

# Are we really ready to launch cell and gene products (Logistically)?

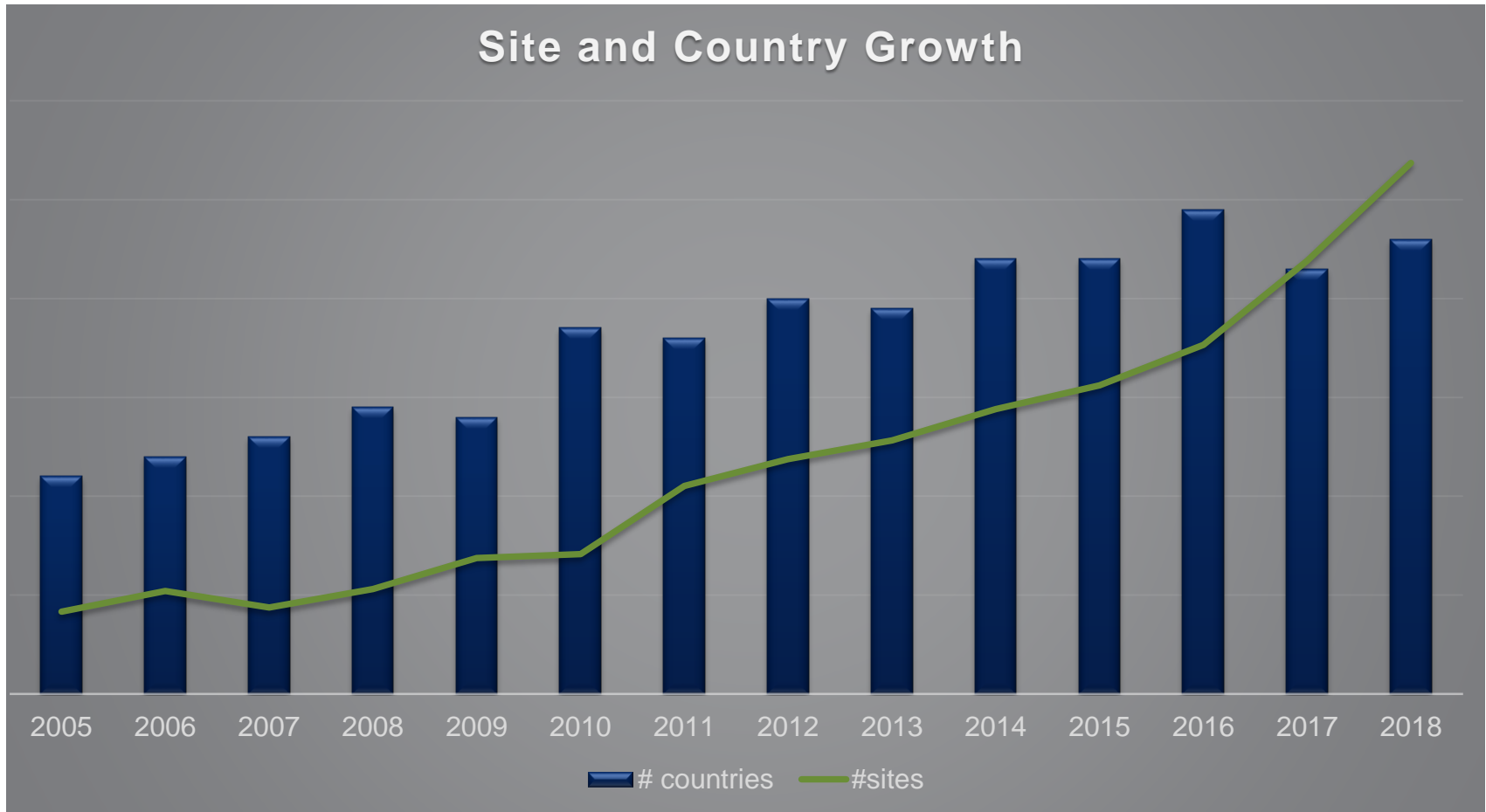
ISCT Signature Series - Miami

22/01/2019

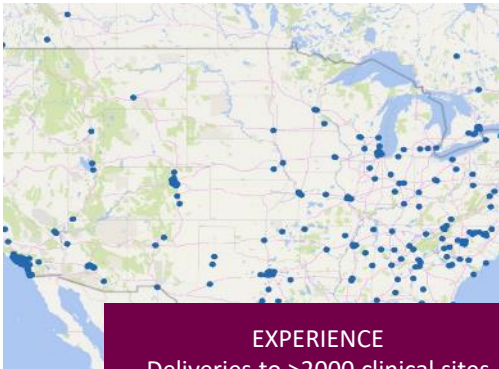
Simon Ellison



# Scene Setting



# World Courier - Trust and Consistency



**EXPERIENCE**  
Deliveries to >2000 clinical sites



**SCALABILITY**  
Managing clinical trial and commercial projects



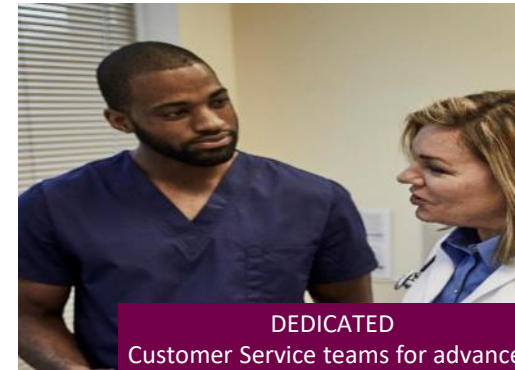
**QUALITY**  
Fully GDP compliant throughout global network



