

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

This document was produced by Simon Ellison, Simon died in the Spring of 2020 after a short illness. He is much missed within the Northern Alliance. He played a transformational role in adapting and enhancing supply chains for cell and gene therapies, part of his commitment to rapid and effective delivery of these advanced therapies to patients over a number of years. We remember Simon with admiration. In recognition of his contribution we note it here.

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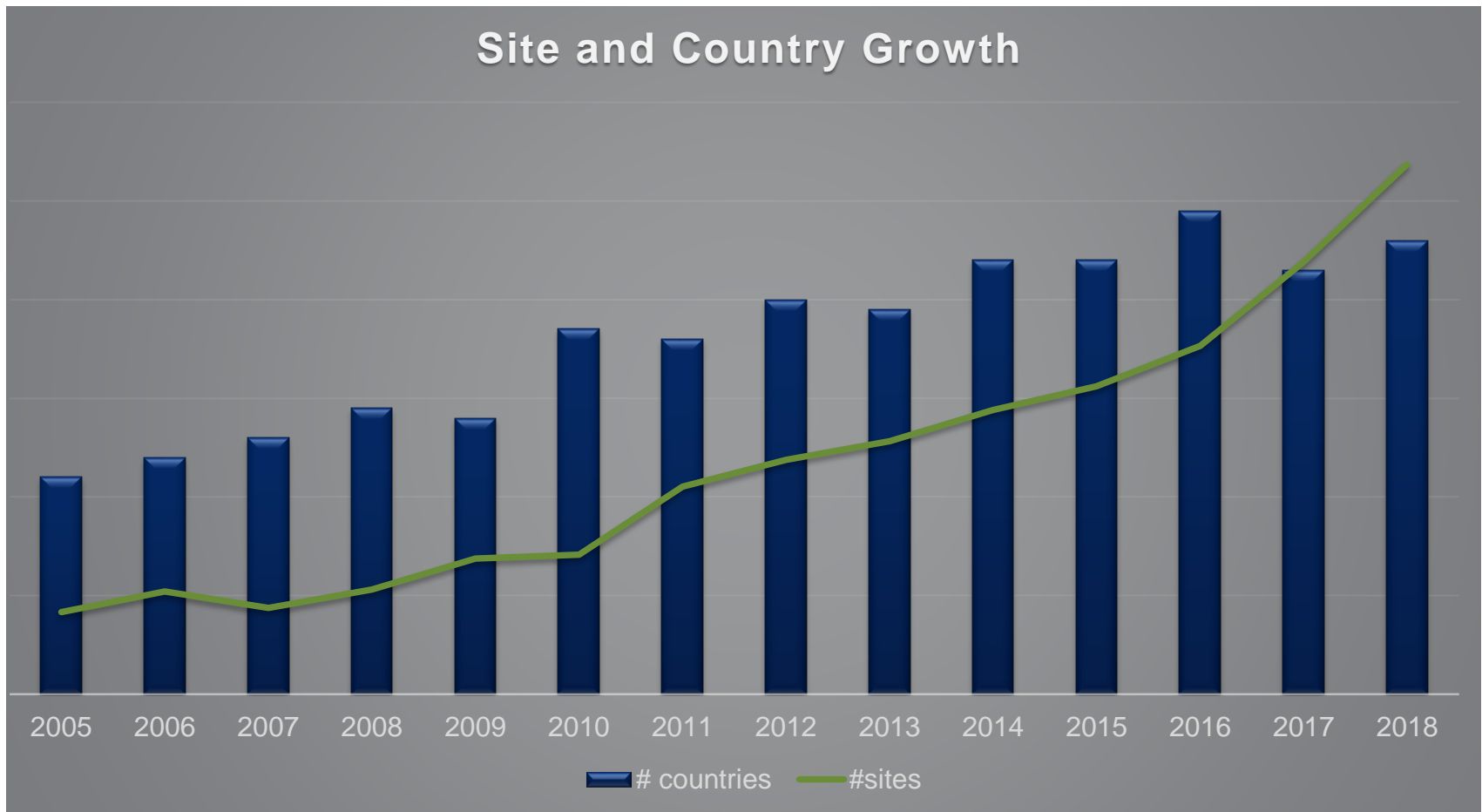
ISCT Signature Series - Miami

