

The Landscape and Evolution of Cell & Gene Therapies & Logistics

13th December 2019

Kelly Frend



Agenda Topics



- Scene Setting
- Landscape of CGT
- What can we do to help support the growth of CGT
- Technology & Integrations Intelligent Temperature Tracking & Trace Solutions
- Securing the Future of CGT
- Brexit

Scene Setting



World Courier - Trust and Consistency

Logistics Platform Developer, managing Time Sensitive / Temperature Critical Shipments for the Advanced Therapy Industry

EXPERIENCE

Deliveries to >2000 clinical sites



SCALABILITY

Managing clinical trial and commercial projects



QUALITY

Fully GDP compliant throughout global network



GLOBAL SUPPORT

140 offices in 50 countries



TEMPERATURE

Supporting +2-8 to -190C shipments



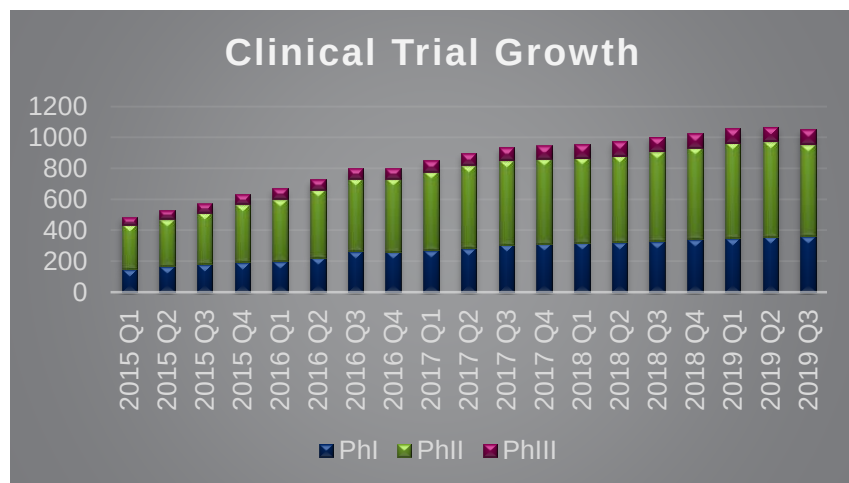
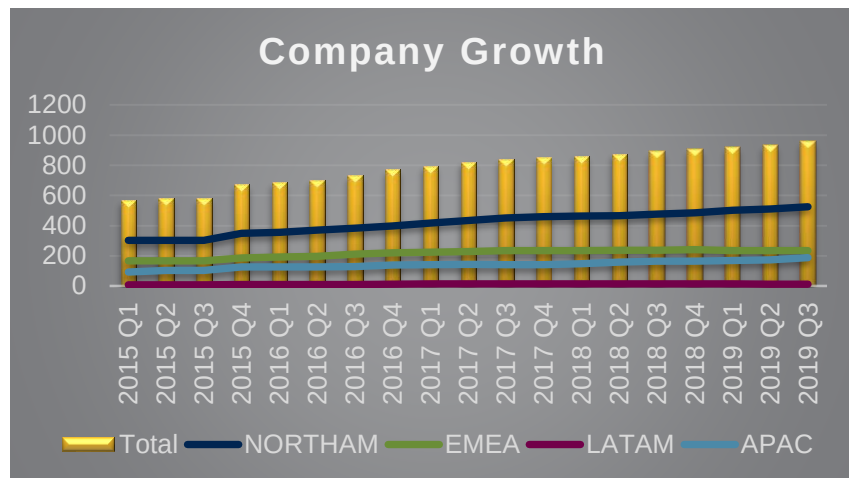
DEDICATED

