

The Use of Digital Technologies in CGT Manufacturing

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—
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Agenda

- 01** Introduction
- 02** Journey to cGMP Manufacturing
- 03** Digital Technology Applications in CGT
- 04** Implementation Challenges & Requirements
- 05** Innovate UK Project
- 06** Key Takeaways





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CDMO excellence from a global leader

Rentschler Biopharma

Extensive track record,
almost 50 years of experience

cGMP manufacturing
of high-quality biopharmaceuticals

Expert for complex biopharmaceuticals

Milford
MA, USA



Stevenage
UK
Viral Vectors



Laupheim
DE



Digital Technologies Driving Innovation in the CGT Manufacturing Space



Driving Innovation in
CGT Production

Manufacturing advanced therapies is a **complex journey** – traditional solutions typically labor intensive and paper-based

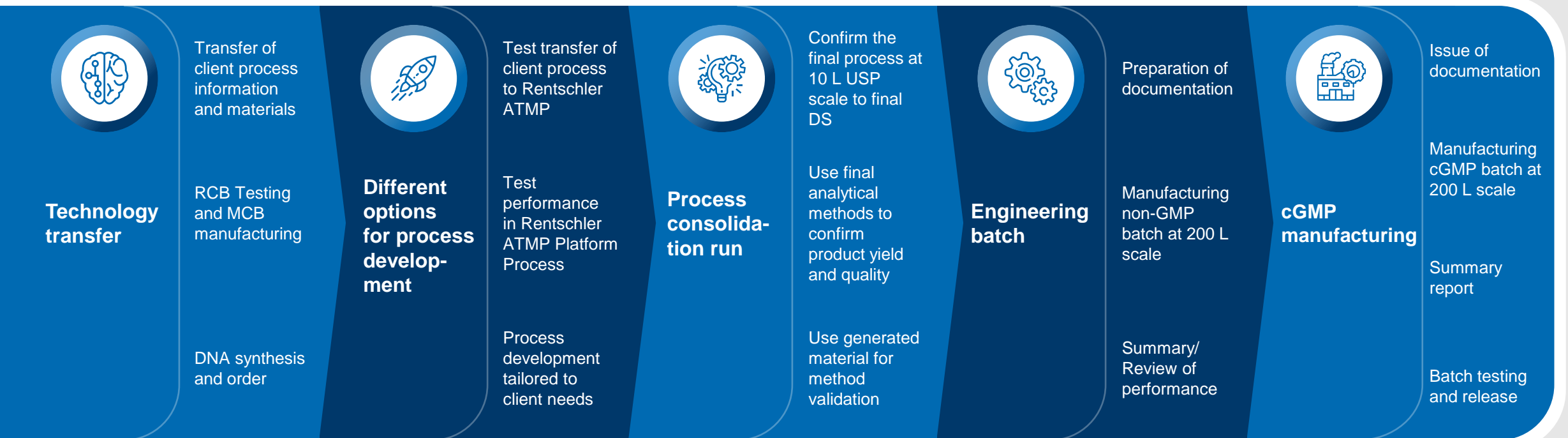
Manual production prone to human error, resulting in product variability, contamination and batch loss

Integration of automation, AI, machine learning, Industry 4.0 technologies

Potential to enhance **manufacturing process**, improve **patient access**, optimize **therapeutic outcomes**

Journey to cGMP Manufacturing

AI coupled with digitalization can facilitate the development of CGTs in almost every step of the journey



Applications of Digital Technologies in CGT



Automated Systems

Increase production efficiency and consistency



Streamlined Processes

Optimise process development and characterisation, and scale-up efficiently to meet demand



Advanced Analytics

Enhance decision-making and quality control



Quality and Compliance

Streamline regulatory compliance, and ensure CGTs meet quality standards



Operational Excellence

Improving operations and supply chain management, and productivity



Personalized Therapies

Precise targeting and customization of therapies to individual patient needs



Team Collaboration

Facilitates seamless team collaboration, knowledge sharing and integrated operations



