

# Technology & Innovation Roadmap Refresh

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- MMIP Mission and Vision
- Drivers (What has changed since the last T&I update in 2017?)
- What progress was made since 2017?
- Summary of Proposed Response
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# MMIP Mission and Vision



## Mission of MMIP:

Become a leading force in manufacturing innovation, to maximise ROI from the exceptional UK LS R&D base, to be the leading force in manufacturing innovation, ensuring national and regional economic benefits and a secure supply of medicines for patients in the UK.

## Vision for MMIP:

Focusing on technology and Innovation leadership to make the UK the best place in the world for medicines manufacturing through:

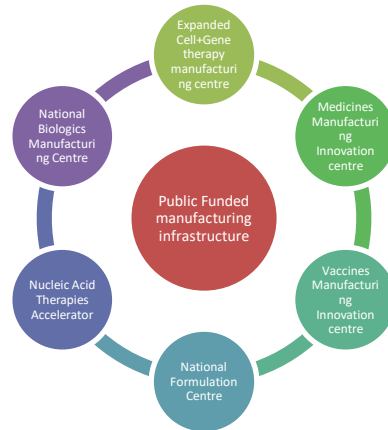
1. Our ability to develop the manufacturing process for new medicines and rapidly move from research through development to launch is world class.
2. Our ability to bring innovative advanced manufacturing methods to medicines manufacture to ensure high quality and high productivity is world class.

### Drivers

- Providing access to innovative medicines
- Moving towards personalised medicines.
- Delivering a Net Zero economy
- Changing Portfolio - Advanced Therapies – ADCs, Vaccines, Nucleic Acids, Oligos, Cell based therapies
- Shortening Development and Launch times
- Harnessing the potential from the UK medicine manufacturing ecosystem
- Increase the impact of Digital Transformation from molecule to patient

New Business Models

### Infrastructure



### Strategic Grand Challenges

#### Current

- Digitalisation
- Continuous Manufacturing
- ATMPs manufacturing & delivery

#### Potential Future

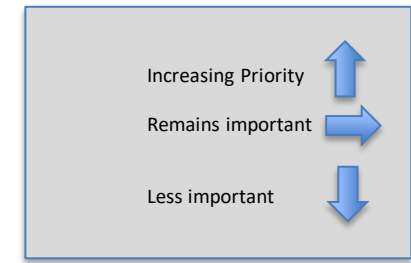
1. Robust Agile Supply Chains
2. Future Sterile Manufacturing
3. A Net zero approach to medicines manufacture
4. Next Generation Biopharma
5. Nanotherapeutics for Intercellular Drug Delivery

### Technology opportunities

- Digital Design/Supply chain – from Molecule to patient
- On Demand Manufacturing
- On Demand Sterile manufacturing capacity
- Cell free systems for development and manufacture.
- Real time release for Advanced Therapies
- Advanced Bioprocess control
- Infrastructure to support the industrialization of future therapies (LNP)

Fiscal, Regulatory, Skills, Advanced Therapies, Community Build, Technology & Innovation

# Drivers



## 2017

- Providing access to innovative medicines
- Moving towards personalised medicines.
- Delivering a Net Zero economy
- Changing Portfolio - Advanced Therapies – ADCs, Vaccines, Nucleic Acids, Oligos, Cell based therapies
- Shortening Development and Launch times
- Harnessing the potential from the UK medicine manufacturing ecosystem
- Increase the impact of Digital Transformation from molecule to patient



## 2020

- Providing access to innovative medicines
- Moving towards personalised medicines.
- Delivering a Net Zero economy
- Changing Portfolio - Advanced Therapies – ADCs, Vaccines, Nucleic Acids, Oligos, Cell based therapies
- Shortening Development and Launch times
- Harnessing the potential from the UK medicine manufacturing ecosystem to **deliver a more resilient end 2 end medicine supply chain**
- **Improve the preparedness for future pandemics**
- **New ways of working.**
- **New Business models**
- Increase the impact of Digital Transformation from molecule to patient



