

# Innovate UK Transforming Medicines Manufacturing Community of Practice

## Workstreams Launch Event

4<sup>th</sup> October 2023 - Zoom



# House keeping:

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- Please keep microphones and videos off if you are not participating.
- During Q&A sessions please raise your hand if you would like to speak
- If you haven't already done so please sign up to the TMM CoP mailing list to hear about upcoming activities, events and outputs.

<https://info.ktn-uk.org/p/2VFU-F2M/medicines-manufacturing-cop>

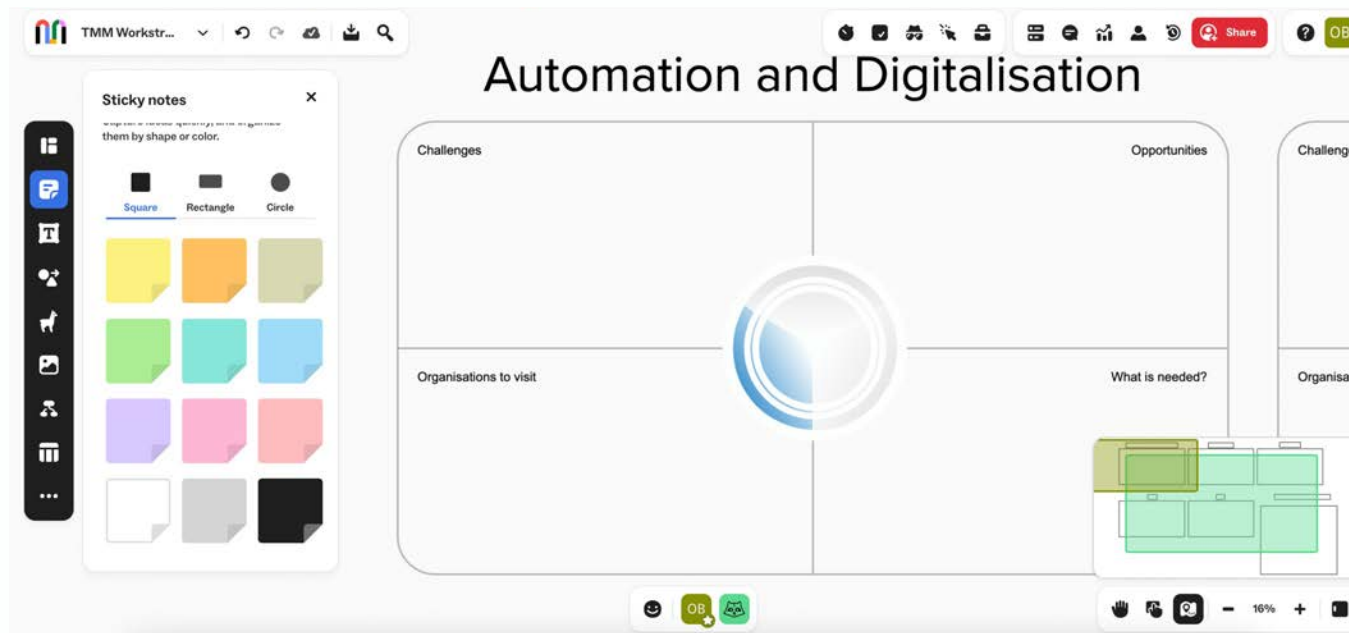
- You can also find more at the website:

<https://iuk.ktn-uk.org/programme/medicines-manufacturing/community-of-practice/>



# Mural Boards:

- Throughout presentations there will be an interactive mural white board open in the background where you can add ideas.
- No need to register – just start adding your thoughts ([https://bit.ly/TMM\\_Mural](https://bit.ly/TMM_Mural))
  - Challenges that you face
  - Opportunities we should leverage
  - Names of organisations you would like to visit
  - (HOST) Name of your organization if you'd be happy to host
  - What type of interaction/event/workshop you think would help



