



Taking Digital Control of Cell Therapy Logistics

Advanced Therapy Treatment Centre network case study



Dedicated to the memory of
Simon Ellison



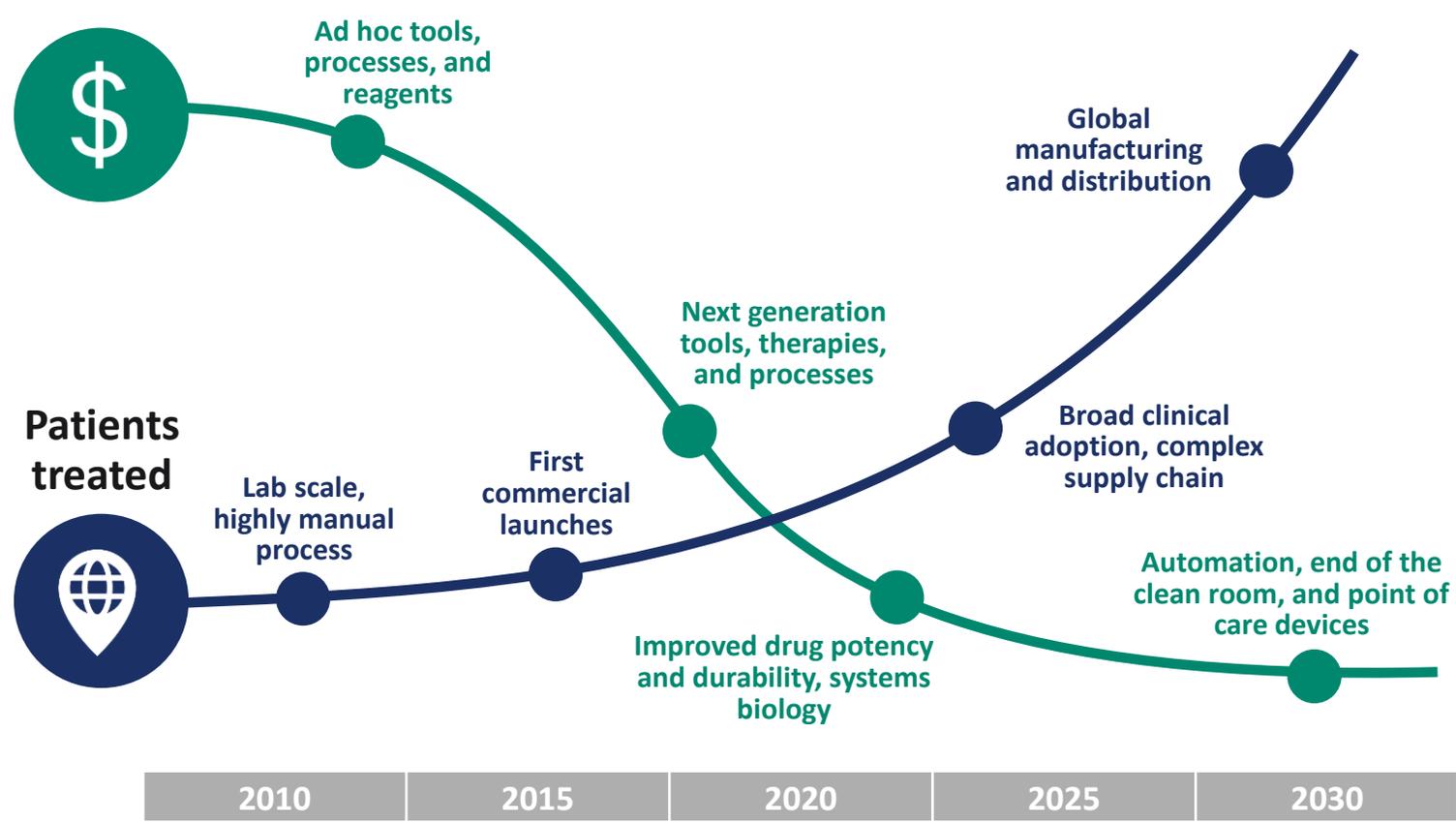
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Changing dynamics of cell and gene therapy manufacturing