**The Drivers haven't changed significantly since 2017. They have however become an imperative!**

# Progress from 2017 to 2020 Roadmap



## 2017 Proposed

## Actioned

## Impact Delivered

- **Create a physical infrastructure and capability for radical and disruptive innovation in chemical/pharmaceutical manufacturing**
  - **Medicines Manufacturing Innovation Centre**
  - **Complex Medicines Centre of Excellence**
  - **Packaging and Device Centre of Excellence**
  - **Specialist Cell and Gene Therapy Manufacturing Operation**
- **Embed Automation and Industry 4.0 in delivering next gen processes – continuous manufacturing and clinical supply chain**
- **Support the increased development of Digital Capabilities to support development – ADDoPT partnership with CMAC.**
- Proposal to leverage support from NHS regional test beds.
- Growing capability in Green Chemistry and Sustainable processing
- Flexible production supply chain
- Creating effective ATMP supply chain – viral vector and Biologics

- Invested in MMIC<sup>1</sup>, VMIC, C&GT expansion, Advanced Therapies treatment centres, Medicines Manufacturing Collaborative R&D
- Digitisation Wave 1
- ISCF - Digitalisation of Medicines Manufacturing
- IUK Viral Vector Manufacturing – Capex enabling technologies
- BIA paper on Advanced Analytics report.
- Funding of Digital Accelerator activities
- Cross Industry “Made Smarter” Digitisation -Several applications against Made Smarter Challenge fund and increased engagement.
- CPI developed significant capability in smart packaging of medicines.

- Access to C&GT Capability and VMIC has improved our ability to respond to the Covid 19 Pandemic
- Planned MMIC has attracted additional industry support and is expected to lead to increased investment in UK based sites.
- IUK Viral Vector funding – catalysed further investment in Viral Vector manufacturing in the UK
- Investment in infrastructure will ensure continued industry investment in medicine manufacturing in the UK – attractive proposition to share risk and benefits of partnering to solve grand challenges.
- Physical innovation infrastructure has offered a clearer path of industrialisation from early TRL activities funded by UKRI to delivering impact in industry and broader UK economy.

<sup>1</sup>“£56m UK Innovation Centre will transform Medicines Manufacture” .... A new £56 million UK innovation centre, set to revolutionise how medicines are manufactured, is to be located in Renfrewshire, Scotland, allowing the UK to capture a bigger slice of the global £98 billion small molecule pharma market.

# Proposals to deliver T&I Roadmap Ambition



1. Identification and funding of projects under proposed “Grand Challenges” – (£150 m over 4 years)
  - I. Robust Agile Supply chains
  - II. Future Sterile Manufacturing
  - III. Next Generation Biopharm
  - IV. Nanotherapeutics for Intercellular Drug Delivery
  - V. Net Zero
2. Signpost the “Industry needs” and engage with Innovation ecosystem to understand the “Opportunities” presented by advances in science and technology in other enabling technologies and capabilities (Technology Strands).
  - Increase awareness of Medicine Manufacturing challenges and how they link with other ISCF e.g. Made Smarter.
  - Regular engagement with Research Councils to understand progression of the technology strands (Industrial readiness), and support required.
  - Regular updates on MMIP website to engage with broader community on plans and future opportunities.
3. Continue to identify incentives and methods to improve broader accessibility to advanced technologies.

# 1-Proposed Grand Challenges

These are the specific challenges which will help bring us closer to the long term ambition for Medicines Manufacturing.



