



CMAC Strategy
Transforming Medicines
Development & Manufacture



CMAC
FUTURE MANUFACTURING
RESEARCH HUB

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Strategy Refresh

This Strategy Refresh document provides a common vision for the CMAC direction, with particular focus on the implementation and translation of our manufacturing research programme.

As host of CMAC, the University of Strathclyde leads the National Manufacturing Institute of Scotland (NMIS) and is a strategic partner in Medicines Manufacturing Innovation Centre (MMIC). As these key programmes develop there is significant opportunity for CMAC and the partner academic network to contribute to the UK Industrial Strategy.

We would like to thank the CMAC Industry Board, Advisory Board and staff for their contribution and look forward to the exciting delivery plan!

CRAIG JOHNSTON & PROF ALASTAIR FLORENCE, CMAC

Foreword

The pharmaceutical industry is dealing with significant change as demands from patients, payers and healthcare systems drive increased complexity in the design, development, manufacturing and supply of future medicines. CMAC, with 8 Tier 1 Pharma companies and a thriving Tier 2 community, has been built on pre competitive, industry led collaboration and is delivering an ambitious and impactful research programme. Ensuring CMAC delivers research excellence and outstanding skills development, whilst establishing world class facilities and promoting exemplary translation to industry, is critical to sustainable success and a focus for the industry partners. The environment is changing with the formation of the UK Research and Innovation body (UKRI), the Medicines Manufacturing Industry Partnership (MMIP) and targeted funding through the Industrial Strategy Challenge Fund, and as such, CMAC is well positioned in providing a clear and influential voice in this new international ecosystem.

DR JON-PAUL SHERLOCK, AZ, CMAC CHAIR

Background and Achievements

CMAC's vision has been developed through close collaboration with industry and the support of its Tier 1 partners, AstraZeneca, Bayer, GlaxoSmithKline, Lilly, Novartis, Pfizer, Roche and Takeda and a wide range of technology companies.

CMAC has already saved companies £20M p.a, leveraged a £150M funding portfolio, and currently comprises more than 130 staff and researchers, including academics, post docs, 50 PhD students and an experienced support team.

In 2017, the EPSRC Future Manufacturing Research Hub was launched. This 7 year programme, led from the University of Strathclyde, comprises academic investigators and research staff across 7 leading universities. It will deliver predictive design tools and novel integrated continuous processing platforms for the supply of next generation high performance personalised products.

CMAC

- Develops innovative solutions to address company specific problems
- Creates commercial opportunities for start-ups and major global companies
- Produces a talent pipeline of highly skilled multi-disciplinary staff
- Influences policy, government and regulators
- Drives novel approaches and options from supply chain improvement
- Collaborates with world class business and academia on an international basis



SAVED COMPANIES
>£20M p.a.



**7 LEADING
 UK ACADEMIC
 PARTNERS**



MORE THAN
**130 STAFF AND
 RESEARCHERS**



**15 CMAC ALUMNI
 WORKING AT TIER 1S
 COMPANIES PLUS 15 IN
 SMES AND SUPPLY CHAIN**



**£25M
 CRITICAL MASS
 FUNDING FROM
 EPSRC**



External Environment

- Aging population
- Increasing cost of healthcare
- Outcomes based pricing
- Clinical advances
- Growth in emerging markets
- Cautious regulators
- Patient centricity
- Pressure on process development times and materials costs

SOURCES: KPMG, PHARMA OUTLOOK 2030; PWC PHARMA 2020

WHAT DOES THIS MEAN FOR MEDICINES MANUFACTURING?

<p>Precision medicines driving smaller volume manufacturing and new distribution models</p>	<p>Adaptive and different trial design accelerating clinical and launch phases</p>	<p>Advance drug delivery and increasing molecular and process complexity</p>
<p>Continuous, miniaturised & flexible manufacturing platforms with real time process measurement and control</p>	<p>Advanced analytics and artificial intelligence supporting human decision-making</p>	<p>Digitalisation – embrace emerging technologies towards integrated design manufacturing & supply</p>
<p>Delivering sustainable processes</p>		

CONTINUOUS MANUFACTURING IS A CORNERSTONE

General Summary of companies outlook towards continuous manufacturing.