Customer Service teams for advanced therapies

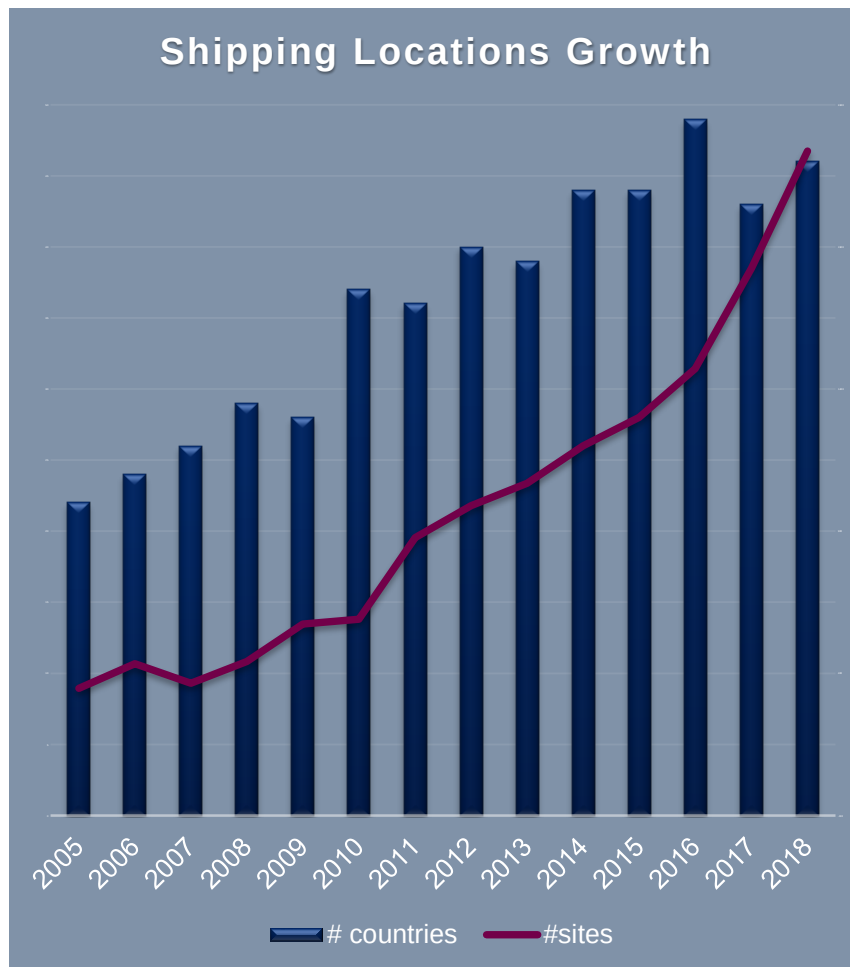


World Courier – global capability & understanding

ARM Quarterly Reports



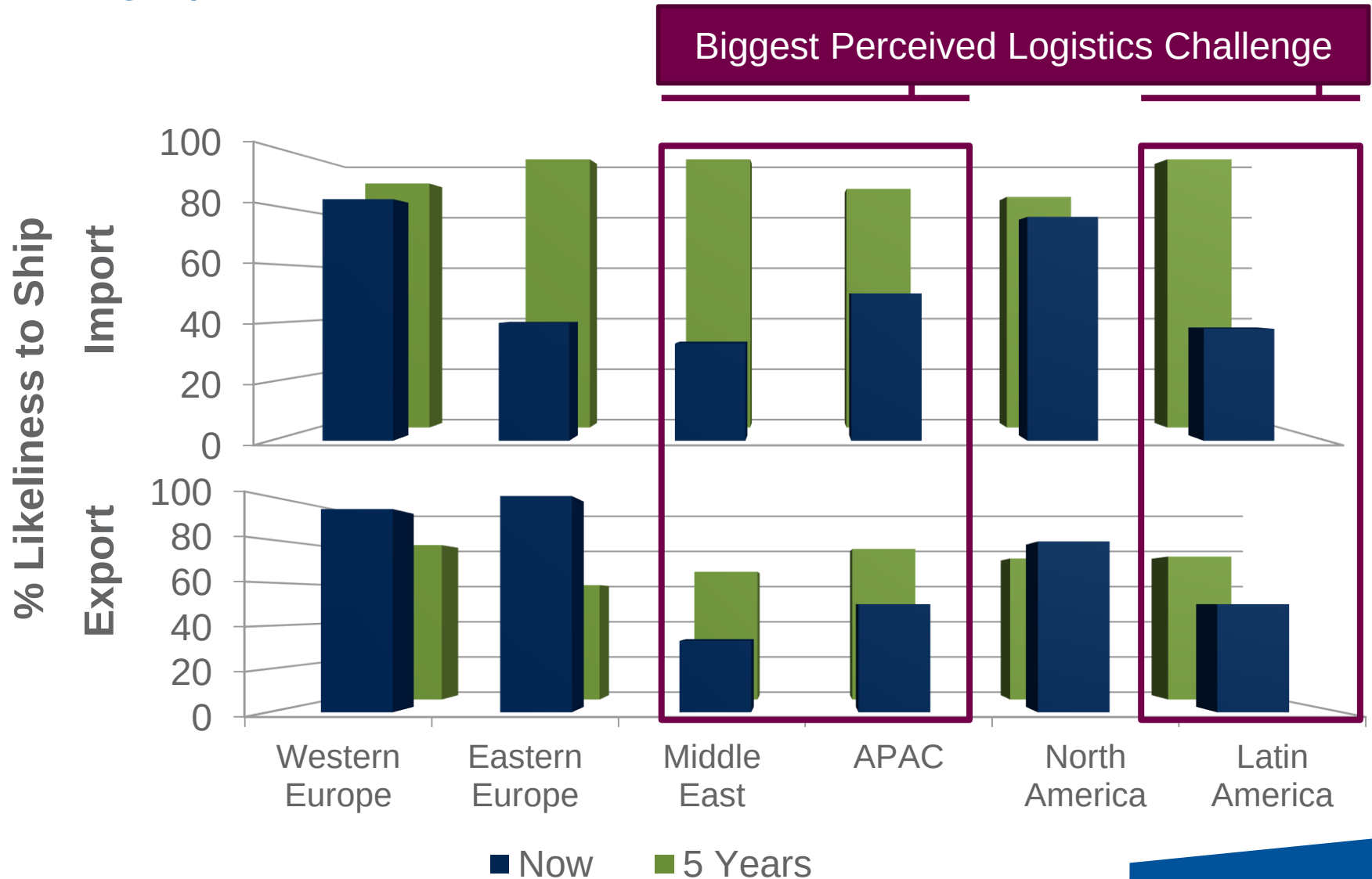
World Courier Internal Data



Landscape of CGT



Geographical Evolution



Europe CGT Capabilities: Last 12 months

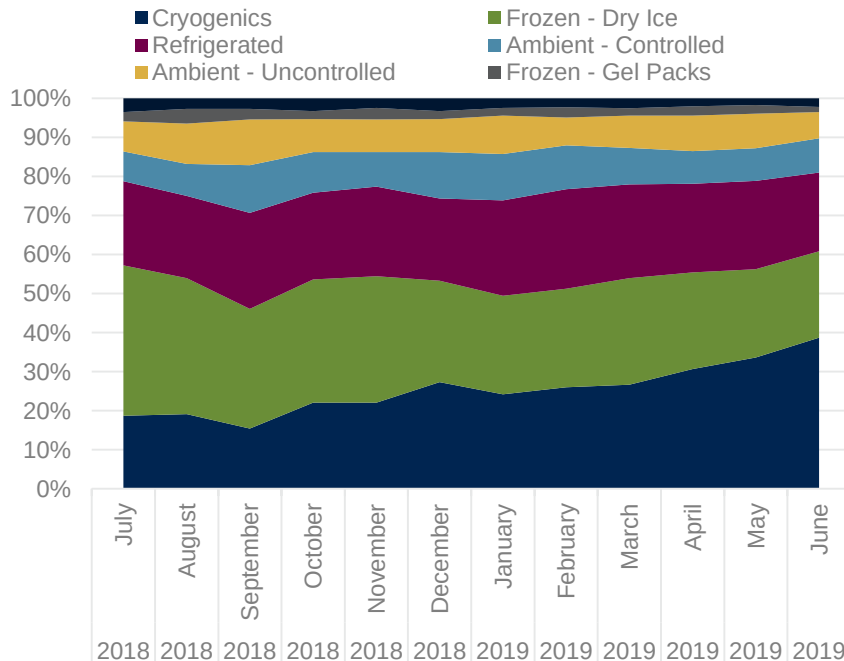


All Shipments
4.2k sites served in
Europe

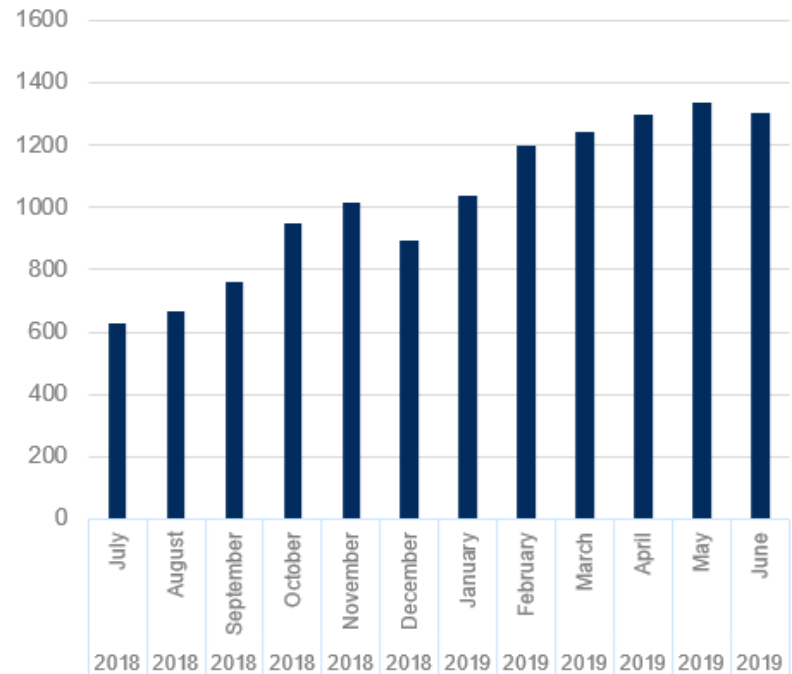
CGT Shipments
476 sites served in
Europe



