

Logistics by Design

Using Critical Logistics Attributes to reduce cost & increase efficiency

Facilitate Leaders World

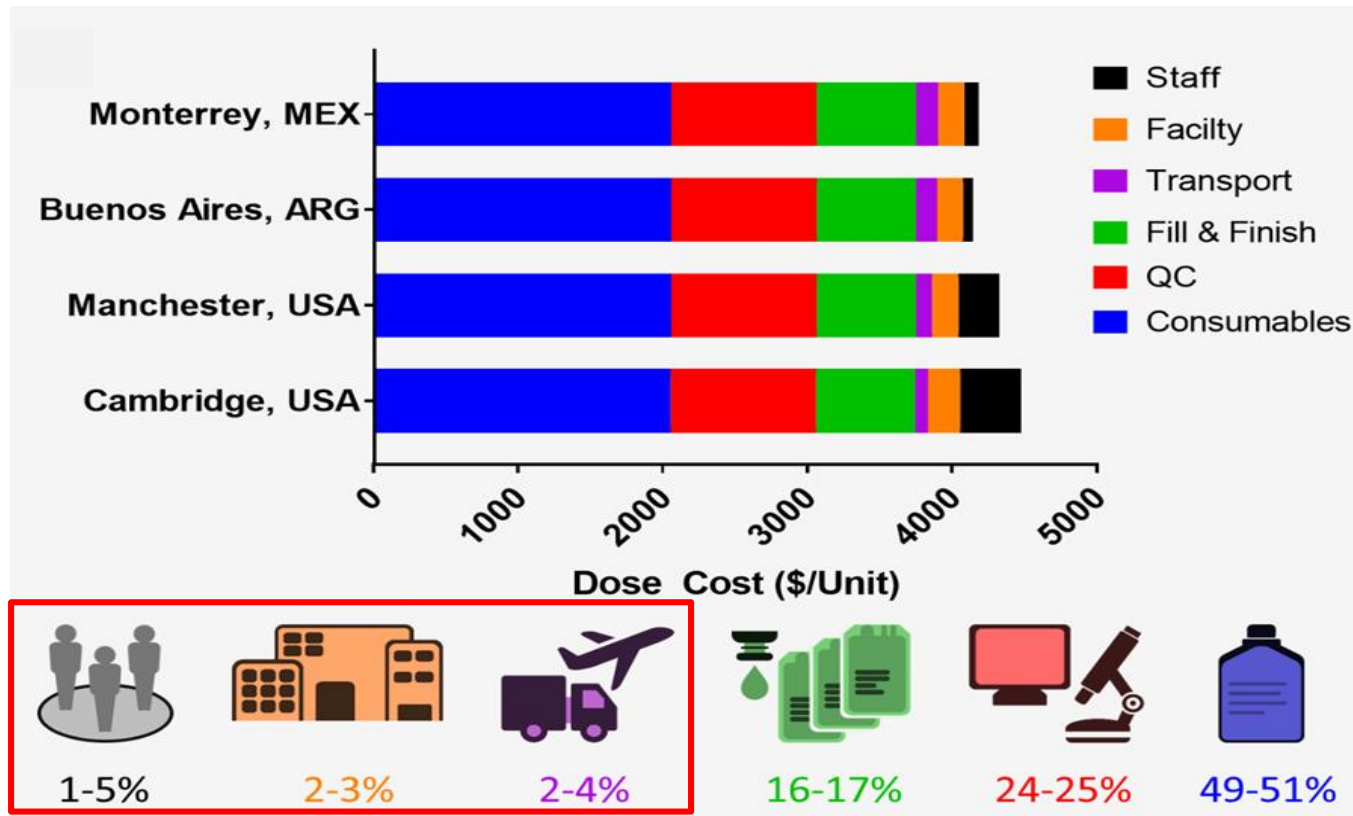
23/01/2019

Simon Ellison

