



Workshop Session

Supply Chain Considerations for Advanced Therapies

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Building Logistics Platforms

NA-ATTC Boiler Shop

21/05/2019

Alan Runacus

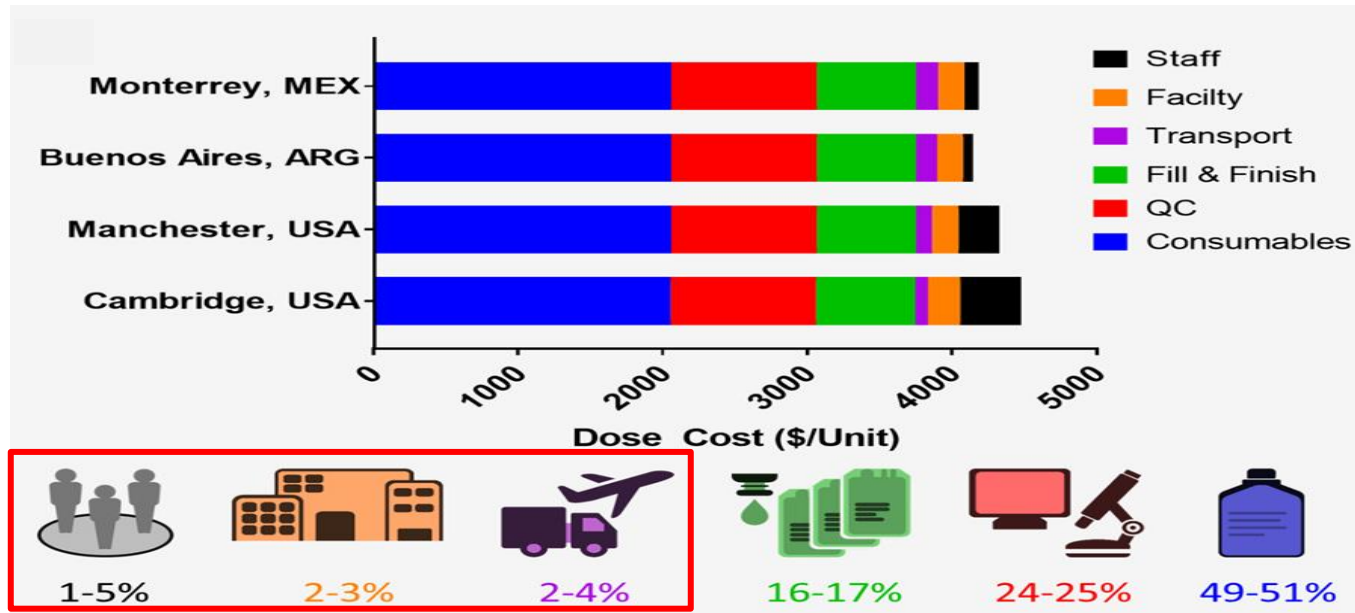


Scene Setting



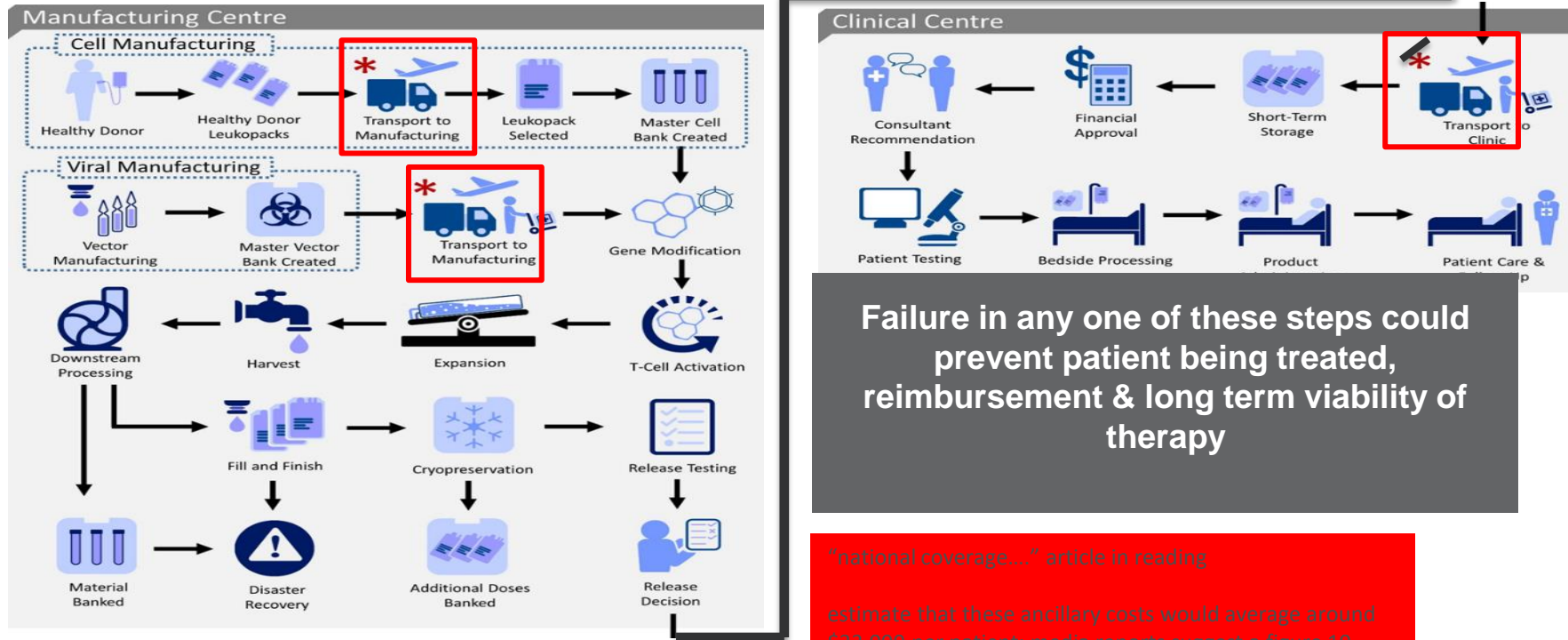
How significant is the cost of logistics?

Logistics has same cost impact as staff and facility costs !



Harrison, Zylberberg, Ellison and Levine, CAR-T Cell Therapy Manufacturing: Modelling the Effect of Offshore Production on Aggregate Cost of Goods

Is Logistics a Critical Manufacturing Step?



Harrison, Zylberberg, Ellison and Levine, CAR-T Cell Therapy Manufacturing: Modeling the Impact of Shippers' Association on Aggregate Cost of Goods

World Courier Overview

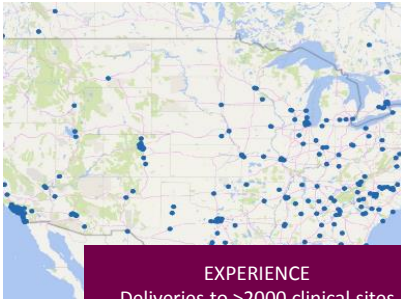


The most trusted
specialty logistics
company in the world.



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



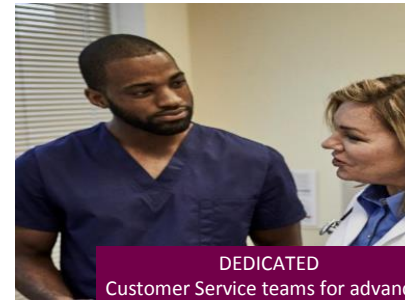
QUALITY
Fully GDP compliant throughout global network