# Agenda:

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10:00-10:15	Introduction to the Transforming Medicines Manufacturing programme, the Community of practice and what we hope to achieve	Hari Markides
10:15-11:15	Introduction to the workstreams and associated themes:  Workstreams: Digitalisation and Automation Manufacturing Formulation Themes: Skills Equality and Diversity	Joana Da Silva (Chair)  Dave Berry Owen Bain Aleksandra Singh Fiona McLaughlin Karen Souza
11:15-11:30	Break	
11:30-12:15	Interactive session: Information gathering helping the CoP to understand what the sector wants/needs	Owen Burbidge (Chair)
12:15-12:30	Looking to the future and closing remarks	Hari Markides and Mark Talford

# 10:00-10:15

## Introduction to Transforming Medicines Manufacturing

Hari Markides

Add your ideas onto the mural board:  
[https://bit.ly/TMM\\_Mural](https://bit.ly/TMM_Mural)

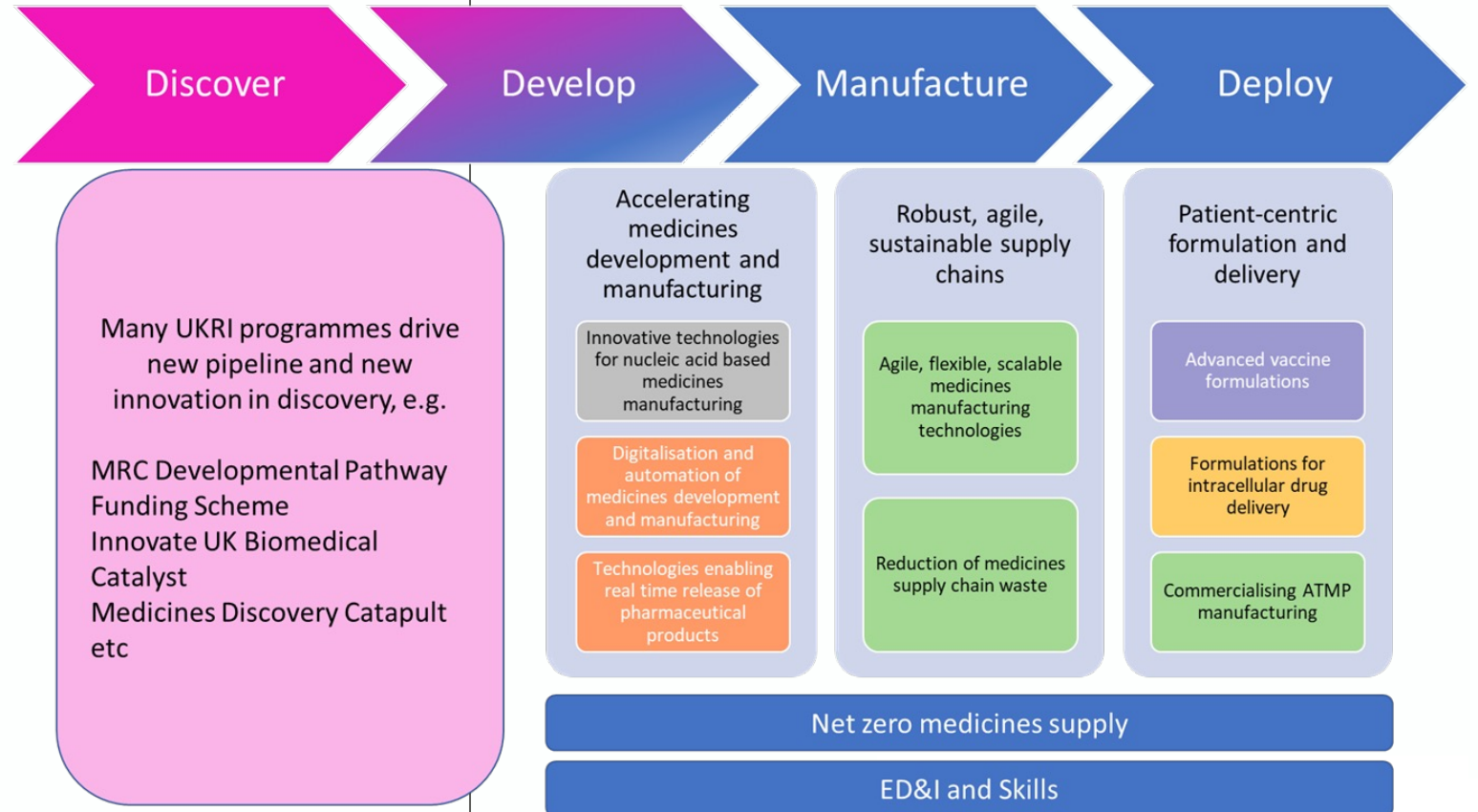