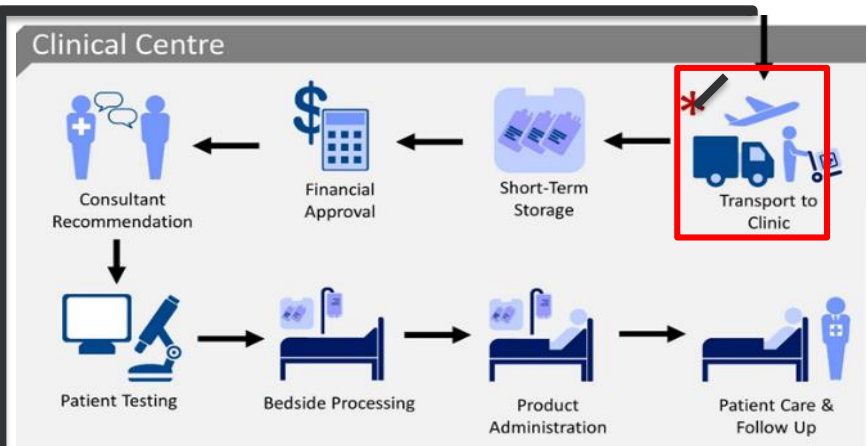
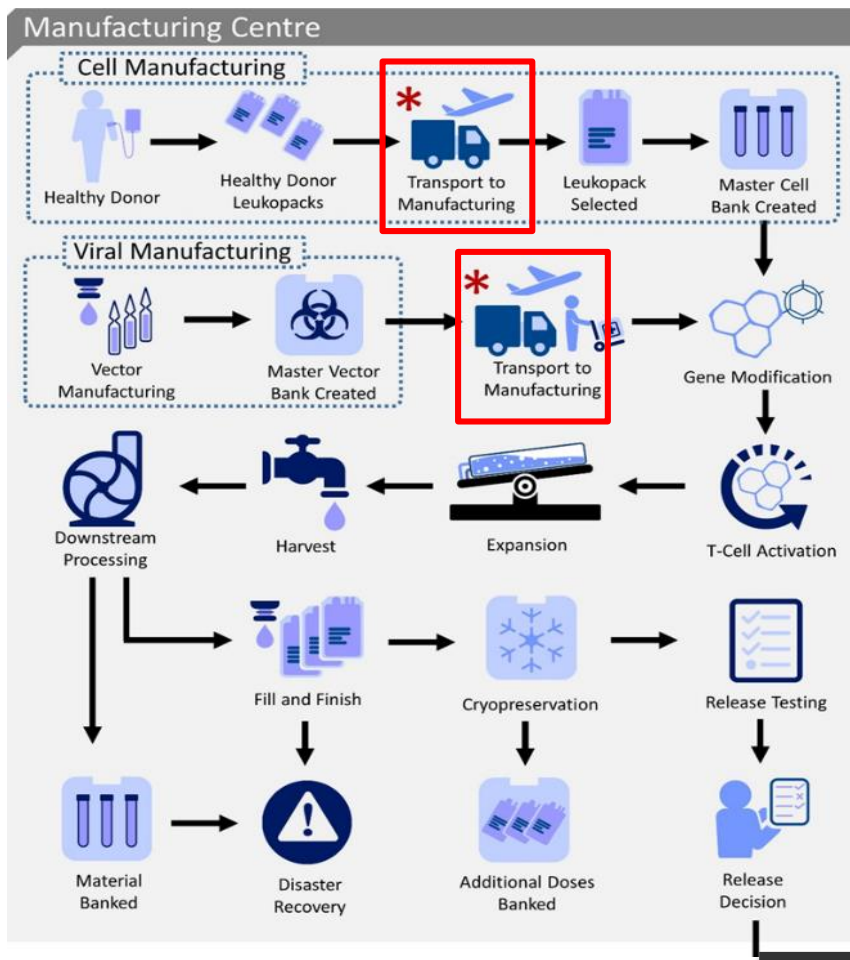


How significant is the cost of logistics?

Logistics has same cost impact as staff and facility costs !