RISK

Cost per dose



Cost Driver	Current	Future
Unit operations	>100	<25
Clean rooms	ISO 7 / Class B in operation conditions	ISO 8 / Class C in operation conditions
Days in process	>10	< 5
Personnel	Masters / Ph.D.	Associates and Bachelors
Reagents	Few suppliers / expensive	Many suppliers / commodity
IP	Protected	Wider FTO
Standards	Few	Many
Automation	None – Little	Broadly adopted
Logistics	Complex, ad hoc, LN ₂	Streamlined & digitized

The cell therapy workflow

Process control, monitoring and data management are critical

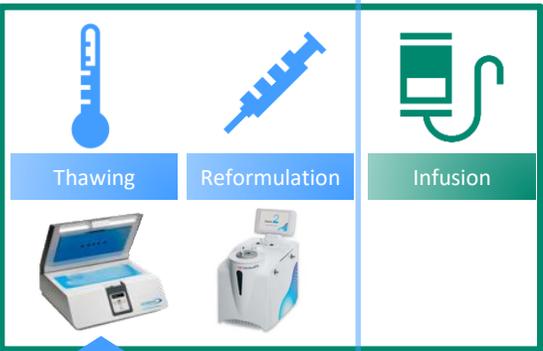
Clinic

Prior to manufacture



Clinic

Prior to delivery



VIA Thaw™ CB1000 for lab and clinical research use only; not registered as clinical thawing device.