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# Grand Challenges



Grand Challenge	Exemplar projects
<b>Robust Agile Supply chains</b> (Improving the Agility and robustness in developing, launching and supplying new products)	<ul style="list-style-type: none"> <li>Continuous DP</li> <li>JIT Clinical</li> <li>Digital Design Accelerator/Digital Design Studio</li> <li>Advanced &amp; Integrated measurement tech (CAMS)</li> </ul>
<b>Sterile Manufacturing for the Future</b> (Delivering sterile manufacturing capacity faster and at lower overall economic cost)	<ul style="list-style-type: none"> <li>Digital twin of fill finish</li> <li>Alternative on demand filling lines</li> <li>Rapid Sterility testing</li> </ul>
<b>Next Generation Biopharm</b> (Harnessing the full potential of future therapies)	<ul style="list-style-type: none"> <li>RTR for Autologous Gene therapies</li> <li>Advanced Bioprocess control</li> <li>Cell free development</li> </ul>
<b>Nanotherapeutics for Intracellular Drug Delivery</b> (Creating a portfolio of "Pharma Ready" modalities)	<ul style="list-style-type: none"> <li>Clinical infrastructure for industrialising of Nucleic based therapies.</li> </ul>
<b>Net Zero</b> (Minimising the carbon impact of medicine supply)	<ul style="list-style-type: none"> <li>Alternative Oligo manufacturing process.</li> <li>Eco Design and Development</li> <li>Sustainable Packaging.</li> </ul>



# Expected Impact based on Proposed 2020 refresh



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Grand Challenge	Impact to Industry	Impact to UK
<b>Robust Agile Supply chains</b> (Improving the Agility and robustness in developing, launching and supplying new products)	<ul style="list-style-type: none"> <li>Continue the industrialisation of continuous drug product processes de-risking potential adoption in industry.</li> <li>Deliver a working JIT Clinical supply chain platform that will allow for the acceleration of clinical supply chains and will inform and de-risk possible future investments in UK based clinical supply chains</li> <li>Develop a strength in the delivery and implementation of Digital based technologies for the modelling of materials and processes for the medicine manufacturing industry</li> </ul>	<ul style="list-style-type: none"> <li>Attracts further inward investment in existing factories to meet new product needs (makes more sense to locate adjacent to COE)</li> <li>Attracts further investment in UK based academic and technical organisations in order to advance the digital capability within the broader Pharma industry.</li> <li>Will make technologies that will improve supply chain responsiveness and resilience more accessible to UK based medicine manufacturing.</li> </ul>
<b>Sterile Manufacturing for the Future</b> (Delivering sterile manufacturing capacity faster and at lower overall economic cost)	<ul style="list-style-type: none"> <li>De-risk and deliver industrialised solutions that will deliver sterile manufacturing capacity at a lower incremental and economic cost</li> </ul>	<ul style="list-style-type: none"> <li>Attracting more inward investment in sterile manufacturing which attracts high value jobs and improves the UK medicine supply chain resilience. (Growth area)</li> <li>Attracts more high value investment to support new product launches.</li> </ul>
<b>Next Generation Biopharm</b> (Harnessing the full potential of future therapies)	<ul style="list-style-type: none"> <li>Deliver end 2 end industrialised solutions leading to reducing the barriers for the delivery and scaling of novel treatments to patients.</li> <li>Improving the productivity</li> </ul>	<ul style="list-style-type: none"> <li>Allowing UK based companies to benefit from adopting new more productive methods when commercialising new products from the clinic</li> <li>Attracting investment in this type of industry will increase economic impact as this is a growth area and will improve over supply chain resilience and responsiveness for future pandemics.</li> </ul>
<b>Nanotherapeutics for Intracellular Drug Delivery</b> (Creating a portfolio of “Pharma Ready” modalities)	<ul style="list-style-type: none"> <li>Deliver an end infrastructure to facilitate the delivery of industry ready intracellular therapeutics that will position the UK as a world leader in nucleic acid therapies, vaccines and ATMP</li> </ul>	<ul style="list-style-type: none"> <li>Provide an infrastructure that will improve the resilience of the UK in response to future Pandemics and enable development of the next generation of therapeutics and vaccines</li> <li>Attract additional investment to fund the development and commercialisation of future nanotherapeutics and vaccine products.</li> </ul>
<b>Net Zero</b> (Minimising the carbon impact of medicine supply)	<ul style="list-style-type: none"> <li>Identify and develop solutions at lower cost that will allow for the pharmaceutical industry to deliver its own Net Zero objectives.</li> </ul>	<ul style="list-style-type: none"> <li>Identify solutions that will help the UK meet its 2050 Net Zero target while also creating an export opportunity to solve the global sustainability challenge.</li> <li>Opportunity to stimulate UK based industry to provide more sustainable more raw materials and processing components to medicine manufacturing.</li> </ul>