GLOBAL SUPPORT
140 offices in 50 countries

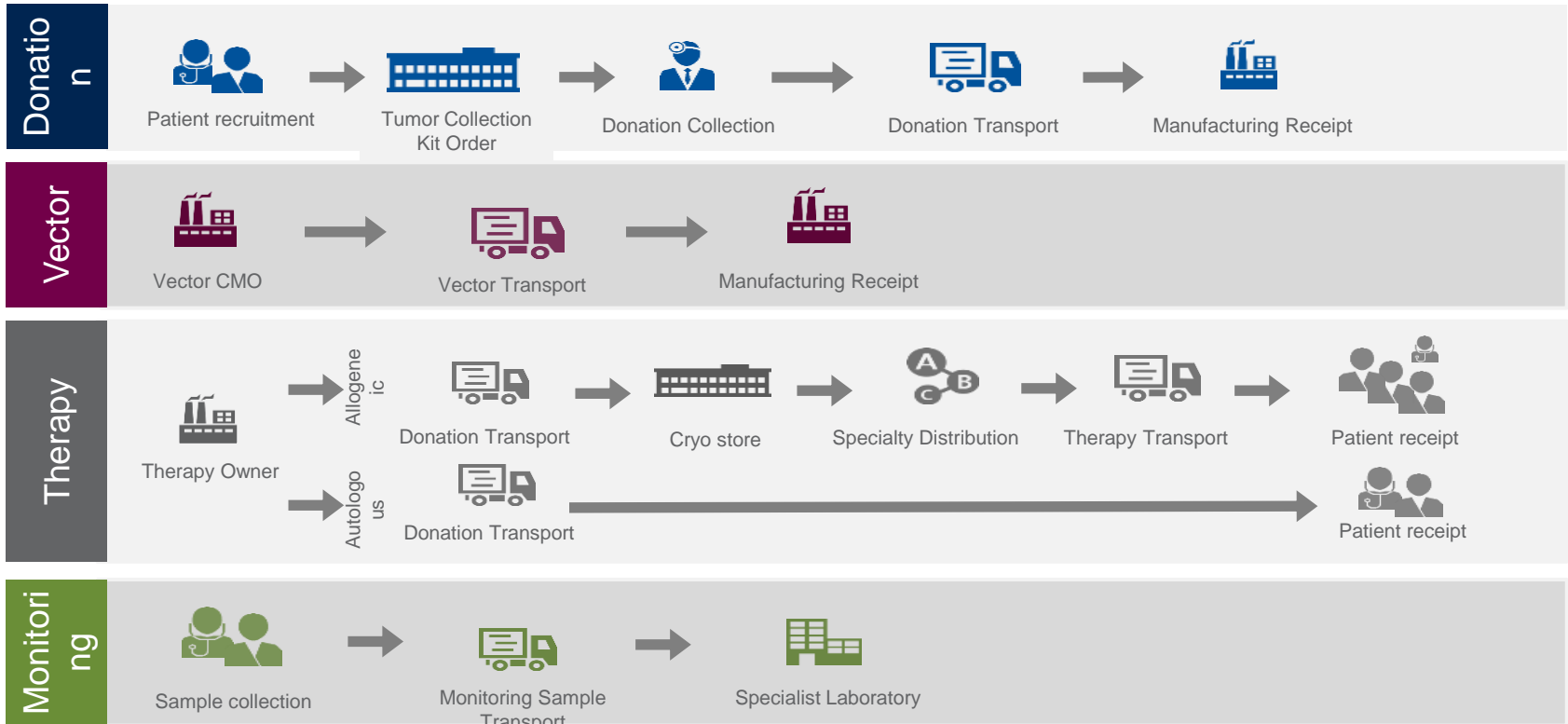


TEMPERATURE
Supporting +37 to -190C shipments



DEDICATED
Customer Service teams for advanced therapies

Advanced Therapy Logistics Platform



UK network of Advance Therapy Treatment centres

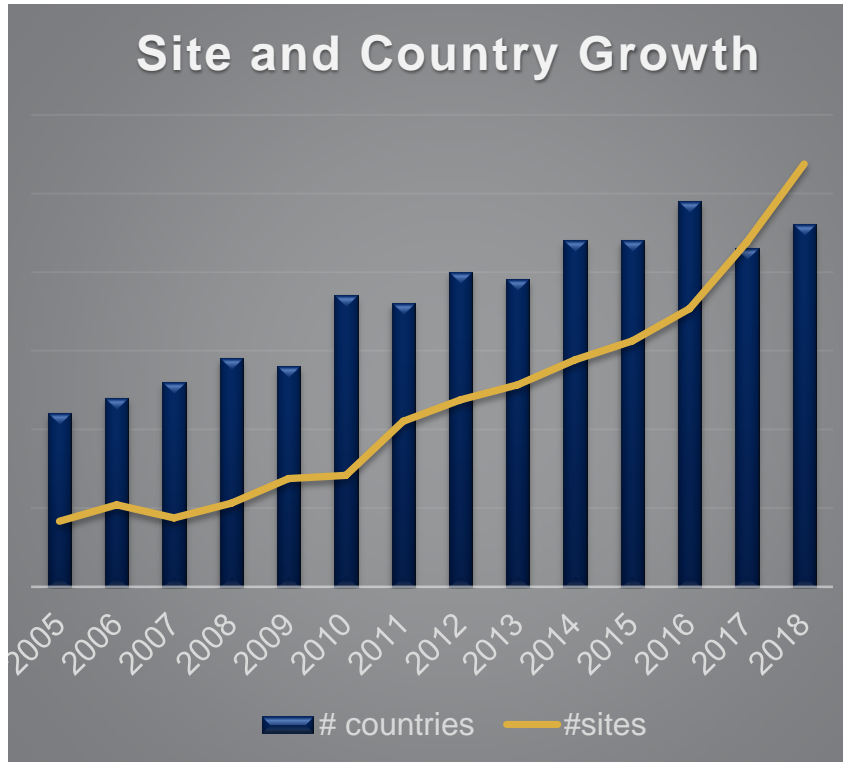


- World Courier
 - Engaged with all networks
 - > NA = Collaborator
 - > iMATCH = sub-contractor
 - > MW = Collaborator
 - > (London ATN – aligned)
 - Led by
 - > Simon Ellison
 - > Cell & Gene Therapy Service Director
 - Aim
 - > Create seamless flow between clinic-manufacturer
 - > Optimise first/last 100m
 - > Apply learnings through global network

Planning for Success



Upcoming Challenge



Challenge

- Multiple therapies being presented to clinical sites
 - Clinical and commercial scale
- With multiple different clinical systems and procedures
 - Storage, surgical intervention, delivery, etc

Solution

- Plan early and have vision for what the commercial supply chain will look like
- Build, test and optimise Logistics Platform through clinical trials