# Innovate UK Transforming Medicines Manufacturing (TMM) Programme

£45M confirmed investment between 2022 and 2025

## Priority themes:

- Nucleic Acid Based Medicines Manufacturing
- Intracellular Drug Delivery
- Digitalisation and Automation
- Flexible, Agile and Scalable Manufacturing Technologies
- Simplified Delivery of Complex Medicines



# The TMM Community of Practice

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## **Bring together all stakeholders in UK Medicines Manufacturing**

- Help organisations to innovate, form new collaborations, discuss common challenges and support each other with identifying solutions – a “safe space”
- Drive engagement with allied sectors
- Provide opportunities for people at all career stages to interact with others outside of their own organisations

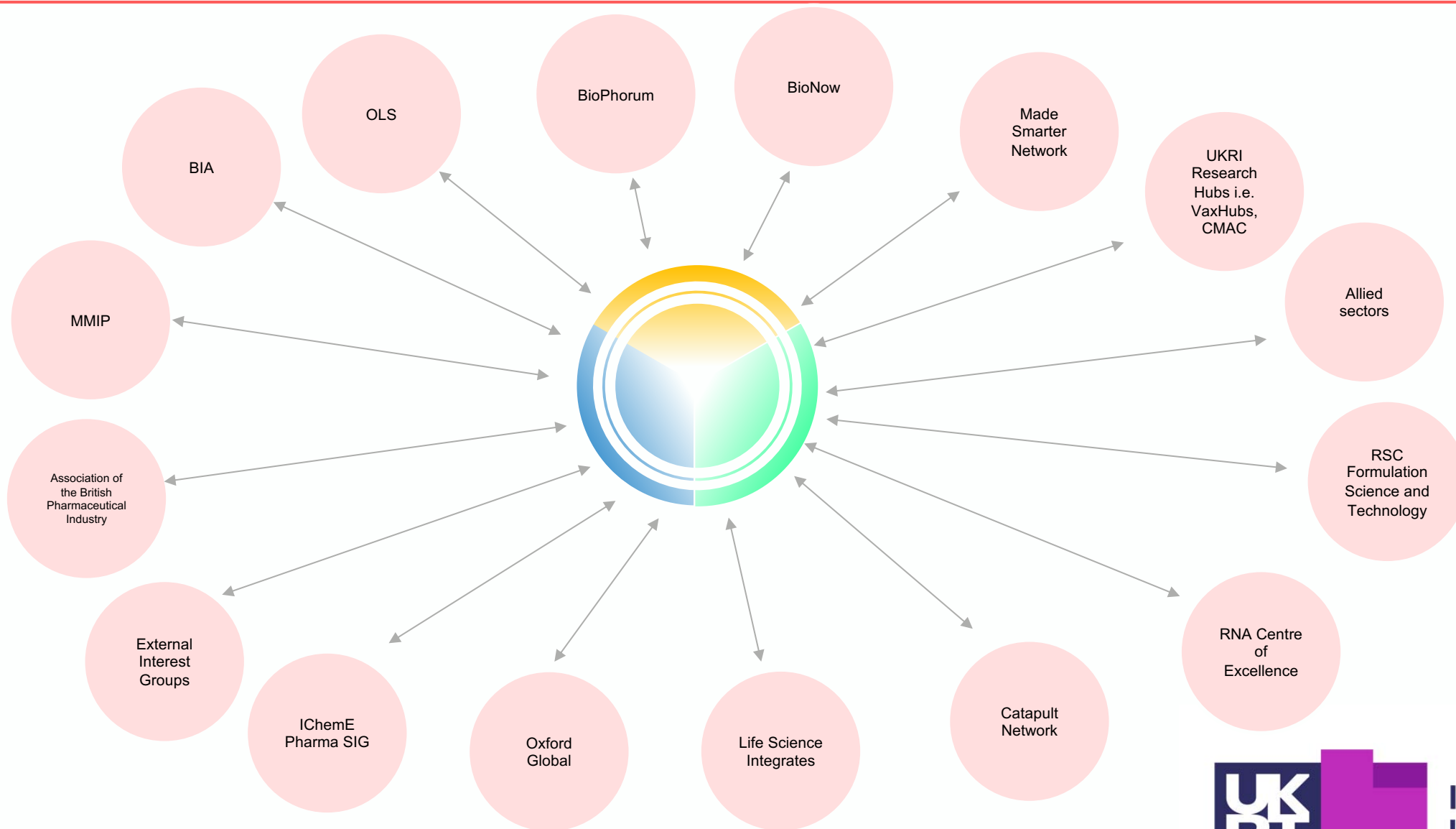
## **Provide a broad input into the medicines manufacturing sector strategy**