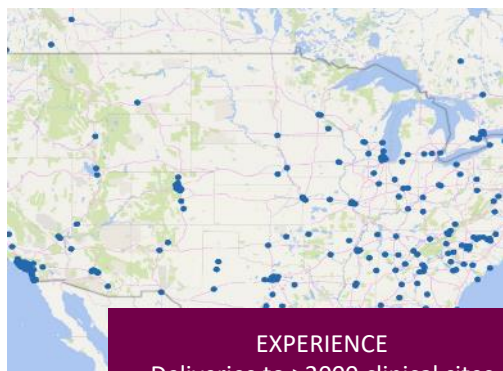


Is Logistics a Critical Manufacturing Step?



Failure in any one of these steps could prevent patient being treated, reimbursement & long term viability of therapy

World Courier - Trust and Consistency



EXPERIENCE
Deliveries to >2000 clinical sites



SCALABILITY
Managing clinical trial and commercial projects



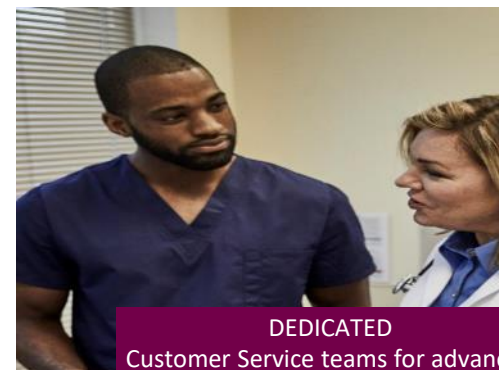
QUALITY
Fully GDP compliant throughout global network



GLOBAL SUPPORT
140 offices in 50 countries



TEMPERATURE
Supporting +37 to -190C shipments



DEDICATED
Customer Service teams for advanced therapies

Logistics by Design

Definition

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

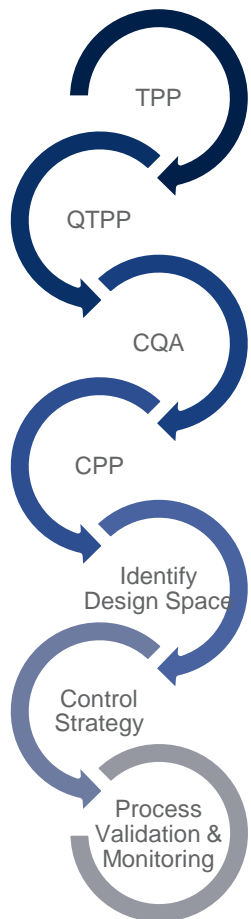
Overview

- 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:

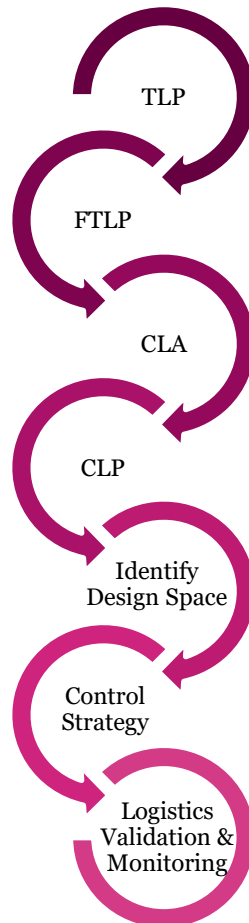


QbD Evolving into Logistics by Design

Quality by Design



Logistics by Design



• Target Logistics Profile

- Overarching objectives of a commercial logistics strategy with respect to supporting business goals, supplying market needs, maintaining regulatory compliance and facilitating clinical adoption.

• Focused Target Logistics Profile

- Prospective summary of the commercial logistics strategy traits that need to be achieved for all components of the value chain, to ensure successful delivery of product to patient whilst maintaining chain of custody and identity

• Critical Logistics Attribute

- A physical, temporal, informatic or operational property that needs to be within an appropriate limit, range, distribution or tracked and traced, to ensure the desired logistics strategy is fulfilled.

• Critical Logistics Parameter

- A logistics parameter whose variability or failure would impact a critical logistics attribute and therefore should be monitored or controlled to ensure the desired logistics strategy is fulfilled.