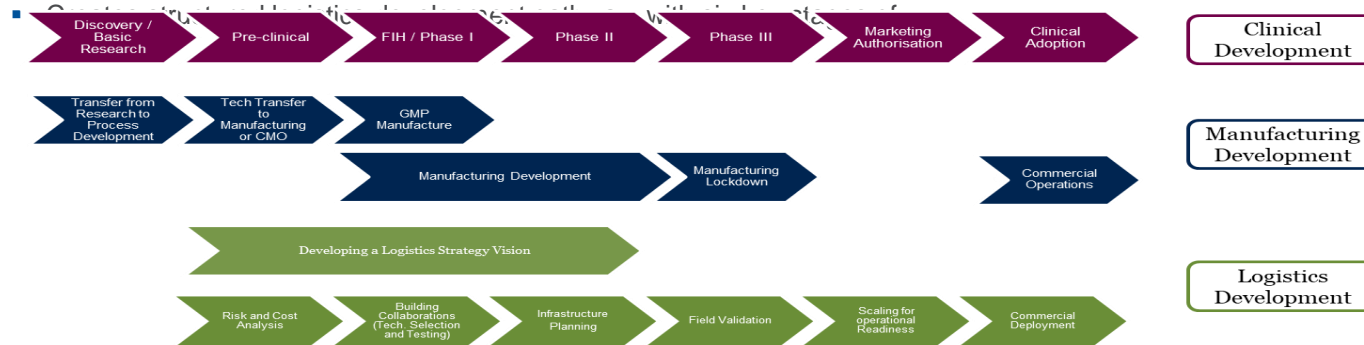
Logistics by Design

Definition

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

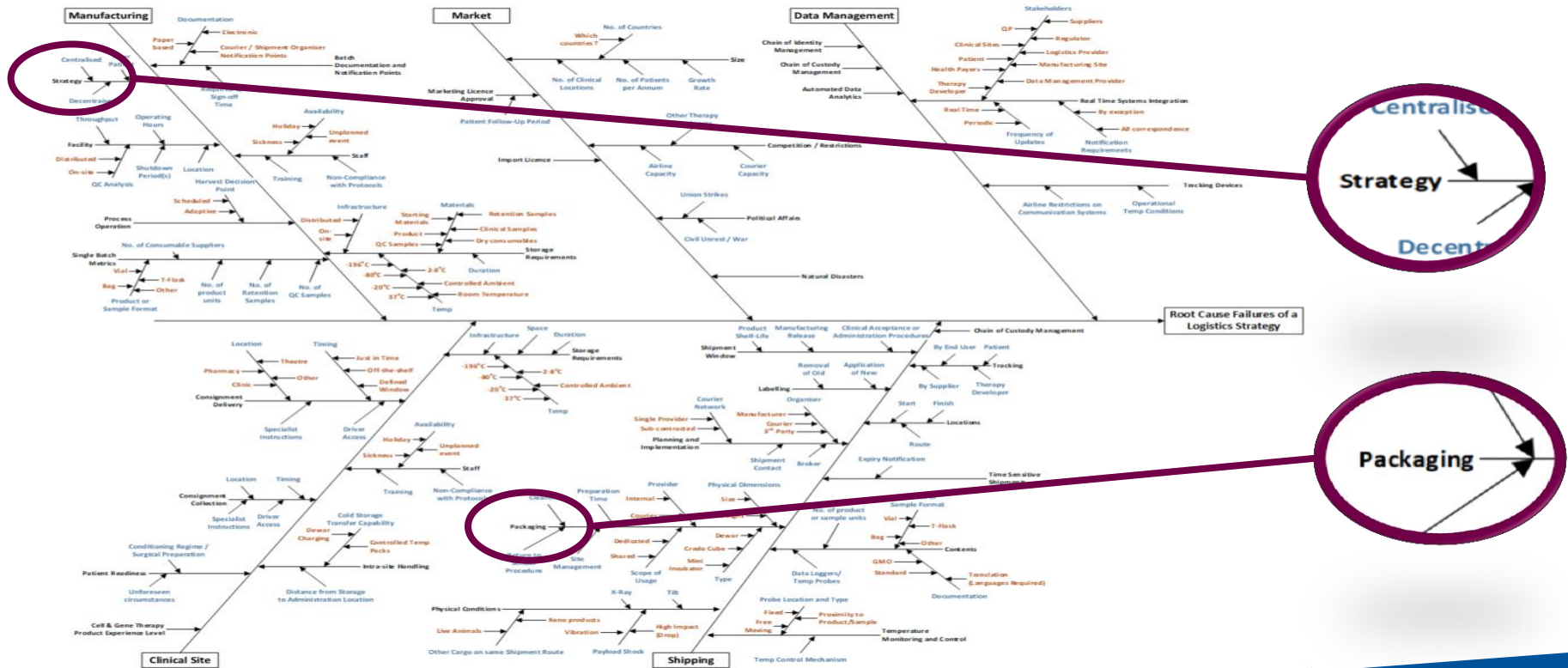
Overview

- 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.