External Collaboration

Seamless collaboration with clients and strategic alliance partners for efficient data exchange

Implementation Challenges in CGT

Manufacturing complexity: CGTs manufacturing processes are highly complex and difficult to scale and standardize

Before integrating AI and automation, it's crucial to **simplify existing processes** to make transition more efficient

Network complexity: The CGT ecosystem characterized by intricate relationships among diverse stakeholders (pharma, biotech, CDMOs, software developers, healthcare providers)

Lack of clear **ownership** and **accountability** for the initiation of the digital transformation

Adaptability and **flexibility** are key – one size doesn't fit all

Complexity
of Cell and
Gene
Therapies



What is Required?



Clear **leadership** and **accountability** in driving digital transformation within the field



Understanding and selecting the **right digital tools** and platforms, and timelines for the implementation



Standardization of datasets for processes to facilitate automation and digitalization



Validation and **data integrity** critical from R&D to product release

Improving AAV Production with Digital Technologies

65% of gene therapies in development currently based on AAV

Current analytical methods mainly rely on manual sampling

Collaboration with **CGT Catapult** and **Refeyn** to address the mutual challenges the CGT industry is facing

Analytical technologies to enhance AAV production and bring therapies to the market faster and at a lower cost

These tools will allow **real-time decision making**, enhanced **process reproducibility** and **batch-to-batch comparability**

 Rentschler
Biopharma

REFEYN
WEIGHING MOLECULES WITH LIGHT

CATAPULT
Cell and Gene Therapy



A New Approach to Digital Transformation



- Digital transformation needs to become a core pillar of CGT companies' vision and strategy
- Industry-wide harmonisation would help reduce the time and cost of digital adoption
- Engagement with regulators and policymakers to facilitate the implementation of digital tools in CGT manufacturing
- Questions remain around:
 - How to harmonise?
 - How to encourage digital adoption?
 - How to achieve harmonization in a highly regulated industry?

Thank you Questions?

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CATAPULT
Cell and Gene Therapy

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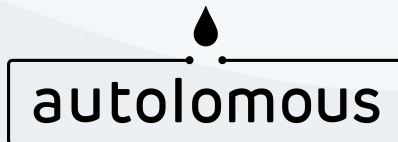
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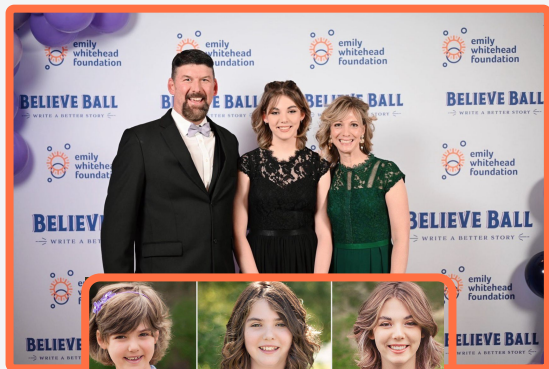
Digital Technologies in Medicines Manufacturing:

Scaling ATMPs to cure more patients

TMM CoP SME Showcase - 13Feb2024



A shared 'WHY': ATMPs save lives



"We have been given so much, and we hope to give much more in return. With your help, we can make a difference!"

The Whitehead family



Cameron Lahti

When Cameron was three years old, a mother's instinct led to a diagnosis that no parent wishes to hear: Leukemia...

[Read More >](#)



Paisley Rae Perrone

At just 10 weeks old, after her parents expressed concern to their pediatrician about an abnormal bump on her head...

[Read More >](#)



Vaibhav

At 8 years old, when sudden weight loss and pain on his lower lips indicated that something was wrong, Vaibhav...



Joe Redmond

At age fourteen, after months of consulting with doctors for unexplained joint pains, Joe was diagnosed with B-cell acute...



Gavin Rowe

At four years old, when a series of recurring ear infections led doctors to recommend additional blood testing, Gavin was diagnosed...