Europe CGT Shipment Temperature Distribution



Europe CGT Shipment Volumes



USA CGT Capabilities: Last 12 months



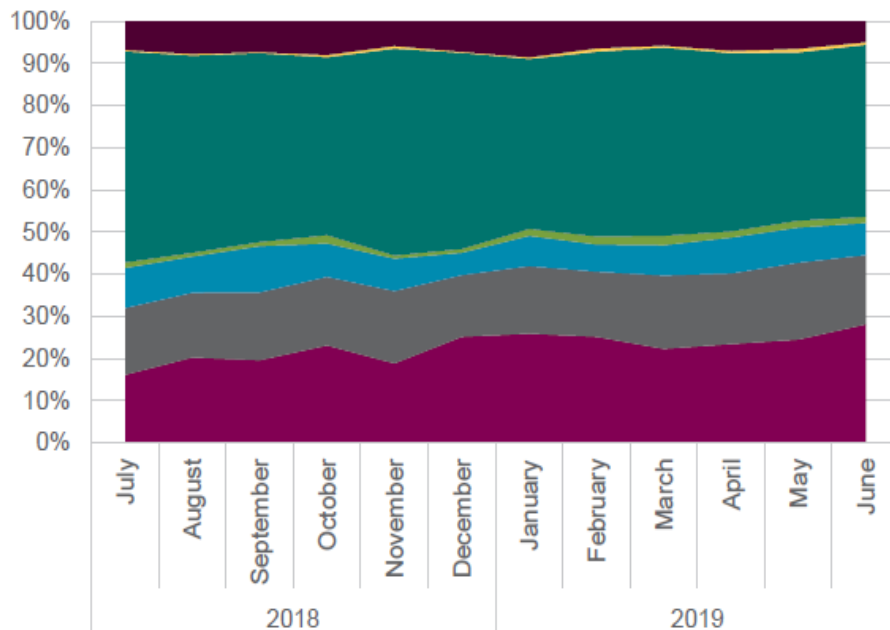
All Shipments
7.2k sites served in USA

CGT Shipments
889 sites served in USA

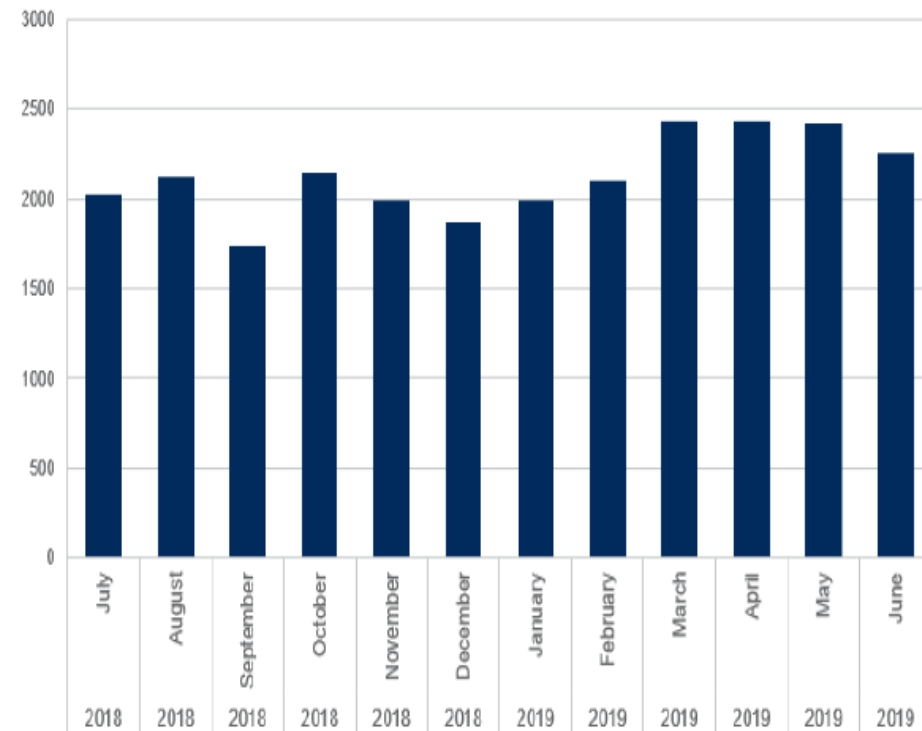


USA CGT Shipment Temperature Distribution

■ Cryogenics ■ Frozen - Dry Ice ■ Refrigerated
■ Ambient - Controlled ■ Ambient - Uncontrolled ■ Frozen - Gel Packs
■ Not Categorised



USA CGT Shipment Volumes



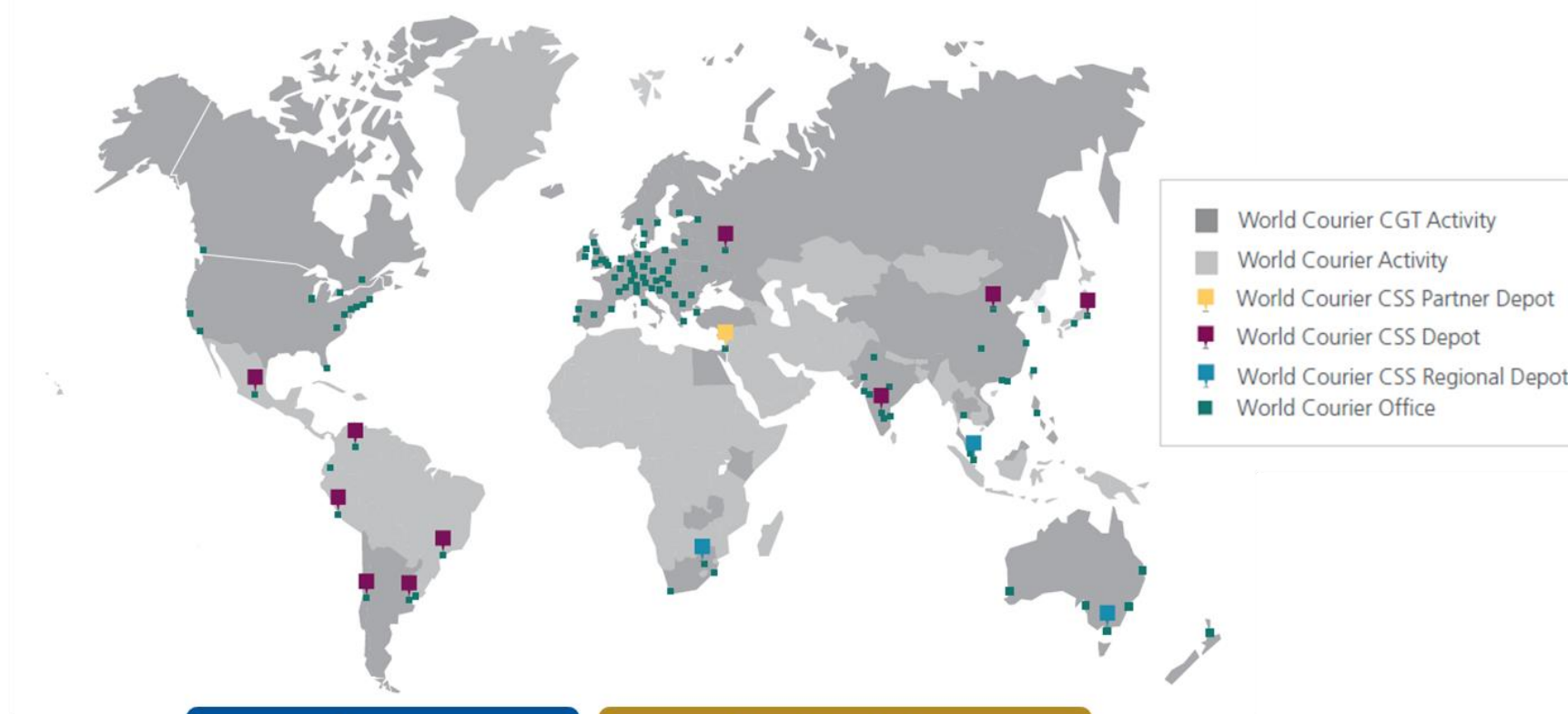
World Courier - Connecting Cell & Gene Therapies to Patients