• Identify Design Space

- The design space or operating ranges for the CLPs are elucidated through practical assessment using supporting tools, such as Design of Experiments (DoE) or through the testing as part of logistics development activities

• Control Strategy

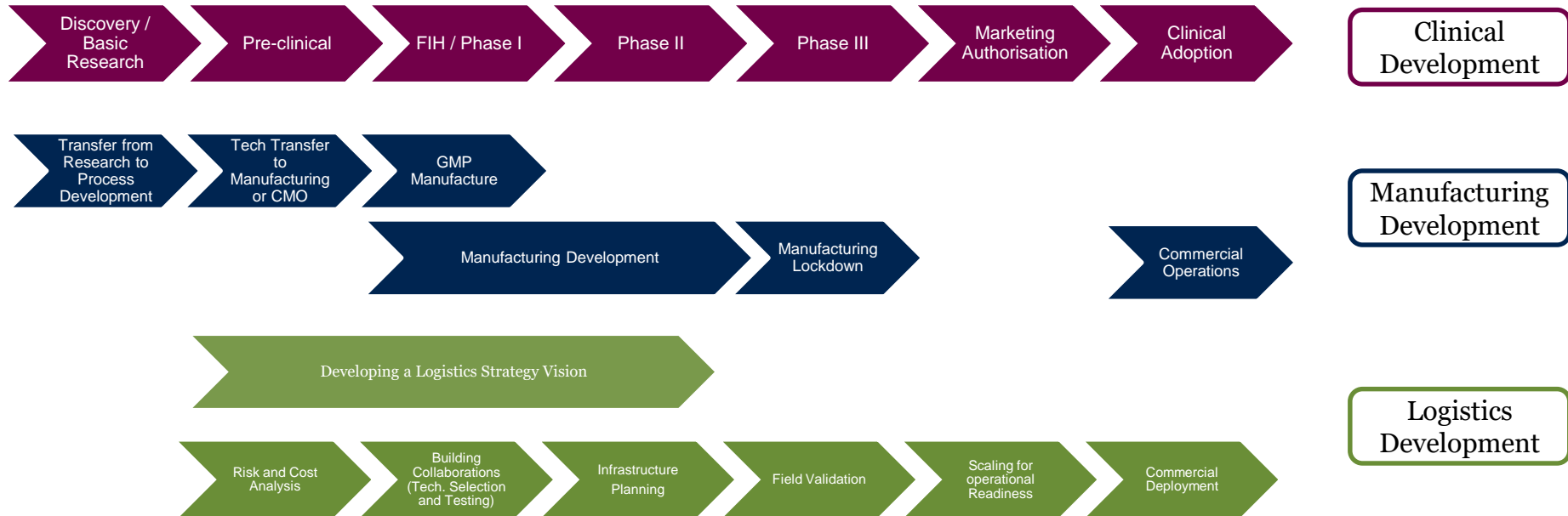
- A planned set of controls, derived from current logistics understanding that ensures service performance and quality. Controls may include parameters and attributes related to physical or informatic characteristics and include frequency of monitoring and control.

• Logistics Validation and Monitoring

- A MAA/launch ready logistics system functional on a global footprint with regular performance review to support real time data driven decision making to further optimise the logistics undertaking.