**GLOBAL SUPPORT**  
140 offices in 50 countries

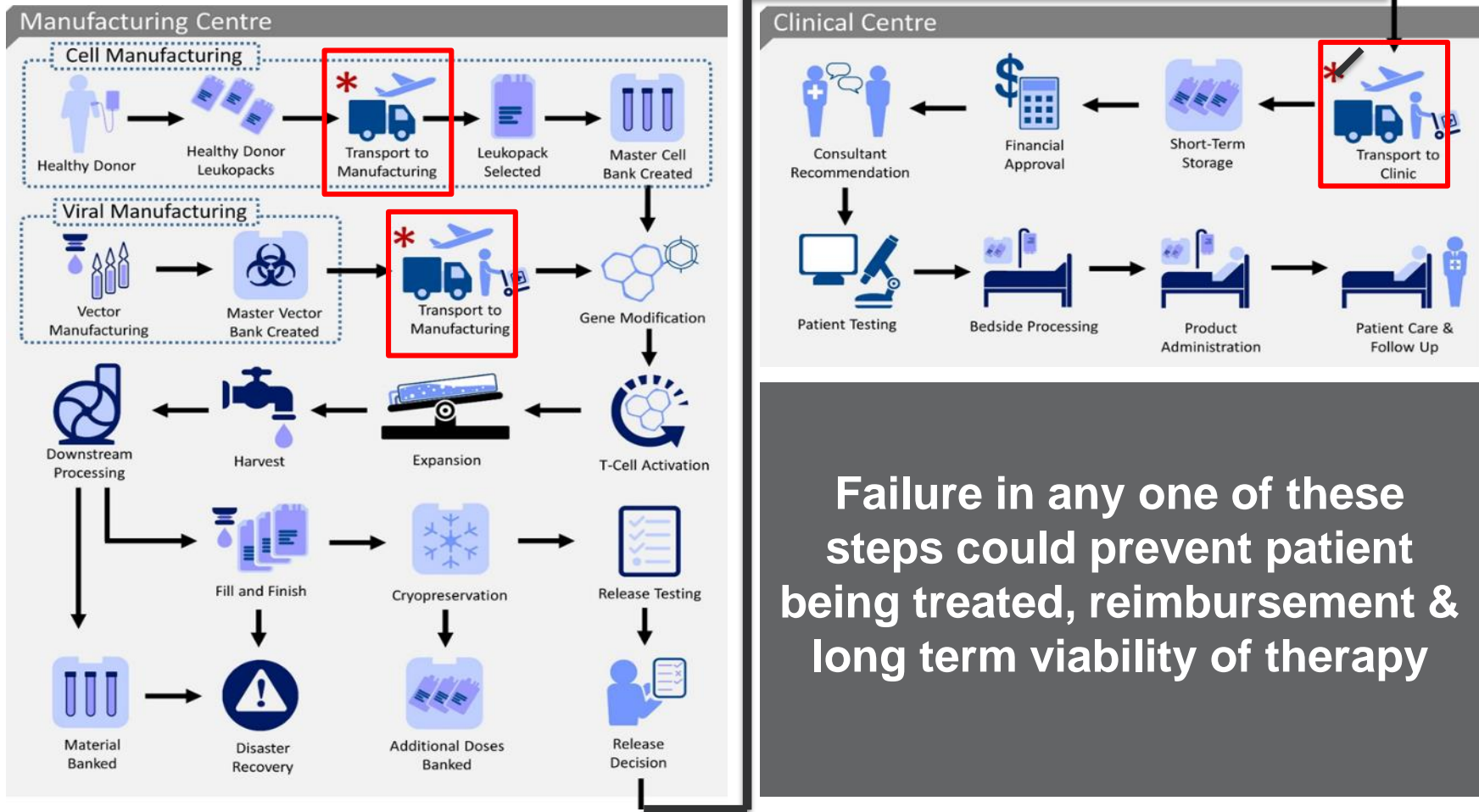


**TEMPERATURE**  
Supporting +37 to -190C shipments



**DEDICATED**  
Customer Service teams for advanced therapies

