

ATMP Scale-Up Storage and Distribution Cost Modelling



Background

Thermo Fisher Scientific is proud to be a member of the Innovate UK funded Midlands-Wales and Northern Alliance Advanced Therapies Treatment Centres. The network of Advanced Therapies Treatment Centres (ATTCs) has been set up to enable collaboration across industrial and NHS partners to develop ways of working within and across centres that smooths the path to Advanced Therapy Medicinal Products (ATMPs) adoption into routine medical practice and support the dramatic increase in clinical trial activity across the country. They also present an opportunity to place the UK at the forefront of this technology and for the country to be the place to bring these treatments to patients as they move from clinical trial to marketed products.

The ATMP industry is undergoing a huge expansion in the number of treatments required for future clinical and commercial supply. Global investment in ATMP development in 2019 totalled \$9.8bn (Alliance for Regenerative Medicine Annual Report 2019) with manufacture of ~100m ATMP doses forecast by 2025 (Phacilitate Advanced Therapies Investment Report 2017). This rapidly expanding sector is predicted to be worth £10bn to the UK economy, supporting 18,000 high value jobs by 2035 (Cell and Gene Therapy Catapult Annual Review 2019/20).

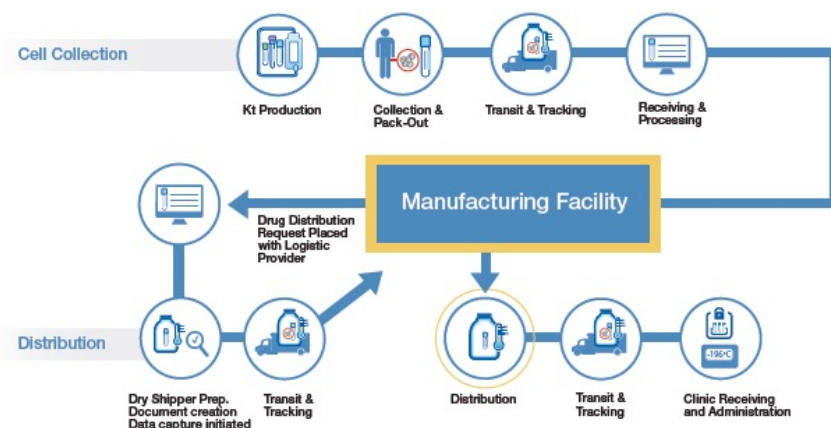
Critical to delivering this increase is the supply chain which without the introduction of game changing innovations, will not be able to handle the predicted volumes throttling the opportunities presented by ATMPs. The supply chain though has the opportunity to learn from other sectors such as fast-moving consumer goods and the automotive industry to understand the characteristics and benefits of a highly developed and mature supply chain, whilst adapting them to the specific needs of the ATMP sector.

Introduction

The majority of current ATMP manufactures are SME's focused on getting their product through clinical trials and receiving authority for use. However, the challenges of moving from small-scale clinical trial production through to commercial volumes needs to be considered early on in the development cycle to ensure that an organisation is ready to take the necessary step to capitalise on the rapidly expanding market once authority is granted. One simple question that is not currently easy to answer is "What will the cost be?"

The ultimate success of ATMPs relies on the ability to deliver a viable, potent product to the patient. Ensuring this living drug is delivered to the right patient at the right time, location, and temperature is essential to patient safety and product efficacy. From an operational perspective the supply chain is a complex, organisationally fragmented and often geographically spread process requiring specialist handling, storage and transport businesses to ensure the ultimate delivery of a viable product to the patient.

Autologous Therapy Logistics



Allogeneic Therapy Logistics



Understanding Scale-up Storage and Distribution Costs

Increasing product volumes and wider geographic markets that follow from successful commercialisation further add to the existing supply chain complexity. For example, the need for country specific secondary packaging and labelling.

Commercial scale-up may also require a manufacturer to change to their storage regime. For example, a manufacturer may have developed a product that requires minimal temperature-controlled storage for clinical trial stages, however, scale up and wider geographic penetration may mean that medium and long term storage becomes the most effective method of balancing production runs to patient needs, whilst maintaining product viability.

The ability of a manufacturer to understand potential costs in a range of different storage and delivery pathways is critical to making informed business decisions on future operation models. However, identifying these costs is not currently an easy task.

As part of the Midlands and Wales and Northern Alliance ATTCs, which has brought together a large number of organisations across the ATMP supply chain Thermo Fisher Scientific recognised the need for a tool that would help manufacturers understand and explore the impact of various current and future scenarios on costs, assisting in their business decision making.