- Feed into and support the trade associations and MMIP long-term strategy
- Support Innovate UK and Innovate UK KTN in shaping future medicines manufacturing innovation support
- The CoP shouldn't replicate or duplicate existing activities but strengthen these

**Ultimate goal is to become self-sustaining**



# The Community of Practice and the wider sector





# Community of Practice structure, workstreams and themes

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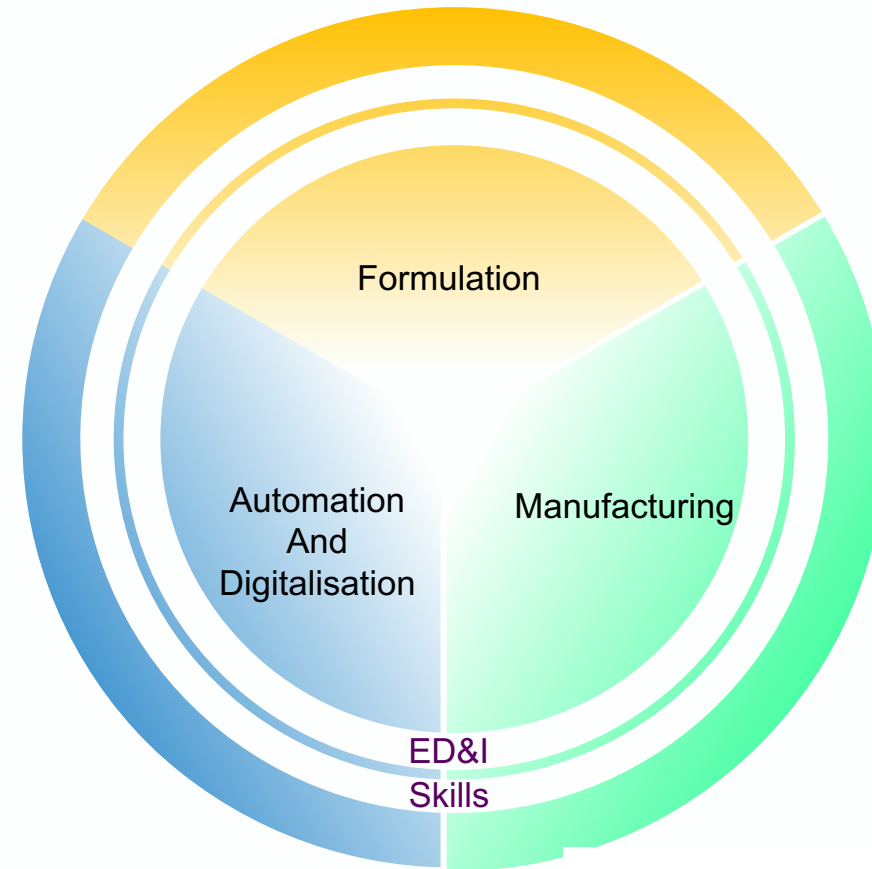
## 3 workstreams

- Automation and Digitalisation
- Manufacturing
- Formulation

## 2 overarching themes

- Equality, Diversity and Inclusion
- Skills

## 1 Community for the Medicines Manufacturing sector



# Who is involved in the TMM Community of Practice?



**10:15-11:15**

# **Introduction to Community of Practice workstreams and associated themes**

**Chair: Joana Da Silva**

**Dave Berry**

**Owen Bain**

**Aleksandra Singh**

**Fiona McLaughlin**

**Karen Souza**

**Automation and Digitalisation**

**Manufacturing**

**Formulation**

**Skills**

**Equality, Diversity and Inclusion**

**Add your ideas onto the mural board:**

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**Innovate  
UK**

# Automation and Digitalisation

Dave Berry

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# Automation and Digitalisation Workstream