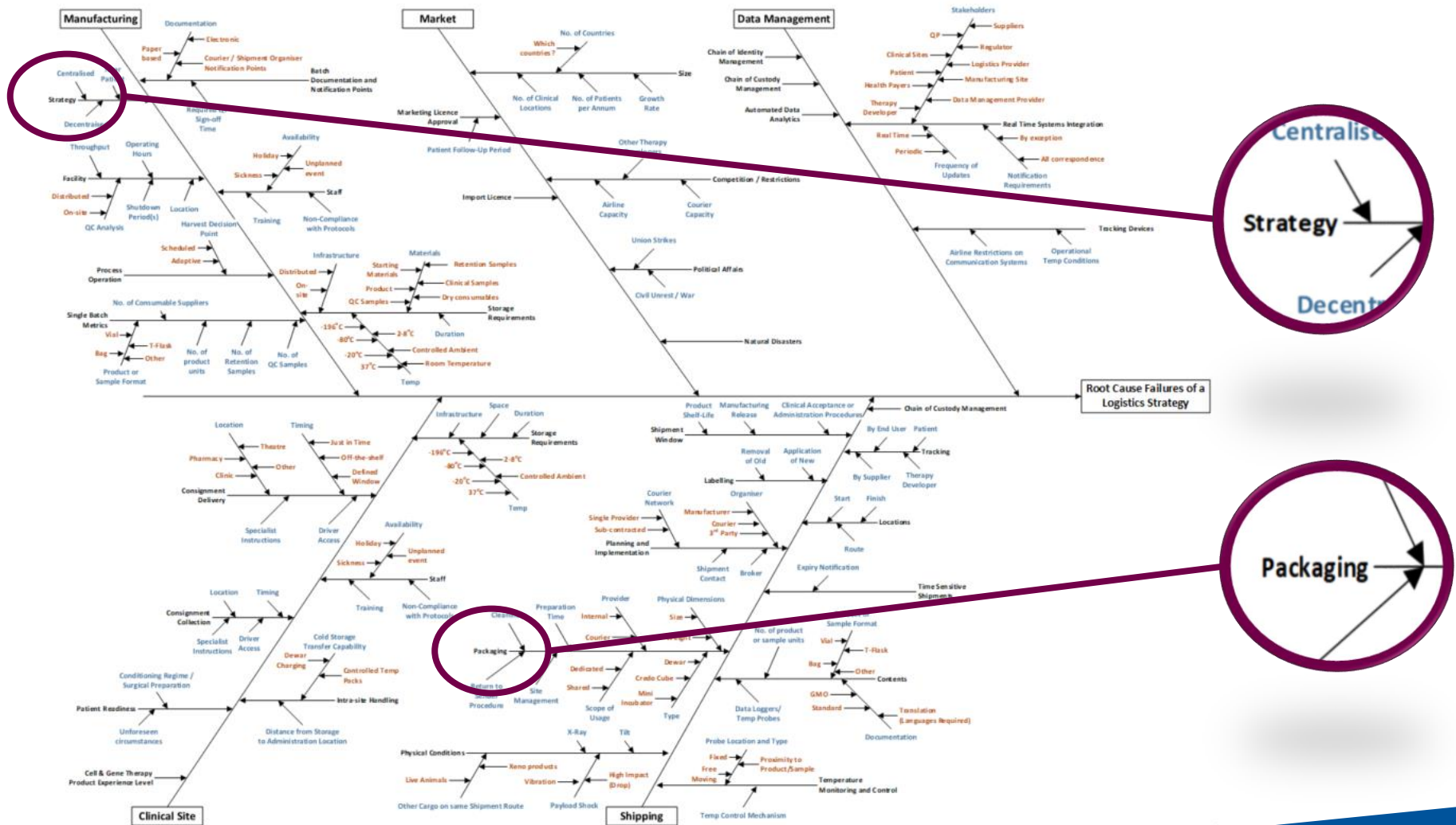
Ellison*, McCoy*, Bell, Frend, Ward (*Joint 1st Author), Logistics by Design – A framework for advanced therapy developers to create optimal Logistics Platforms, Cell and Gene Therapy Insights, Dec 2018