ATMP Scale-up Storage and Distribution Cost Model



Thermo Fisher Scientific has created a modelling tool that provides indicative costs for storage and distribution based on a number of manufacturer defined variables. These include origin to destination shipping, number of shipments per month, storage locations, temperatures, product storage volumes and primary packaging type.

The user defined variables include:

- Volume of product held in storage
- Type of primary container, vial or bag
- Temperature control requirements
- Origin and Destination of shipments
- Number of shipments per month
- Courier type, Premium or standard

ThermoFisher
S C I E N T I F I C

This modelling tool provides indicative costs for storage and distribution across a range of user defined parameters, including; manufacturing, storage and clinic sites, vials and bags and temperatures.

Its purpose is to help manufacturers understand and explore the impact of various current and future scenarios on costs, assiting in business decision making

| | | |
|---|--|----|
| Storage and Distribution costs per month | | £0 |
|---|--|----|

| | | |
|------------------------|-----------------|------------|
| Storage Temperature | Liquid Nitrogen | |
| Courier Type | Premium | |
| Manufacturing location | Stevenage | Vials |
| Storage location | UK Thermo | |
| Clinic 1 | UK | Birmingham |
| Clinic 2 | UK | Swansea |
| Clinic 3 | Germany | Cologne |
| | | 0 |
| | | 0 |
| | | 0 |

| | |
|--|--------|
| Storage/Distribution requirements | Volume |
| Number of receipts per month in to storage | 0 |
| Number of shipments to clinics per month | 0 |
| Amount in storage | 0 |

ATMP Scale-up Storage and Distribution Cost Model

The tool utilises a number of configured and conditional drop-down menus to quickly produce budget costs and enabling a range of scenarios to be compared.

The model currently focuses on UK and European storage and distribution, but other worldwide destinations can be added easily dependent based on a manufacturer's specific needs.

This modelling tool provides indicative costs for storage and distribution across parameters, including; manufacturing, storage and clinic sites, vials and bags. Its purpose is to help manufacturers understand and explore the impact of various scenarios on costs, assisting in business decision making.

Storage and Distribution costs per month

| | |
|------------------------|---------------------------------|
| Storage Temperature | Liquid Nitrogen |
| Courier Type | Controlled Ambient |
| | Room Temperature (15 to 30 C) |
| | Refrigerated (2 to 8C) |
| | Freezer (-15 to -50C) |
| | Ultra-Low Freezer (-70 to -90C) |
| Manufacturing location | Germany |
| Clinic 1 | Cologne |
| Clinic 2 | |
| Clinic 3 | |

| Storage/Distribution requirements | Volume |
|--|--------|
| Number of receipts per month in to storage | 0 |
| Number of shipments to clinics per month | 0 |
| Amount in storage | 0 |

This modelling tool provides indicative costs for storage and distribution across parameters, including; manufacturing, storage and clinic sites, vials and bags. Its purpose is to help manufacturers understand and explore the impact of various scenarios on costs, assisting in business decision making.

Storage and Distribution costs per month

| | |
|------------------------|-----------------|
| Storage Temperature | Liquid Nitrogen |
| Courier Type | Premium |
| Manufacturing location | Galway |
| Storage location | Stevenage |
| Clinic 1 | Cambridge |
| Clinic 2 | Birmingham |
| Clinic 3 | Swansea |
| | Germany |
| | Cologne |

| Storage/Distribution requirements | Volume |
|--|--------|
| Number of receipts per month in to storage | 0 |
| Number of shipments to clinics per month | 0 |
| Amount in storage | 0 |

This modelling tool provides indicative costs for storage and distribution across a range of parameters, including; manufacturing, storage and clinic sites, vials and bags and temperatures. Its purpose is to help manufacturers understand and explore the impact of various current scenarios on costs, assisting in business decision making.

Storage and Distribution costs per month

| | |
|------------------------|-----------------|
| Storage Temperature | Liquid Nitrogen |
| Courier Type | Premium |
| Manufacturing location | Galway |
| Storage location | UK Thermo |
| Clinic 1 | UK |
| Clinic 2 | UK |
| Clinic 3 | Germany |

| Storage/Distribution requirements | Volume |
|--|--------|
| Number of receipts per month in to storage | 0 |
| Number of shipments to clinics per month | 0 |
| Amount in storage | 0 |

This modelling tool provides indicative costs for storage and distribution across a range of user defined parameters, including; manufacturing, storage and clinic sites, vials and bags and temperatures. Its purpose is to help manufacturers understand and explore the impact of various current and future scenarios on costs, assisting in business decision making.