<p>90%</p> <p>... see CM as important for the supply of their products in the next 5 to 10 years.</p>	<p>>80%</p> <p>... consider their C-level to be well aware about the importance of CM.</p>	<p>59%</p> <p>... have an ambitious adoption strategy driving agenda with regulatory bodies, equipment providers, ecosystem partners etc.</p>	<p>17%</p> <p>... consider their CM strategy as mature whereas CM strategy still at exploratory stage for all others; approximately 1/2 consider themselves early adopters.</p>
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SOURCE: ACCENTURE, ADAPTED BY DR JP SHERLOCK, OPEN DAY 2018

Future State: 2023 Vision

MISSION

Transforming medicines manufacture, development time and cost to market through the use of digital twins and microfactories.

1 Develop conti processes with 10g within a month enabling a tiered drug product approach.

Exploit production tools to accelerate product and process development.

2 Produce digital twins based on multiscale models.

Extract value from data and link multiscale models.

3 Demonstrate case studies and advocate business cases in development and manufacturing.

Demonstrate technical and operational benefits of digital tools and continuous processes.

4 Strengthen understanding of material attributes.

Pharmaceutical materials science underpinning stability, manufacturability and performance.

5 Paths to translation through Tier 1s, spin outs, ecosystem and MMIC.

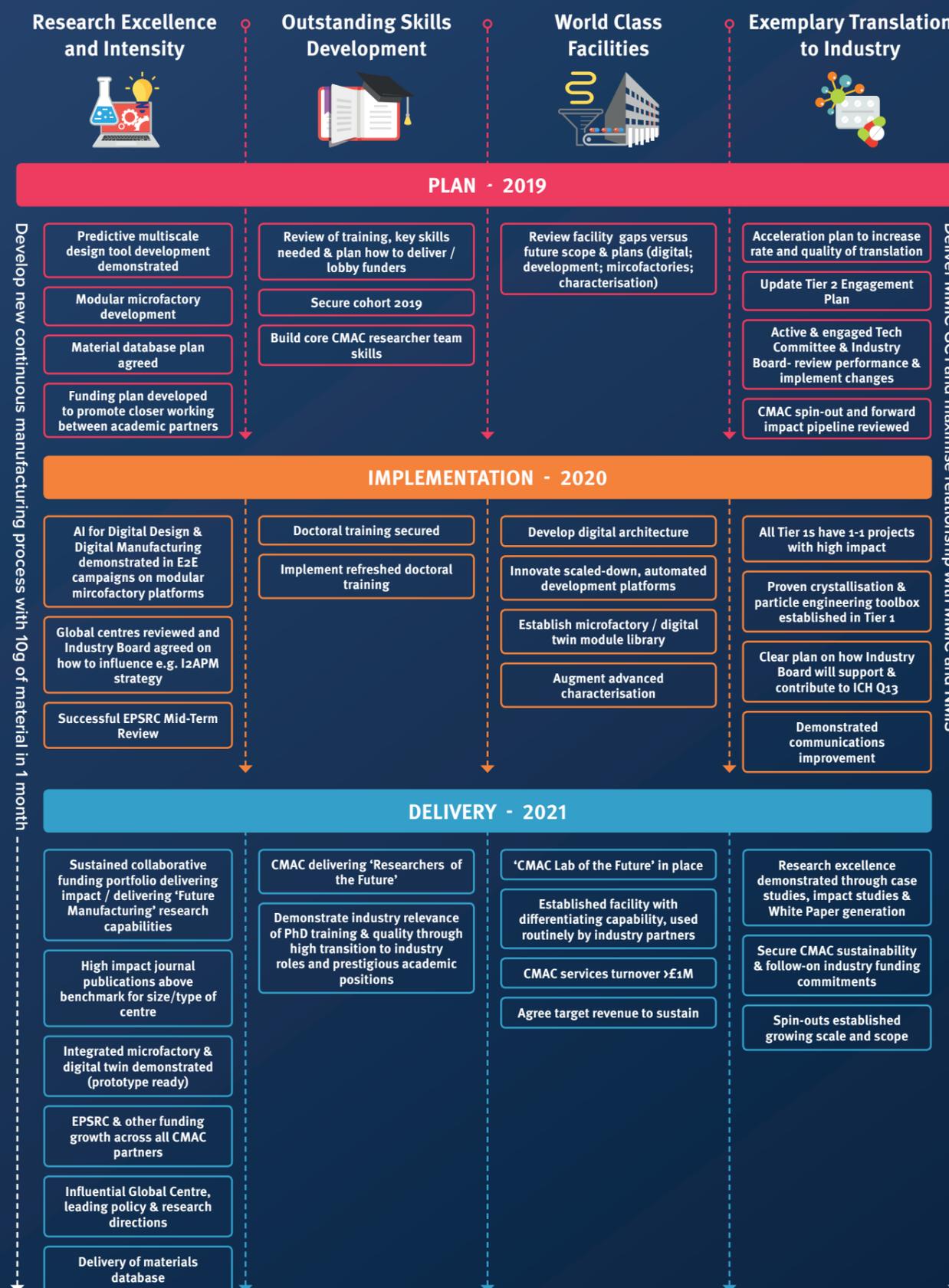
Demonstrate impact of research through best in class translation and exemplary talent pipeline.