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Melissa Hanna-Brown  
Pfizer



Dave Berry  
CPI



Kwok Pang  
Autolomous



Charles Heise  
Fujifilm Diosynth  
Biotechnologies



Graham McCreath  
Fujifilm Diosynth  
Biotechnologies

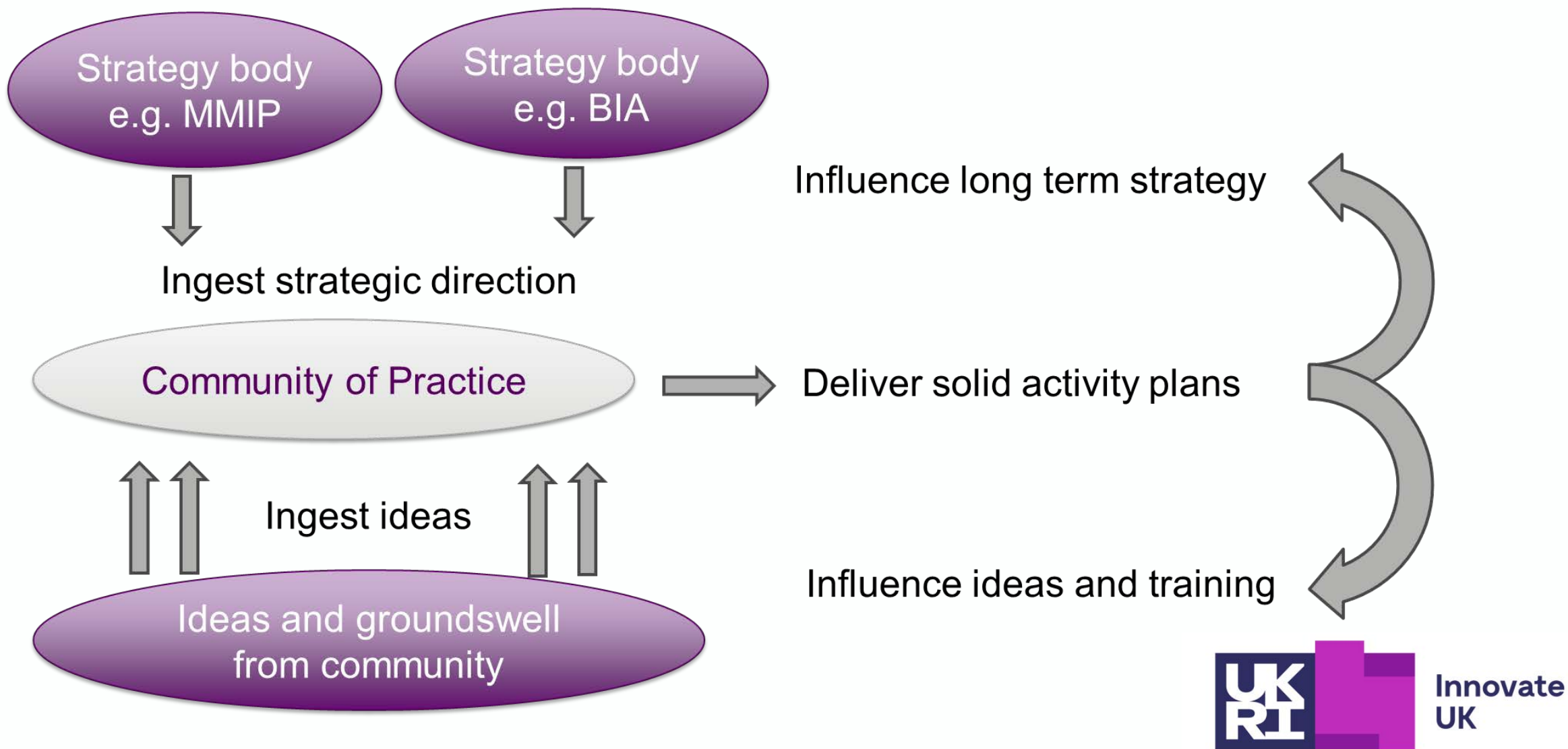


Blair Johnston  
University of Strathclyde



Apprentice  
TBD

# How will the workstream operate - we need you!



# Hot Topics- CGT and Personalised-Medicines perspective

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**Autologous manufacturing** - Manufacturing intensification ( today, ~10 parallel products in single cleanroom, Next generation technology innovators are aiming to 5x )