LbD Aligns Development



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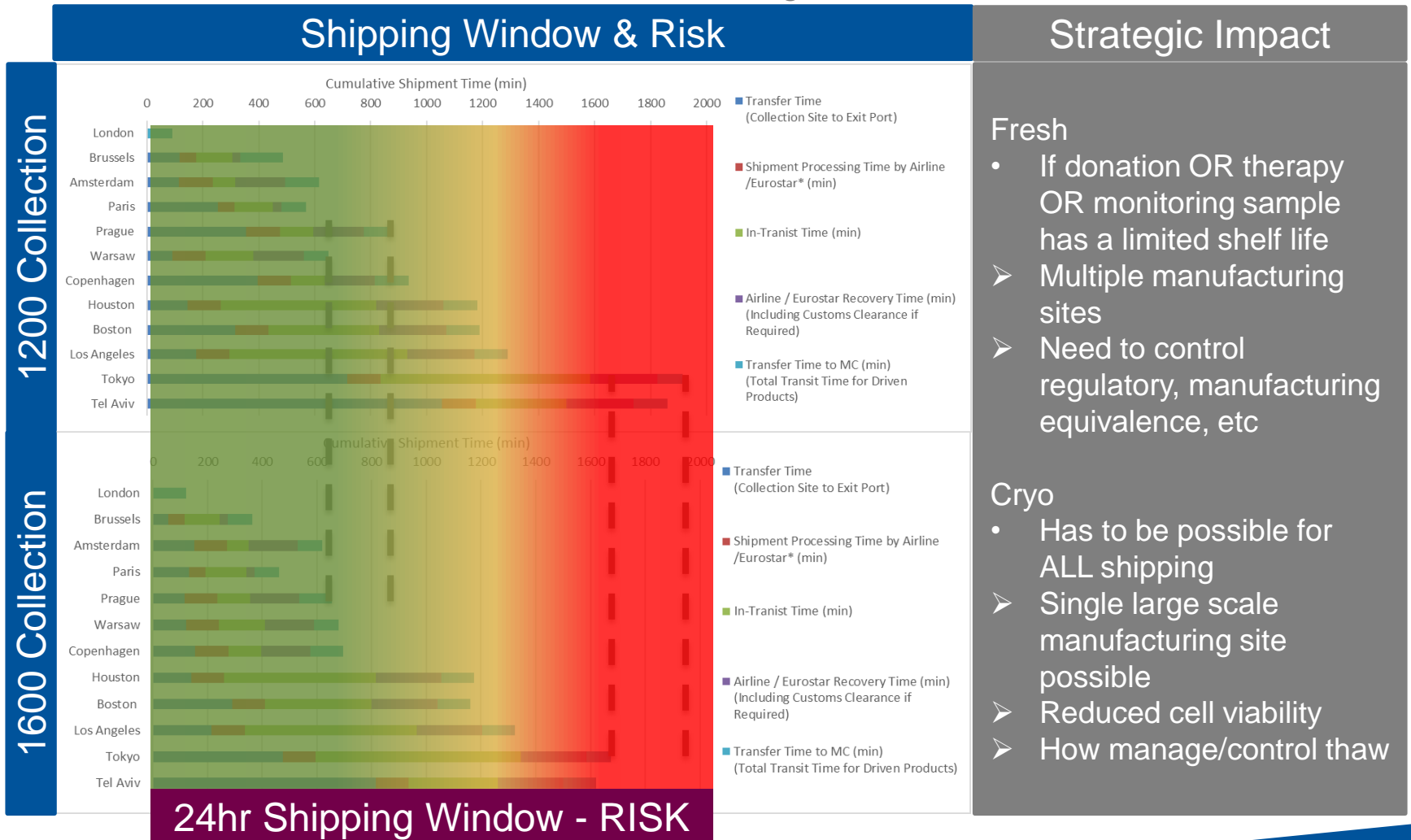
LbD Built on Risk Based Analysis