6 Strengthen position as Global Manufacturing Research Centre.

Attract global talent and grow funding base with cutting edge facilities.

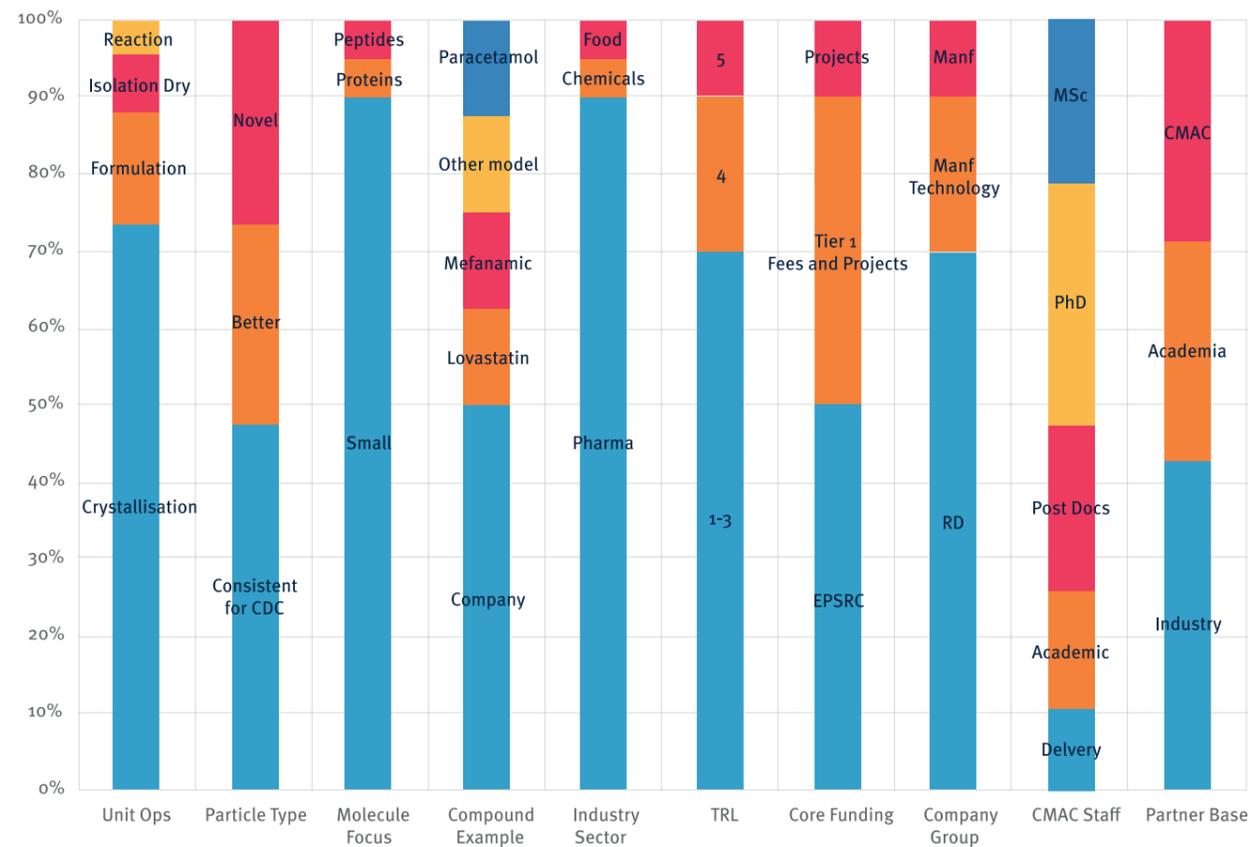
Making it Happen

IMPLEMENTATION PLAN



Technical Portfolio January 2019

The entire CMAC research portfolio currently comprises over 80 projects. Our Tier 1 partner companies support collaborative research through the CMAC membership structure as well as proprietary projects, on a case by case basis. These are reviewed annually.

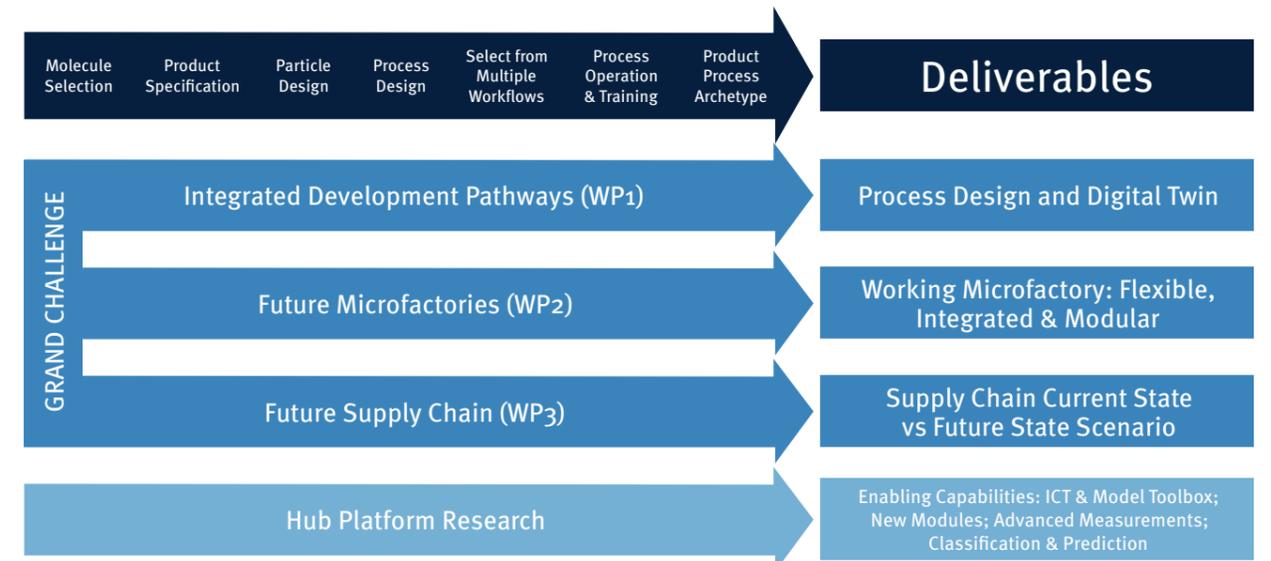


KEY WAYS THAT TIER 1S INTERACT WITH CMAC



Research Goals

CMAC's research focus will be to deliver novel manufacturing technology that will enable industry to deliver better products, quickly, economically and sustainably. This will meet the demand for reduced development time, costs and to exploit emerging opportunities driven by the urgent needs of patients and consumers for more personalised product performance.



CMAC DRIVEN BY INDUSTRY PROBLEM STATEMENTS

Detailed technology road mapping sessions in 2017. Heat map shows current relative activity against 10 problem statements. These are refreshed biannually.



Our Partners

Academic Partners



Tier 1



Tier 2



Innovation Spokes



CMAC ALSO WORKS WITH A BROAD RANGE OF COLLABORATORS.

POSITION IN JANUARY 2019





CMAC
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RESEARCH HUB

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EPSRC
Investing in research for
discovery and innovation