- Automation to support simplification, reduce reliance on high skilled labour, mitigate scale up risk, streamline data capture, drug certification and drive down costs of goods

## Point-of-Care manufacturing

- Close to patient manufacturing
- Digitisation will support
  - Regulation- Federated hub and scope manufacturing control strategy
  - Real-time visibility- location to location comparability

## Manufacturing technologies

- Process Analytical Technologies- shift to continuous improvement
- Next gen manufacturing platforms
  - Federated /accelerated fleet learning ( eg. Telsa autopilot)
  - New business models IDMO (Cellares - Integrated development manufacturing organisation. Vertically integrated strategy- manufacturing hardware and CDMO offering combined)
- Unlocking capability to build digital twins
  - Resource optimisation
  - Capacity forecasting



# Hot Topics- Recombinant Protein Production perspective

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- **Autonomous manufacturing**
  - Automation to reduce reliance on high skilled labour, streamline data capture and accelerate drug substance disposition
  - Automation to support continuous operations for time-based scale-out
  - Automation for deviation prediction
- **Manufacturing technologies**
  - Process Analytical Technologies
    - Increased data acquisition (quantity and frequency)
    - Enhanced measurement capabilities (e.g. full spectrum spectroscopy)
  - Next gen manufacturing platforms
    - Predictive/adaptive Control Strategy
    - End-to-end integrated processes
  - Unlocking capability to build digital twins
    - Reduced process optimisation and technology transfer activities
    - Process and resource optimisation
    - Capacity forecasting



# Hot Topics- How will we work ideas into action?

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## Medicines Manufacturing Data Institute (what we think it is)

- Provide a platform for sharing of blinded data
- Provide and police security standards that assured all party data in a zero-trust fashion
- Deliver and maintain standards for materials property data (first deliverable) as well as for manufacturing data (secondary deliverable) re. what to record, how to record it and how to safely share it
- House and connect companies to a training centre to educate and inform re. best modelling and data science practices re. desired company outcomes