# Is Logistics a Critical Manufacturing Step?



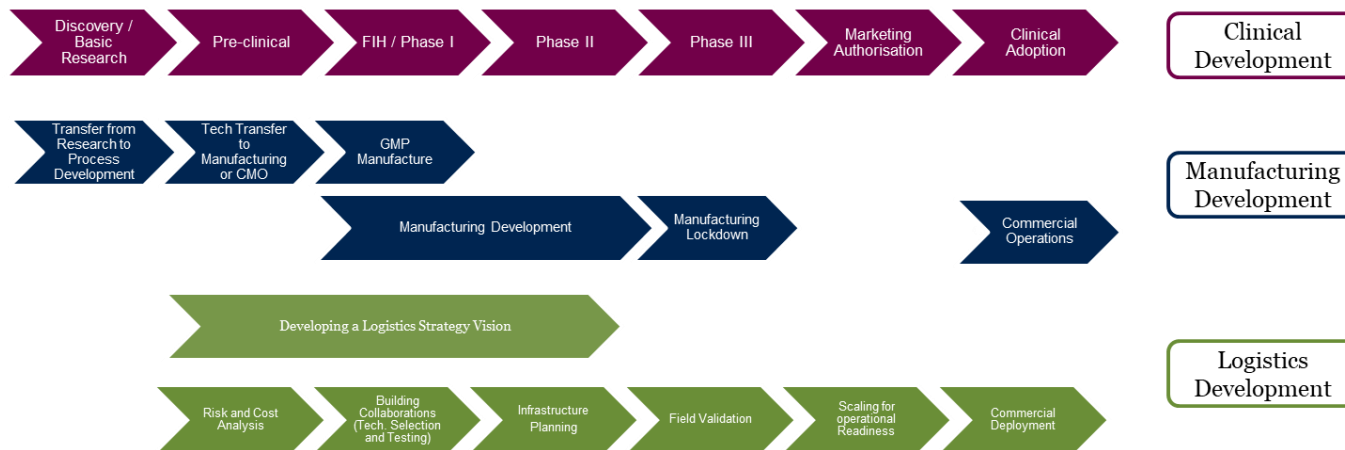
# Logistics by Design

## Definition

- LbD is a framework for logistics-based decision making, based in-part, on Quality by Design principles

