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ADVANCED DIGITAL DESIGN OF PHARMACEUTICAL THERAPEUTICS

A view from Several Perspectives.

Andy Jones Industrial Strategy Challenge Fund Director

Medicines MAnufacture

The Elephant an the Blind Men

AstraZeneca **Manufacturing Science and Technology**

AstraZeneca **Pharmaceutical Innovation**

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Medrus Pharma

INDUSTRIAL STRATEGY
Delivering growth, prosperity, opportunity

Pharmaceutical Innovation

Science and Technology Strategy

Innovation, Insight and IP.

Collaboration

A Pharmaceutical Innovation Perspective

GROWTH
Internal Market, Industry, Entrepreneurship and SMEs

Advanced Manufacturing Supply Chain Initiative

Region

UNITED KINGDOM › WEST MIDLANDS

Title of measure

Full title in national language:
Advanced Manufacturing Supply Chain Initiative
Duration:
2012 to 2020

Policy objectives Plus

Presentation of the measure:

The Advanced Manufacturing Supply Chain Initiative (AMSCI) is a £345m (€426m) national programme launched in 2012 providing companies with repayable loans and/or grants to cover part of the cost of undertaking one/all of the following:

- Purchase of capital equipment;
- R&D that improves manufacturing equipment, systems or processes;
- Specific training and skills development to support the project proposal.

About ADDoPT

ADDoPT is a four-year collaboration between pharmaceutical companies, solution providers and academia. Part-funded under the Advanced Manufacturing Supply Chains Initiative (AMSCI) and supported by the Medicines Manufacturing Industry Partnership (MMIP), It aims to make existing and new Digital Design approaches widely usable within the pharmaceutical industry and thereby increase efficiency and effectiveness of drug development and manufacture.

Pharmaceutical Innovation

Innovation Insight – Macro trends

- Genomics
- Digitalisation

Implications

- Market Fragmentation – the death of the megabrand
- Speed to Market –who's on the critical path

Impact

- More products with smaller market share – capacity
- Faster development targets

Manufacturing Science and Technology

The Opportunity

Can we digitise all our Development Data in order to be able to produce a “ Digital Design Space”?

Can we create a virtual model of the manufacturing Process?

Can we use the process model to define the data capture requirements from the manufacturing information?

Can we combine this process data with Input Material and Product quality data to drive process optimisation?

Can we combine manufacturing & development data to strengthen the model?

Can we use A.I. to allow the process to learn?

Can we do this continuously, dynamically, and autonomously?

The Intelligent Factory Vision:
The Big Hairy Audacious Goal The BHAG

We understand all the critical quality attributes of all our products

We have a virtual Process model for all our processes – a Digital Design Space

We combine development and commercial data to strengthen the model

The model is used to control manufacture and has the capability to learn

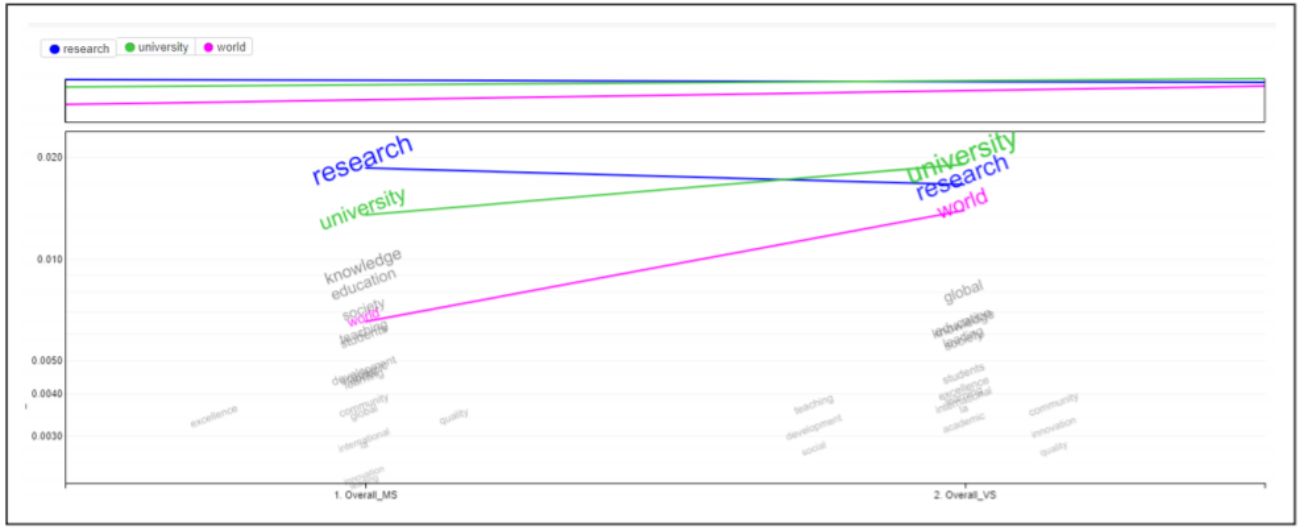
The quality of our products is controlled automatically and the processes are continuously, dynamically and autonomously optimised.

