Digital pharmaceutical supply chains enabling adaptive & personalized medicine supply

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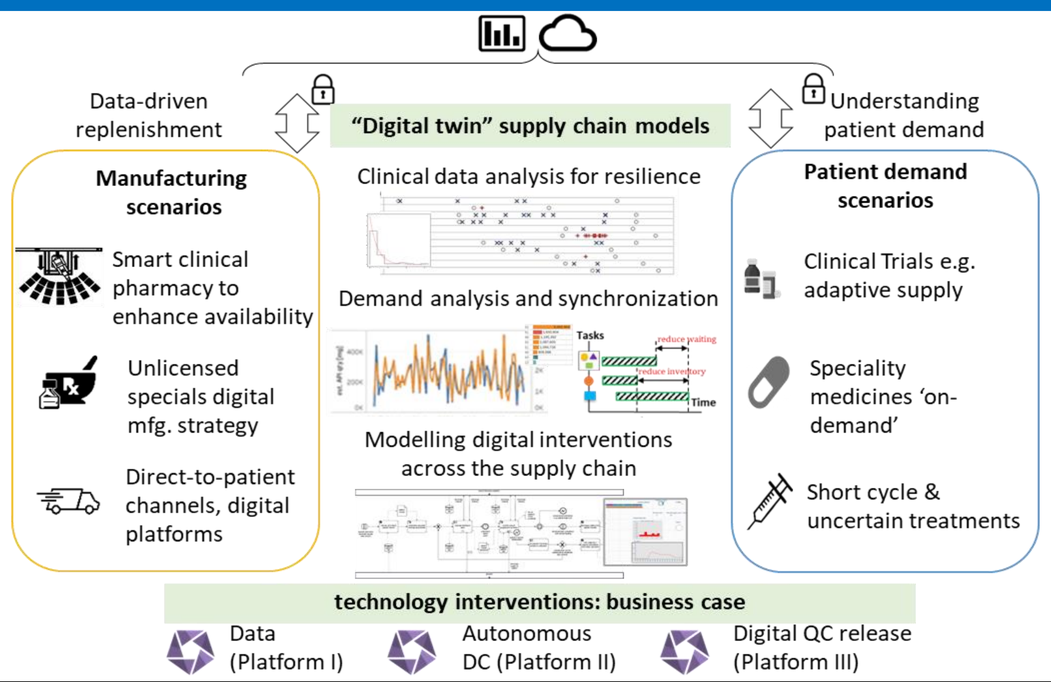
Industrial digital technologies for adaptive, patient-centric supply (JSS-jss46@cam.ac.uk)



Platform 4 focuses on the design and operational analysis of pharmaceutical supply chains, and how these might be reconfigured through the application of Industrial Digital Technologies, or IDTs. Reconfiguration may involve IDT application within current production operations through smart factory developments and synchronisation, alternative production processes offering different volume-variety and cycle-time scenarios, and digital twin supply chains that can enable data-driven replenishment based on actual user demand. Engagement with industry partners brought about 3 Digital Supply Chain Use-Case Models for the development of alternative digital supply chain configurations, based on autonomous manufacturing and driven by patient need.

- The first case is centred on digital platform developments, connecting pharmaceutical and medical device manufacturing operations to downstream healthcare-product procurement systems to enhance availability at the hospital or clinic and through to the home.
- The second case study focuses on unlicensed specialty medicines and combines real-world demand signal analysis with a Smart Manufacturing Environment to support synchronised planning and control.
- The third case study leverages extensive analysis of clinical trial supply chain data, and digital interventions to improve resilience by preventing stock-out events, combining insights from multiple data analytics perspectives and tools.