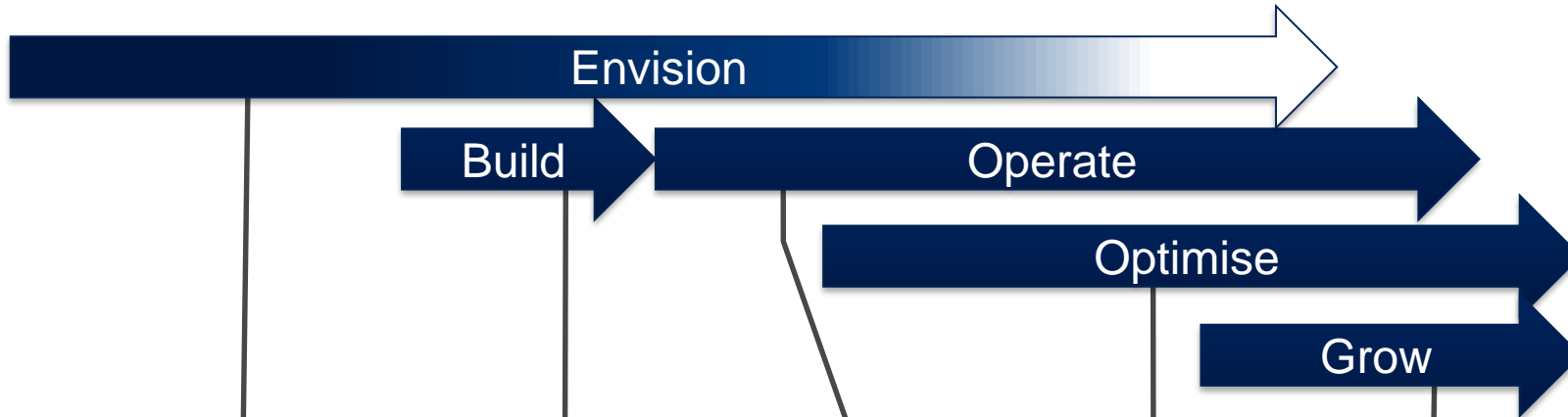
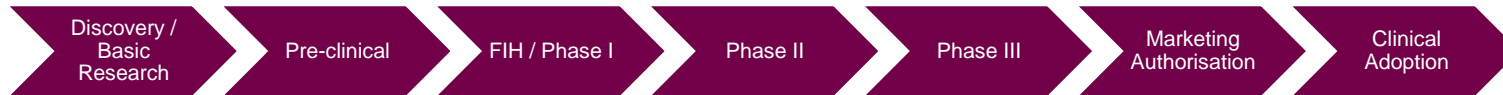
## Overview

- Key to logistics success is designing in “quality” from the outset.
- This enables challenges in delivering the logistics strategy to be identified early
- Provides sufficient time to consult with key stakeholders (e.g. manufacturing, clinical teams and providers) and tailor the development program to address any high risk or cost drivers.
- Creates structured logistics development pathway, with six key stages of:



Ellison\*, McCoy\*, Bell, Frend, Ward (\*Joint 1st Author), Logistics by Design – A framework for advanced therapy developers to create optimal Logistics Platforms, Cell and Gene Therapy Insights, Dec 2018

# Rethinking Development Pathways



What is the commercial supply chain going to look like?

How do we deliver at clinical but have eye on commercial

Can I expand globally, and have a template for my next asset?

What are the core principles that need to be established at PhI?

What are the lessons learned?

**Use the experience of logistics experts**



# Are we really ready to launch cell and gene products? (Logistically)



- Logistics is critical to patient treatment & commercial reality



- Logistics by Design
- Think early and think big !



- Use vendors as experts



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reach and partnership  
shape healthcare delivery.