Global network of
140
owned offices

Fully
GxP
compliant

Controlled deliveries at
+18 to -190° C
globally

NOW



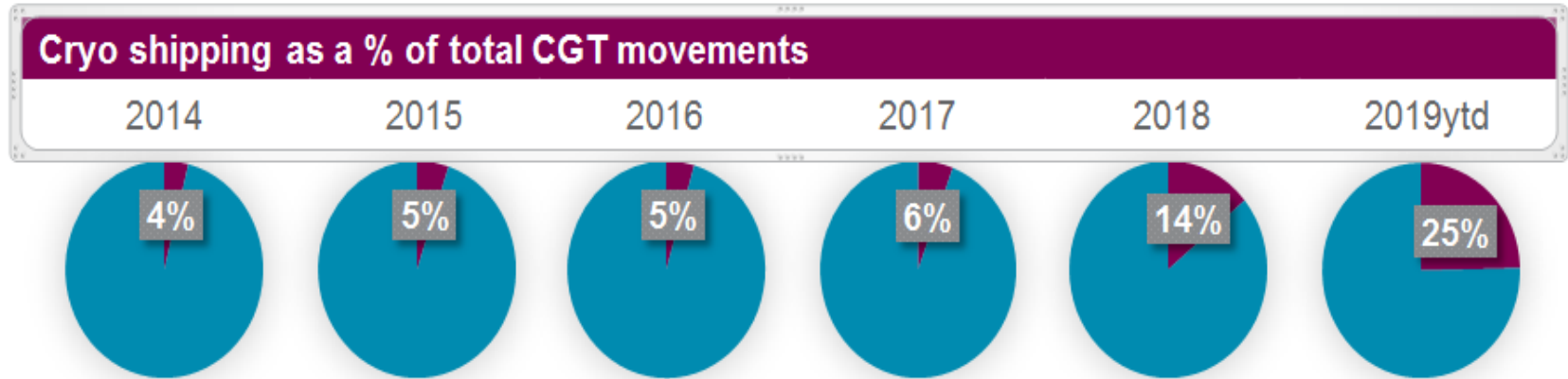
Managing
3
commercial scale therapies

Actively involved in
>50%
Cell & Gene Therapy Clinical Trials

What can we do to Help Support the Growth of CGT



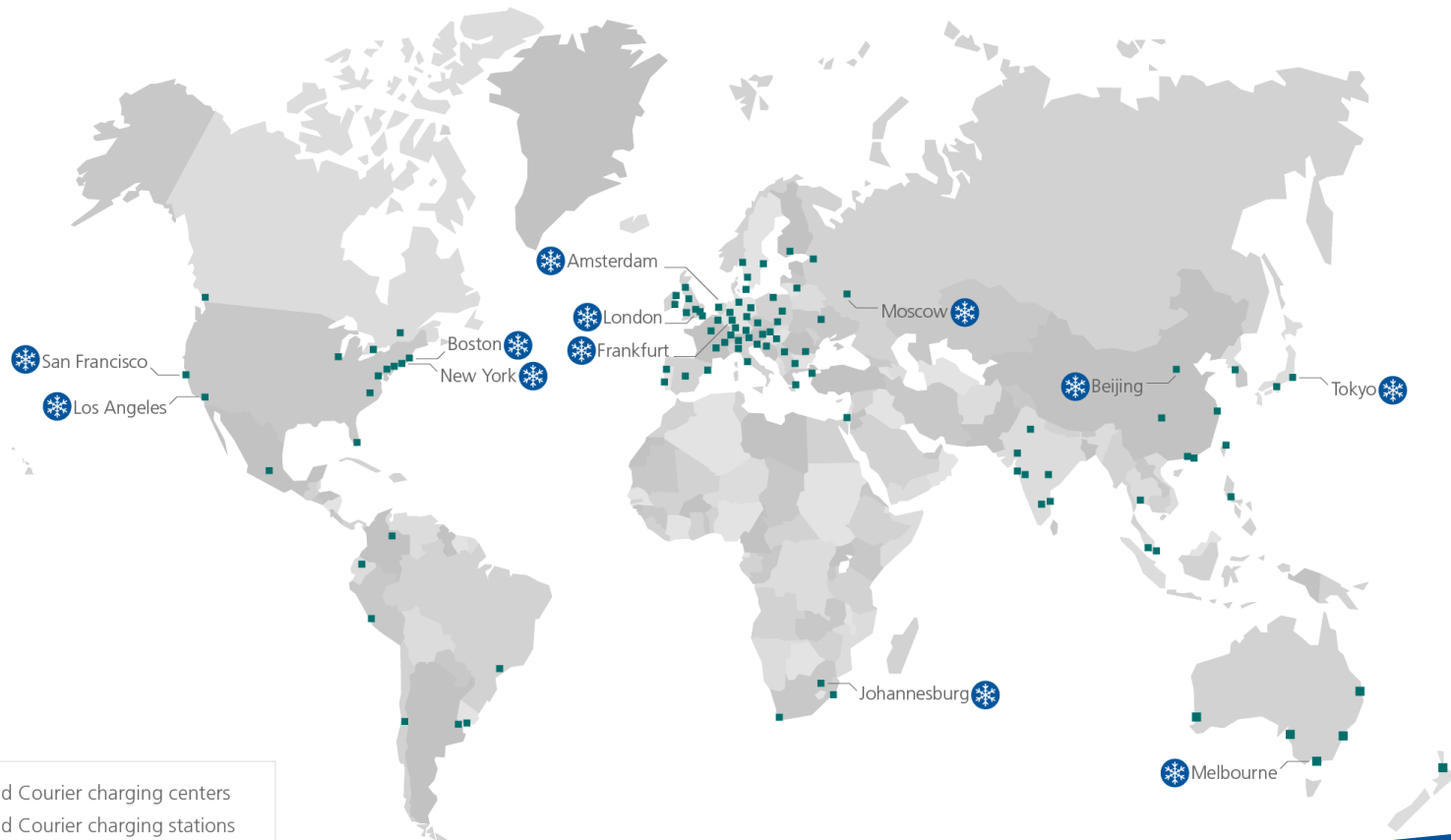
Will Cryo Shipping continue to Increase?



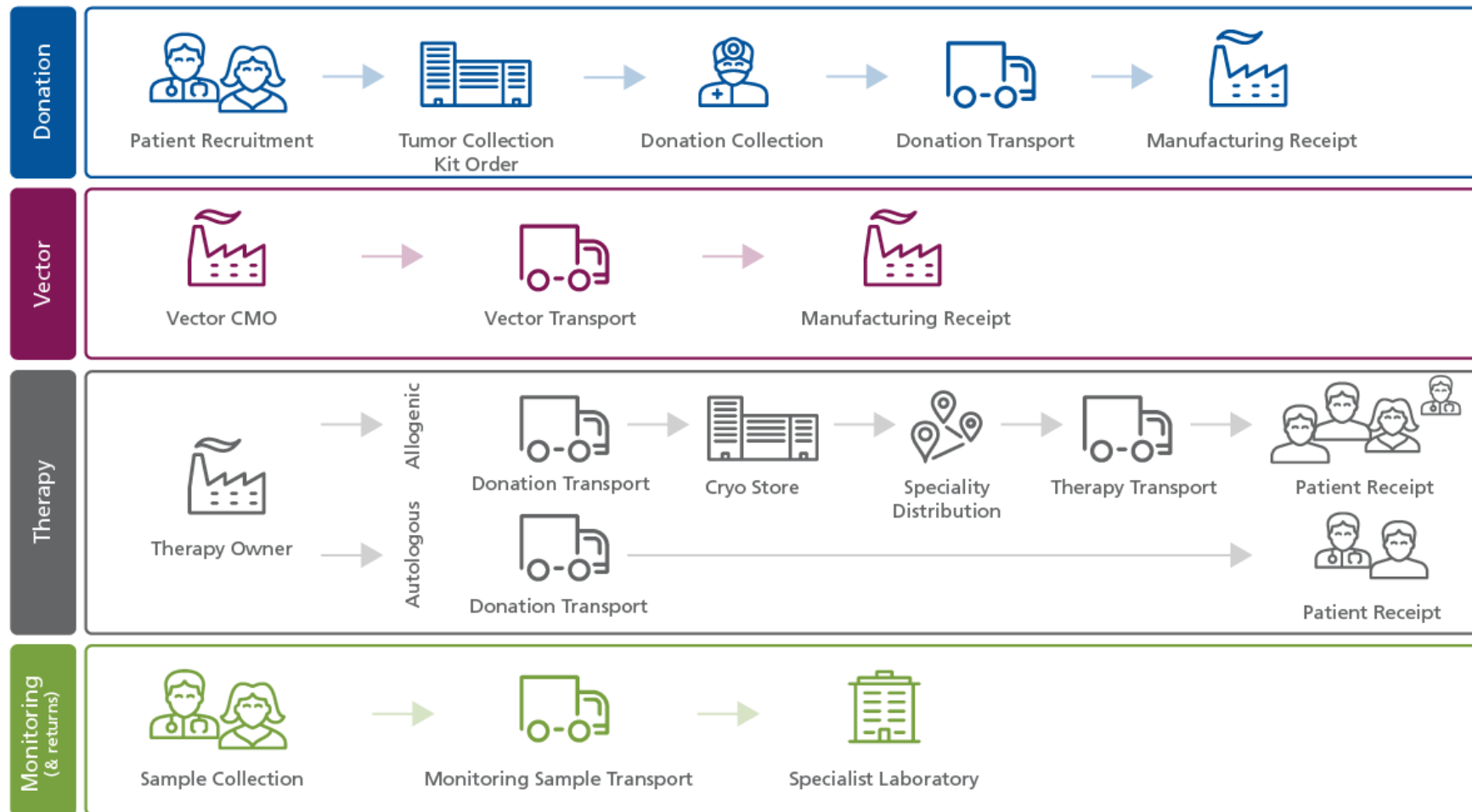
- Will donations always be shipped fresh (2-8C or 18-25C)?
- The market is getting saturated for LN shipments/Shippers, will storage capacity of full and empty dewars be an issue in clinics
- What is the impact of allo? Initially and as it becomes more widely adopted?
- Is there a value in shipping at +37?
- Will gene therapies stay at -80C or get warmer/colder?
- What is the value of just in time delivery vs near patient storage
- How valuable is our ability to charge with LN2 through the network?