Inside ADDoPT

Healthy Tension

A four year collaboration between pharmaceutical companies, solution providers and academia .

Common areas of interest Differing Missions



Source: the author based on QS (2016) and university websites, and processed by *Voyant Tools*.

Mission and Vision Statements of Universities Worldwide - A Content Analysis

Julián David Cortés-Sánchez

with the exception of competence, environment and awareness there were no discernible similarities (*in mission statements)* in terms between private organizations and universities,

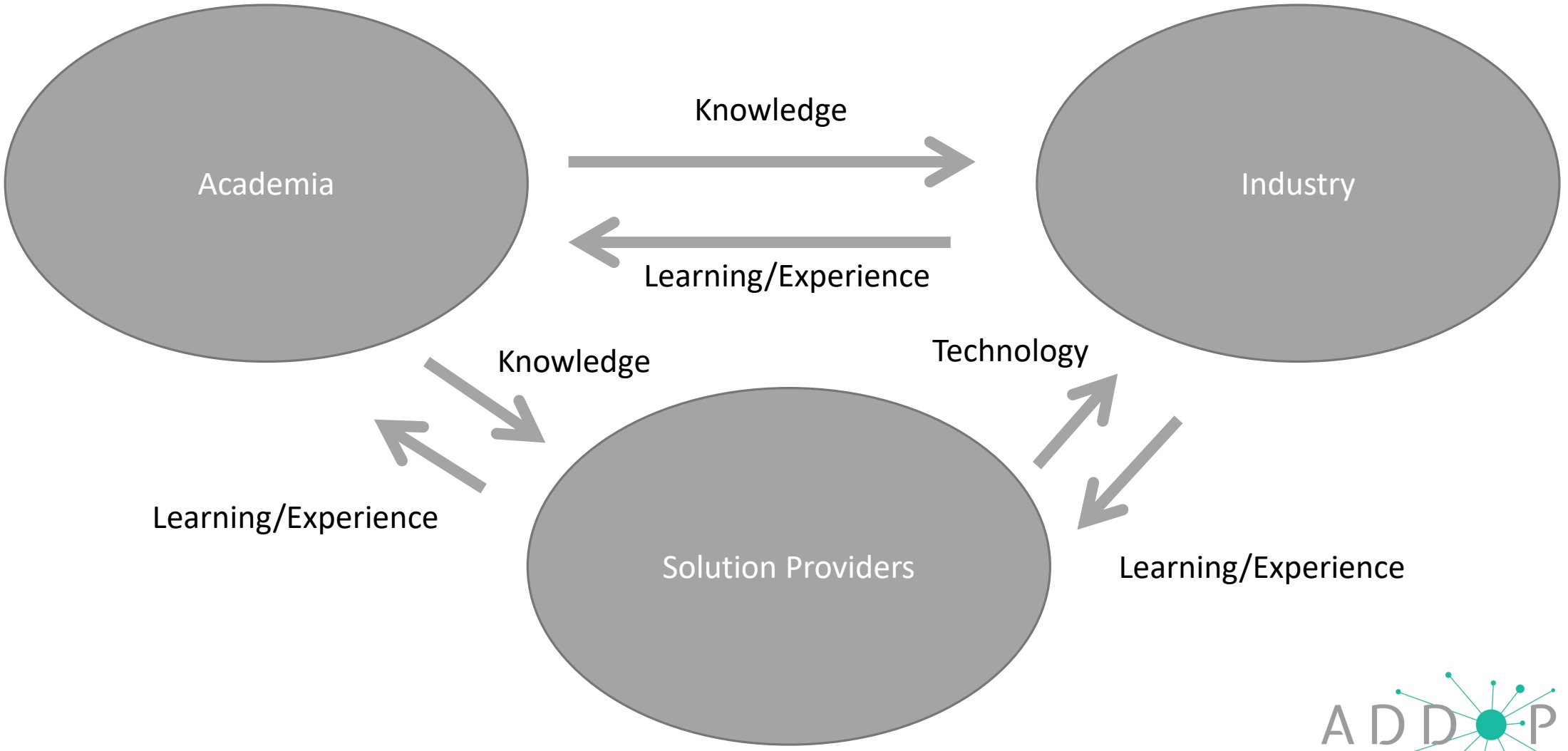
we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products.

Our mission is to help people do more, feel better, live longer. The business is focused around the delivery of three strategic priorities which aim to increase **growth**, reduce risk and improve our long-term financial performance.

to create a meaningful difference in the lives of the patients we serve and the people who work here.

To discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

The ADDoPT Advantage – A virtuous collaboration circle



Results

Using Big Data to Resolve Tablet Sticking Issues

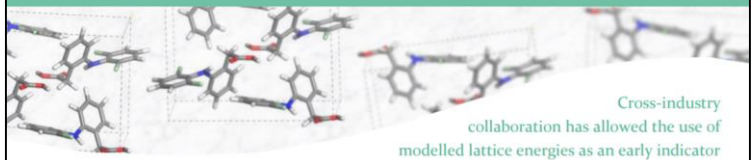
Holistically mapping material attributes to a challenging manufacturing KPI

Drivers

An all-encompassing data-driven approach is being used to fully address a processing challenge intractable to routine problem-solving methods

Lattice Energy Prediction using Big Data Approaches

Understanding and predicting API solubility early in the development cycle



Cross-industry collaboration has allowed the use of modelled lattice energies as an early indicator of API solubility to be demonstrated

Mechanistic Modelling of Powder Feeding

Predicting flow performance and mitigating process impacts for new materials

A useful, user-friendly tool for predicting powder feeder performance has been developed with the potential for further development

A Process Model for Twin Screw Granulation

Using models to optimise implementation of new technology platforms

Drivers

A cutting-edge modelling approach can dramatically reduce experimental burden without sacrificing process understanding

Understanding Powder Flow for Continuous Processing

Earlier and better decision making about how to formulate APIs successfully

Drivers

Working together to understand how to use particle fundamentals to inform an earlier choice of formulation platform for new materials

Early Stage Prediction of Crystal Morphology

Accelerating and de-risking drug development pathways and reducing costs

Drivers

Predictive modelling is allowing fast and material free risk assessment of potential for morphology related processing issues in early in development

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The Present and (near) Future

Medicines Manufacturing

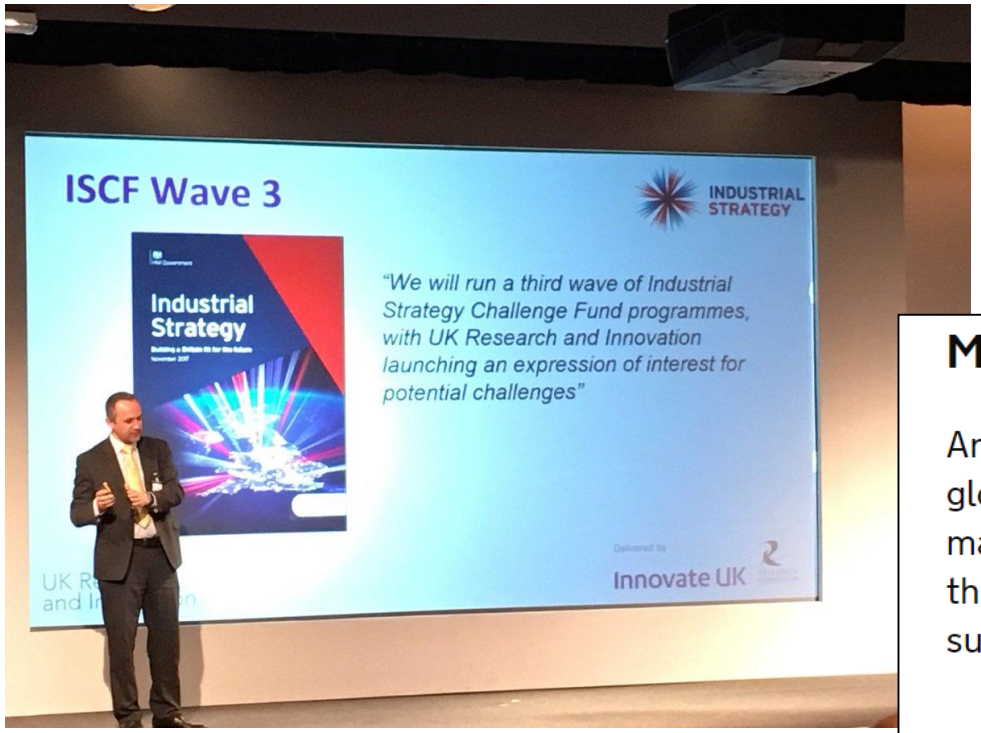
The **MMIC** is intended to help the UK lead the world in the development of new technologies and processes in small molecule **pharmaceutical** and fine chemical **manufacturing**. This is how the majority of **medicines** are currently made and the **centre** is intended to boost capabilities in these forms of **manufacturing medicines**. 18 Jun 2018

Faster medicine: £56 million innovation centre for Scotland - GOV.UK

https://www.gov.uk/.../news/faster-medicine-56-million-innovation-centre-for-scotland

MMIC is a huge Opportunity to demonstrate the Utility of Digital Design and Manufacture

Industrial Digitalisation



Manufacturing made smarter

Another announcement from Budget 2018, this challenge will make the UK a global leader in industrial digitalisation, delivering a 30% increase in manufacturing productivity by 2030. The challenge aligns with the vision of the Juergen Maier led Made Smarter review and has significant cross-sector support.

- Subject to business case and match funding from industry, government has announced that it is prepared to invest up to £121 million in this challenge