Storage and Distribution costs per month

| | |
|------------------------|-----------------|
| Storage Temperature | Liquid Nitrogen |
| Courier Type | Premium |
| Manufacturing location | Stevenage |
| Storage location | UK Thermo |
| Clinic 1 | UK |
| Clinic 2 | UK |
| Clinic 3 | Germany |

| Storage/Distribution requirements | Volume |
|--|--------|
| Number of receipts per month in to storage | 4 |
| Number of shipments to clinics per month | 12 |
| Amount in storage | 800 |

Storage and Distribution costs per month

£14,750

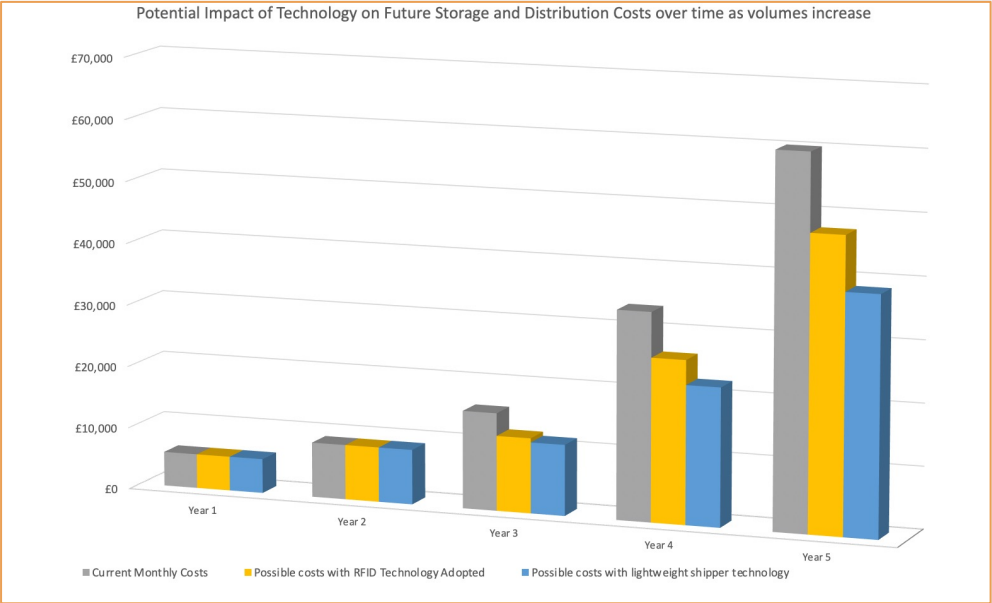
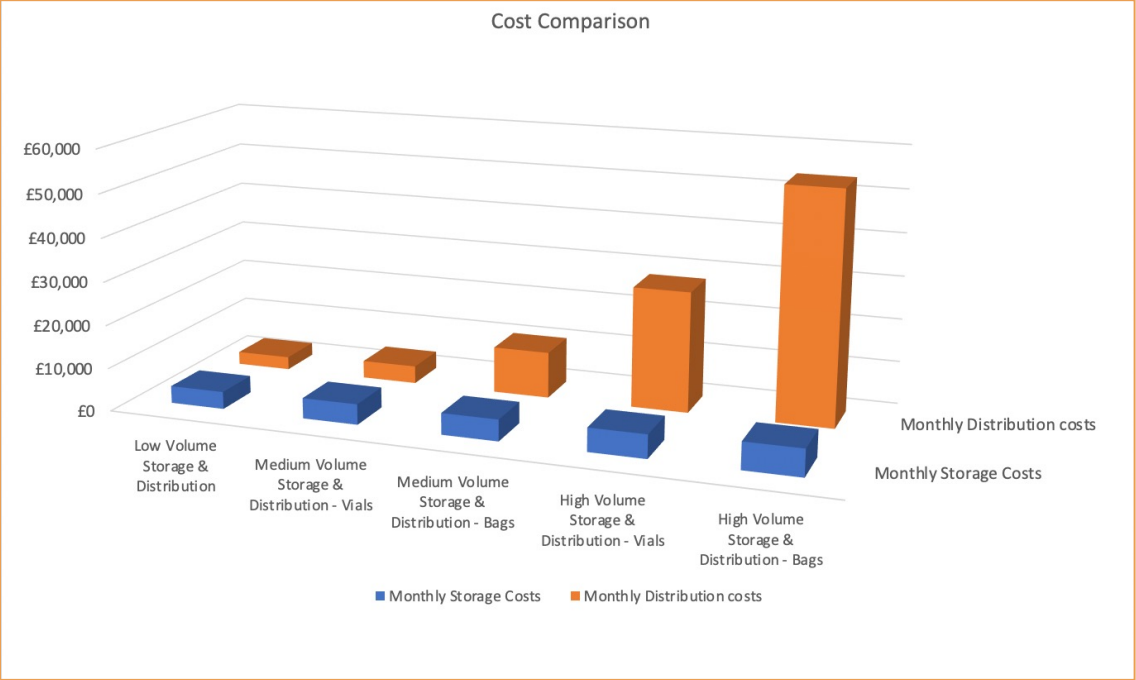
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| Storage/Distribution requirements | Volume |
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| Number of receipts per month in to storage | 4 |
| Number of shipments to clinics per month | 12 |
| Amount in storage | 800 |