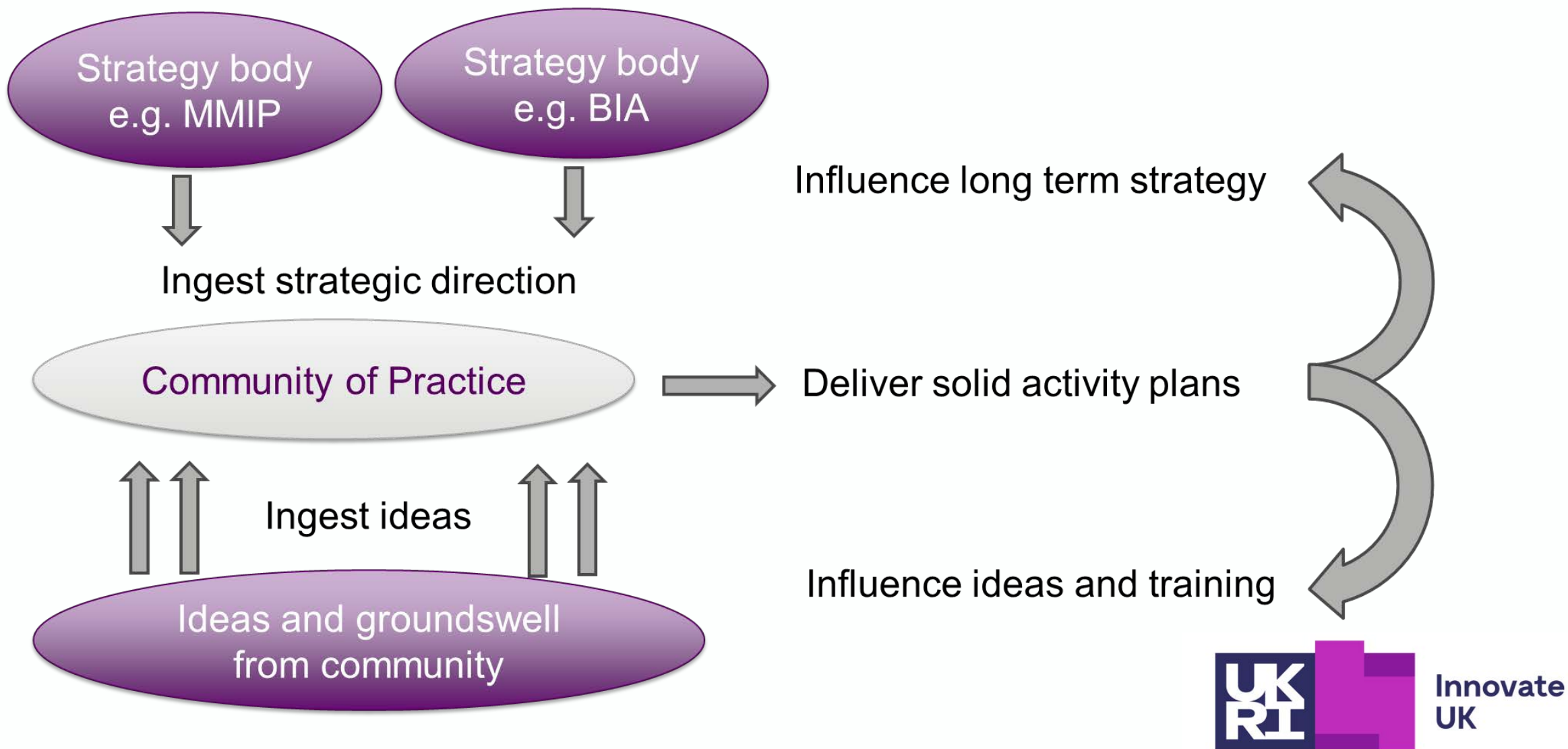
**We need you to turn it into an actionable program**

**We will put a call out for a meeting in November to discuss it and use that as a means of templating the CoP's ways of working**

**Please speak to us later to say how you can help us put these ideas into actions**



# How will the workstream operate - we need you!



# Driving change for advanced medicine manufacturing

Owen Bain

Add your ideas onto the mural board:  
[https://bit.ly/TMM\\_Mural](https://bit.ly/TMM_Mural)



# Manufacturing Workstream

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Gareth Jenkins  
Quotient Biosciences



Owen Bain  
Royal Free Hospital



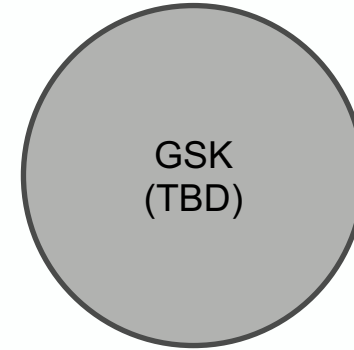
Lee Dunham  
Cell and Gene Therapy  
Catapult



Karen Coopman  
Loughborough University



Emelia Reyes Pabon  
Oxford BioManufacturing Facility



GSK  
(TBD)

GSK  
TBD



Innovate  
UK

# Collaborations for the CoP

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Each sector has its own affiliated groups

For example the Advanced Therapy Manufacturing Community (AMC)  
Advanced Therapy Treatment Centres.

Leverage members' affiliations within workstream and community

# Supporting the MMIP

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Understanding through the community of practice what the key obstacles are.

What cutting edge manufacturing technology is a game changer and what is hype.