## 2 - Enabling Technologies & Capabilities (Technology Strands)

These are the enabling technologies which when combined present opportunities to address medicine manufacturing needs. The continued focus on these technologies and capabilities will deliver a strong pipeline of new solutions to address medicine manufacturing needs.

# Enabling Technologies & Capabilities (Tech Strands)



MMIP



- These are the common technology and capabilities that with continued development will present new opportunities in solving the broader industry challenges.
- We expect that the development of some of these Tech strands will be progressed through the Grand Challenges but we want to highlight the importance of continued support outside of the Grand Challenge support to maintain a strong technology pipeline for the future.
- Some of these are common across multiple industries and so highlights the opportunity to leverage across industry sectors and adapt as needed to meet specific Medicine Manufacturing needs e.g. Made Smarter and Advanced Materials.
- The development and the associated impact of these technologies will be dependent on accessing a skilled workforce. Development of future workforce should be in considered in parallel to technology development.
- Emerging tech reflects the technologies that will present new opportunities to how we deliver new treatments and so will present new opportunities or challenges for medicine manufacturing.

### 3 - Continue to identify incentives and methods to improve adoption of advanced technologies.

How might we incentivise the adoption of the new tech?



# Translation of Innovation to Industry Impact



Review scientific knowledge base

Develop hypothesis design- research ideas and protocols

Technology identification – initial POC demonstrated in a limited number of in-vitro models

Tech optimisation – PoC and safety of candidate is demonstrated in a defined laboratory/animal

Initiation of GMP process development – tox undertaken sufficient to support IND application

Phase 1 GMP Pilot clinical studies support prior to Phase 2. IND application submitted and reviewed by regulator

GMP process scale up of to Phase 2 completed. Phase 3 clinical plan approved by the regulator.

GMP process validation and Phase 3 completed.

Post approval changes & post marketing surveillance including real life studies.

**How do we ensure that the output of the innovation pipeline translates to impact in Industry and UK economy and society.**



Manufacturing Concepts Identified

Manufacturing processes demonstrated in lab environment

Product produced on new manufacturing process in lab environment

Product Produced in pilot plant or other production representative environment

System prototype demonstrated in operational environment

System completed and qualified

Actual System proven in operational environment

Research Councils (EPSRC, MRC, ESC BBSRC, etc)

ISCF (Medicine, Made Smarter, Net Zero)

RTOs/CPI/Catapult/SMEs

 **Industry Adoption**

## Proposed Action

- Communicate broader industry needs and engage to understand alignment of opportunities
- Monitor the progress of Technology strands to understand the opportunity presented by advances in science and technology
- Signpost potential areas of science which will need support in order to develop to industrialisation

- Seek to leverage technologies/solutions from other industries and adapt to better reflect specific Medicine Manufacturing needs.
- Monitor the progression of activities in the RTOs against industry needs.
- Refresh Industry needs to inform priority allocation of funding to new technologies, SMEs etc.
- Develop the current/future workforce while developing new technologies.



# MMIP Technology & Innovation Summary on “One Page”

# Deliver a more agile, adaptable, scalable, sustainable medicine manufacturing ecosystem that will deliver economic impact to the UK and deliver medicines to patients faster in a more sustainable way.