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

Manufacturing Strategy Driven by Shelf Life

Different clinical collection times enable different flights to be utilised



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

Packaging System Impacts Scalability

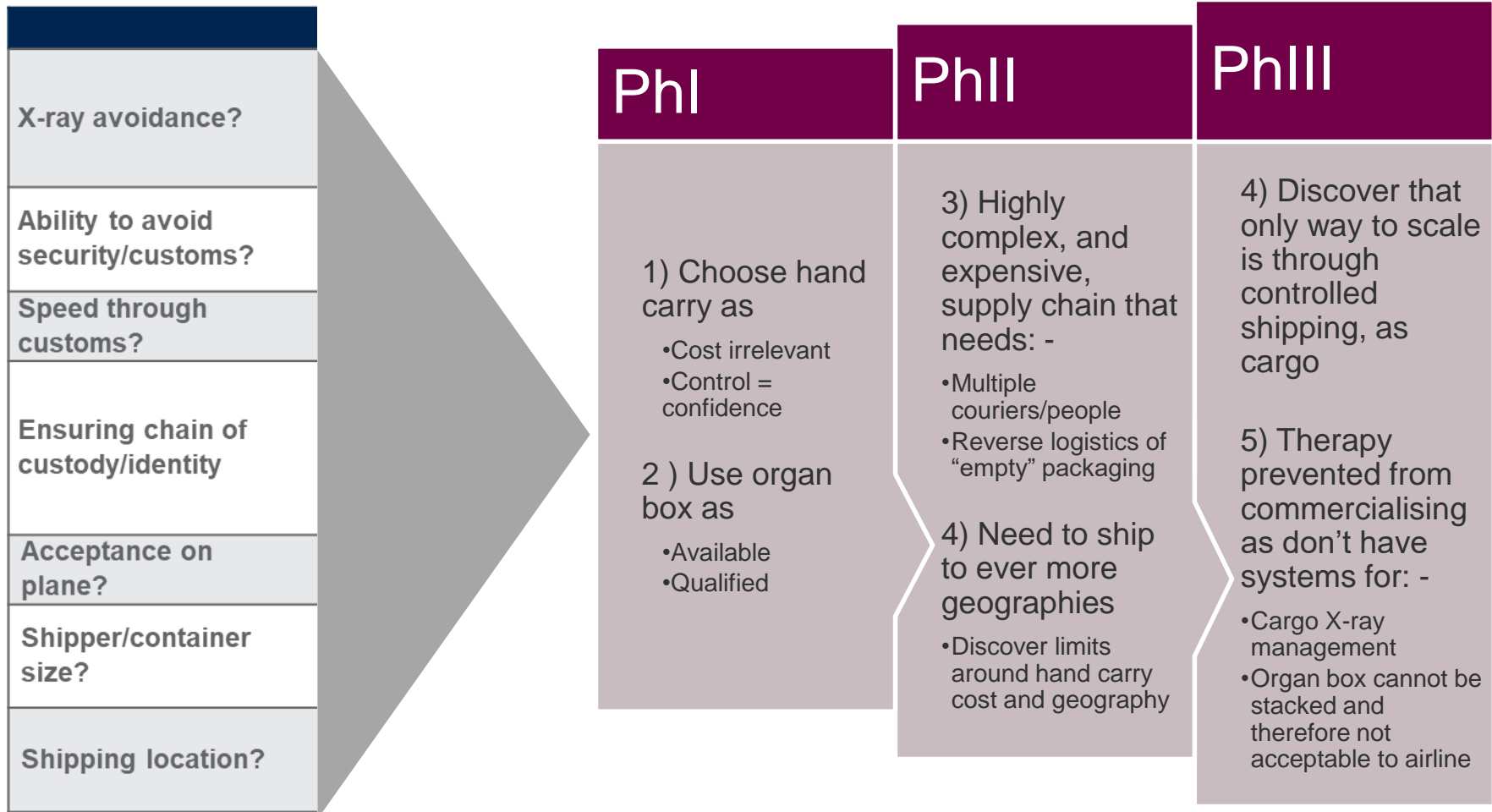
Is hand carry the solution?

