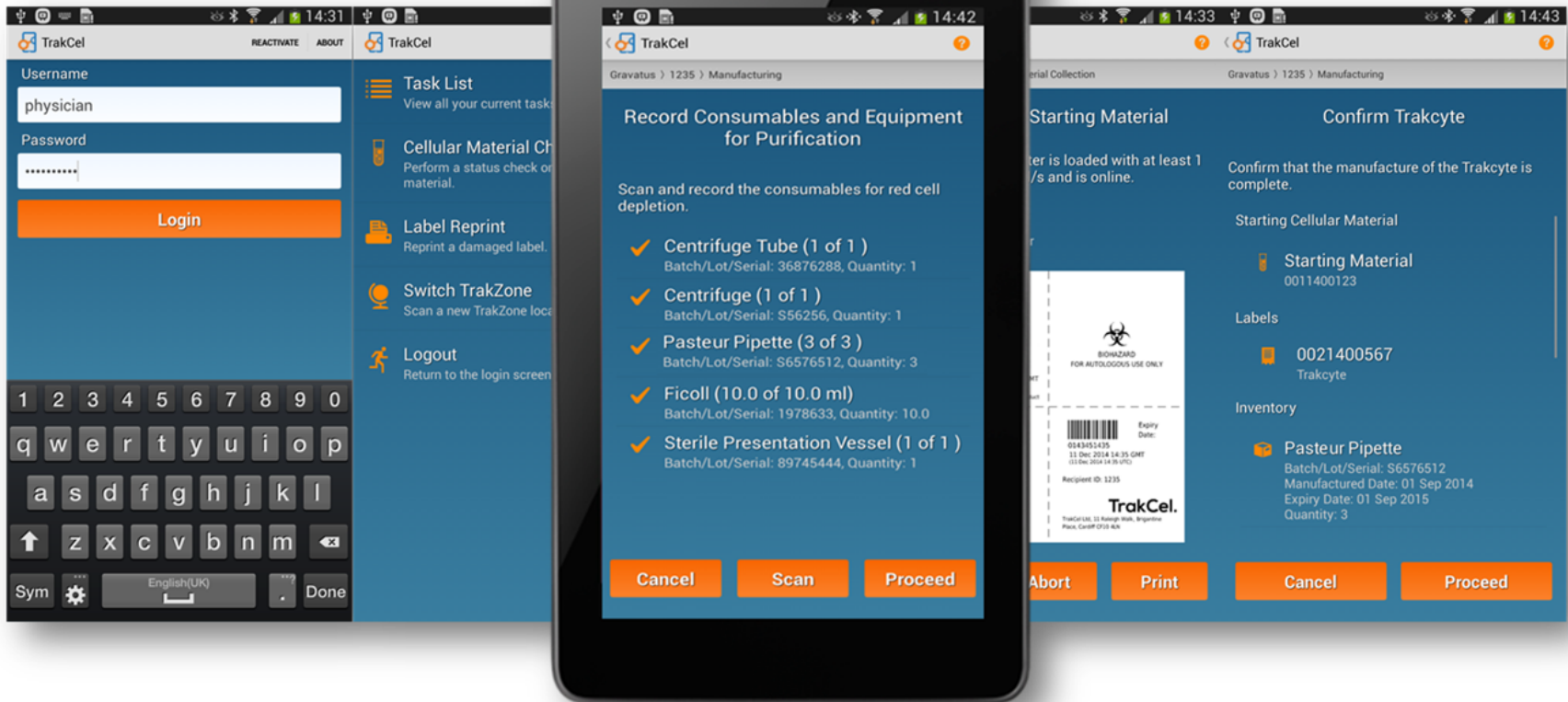
Hardware Interfacing
Automate the integration of data collected by manufacturing equipment into the TrakCel system, saving time and reducing errors.