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 Built on Risk Based Analysis



Ellison*, McCoy*, Bell, Frennd, 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

Shipping Window & Risk



Strategic Impact

Fresh

- If donation OR therapy OR monitoring sample has a limited shelf life
- Multiple manufacturing sites
- Need to control regulatory, manufacturing equivalence, etc

Cryo

- Has to be possible for ALL shipping
- Single large scale manufacturing site possible
- Reduced cell viability
- How manage/control thaw

Ellison*, McCoy*, Bell, Frennd, 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

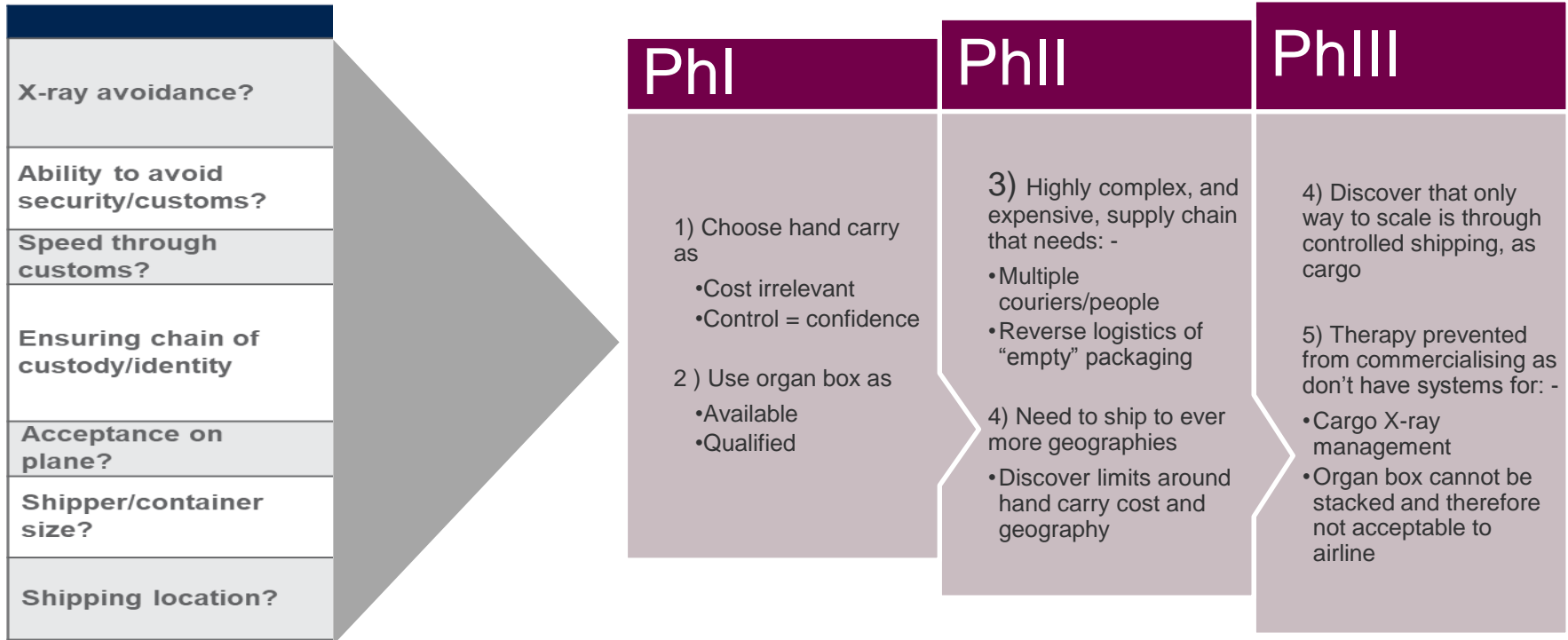
Packaging System Impacts Scalability

Is hand carry the solution?