Drop down menus can be customised to a manufacturer's requirements. e.g. number of clinics, locations etc.

ATMP Scale-up Storage and Distribution Cost Model

The model enables manufacturers to examine and compare the costs of various storage and distribution strategies, providing valuable insight to inform business planning decisions, particularly around scale-up.



The tool can also be easily modified to incorporate new data as it becomes available. For example, the tool can be used to examine the possible cost impact of new innovations within the supply chain, considering both possible savings and when they may come on stream.

Summary

- The tool has been created to provide indicative costs based on a variety of user selected inputs enabling a manufacture to gain an understanding of costs associate with different storage and distribution scenarios.
- The tool enables manufacturers to make informed decisions on different storage and distribution scenarios as they scale up their manufacture and expand their market.
- Current user defined variables include:
 - Volume of product held in storage
 - Type of primary container, vial or bag
 - Temperature control requirements
 - Origin and Destination of shipments
 - Number of shipments per month
 - Courier type, Premium or standard
- The tool can be easily modified to add additional functionality based on a manufacturer's individual needs.
- The tool is able to examine possible future costs savings due to new innovations being introduced within the supply chain.
- The tool contains commercial information and so cannot be distributed. However, Thermo Fisher Scientific will run the model for any manufacturer based on their unique requirements to provide outputs that assist in their future business decision making.

About Thermo Fisher Scientific

With unwavering commitment to service, science and process engineering, Thermo Fisher Scientific is powered by people with an exceptional commitment to quality, deeply instilled ethics of personal responsibility and unrivalled expertise.

Thermo Fisher Scientific is the world leader in serving science, with revenues of more than \$24 billion and approximately 70,000 employees globally. Our mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market and increase laboratory productivity. Through our premier brands—Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific and Unity Lab Services—we offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive services.

As the leading service provider to the cell and gene therapy community, Thermo Fisher Scientific, is uniquely positioned with the experience, resources, and global expertise to support our customers on their path towards commercialization. Our global infrastructure enables customers to seamlessly conduct clinical trials across multiple geographies while providing patients around the world with access to life changing therapies. Our cryogenic storage and logistics, combined with proven components and validated procedures, allow us to configure and replicate each site to meet the specific requirements of individual clinical trials with minimal variation, regardless of volume or geographic location. This is supported by a global comprehensive and integrated Quality System based on regulatory requirements, industry best practices and highly trained personnel.

About Advanced Therapy Treatment Centres

The ATTC network is a world-first, national system of Advanced Therapy Treatment Centres operating within the NHS framework and coordinated by the Cell and Gene Therapy Catapult to address the unique and complex challenges of bringing pioneering ATMPs to patients.

The centres include:

- Innovate Manchester Advanced Therapy Centre Hub (iMATCH)
- Midlands-Wales Advanced Therapy Treatment Centre (MW-ATTC, comprising Birmingham, Bristol, Cardiff, Leicester, Nottingham, Swansea, Oxford and Cambridge)
- Northern Alliance Advanced Therapies Treatment Centre (NA-ATTC, comprising Edinburgh Glasgow, Leeds and Newcastle)

The CGT Catapult is playing a central coordination role for the network and provide support to manufacturing, supply chain logistics, regulatory affairs, clinical trial capability, R&D support and upskilling via specialist training and development.

The network is supported by the UK Research and Innovation's Industrial Strategy Challenge Fund.

Funded by



Coordinated by





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