22/01/2019

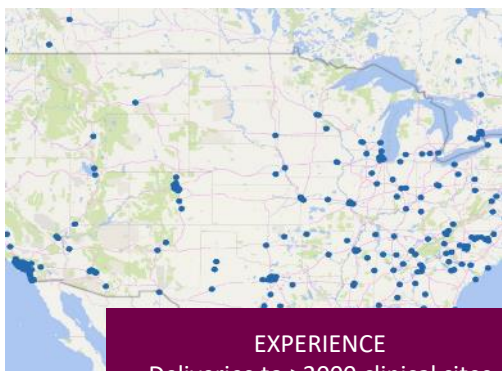
Simon Ellison



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

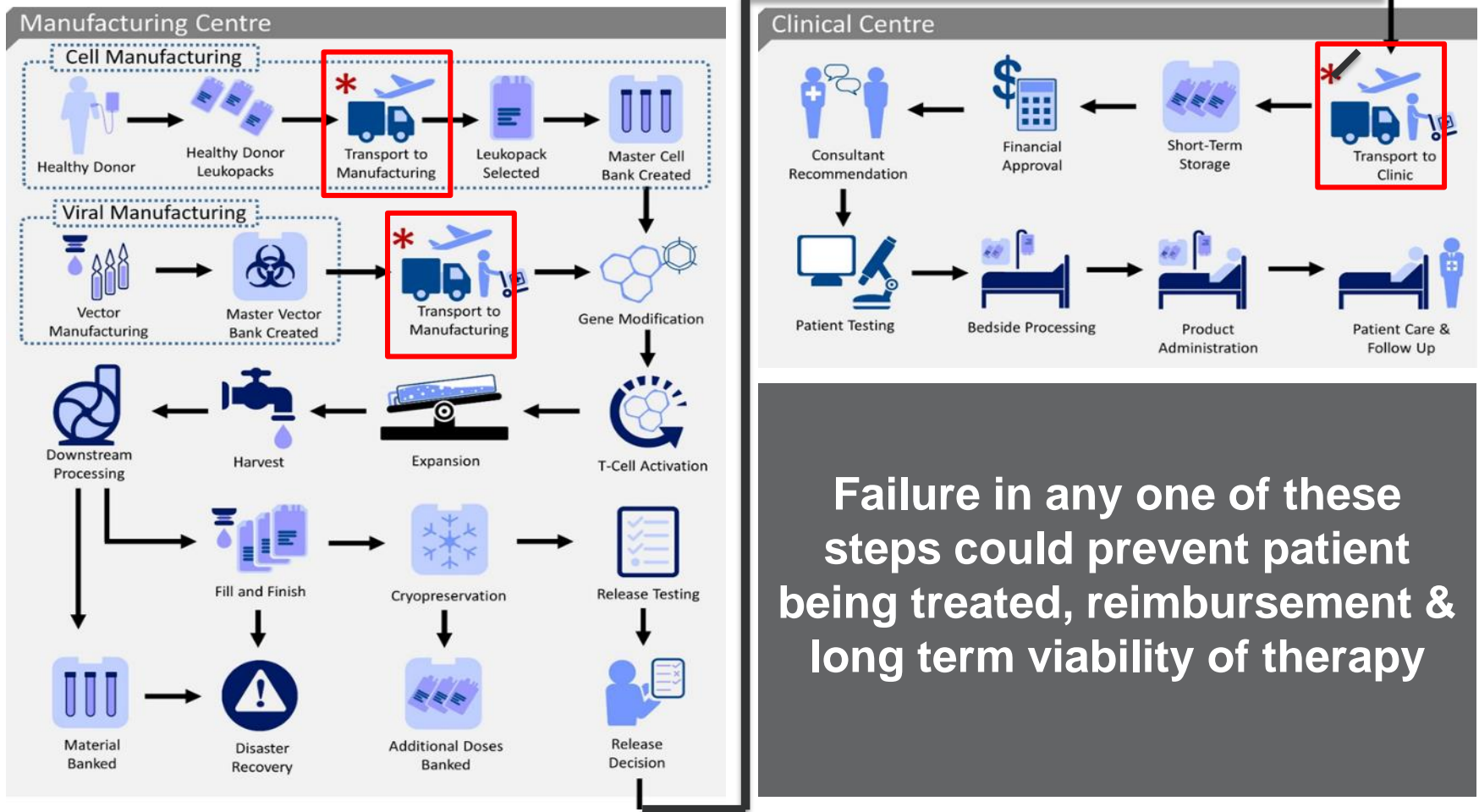


TEMPERATURE
Supporting +37 to -190C shipments



DEDICATED
Customer Service teams for advanced therapies

Is Logistics a Critical Manufacturing Step?