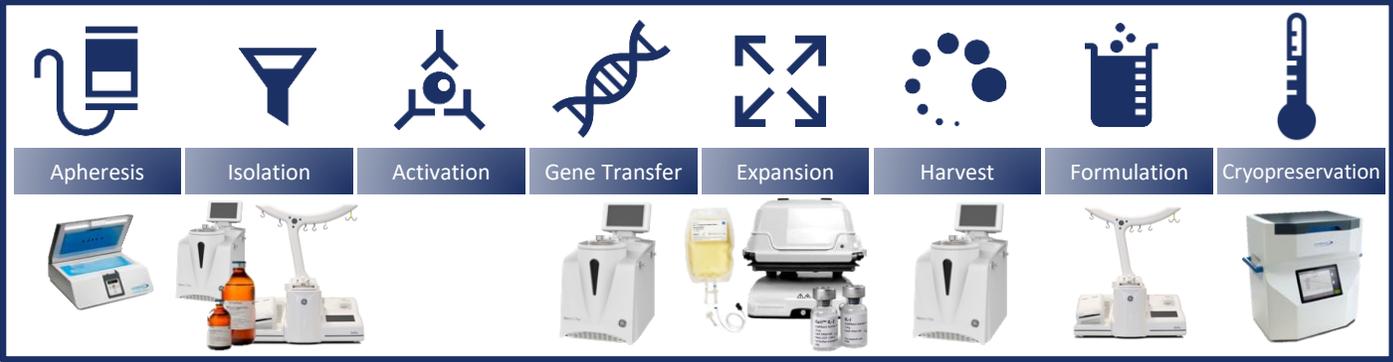
2°C to 8°C shipment

-120°C shipment

-120°C shipment

Manufacturer

Production of therapy



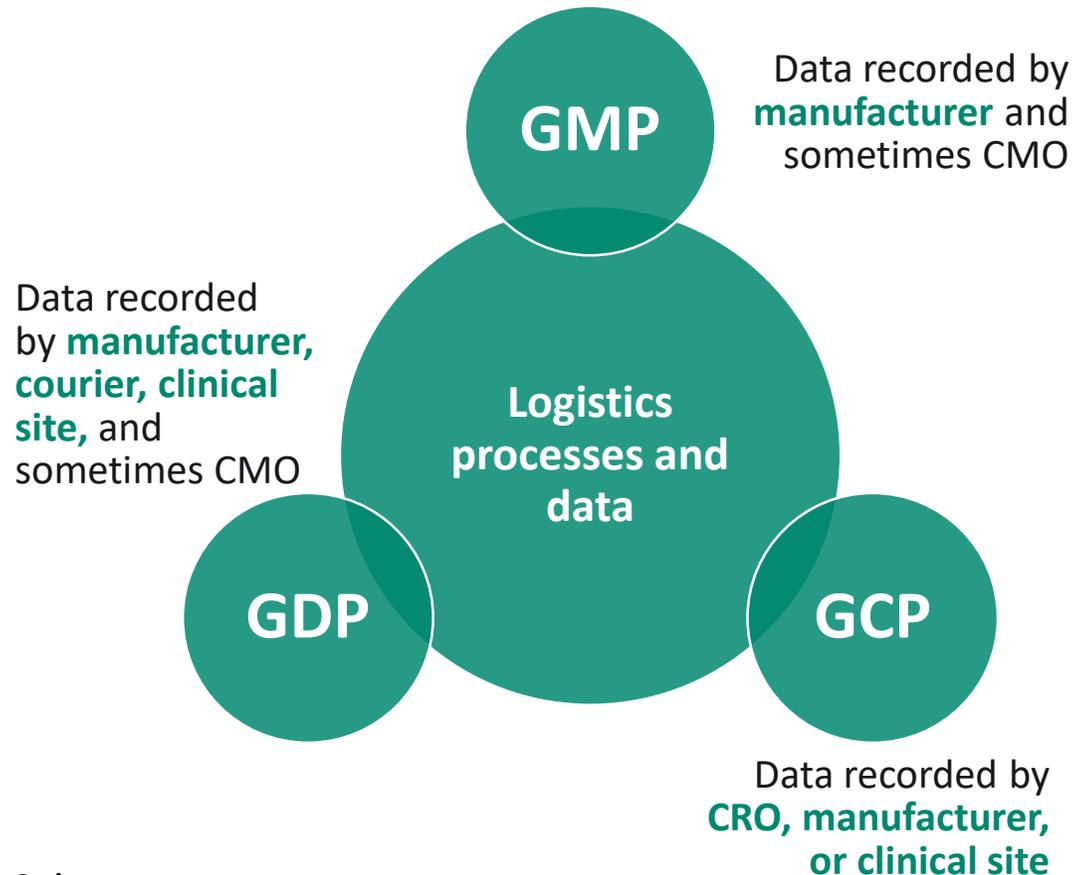
Challenges: Logistics process control and monitoring

Some risk factors to control and where they occur during the logistics process

	Cell therapy manufacturer	Courier	Clinical sites
Ensure no damage to cell therapy containers during loading/ unloading	✓		✓
Ensure right treatment reaches right patient	✓	✓	✓
Scalable shipping processes	✓	✓	✓
Traceable transfer of sample through logistics chain	✓	✓	✓
Mitigate against customs delays	✓	✓	
Monitor critical transport conditions, intervene where required e.g. tilt	✓	✓	

Challenges: logistics data fragmentation

Data collection involves at least three parties



- Multi-party data management records
- Disparate data systems don't communicate
- Clinical setting often limited to paper records
- All require complex cross checking
- Not aligned with manufacturing batch record
- FDA takes data integrity breaches seriously¹

1. <https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-fy-drug-gmp-warning-letters-0003>