Colton Matter

At age nine, Colton Matter crashed while jumping his scooter over a bike ramp. His elbow was bleeding, and he had terrible...



Kaitlyn Johnson

At just 18 months old, following a series of unexplained symptoms, Kaitlyn was diagnosed with acute lymphoblastic leukemia. When her...

[Read More >](#)



Sam Tinaglia

At age five, Sam was diagnosed with acute lymphoblastic leukemia. After near a decade of enduring multiple relapses, he was...

[Read More >](#)



Jace Ward

In May 2019, Jace Ward noticed a change in his peripheral vision — a symptom which ultimately led to a...

[Read More >](#)



Opie Jones

At just 5 months old, in October 2020, Opie was diagnosed with infant acute lymphoblastic leukemia (ALL). When a bone...

[Read More >](#)



Jordan McInerney

At just four months old, when unexplained bruising led to an urgent hospital visit, Jordan was diagnosed with infantile acute...



The Gupta Family

At two years old, when a recurring fever prompted a routine panel of blood work, Chinmay was diagnosed with acute...



The industry is growing, but not scaling

North America

↗ **71% increase**

Developers **1,115**

Clinical Trials **941**

Europe

↗ **124*% increase**

514

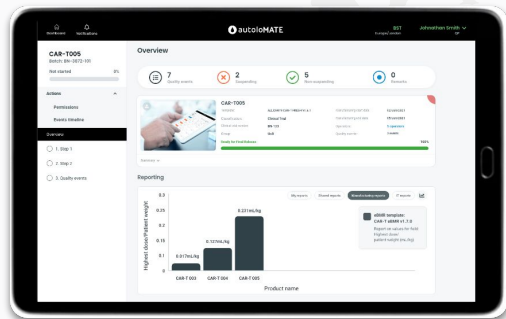
340

Asia Pacific


↗ **90% increase**

861

747




**Mitigate & reduce
reliance on scarce ATMP
specific expertise**


**Removal of data silos
between clinic &
manufacturing sites**

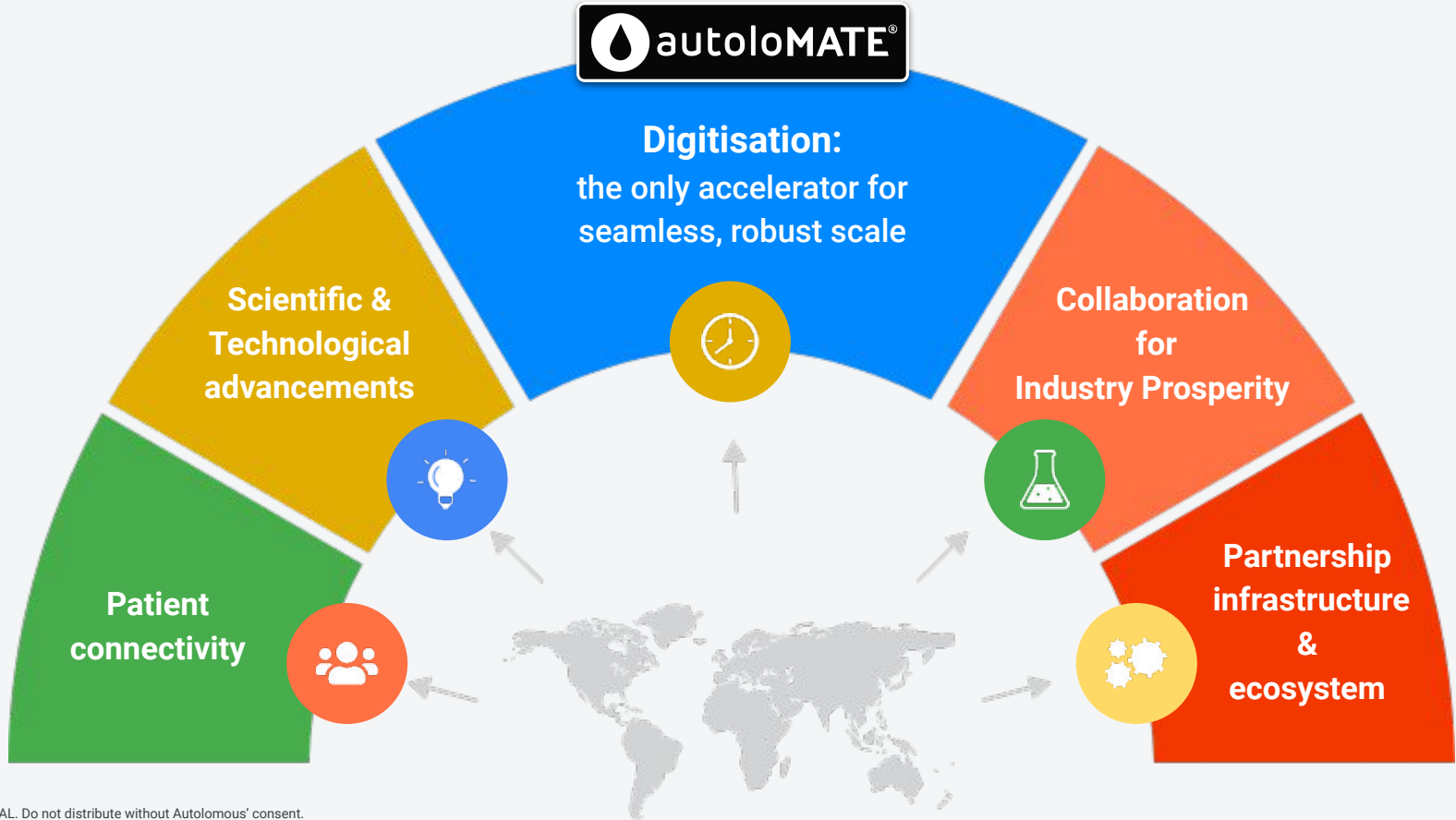

**Enhance compliance
and mitigate clinical
delivery risk**


**Globally manage
100s & 1000s parallel
supply chains across
multiple sites**


**Deliver more
medicines, faster and