World Courier – Global LN₂ Management & Charging Capability

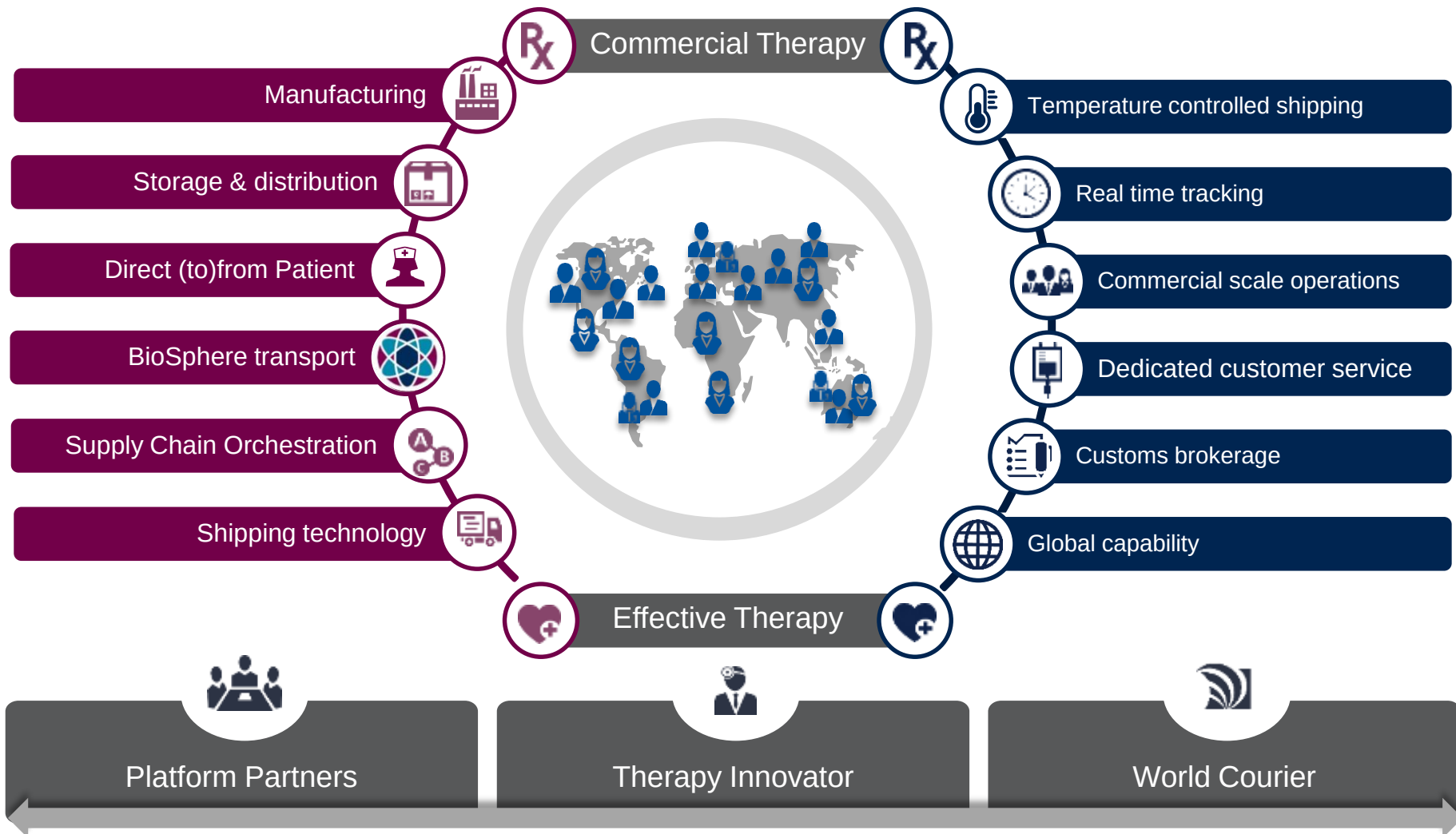
- 12 charging centres, and capability throughout global network
- Driven by a single quality system and underpinned by established SOPs
- Supporting over 12,000 cryo shipments annually



World Courier - Advanced Therapy Integrated Support



Building a Logistics Platform



Dedicated leads are responsible for each Service line

Services

Delivery support

Clinical Supply Solutions



Cell and gene therapy



Direct-to-patient



BioSphere (hybrid)



Project management



Paula Pulsoni
Senior Director
Clinical Supply
Solutions

CSS Lead Team



Simon Ellison
Director Cell and
Gene Therapy
Service

Services Manager



Mike Sweeney
Senior Director
Patient Centric
Logistics



Stewart Black
Director
Partnership
Logistics

Partnership
Logistics Manager

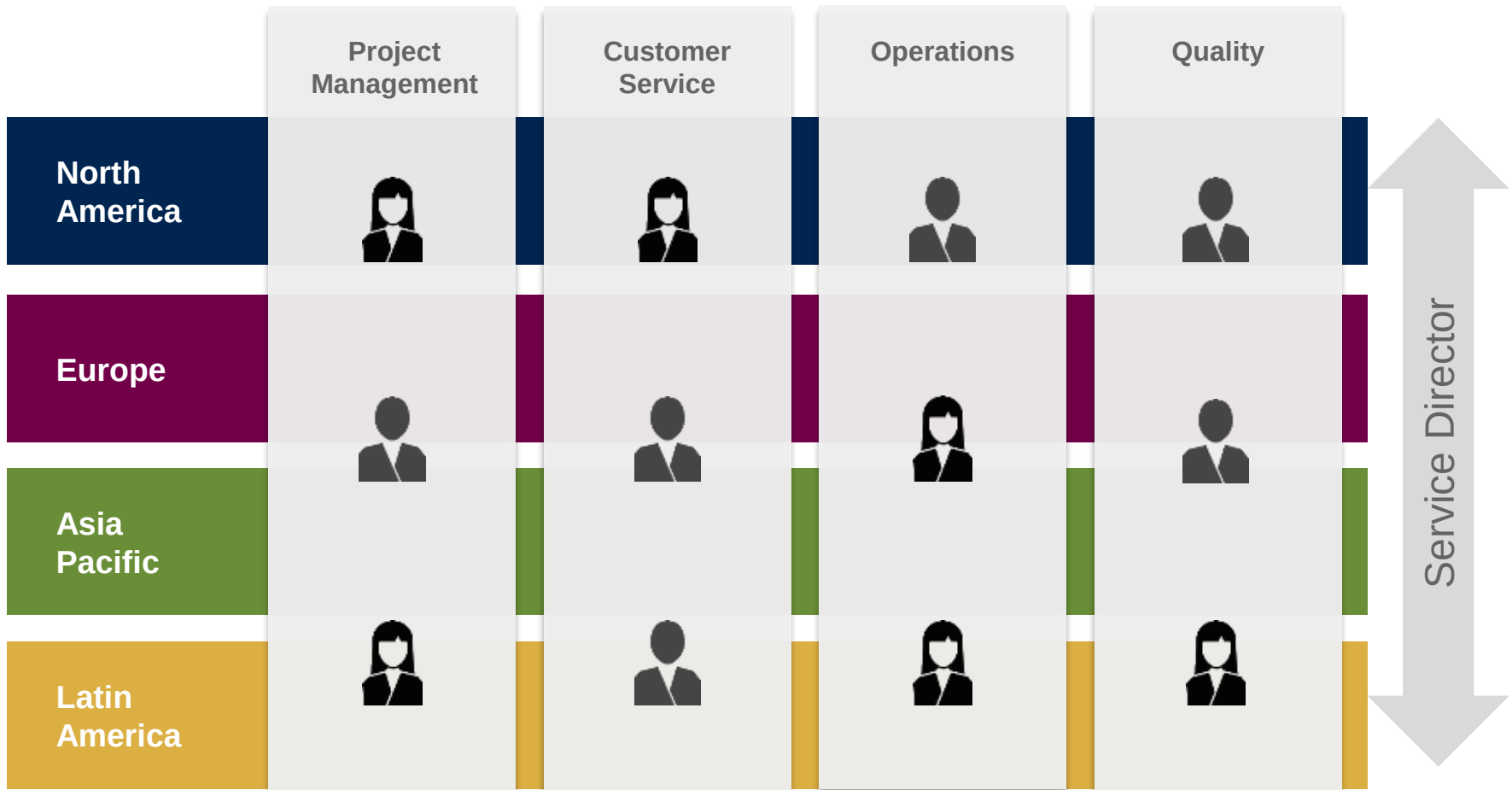


Erika Rabak
Director Services
Project
Management
Office

Services Project
Manager

Project Management – Local and Central Support

Overarching Management – Defined Operational Project Lead



World Courier's People, Operational Expertise, and Office Locations Enable the Success of Your Therapy



Focus on Communication: Automated updates; 24/7 dedicated Customer Service and Clinical Trial teams; GPS tracking; unparalleled emergency response



Pro-Active Chain of Custody: Thorough SOPs and Work Instructions to maintain chain of custody; shipment tracking through systems and GPS



Own Office Network: 98% percent of all activity takes place in countries where we have offices (including pick up, drop off, and transhipments)



Contingency Planning: Pre-arrangements with emergency services (ambulances, local police escorts, helicopter); WC office dry shipper supply



State of the Art Training: Proprietary Training Resource Center and Agent Resource Center; Site training plan



Scalable Processes: Training infrastructure; Packaging Management Hubs (PH1); extensive network; Technology (Biostar); Quality Management System



Preferred Partner: FCPA compliant; regular local and global audits; constantly investing to support client needs; resourced to overcome any challenge

Technology & Integrations

Intelligent Temperature Tracking & Trace Solutions



Controlled Temperature Packaging

- Cont. Amb. (+15/+25C)
- Refrigerated (+2/+8)
- Frozen (-25/-15C)
- Deep Frozen (-80C with dry ice)
- Liquid Nitrogen (-190C)