CMO contract manufacturing organization

CRO contract research organization

The ideal logistics records

Parameters for a complete logistics record

Logistics process standardization

Consistent processes delivered throughout, easily scalable

Chain of custody

Visible and controlled transfer of sample through logistics process

Chain of identity

Control measures to ensure right treatment reaches right patient

Condition continuity

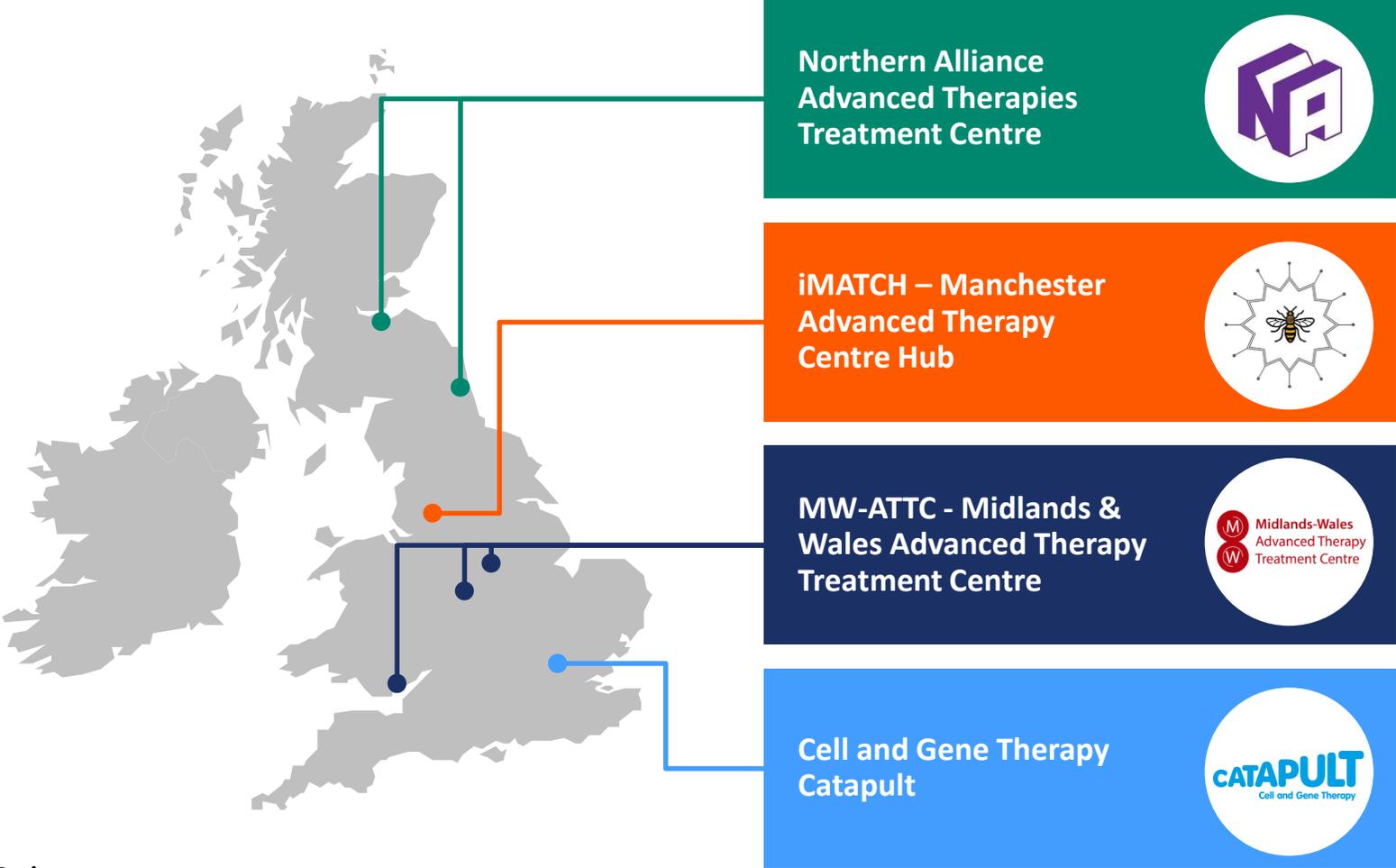
Monitoring of shipment to verify that critical condition parameters are maintained

Ideal data management system

- Single management system for all logistics data used by all parties
- Digital record
- Integrate with manufacturing record

ATTC™ network logistics trials

Advanced Therapy Treatment Centre (ATTC) network



ATTC
Advanced Therapies
Treatment Centres

CATAPULT
Cell and Gene Therapy

**Building systems
for the delivery of
cutting edge cell and
gene therapies**

www.theattnetwork.co.uk

ATTC logistics trial

Objectives

- Develop and test an integrated cell therapy logistic network of manufacturers, couriers, distribution centres and clinical trial sites
- Ensure robust processes in place for delivery into the clinical setting