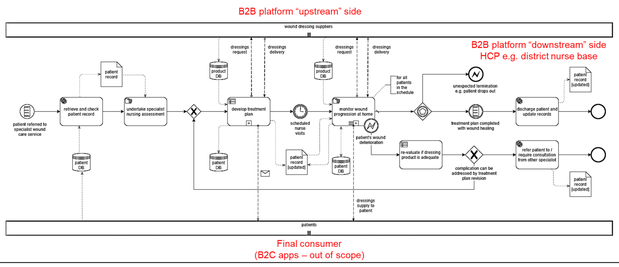
Network reconfiguration redesign enabled by digital medicines mfg. technologies (ES-es679@cam.ac.uk)

B2B platform perspective: digitalising "downstream" interaction between medicines manufacturing and healthcare providers (medical device case, D2P supply) – can be extended to upstream B2B platforms.

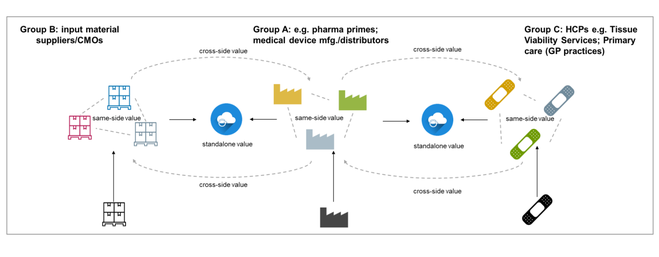
Future state rationale for short & uncertain treatments:

- Automation of non-prescription wound care product management systems with HCP, patients and suppliers
- Alternative supply routes to reduce time, stock, waste, HCP spend, point-of-care variation

Current state (BPMN map excerpt)

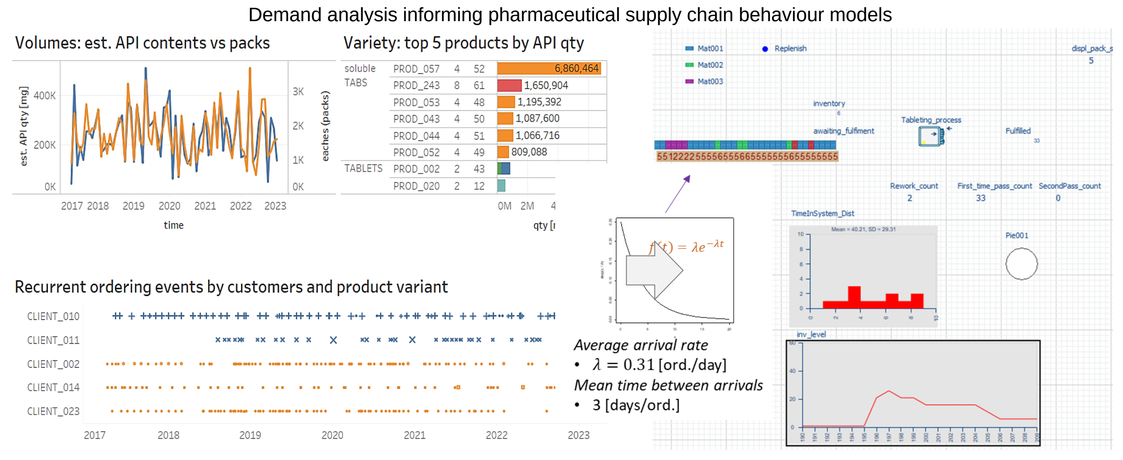


Future state: B2B digital platform (value framework)