better**



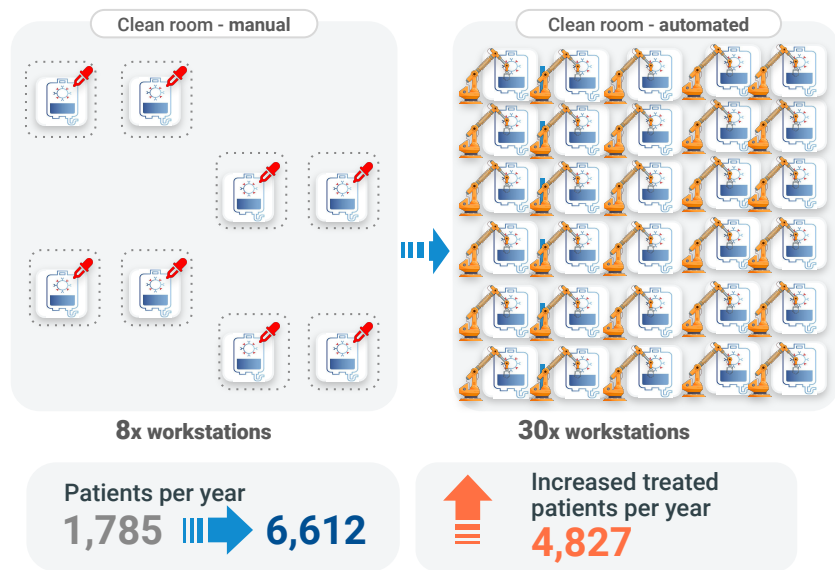
The doorway to scale



Scaling in ATMP

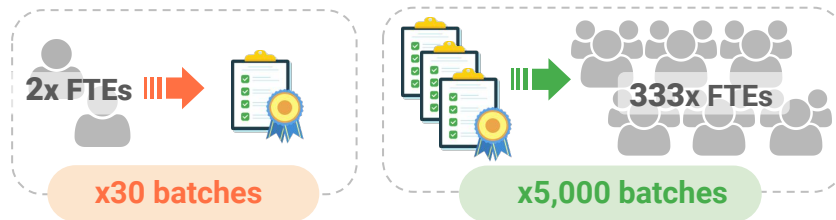
Challenge: Saving more lives

- **Manual** manufacturing constraints production
- **Automation** provides scalability



Challenge: Lack of resources & cost viability

- **120 hours** per autologous therapy treatment release*



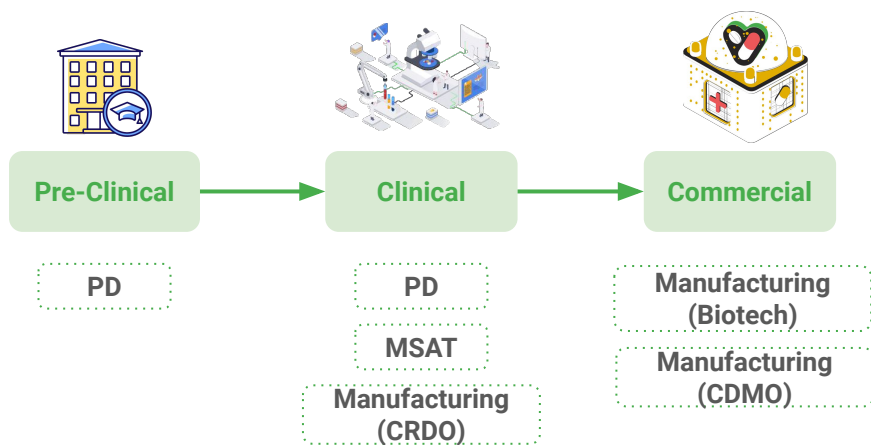
- For 30 patient treatments / year
 - **2 FTEs** performing batch release
- For 5000 patient treatments / year (scaled, commercial process)
 - **333 FTEs** performing batch release



Scaling in ATMP

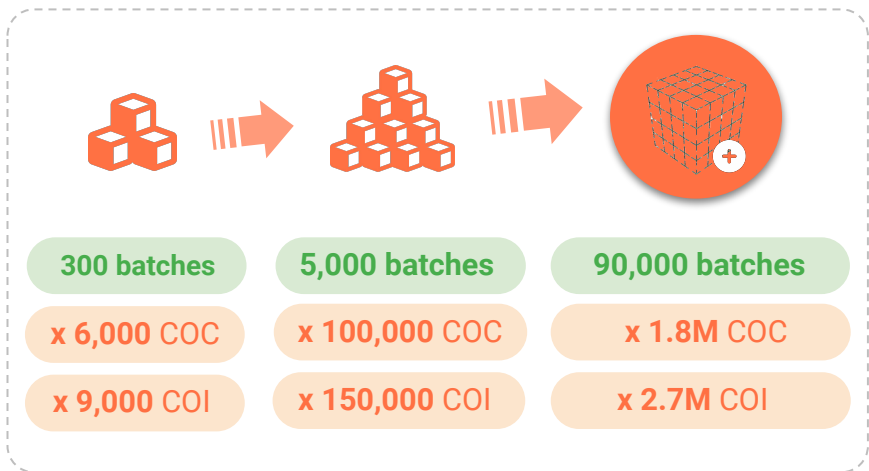
Challenge: Time to market

- Three distinct development **stages**
- Translation between each takes **months**
- Through digital tech transfer - **instantaneous**