Key personnel in the project



Dr. Stephen Elliman

Chief Scientific Officer,
Orbsen Therapeutics



Dr. Stuart Curbishley

Senior Research Fellow,
University of Birmingham

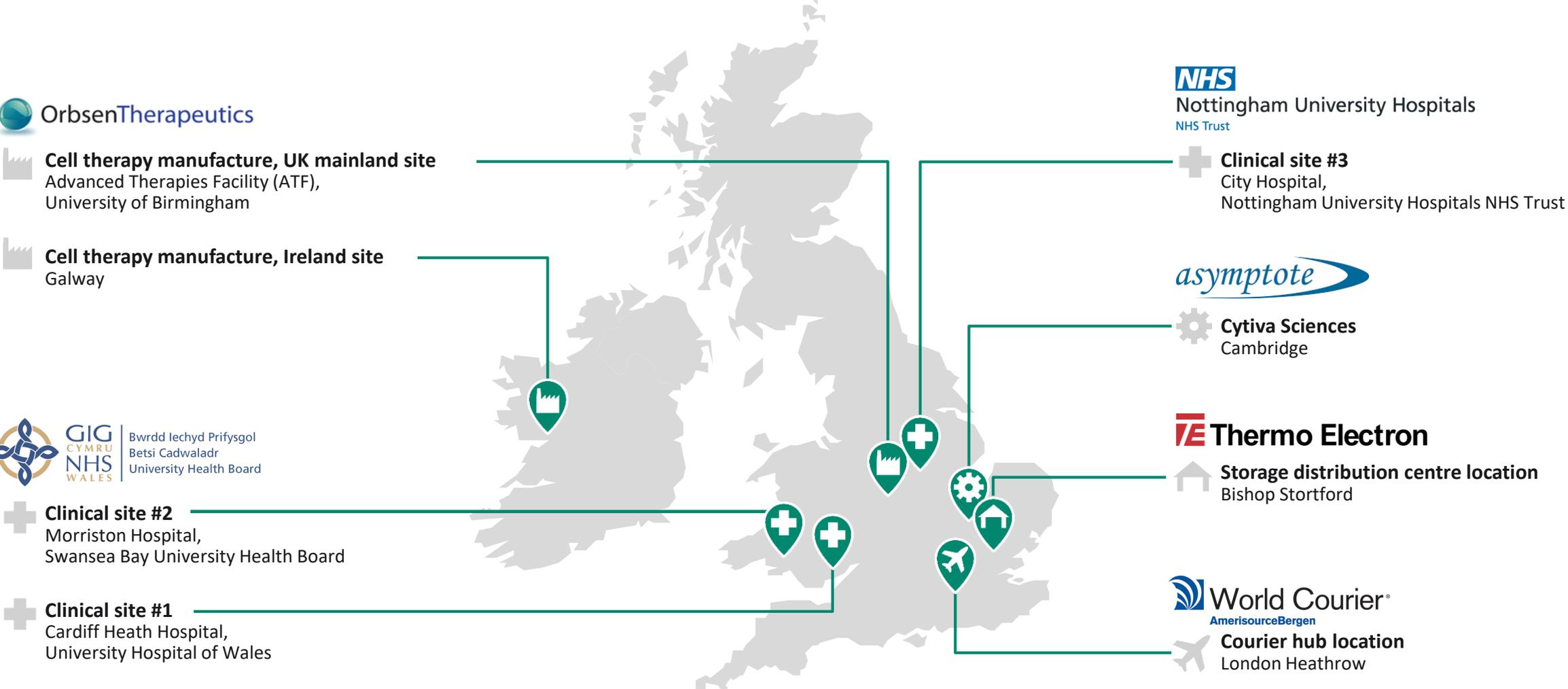


Dr. Bill Shingleton

Alliances Manager,
Cytiva Sciences

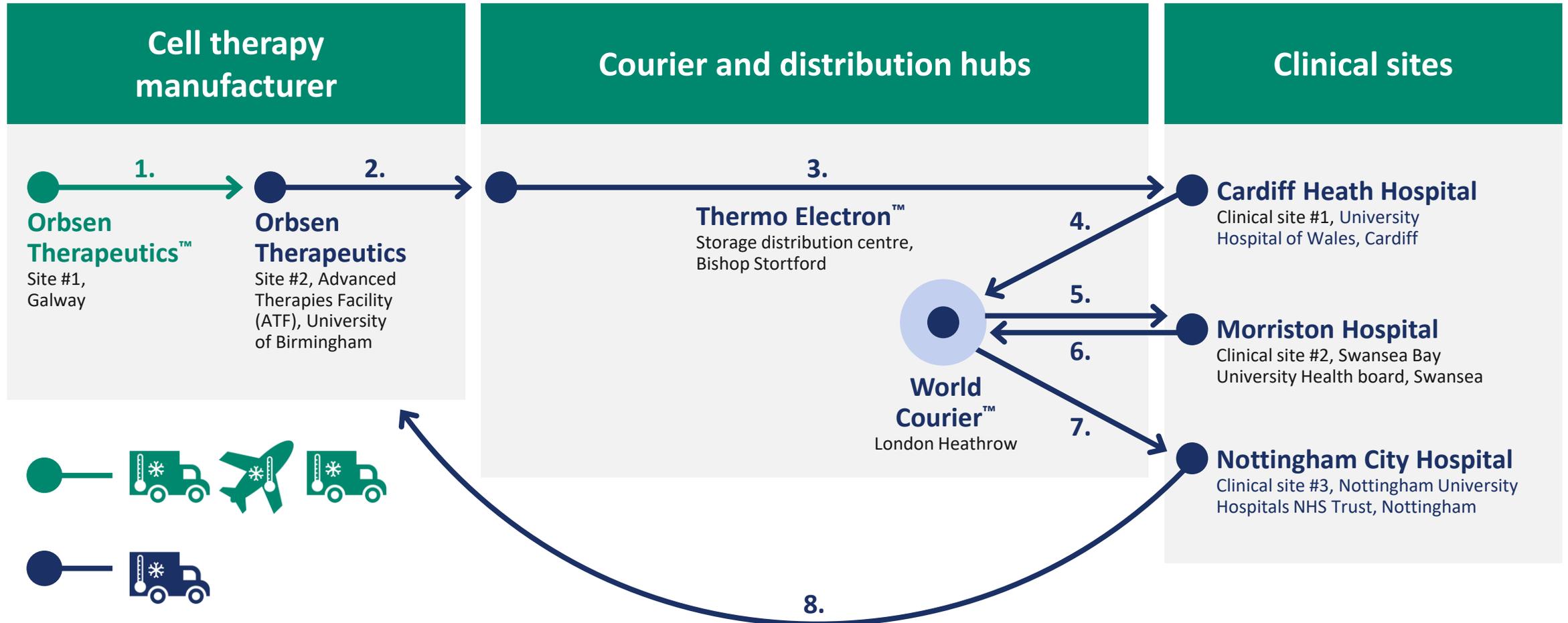
An integrated logistics network – MW-ATTC trialists

