International Society
ISCT
Cell & Gene Therapy

ISCT Commercialisation Committee – Logistics Session

Future proofing your supply chain; using the lessons of the past to create commercially viable logistics platforms for the future

Annual Conference

Montreal

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Overview

- This session used MACI, Strimvelis and Provenge as applied examples, then overlaid the broader view of a CMO to identify lessons learned and suggest what supply chains of the future should look like.

- Highlighting topics such as how to manage:
  - Cost by reducing complexity
  - Vein to vein journey as a single inter-related system
  - Scale up/out by utilising a logistics platform early in the development pathway

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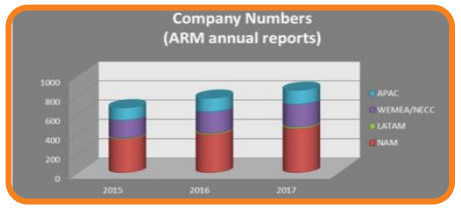
Scene Setting



Strength

- ARM data shows annual increase in both company numbers and clinical trials
- Additionally significant investments are driving confidence in the industry

Weakness

- Companies can manage small scale clinical trials in-house but as patient numbers and geographies increase the complexity becomes a limiting factor

Opportunity

- Collaboration in the development of advanced therapies has been higher than in any other industry. This needs to continue so that developers create logistics platforms to deliver their therapies

"My logisticians are a humorless lot … they know if my campaign fails, they are the first ones I will slay."
Alexander the Great

Threat

- Connecting therapies to patients is a critical part of the value chain for advanced therapies, otherwise the value of the therapy is lost to both the patient and the developer

Key Discussion Points - Vision

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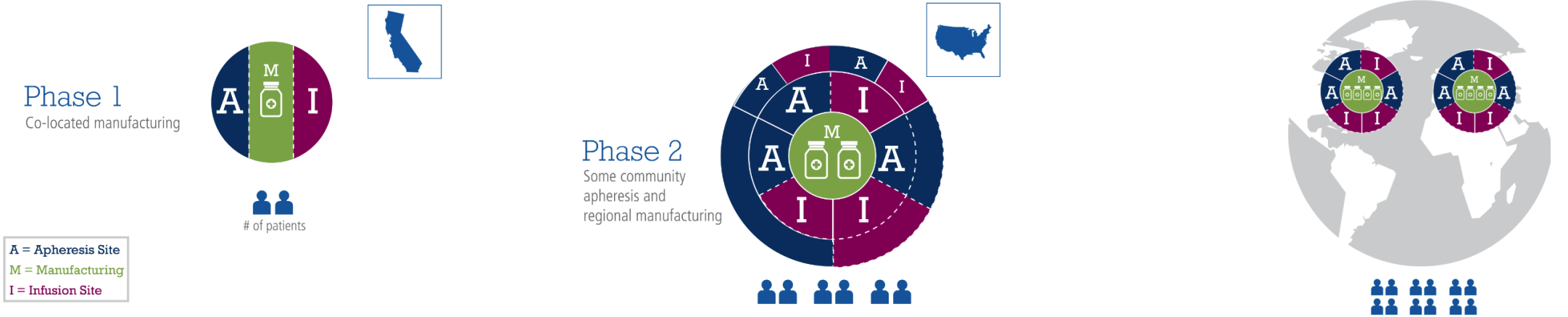
- It is critical to have a vision of what a therapy's commercial scale supply chain will look like
- Then therapy developers can work with their logistics partners to build, test and optimise a logistics platform through clinical trials
- This enables evaluation of shelf-life vs logistics capability vs manufacturing capability, because:
  - A manufacturing site that is cheap to build may be more expensive in the long term if it does not have a logistical connection to patients
  - Building a logistics platform to meet the immediate clinical needs whilst being ready for commercial launch will allow quick launch post MAA

Logistics and Manufacturing Scaling Up as the Study Moves Through the Phases

(provided courtesy of World Courier)