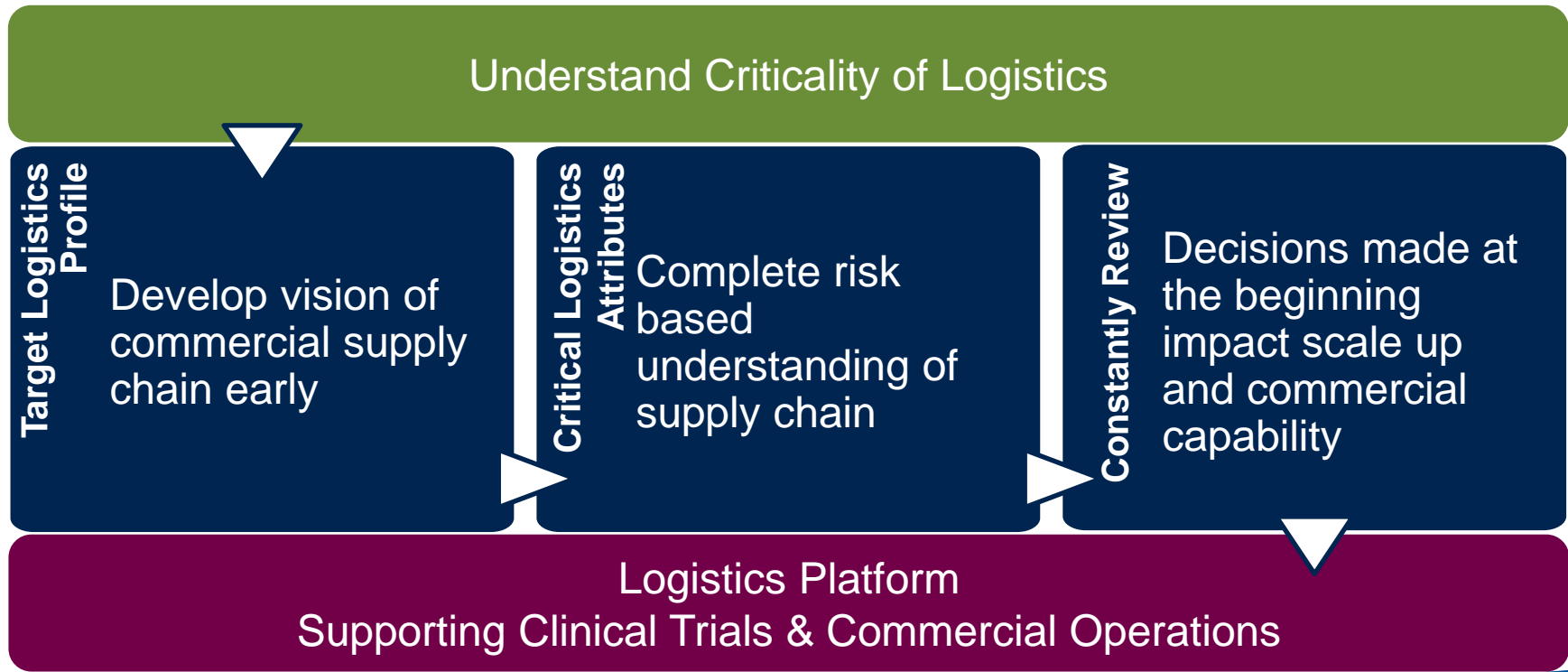
Hand Carry vs Controlled Shipping	
X-ray avoidance?	Regardless of transport strategy, all shipments are subject to x-ray unless the correct exemption paperwork and alternative security measures are in place. Managing xray exposure can only be achieved by working with an experienced logistics expert.
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





AmerisourceBergen®

Where knowledge,
reach and partnership
shape healthcare delivery.