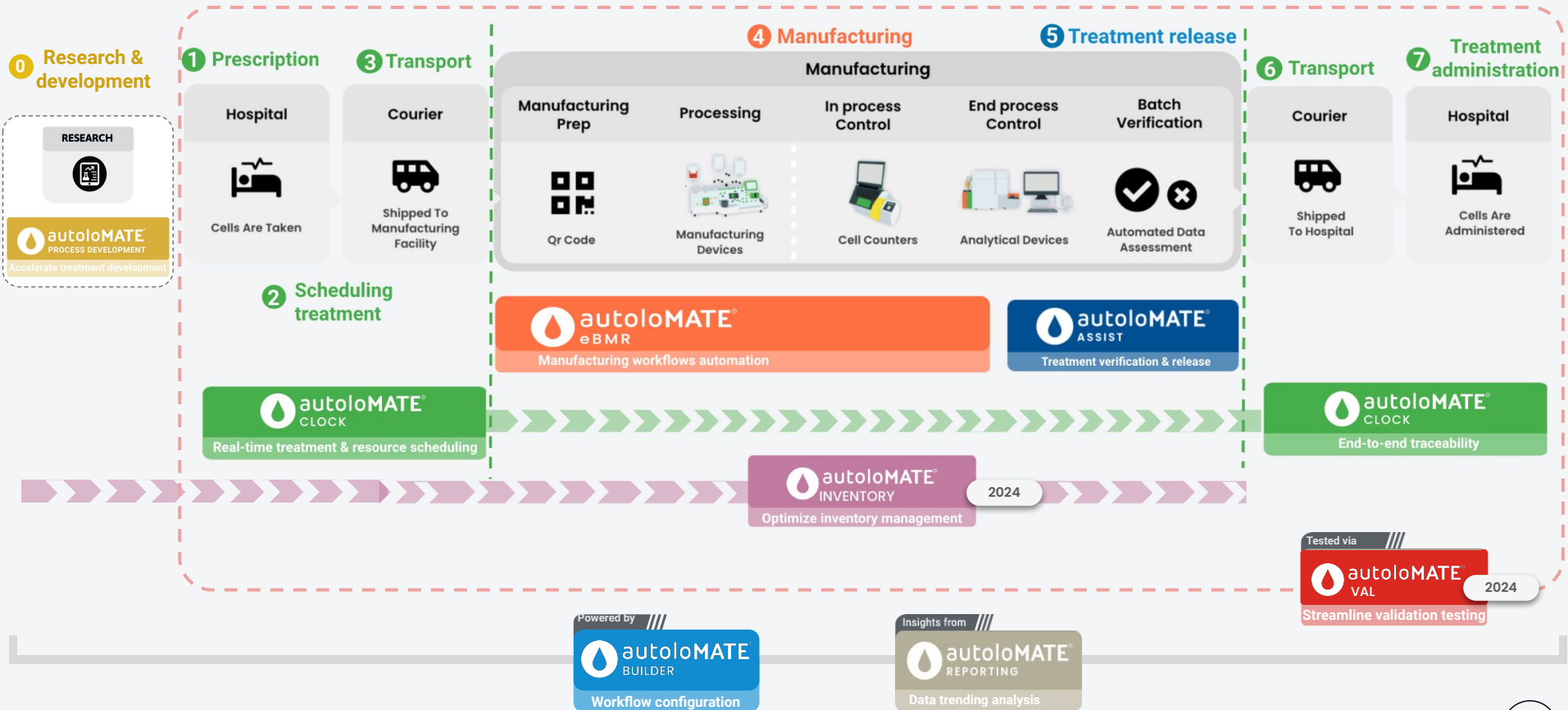


Challenge: Logistical complexity

- **One patient** - 50 product traceability events to track
- **5,000 patients** - approx. 250k events to track



autoloMATE[®] facilitates the end-to-end patient journey



Game-changing efficiencies

DELIVER IT...