• GTC



• VIP

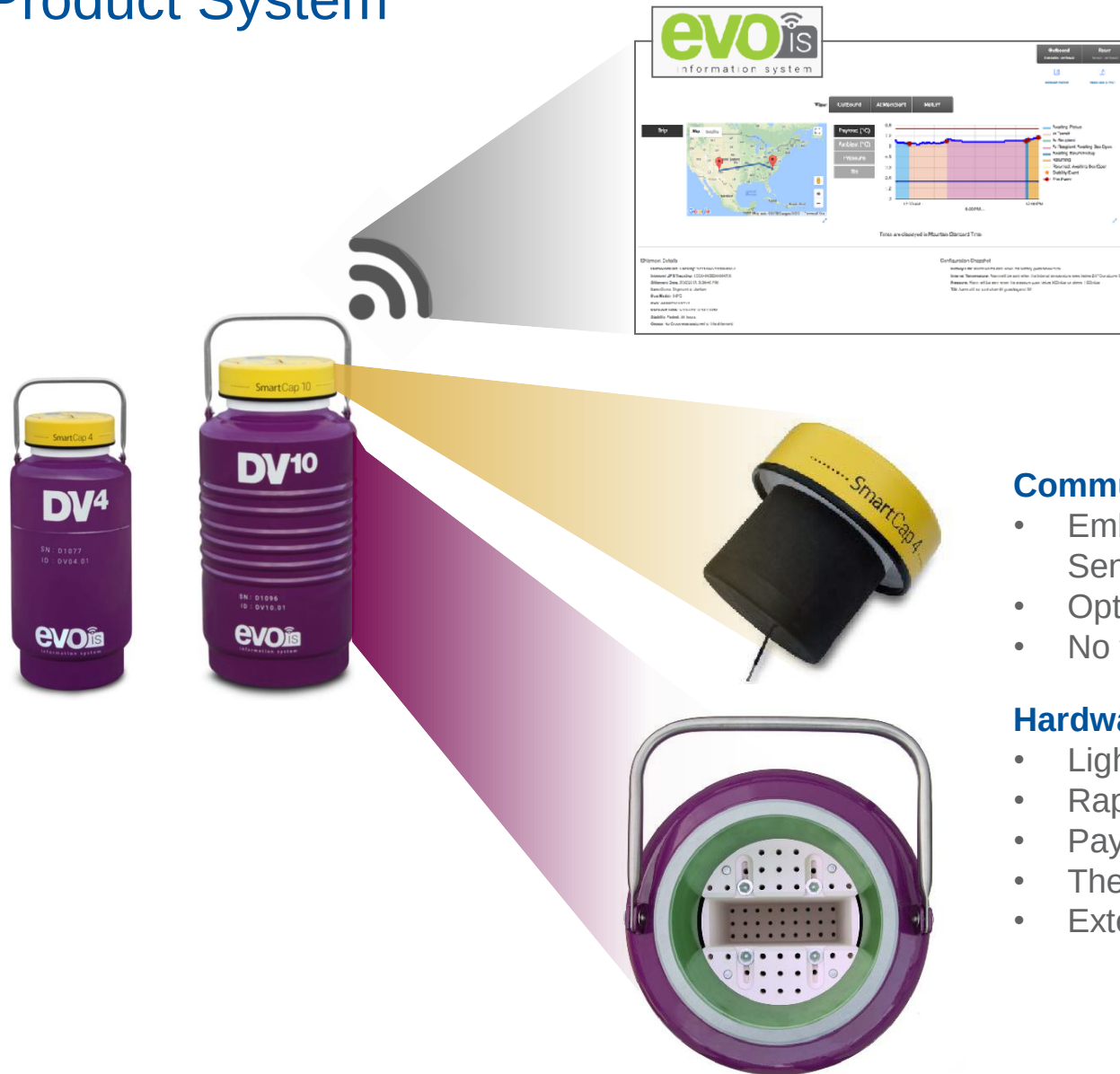


• Dewar



• SAVSU

Product System



Software

- Cloud based ops and customer portal
- Access to real-time and historic location and environmental data
- Alerts and other standard triggers

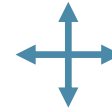
Communication

- Embedded sensors and Sendum device in SmartCap
- Optimally located temp probe
- No frost venting system

Hardware

- Lightweight
- Rapid Charging (20 mins)
- Payload Security
- Thermal Stability
- Extended Performance

Product: Key specifications



14.3 kg
*Volumetric (with
outer packaging)*

17 kg
*Packaged
Charged*



20 mins
Charge time



4.8 days
Upright hold time



1.8 days
Dynamic hold time

**160 x 56 x
295mm**

*Standard core
payload*

180 mm
Throat opening

Real time data

- GPS location
- Temperature: payload and external
- Barometric pressure
- Humidity
- Payload light
- Tilt / orientation (accessibility to narrow body planes)
- System: battery charge and signal strength



28 kg
*Volumetric (with
outer packaging)*

37.5 kg
*Packaged
Charged*



40 mins
Charge time



10 days
Upright hold time



8.7 days
Dynamic hold time

**160 x 102 x
292mm**

*Standard core
payload*

215 mm
Throat opening

What is Customer Integration?

Creating Value thru Technology

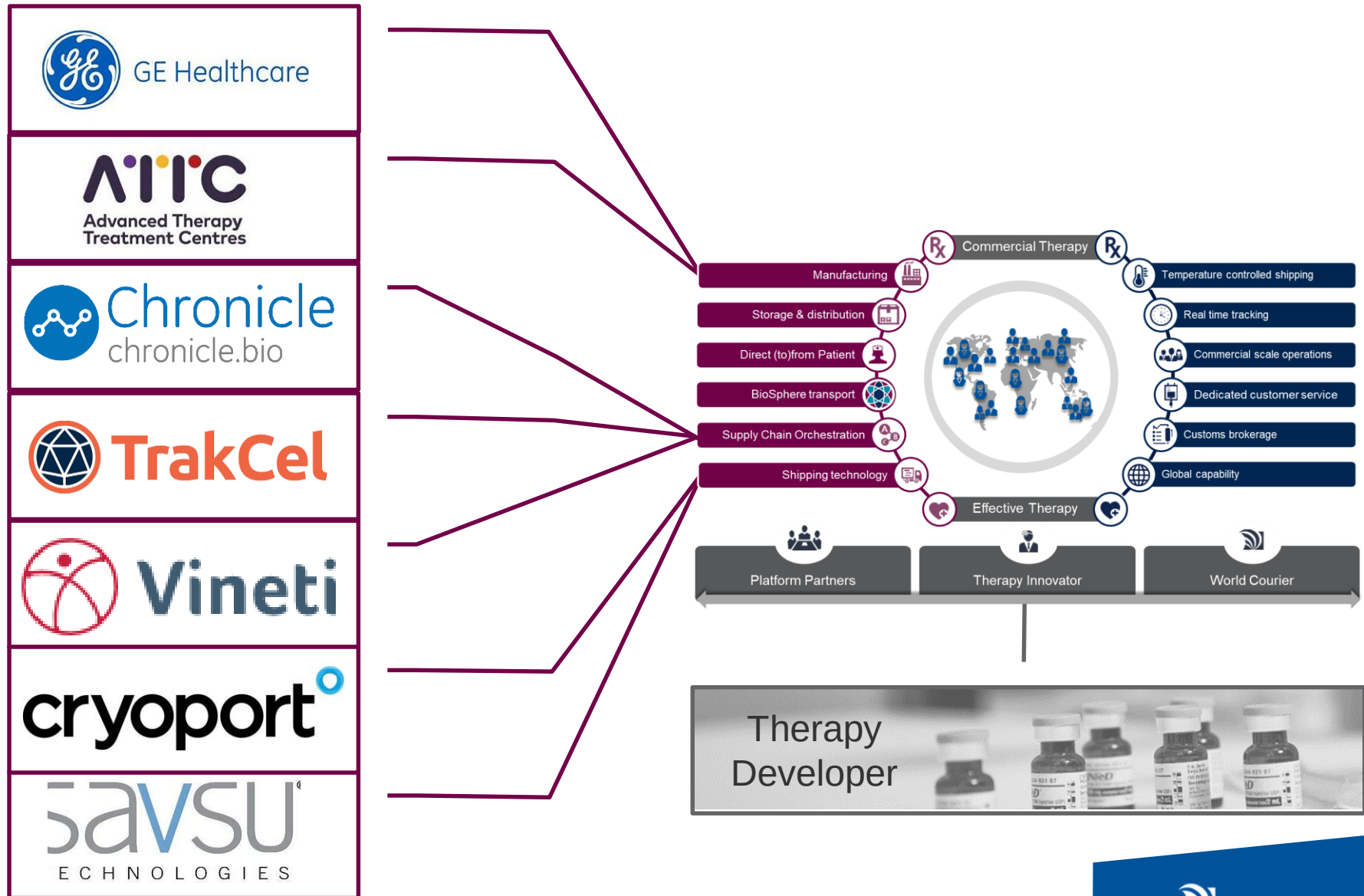
1

At World Courier, we value our relationships and have developed *Customer Integration Services* that leverage technology to create a tighter linkage between World Courier and our Customers.