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TrakCel

Configures and implements every single process in your supply chain

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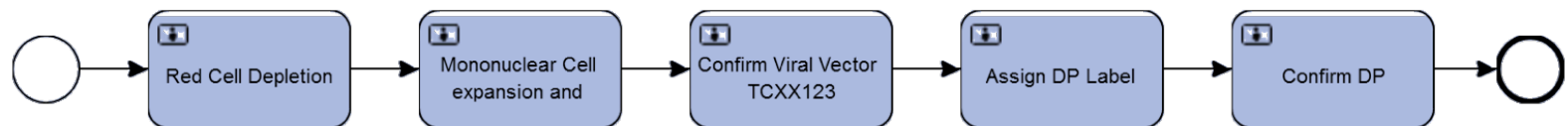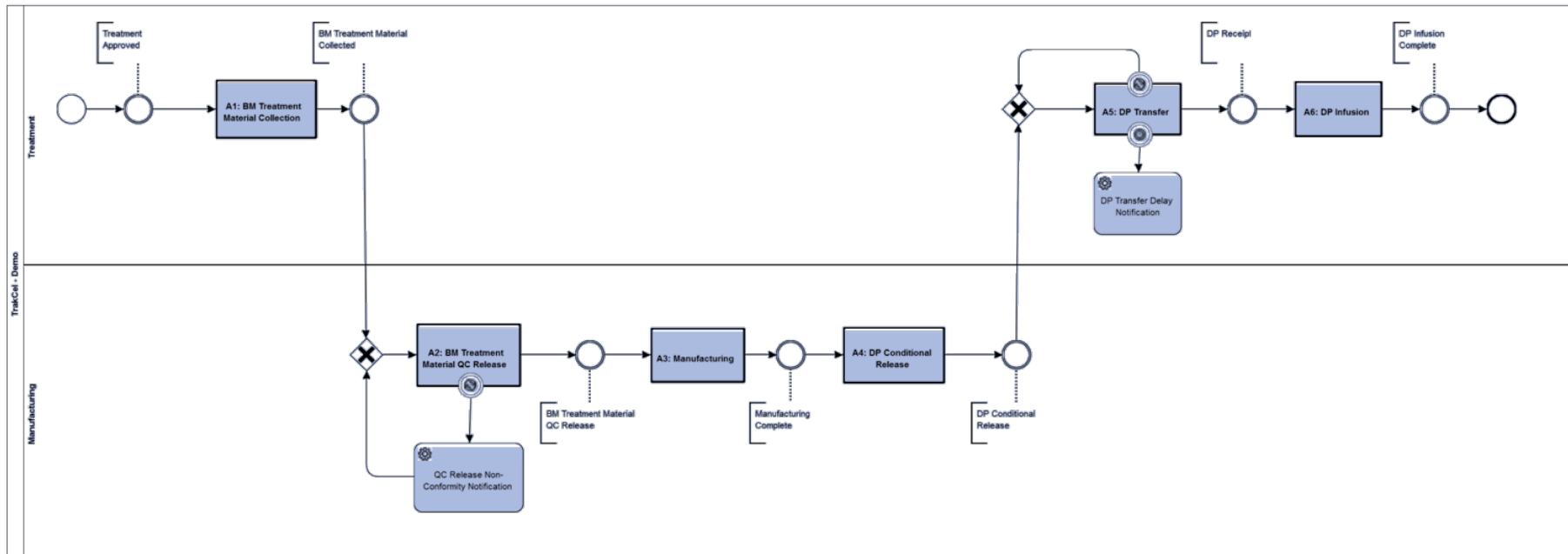
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Validated & Regulatory Compliance

Good Manufacturing Practice (GMP)
FDA 21 CFR Part 11 (and predicate rules)
EudraLex Vol. 4 Annex 11, Vol. 4 Chapter 4

EU Tissue and Cells Directives
Directive 2004/23/EC, 2006/17/EC, 2006/86/EC

Good Clinical Practice
– MHRA Good Clinical Practice Guide

PII (Personally Identifiable Information)
HIPAA - Health Insurance Portability and Accountability Act

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KNOWN
TO OTHERS

KNOWLEDGE
&
SKILLS

SEA LEVEL

ATTITUDE

UNKNOWN
TO OTHERS

These require zero talent.

1. Being on time
2. Work ethic
3. Effort
4. Body Language
5. Energy
6. Attitude
7. Passion
8. Being coachable
9. Doing extra
10. Being prepared