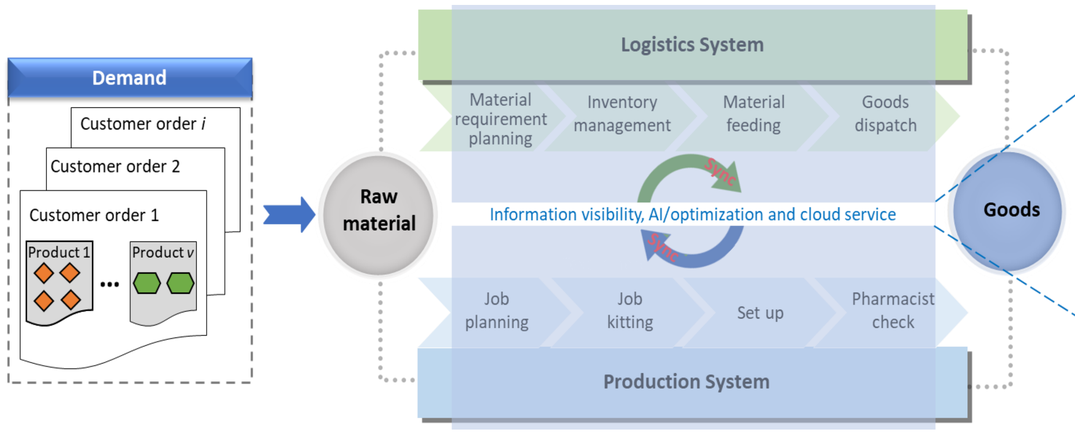


Supply network design: digital / advanced mfg. technology interventions provide configuration options → reductions in safety stock for given service level targets

Demand analysis informing pharmaceutical supply chain behaviour models



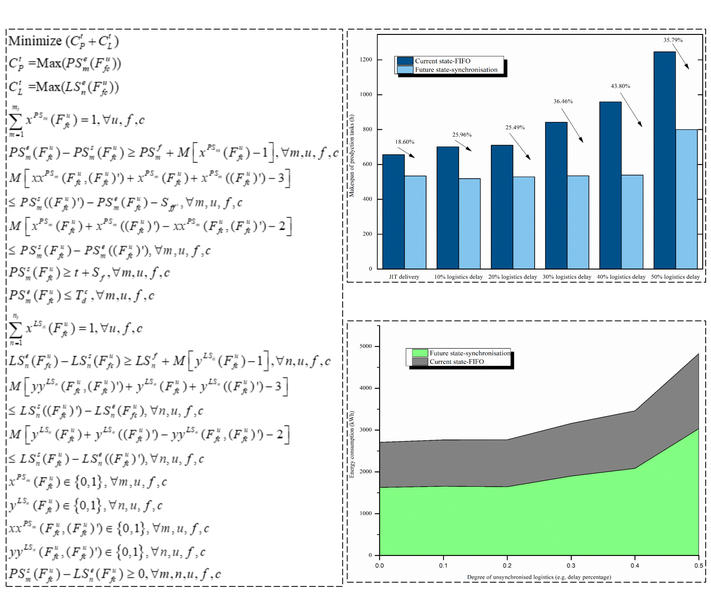
Smart production and logistics synchronisation for medicine manufacturing (DG-dg654@cam.ac.uk)



- Real-world demand signal-driven
- Cut unnecessary operations, shorten lead time, reduce waste and enhance sustainability
- Leverage real-time information flow, informed coordinated decision-making and cloud service

- Smart production and logistics synchronisation results in an avg. reduction of 31% in production lead time and 34% total energy consumption
- The more severe the logistics delay, the greater the advantages of synchronisation

Informed coordinated decision-making model

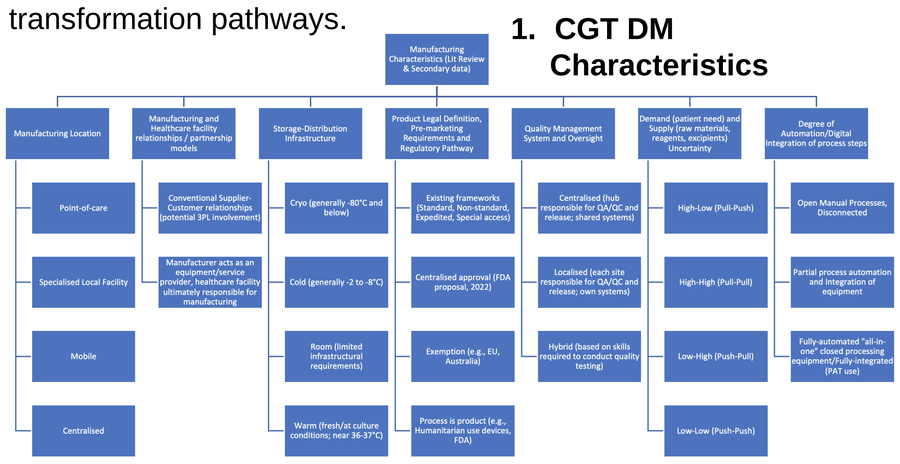


Simulation results

Distributed Manufacturing of Cell and Gene Therapies: Models and Enablers (PB-phb31@cam.ac.uk)