2

Customer Integration is intended to improve operational processes, communication, save time and drive efficiencies into the Customer's organization.

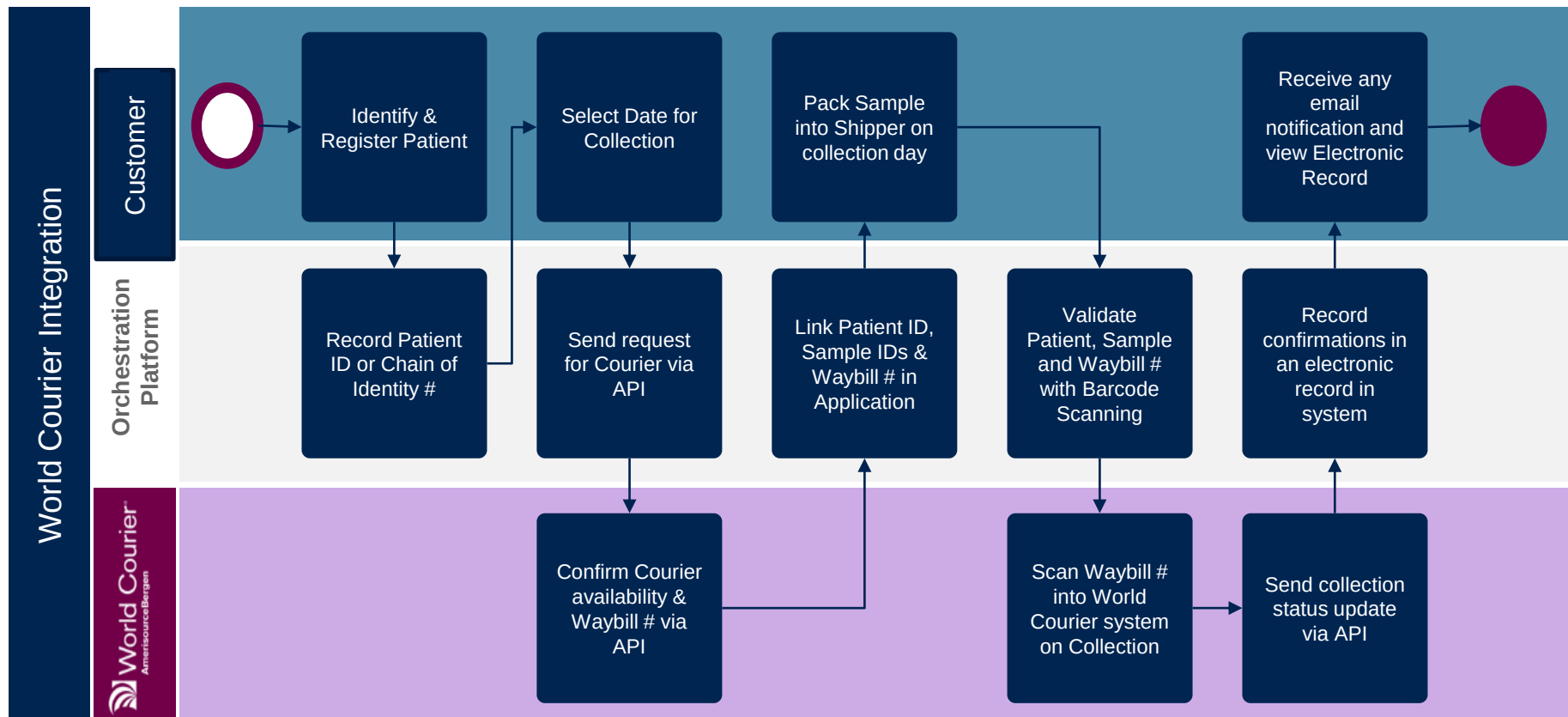
Success from Partnership (incl. Integration platforms)



Customer Integration Services – *Orchestration Platforms*

Seamless Ordering & Tracking via Web Service Products

World Courier has also integrated with the *TrakCel*, *Vineti*, and *Chronicle* Orchestration Platform using our Web Service products for fully traceable integration and tracking of Patient ID



Securing the Future of CGT



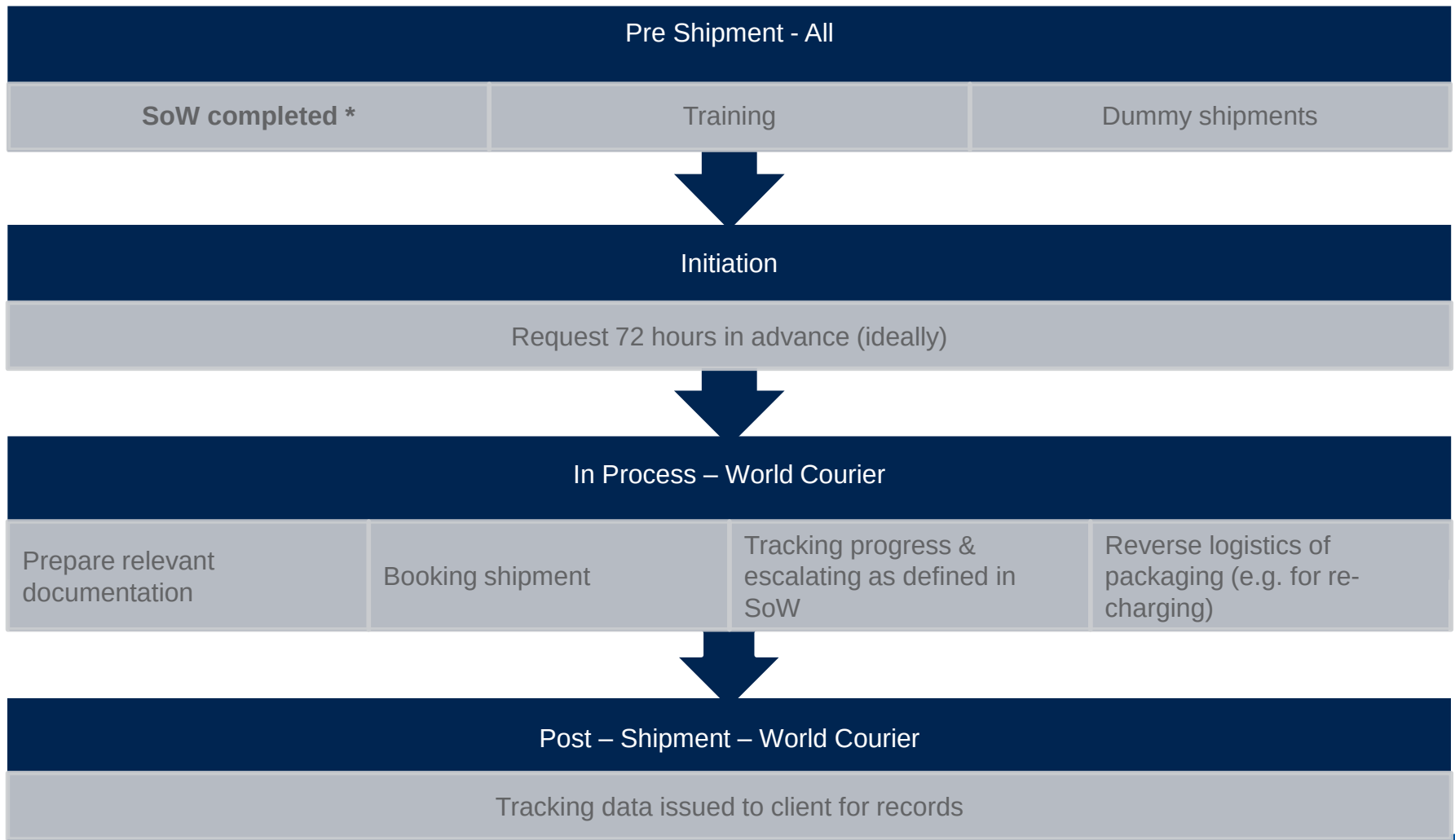
What Should we be Thinking About?