Hand Carry vs Controlled Shipping

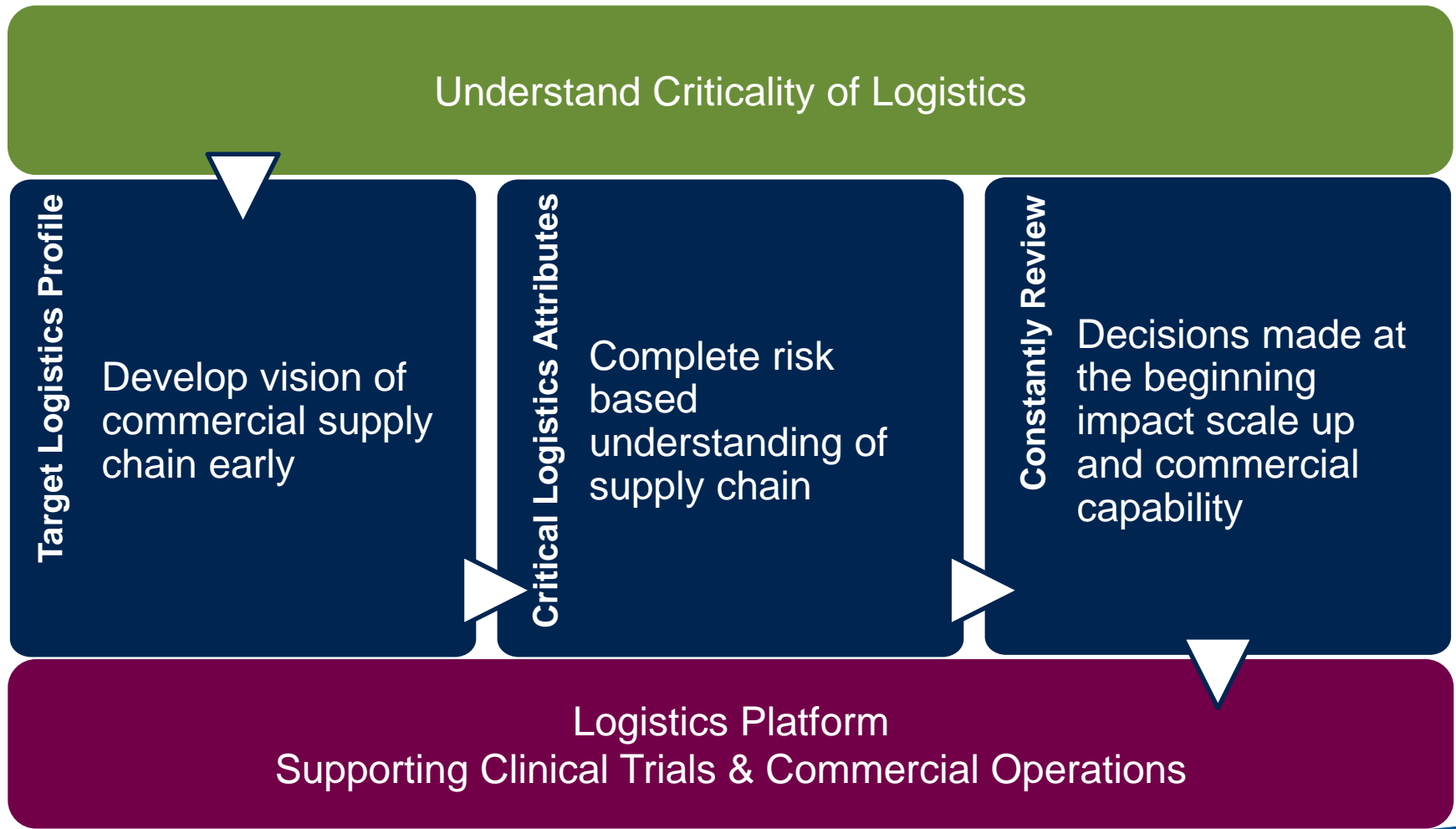
X-ray avoidance?	Regardless of transport strategy, all shipments are subject to x-ray unless the correct exemption paperwork and alternative security measures are in place. Managing xray exposure can only be achieved by working with an experienced logistics expert.
Ability to avoid security/customs?	All imports have to pass through security and customs checks as they enter the country. Requirements for import/export change on a frequent basis and as such the HC capability's could change.
Speed through customs?	HC possibly faster, depending on size of immigration que, and efficiency of airline in making freight available (if shipped in the hold)
Ensuring chain of custody/identity	Depending on package size hand carries may be placed, out of site, in overhead lockers. In addition on small domestic flights hand luggage is limited and anything larger than a laptop is placed in the hold
Acceptance on plane?	The pilot is ultimate authority on any flight and can refuse to let any item, for any reason, into the cabin
Shipper/container size?	Only packages that comply with the airlines hand-baggage & IATA restrictions can travel in the cabin. This massively constrains the ability to scale up and commercialise with HC.
Shipping location?	Depending on the airline, the package, and how many seats have been booked. All packages have to be placed in overhead lockers. This may lead to crush damage if the flight is crowded and means that the package is out of sight.

Packaging System Impacts Scalability

Is hand carry the solution? - Case Study



Using Logistics by Design to De-Risk Commercialisation





Where knowledge,
reach and partnership
shape healthcare delivery.