## Drivers

### Industry

- Providing access to innovative medicines
- Moving towards personalised medicines.
- Delivering a Net Zero economy
- Changing Portfolio - Advanced Therapies – ADCs, Vaccines, Nucleic Acids, Oligos, Cell based therapies
- **Shortening Development and Launch times (Pandemic Responsiveness)**
- **Harnessing the potential from the UK medicine manufacturing ecosystem (Robust Manufacturing Supply chain and Pandemic response)**
- **Future of Work**
- **New Business models**
- Increase the impact of Digital Transformation from molecule to patient

### UK

- Increase the level of investment in medicine manufacturing in the UK – attract new investment in manufacturing capacity
- Maximise economic impact from investment in research and dev – contribute to the green recovery
- Deliver the Net Zero ambition by 2050
- Have right infrastructure and capability in place delivering a more sustainable resilient medicine supply chain to support the UK needs

## Response

### Grand Challenges 2021 -2025



- Support challenges which have the potential to deliver significant impact that have TRL 3-4 and unlikely to be undertaken by a single company and the UK Innovation ecosystem is well positioned to address. **1-Robust Agile Supply chains, 2-Future Sterile Manufacturing, 3-Next Generation Biopharma, 4-Nanotherapeutics for Intercellular Drug Delivery, 5- Net Zero.**
- Leverage and augment UK innovation ecosystems infrastructure to focus on new Grand Challenges
- Increase focus on advancing areas of emerging technologies in new modalities.
- Increased focus on improving responsiveness for future pandemics
- Deliver “Digital ready” industry relevant technologies
- Increased focus on improving sustainability of the current and new medicines
- Seek deliver more end 2 end solutions leveraging collective ecosystem – avoid duplication and seek opportunity to collaborate.

### Continued Investment in Technology Pipeline (Technology Strands)



- **Future Factory**
  - Lab of the Future
  - Factory Design
  - Process Tech
  - In-line process control & RTR
  - Flex Production facilities & supply chain
- **Digital Design & Analytics**
  - Digital Design & Modelling
  - High performance computing
  - Integrated analytical measurement
- **Enabling**
  - Standards
  - Skills & Training
- **Emerging Tech**
  - Genomics
  - Future Modalities
- **Advanced Materials**
  - Green Chemistry
  - Synthetic Biology
  - API/Formulation
  - Packaging Tech & Materials
- **Transformative Technologies**
  - Link to Made Smarter

## Impact

### Industry

- Create consortiums where significantly challenging and impactful opportunities are addressed by harnessing the collective UK Innovation ecosystem
- Deliver more agile, productive solutions to accelerate the development, launch and scaling of new products.
- Accelerate the development, commercialisation and scaling of new products through new capabilities and technologies.
- Improve the productivity and agility to respond to changing portfolio demands e.g. ATMP and Sterile manufacturing capacity.
- Access to more “Industry Ready” technology at lower cost to help commercialise research in UK e.g. sterile manufacturing

### UK Economy

- Attract more investment and associated employment in commercialising new products using UK based manufacturing and increase the contribution of GVA by medicine manufacturing
- Create new opportunities for UK SMEs to support both local and global manufacturing challenges.
- **Have a more sustainable resilient medicine supply chain better prepared for future pandemics and contributing to the UK Net Zero ambition.**

### Health Service and Patients

- Securing access to more affordable treatments for patients
- Improving the resilience of medicine supply chain to meet patient needs
- Early access of new medicines commercialised in UK

# Acknowledgements



Name	Affiliation	Name	Affiliation
Karen Wilkinson	KTN Health	James Miskin	Oxford Biomedica
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JP Sherlock	AZ	Susan Fayinka	GSK
Andy Dwyer	GSK	Dave Tudor	MMIC/CPI
Bob Docherty	Pfizer	Chris Courtney	Innovate UK/Made Smarter
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Julie Anderson	CPI	Laura Dickens/Stephen Oakeshott	MRC
Lucy Foley	CPI	Bob Yule	GSK
Damian Marshall	C&GT Catapult		