Manufacturing CGTs differs from established pharma- and biopharmaceuticals. Existing SC for these have often proven ineffective. Distributed manufacturing (DM) is a digitally-enabled solution – we review, capture potential models and describe transformation pathways.

1. CGT DM Characteristics



2. Emerging CGT DM Models (Regulatory perspectives)

Manufacturing mode terminologies employed by authorities & Similarity to models shown

Model	FDA	MHRA	Literature
A	Centralized	Centralized	Centralized
B	Point-of-care	Point-of-care	Decentralized
C	Distributed	Mobile	Mobile micro-factories
D	Decentralized	Modular	Multi-domestic replication
N/A	-	Home-based	-

Operating requirements (non-exhaustive; exemplars)

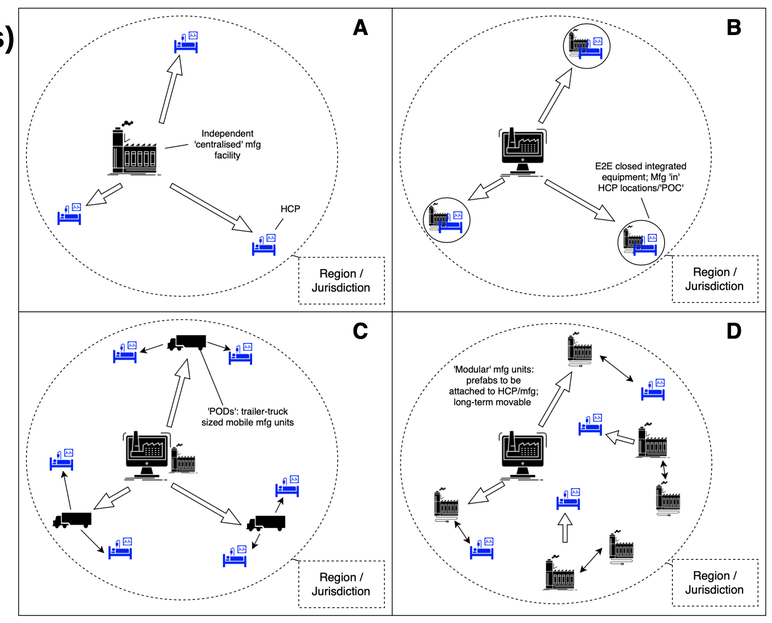
Model	Centralized QC	Assay Bridging	Analytical Comparability	E2E closed integrated equip.	Cryopreservation (store-transport)	Manufacture under GMP
A	-	-	-	-	•	•
B	•	•	•	•	○	-
C	•	•	•	•	○	○
D	○	•	○	○	○ or •	•

- • Necessary
- ○ Not necessary / may prove beneficial
- - Not necessary / potentially hurtful

'In' – HCP owned facility acts as GMP **(B)**
'At' – separate facility at HCP premises acts as GMP **(D)**
'Near' – separate facility located within close distance off HCP premises **(C)**
'Bedside' – "holy grail"; mfg at patient bedside, not shown. (MHRA 'home-based')

3. Industry case studies explored (WIP):

Carvykti (commercial; Janssen), Atalanta/Euplagia (PI/II clinical studies; Galapagos Therapeutics)



Acknowledgment: The authors would like to thank the Digital Medicines Manufacturing (DM²) Research Centre (Grant Ref: EP/V062077/1) for funding this work. DM² is co-funded by the Made Smarter Innovation challenge at UK Research and Innovation and partner organisations from the medicines manufacturing sector. For more information, visit cmac.ac.uk/dm2-home

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DM² Digital Medicines Manufacturing