Multi-party trial involving Midland-Wales ATTC hub parties



Multi-party, multi-leg, multi-process journey

2 cell therapy manufacture sites, 3 clinical sites, 8 leg journey, road and air transits



Our role: Chronicle™ manufacturing automation software

Directs operators and captures process data units with hardware monitoring data in digital e-batch records



Chronicle logistics features used throughout trial

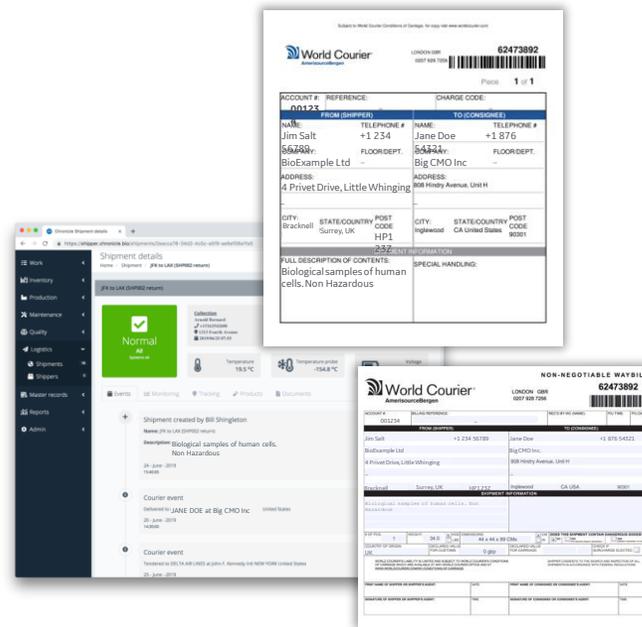
Logistics process control, monitoring and documentation tools

eSOP tool



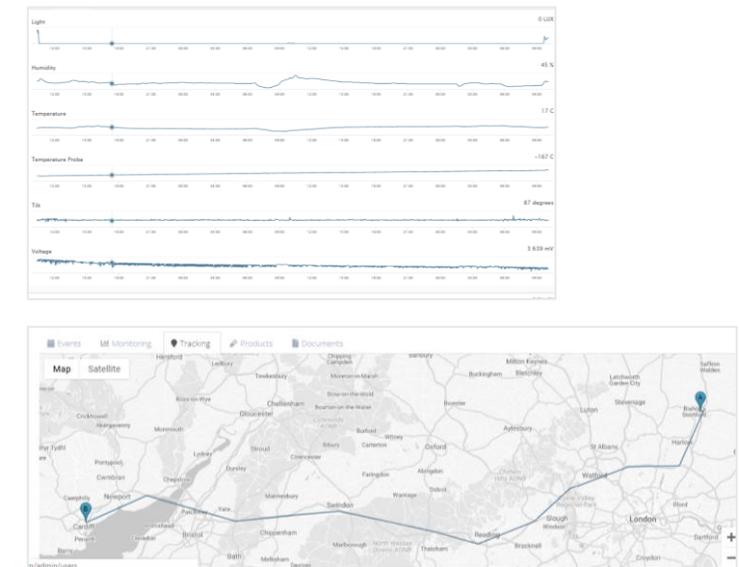
- Logistics process standardization
- Chain of custody captured
- Chain of identity controlled