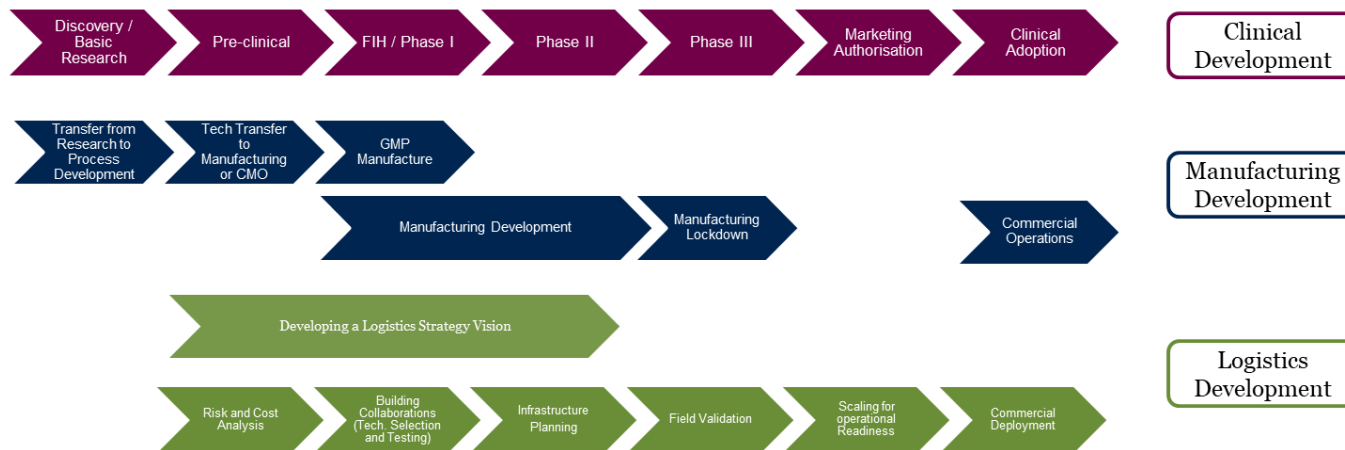
Logistics by Design

Definition

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

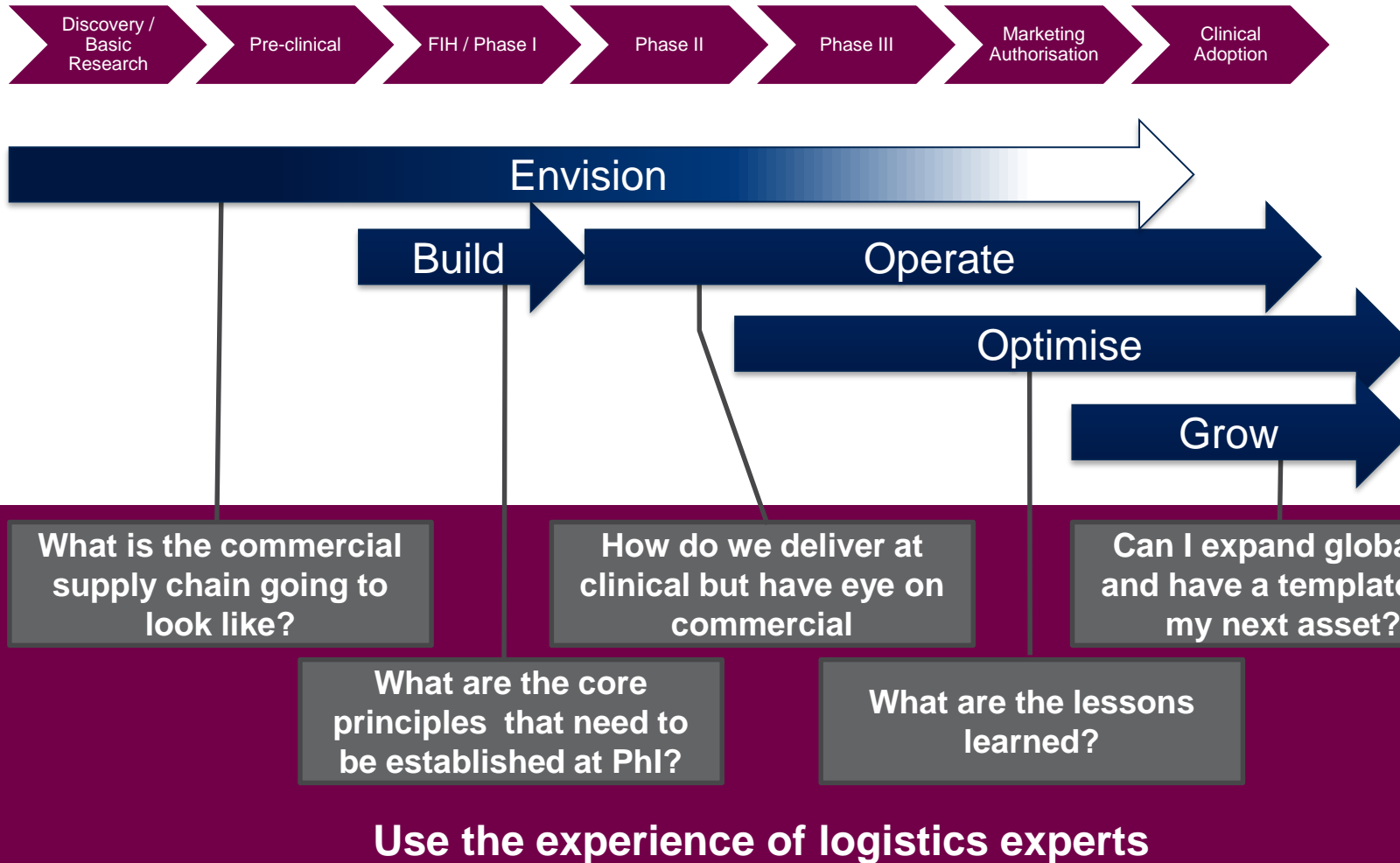
Overview

- 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



Ellison, Hagan, Suchet, Commercial Lessons for Clinical Success, CGTI Innovator Focus, Dec 2018

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



Where knowledge,
reach and partnership
shape healthcare delivery.