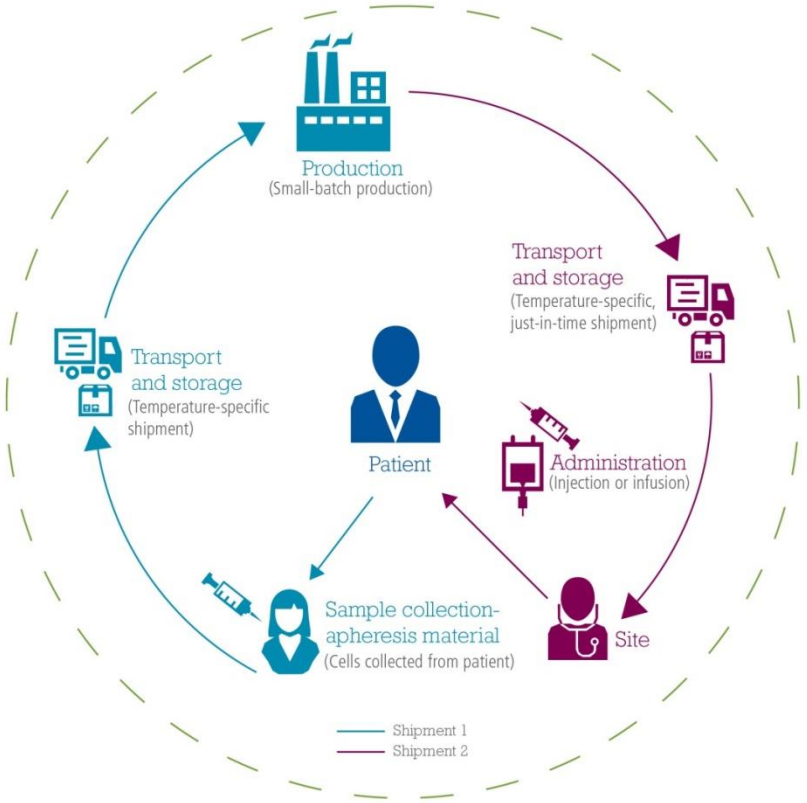


Key Discussion Points - Communicate

- The biggest point of failure within any supply chain is the transfer between unit operations, as illustrated by the arrows (opposite)
- IT integration through orchestration platforms will help with this transfer, but clear communication between all the partners within the supply chain is critical
- Unlike within more established pharma supply chains, the partners cannot operate in silos. The therapy developer needs to facilitate interaction to create a seamless transition
- This relies on clear details and expectations being set early, but also facilitating face to face communication between all partners

Autologous Supply Chain with Transport and Storage Requirements

(provided courtesy of World Courier)



Key Discussion Points – Product Differentiation through Logistics

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- Once a therapy has received regulatory approval, its manufacturing process is very difficult to change
- However a high quality, patient focused, logistics platform can be used to influence cost/price because:-
  - It is able to be optimised as new packaging technology, better flight availability, etc evolve
  - Whilst process development is effectively a one of cost, logistics will remain with the therapy for its life-time
- Therefore as the market becomes more competitive having a consistent, reliable, simple to operate, easy to access supply chain will support the commercial viability of therapies

A supply chain often defines the final costs to the consumer of the product, and affects how much money can be reinvested by a company to fund future product development [1]

If delivery, manufacturing input or output , surgeon / patient readiness, clinical storage, etc – don't align correctly, then you've lost your product

There can be loses as high as 50%, which bumps up the cost of goods considerably and changes the value proposition for your product[2]

Today it is supply chains that compete, as opposed to businesses [3]

1 - McKinsey & Company - Expect the unexpected: reduce corporate exposure and create value through supply chain risk Management - Katy George, Venu Nagali, Louise Rassey 2015
2 - Abbreviated from http://insights.bio/cell-and-gene-therapy-insights/?bio_journals=approaches-and-challenges-for-the-manufacture-and-scale-out-of-autologous-cell-therapies
3 - Prof Denis Kobzev - Dir of Business Education - Leeds Trinity University

Lessons Learned

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- Create a vision of the commercial scale supply chain early, then work to build, test and optimise the logistics platform so that everything is ready post market authorisation
- Develop long shipping window early in process development. Delays caused by weather will always happen and extending shelf life will increase the ability to treat patients
- Processes that work at clinical trial scale will not work at commercial scale
- Manufacturing location should be informed by logistics capability and the product's shelf life/shipping window
- Don't skimp on quality and maintain patient focus throughout
- Communicate with and between vendors to remove silos and enable seamless transition through the supply chain
- Look at vendors as technical experts who can help connect therapies to patients