World Courier™ integration



- E-booking shipments
- Shipment documentation portal
- Courier handling events

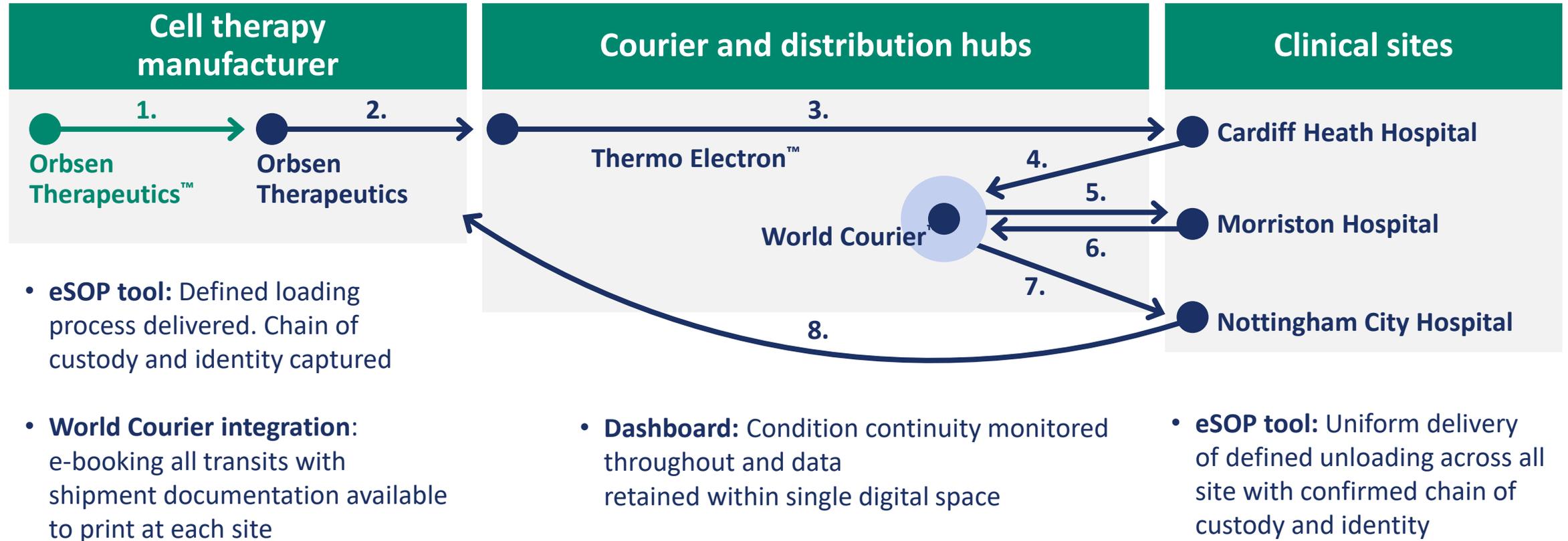
Condition and location dashboard



- Condition continuity monitoring

Chronicle logistics features in practice

Complete electronic shipment record united with electronic batch record within Chronicle