5,000 more patients treated per year in the same cleanroom

+5000
↑

MAKE IT... FASTER

40% faster cycle times

40%
↑

MAKE IT... AFFORDABLE

Saving 70% COGs on resources

70%
↑

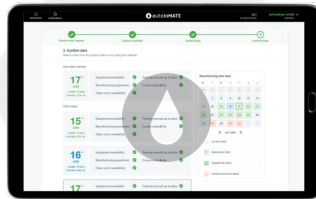
MAKE .. MORE OF IT

4x greater throughput

4x
↑



A de-risked
digitised future powered by...



*Technician using autoLOMATE in the cleanroom



Client highlights

Clinical Centres of Excellence (CoEs)

invest in the CGT industry as products *emerge*



CDMO

partner when CGT developers *scale*



Biotech

engage when CGT developers *accelerate*



"While Autolomous gives us the personalized attention we need, they're also focused on making a transformative impact on the entire field to make cell and gene therapies accessible to every patient that needs one. I'm excited to be a part of that ecosystem."

Patrick Hanley, Ph.D.
Chief & Director, Cellular Therapy Program
Associate Professor, CNH



"The Autolomous team, with their exceptional process and technical expertise, collaborated with our staff, ensuring a seamless and successful integration into our Process Development and Commercial manufacturing workflows."

Jeet Sarkar
VP, Head of IT, Center for
Breakthrough Medicines



"The broad experience of the Autolomous team gave us confidence in delivery of the product on time to meet our ambitious clinical development schedule and route to the market."

Troels Jordansen
Former CEO of
Glycostem



Digitisation delivers ATMPs to patients

Challenge: Saving more lives



Patients per year
1,785 \Rightarrow 6,612



Increased treated patients per year
4,827

- **Automation** provides scalability
- **Digitisation** enables automation

Challenge: Time to market



Pre-Clinical

Clinical

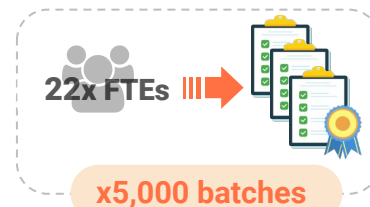
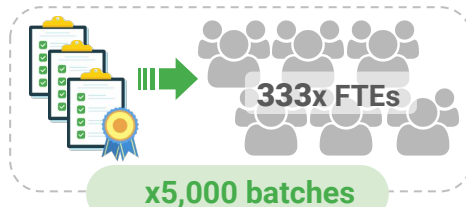
Commercial

- Through digital tech transfer - **instantaneous**

Challenge: Lack of resources & cost viability



- 120 \rightarrow **8 hours** per autologous therapy release



Challenge: Logistical complexity



300 batches

5,000 batches

90,000 batches

x15,000 COI/COC

x250,000 COI/COC

x 4.5M COI/COC

- Tracked **automatically**



Autonomous and Innovate UK



Manufacturing Made Smarter: Empowering NHS IT with eBMR insights

(iUK Project: 93094)
Apr '21 - Sep'22

- Integration with NHS ATTC advanced therapies ordering system
- Pilot implementation at the University of Birmingham Advanced Therapies Facility
- Chosen as showcase iUK project



Digitising Cell & Gene Therapy Batch Verification: AutoloMATE Assist

(iUK Project: 830246)
Apr'21 - Mar'23

- Support the build of **AutoloMATE Assist**
- Key enabler to CGT scalability challenges in batch review and verification
- Engagement with user base and regulatory consultants
- Product released in April 2023



PAT (Process Analytical Technology) for industrial scale Cell & Gene Therapy (CGT) Manufacture

(iUK Project: 10062929)
Jun '23 - May'25

- Implementation at **CGT Catapult**, Braintree
- Integrate novel Process Analytical Technologies (PAT) to autoloMATE
- Demonstrate the value add of digitisation to industrial scale CGT manufacturing



Concluding thoughts... the 'HOW' ...

1

We all share the WHY

- Let's now focus on the HOW

2

Industry progressing

- Technology advancing
- Processes improving
- More indications, trials & approved therapies every year

3

All for nothing without digitisation

- The keystone in the doorway to scaled ATMPs





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