Considerations to mitigate risk – discussion at the earliest opportunity

- Strict temperature ranges and qualification of transportation systems
- Extremely tight turnaround timelines — typically 18 to 36 hours
- Collections and deliveries 24/7, weekends and holidays
- Unique travel limitations such as inability to x-ray. Weather affected Geographies/political action/Technical issues with flights/ATC strikes
- Cross border shipment challenges and regulations
- Track and trace - chain of custody throughout entire supply chain
- A statement of Work (SOW) enables all parties to capture all key info & milestones & contingencies
- Early processes hindering the transition to commercial

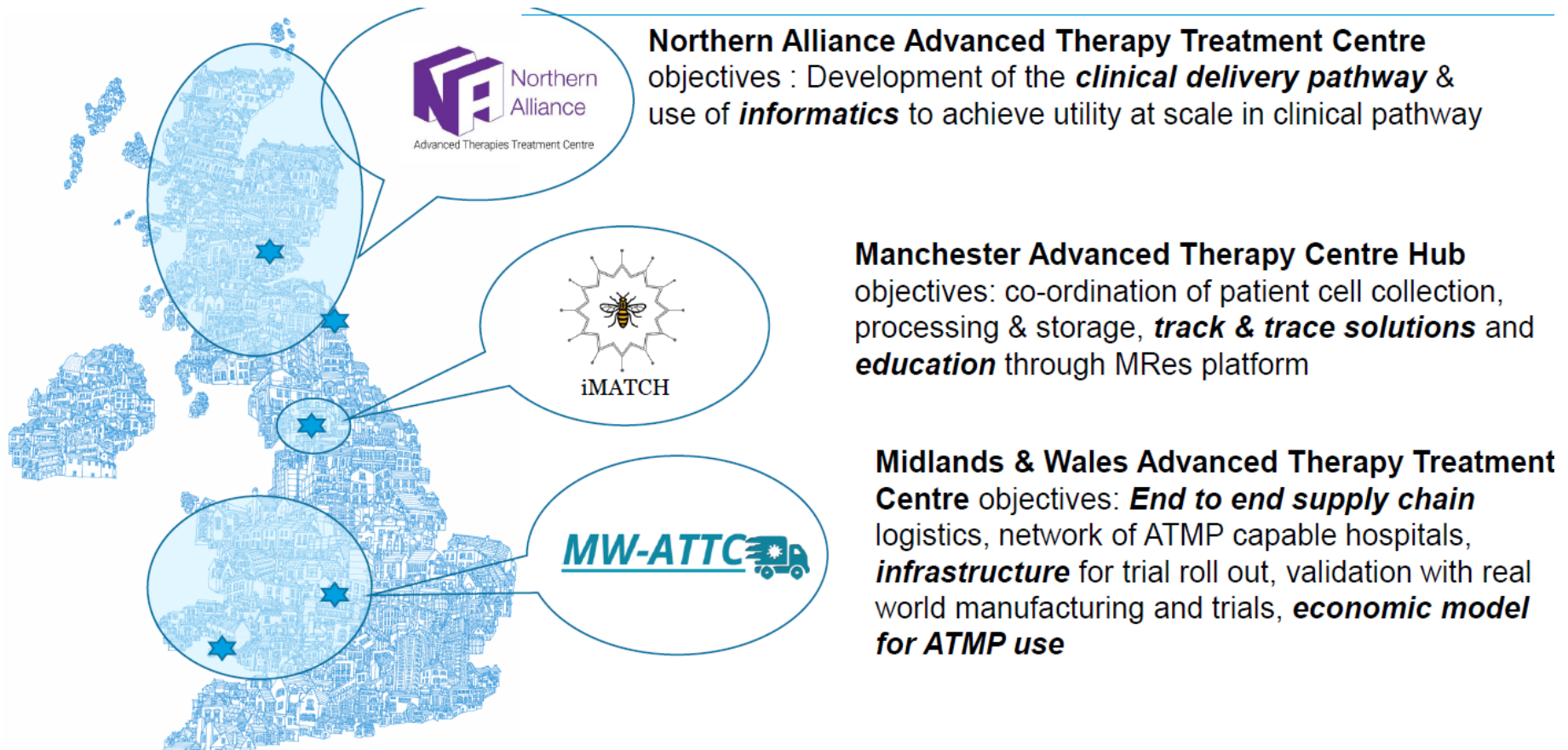


Process Flow



* Detailed Statement of Works that defines critical parameters (temp, shelf life, etc.), ideal shipping lanes, alternatives (if flights delayed, etc.), escalation strategies, key contacts, etc.

Where are the ATTCs consortiums



Quality & Regulatory



The formalization of World Courier's GxP compliance came after:

- Extensive review of international Good Practice (GxP) and Quality Management standards

World Courier GxP Policies: Based on Global GDP Guidance



WHO Good Distribution Practices for Pharmaceutical Products



USP chapter 1079 – Good Storage & Shipping Practice



Health Canada Guidelines – Temperature Control Product for Storage and Transportation



EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use



Health Products Regulatory Agency Guide – Storage & Transportation



IATA Perishable Cargo Regulations Chapter 17

Development of a company-wide GxP policy

Quality System in World Courier

3 pillars underpin World Courier's Quality System



Pillar 1:

- ISO Certification
9001:2015
14001:2015
27000:20
- MRM/Internal Audit processes for continual improvement
- Global SOP system that complies with all applicable Good Practices



Pillar 2:

- Global Training System designed to ensure competent and trained personnel



Pillar 3:

- Management of Outsourced Activities
- Qualified and calibrated equipment

GDP Certification in World Courier

What is so special about this certification?

1

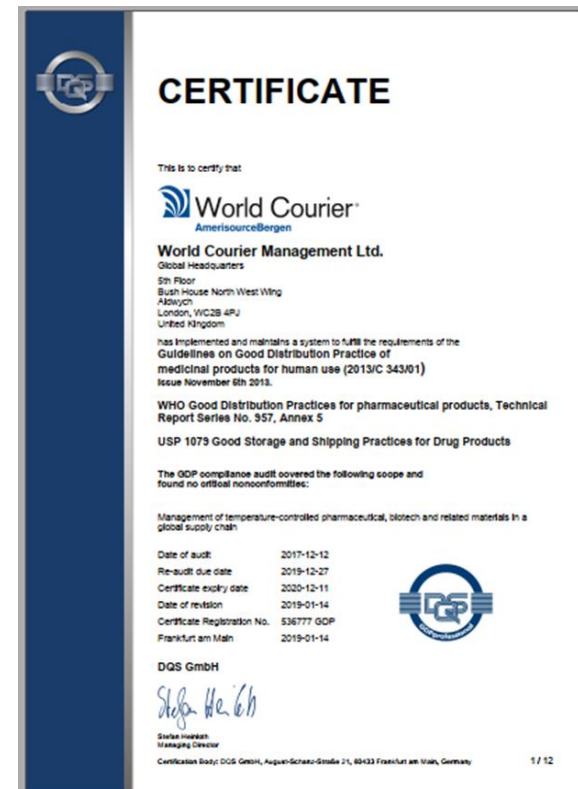
Three internationally recognized standards:
(1) EU GDP, (2) USP 1079, (3) WHO GDP

2

No non-conformances during first certification

3

No other Logistics company holds a certificate like this and we were told to be the first Logistics company with no non-conformances in a global assessment



Brexit



No deal Brexit

What we can expect

- Under the current EU membership, the UK is integrated in the EU medicines regulatory network (EMRN), including the European Medicines Agency (EMA)
- In a no deal, the UK's participation in the European regulatory network would cease.
- The MHRA would take on the functions currently undertaken by the EU for medicines on the UK market. This would require changes to UK law, via the Human Medicines Regulations 2012 (HMRs)
- UK consignments to and from the EU will be subject to the same Customs requirements as current non EU traffic.
- Consignments will need to be accompanied by an invoice for Customs purposes. (The UK will become a 3rd Country)
- Import duties and taxes will be levied according to published duty and VAT rates. Economic Operator Registration Identification (EORI)

World Courier UK & Ireland



- Imports (Brokerage)
- Customer Service
- Operations
- Packaging Hub
- Training Centre
- Storage (in-transit)
- MHRA - WDA Licence
- Regulated Agent
- Authorised Economic Operator (AEOC) Customs Simplification status



World Courier

37,415 followers

3w • Edited

This is incredible news and World Courier is proud to support these life changing therapies, both through direct shipments like this and being involved in the

[#advancedtherapy](#) treatment centres.

[#CarT](#) [#Kymriah](#)

<http://ow.ly/Df5O30nBn1E>



Pioneering cancer therapy for first child

bbc.co.uk



Key Takeaways

Early Collaboration



Training, Knowledge
& Support

Integration



The beginning

“I need to get this document to Europe ASAP!!!!”



1969

- Pioneered “**Next Flight Out**” services
- Same year as DHL was founded and four years before FedEx
- Largely moving urgent legal documents, bill of lading, etc
- Focus on **time-sensitive shipments**