A successful trial – post-thaw viability

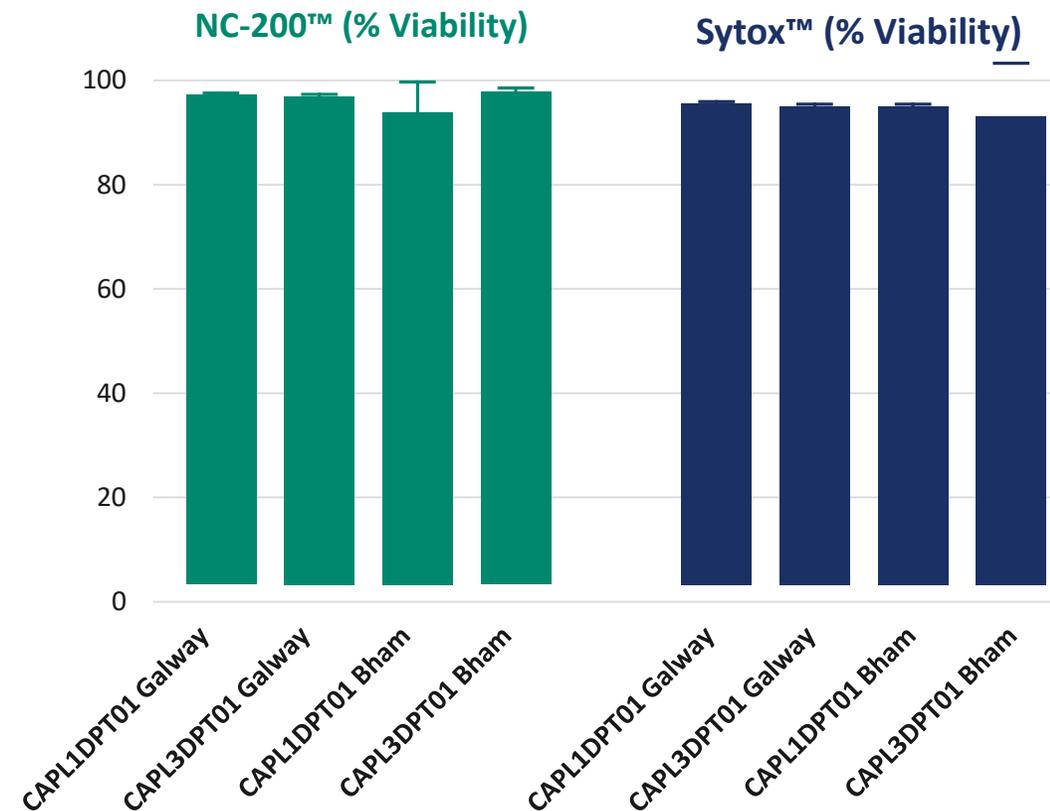
ORBCEL™ – post-thaw viability comparable with cell retained at source site

ORBCEL, a patented, highly purified, stromal cell immunotherapy manufactured by Orbsen Therapeutics™, an allogeneic stromal cell immunotherapy company.

- Viability measured of cells retained at original site: Orbsen Galway site
- Compare to those received at final site in multi-leg shipment: Orbsen Birmingham (Bham) ATF site
- No substantial difference between viability measures

- Each error bar represents two independent vials.
- NC-200 viability is measured immediately post-thaw (fluorescent dyes acridine orange and DAPI automatically stain the total and dead cell populations, respectively.)
- SYTOX blue viability is obtained by flow cytometry within 2 h post-thaw.

End of multi-leg shipment trial viability comparison



Collaborations identify and solve cell therapy challenges

Chronicle now unites manufacturing and logistics records in a single digital space

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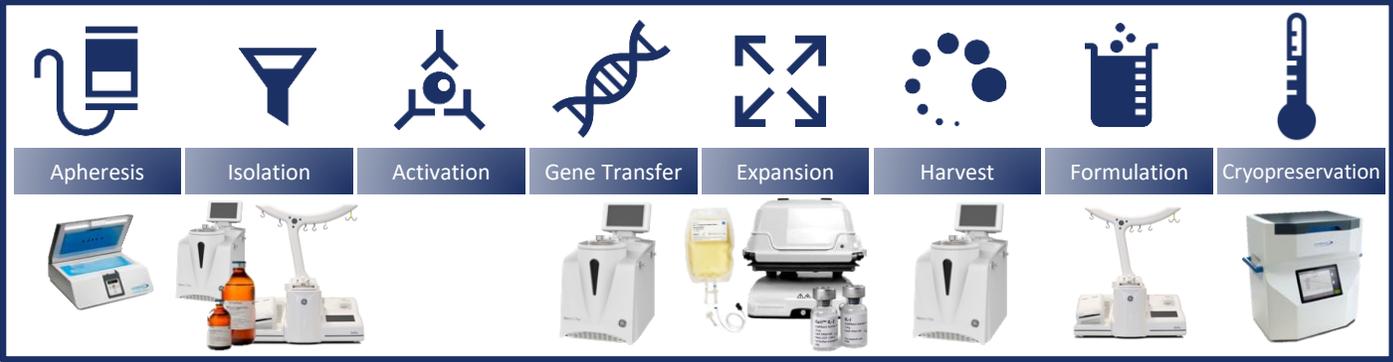
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Manufacturer

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Thank you



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