Where funding is needed to derive the largest impact

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## Problems

- Sustainable manufacturing
- Accelerated clinical development
  - Less time to develop a process
- Scaling
- Continuous manufacturing
- Not enough experienced staff

## Opportunities / Solutions

- Can AI solve all the problems?
- Learning from other industries and medicine types
- Apprenticeship schemes

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**The Obstacle is the Way**



# Future formulation - how can we shape it together?

Aleksandra Singh

Add your ideas onto the mural board:  
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# Formulation Workstream Introduction

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Elena Sanna  
Sixfold Bioscience



Aleksandra Singh  
Sixfold Bioscience



Yvonne Perrie  
University of Strathclyde



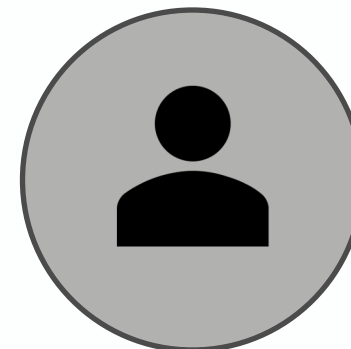
Richard Storey  
AstraZeneca



Ali Al-Khattawi  
Mesox



Farai Carter  
CPI



Rushil Patel  
Cell and Gene Therapy Catapult

# Collaboration with existing initiatives in the area

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<https://www.apsgb.co.uk/>



<https://cmac.ac.uk/about>



<https://pharmahub.org/groups/lyo>



<https://iqconsortium.org/>

## Strategy:

- We want to ensure our presence in already known initiatives
- Bottom up search for innovators and SMEs
- To get involved in the wider ecosystems to bring ideas and hot topics



# Support to MMIP and others in positioning the sector formulation needs

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- Provide regular update to MMIP on current trends in pharmaceutical formulation
- Stronger involvement of innovative SMEs in shaping the future of Medicine Manufacturing
- Stronger links with venture funding making the case for investment in future formulation platforms
- Easier access to high risk - high reward type of grant funding to support the innovation ecosystem with next generation formulation technologies



# Current hot topics in formulation

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- **Improvements in** - continuous processes | sustainability | efficiency | quality | robustness
- **Lipid nanoparticles** - Formulation expertise and skills development (CPI's RNA Centre Of Excellence + training academy and the Intracellular Drug Delivery Centre in partnership with CPI, University of Strathclyde, University of Liverpool and ICL funded by IUK TMM) <https://www.uk-cpi.com/about/national-centres/rna-centre-of-excellence> and <https://www.uk-cpi.com/news/novel-drug-delivery-one-stop-shop>
- **Complex injectables formulation development** - Untapped potential for easier patient access to cost-effective therapeutics
- **Stable drug formulations** - which maintains structures and permits convenient dosage and storage still remains a challenge <https://www.astrazeneca.com/r-d/next-generation-therapeutics.html>
- **Stabilisation of vaccines** - Formulation technologies and future scoping for pandemic preparedness
- **Non-Invasive systemic drug delivery systems** - Intranasal, buccal/sublingual, pulmonary, and transdermal routes
- **Digital formulation platforms** - Plugging the gap between *in silico* drug discovery models for lead discovery and later PK/PD models - towards an integrated and accelerated molecule-patient bedside medicine development journey
- **Enhancing UK's position** and competitiveness in the above is essential as most platforms are owned by players overseas

# Skills

Fiona McLaughlin

Add your ideas onto the mural board:  
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# Overview

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- The Life Sciences Vision set a broad ambition for skills
- At the life sci growth moment, we secured £6.5m to support medicines manufacturing skills
- Skills have been put at the heart of the Community of Practice
- Looking Forward

# The Life Sciences Vision set a broad ambition for skills

There are a unique set of skills and training needs in life sciences, requiring talent routes and associated HMG initiatives to keep pace with advances in science and evolve to meet the needs of the sector.

We are taking a two-pronged approach to support the sector by:

## Developing talent onshore through domestic skills and training policies and programmes

Improve guidance, influence and develop policies which ensure domestic skills and training opportunities work for the Life Sciences Sector.

## Attracting talent from overseas

Collaborate across government, including with DBT, FCDO and HO to develop UK's offer to attract overseas talent and ease of navigating the UK's system.

## Our current priority areas for the next 6-12 months include:



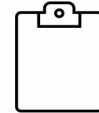
Allocation of the £6.5m to strengthen the UK's Medicines Manufacturing ecosystem.



Enhancing life sciences investor skills.



Policy development on digital and data skills.



Collaboration with MHRA and others to ensure that life sciences regulatory systems can access the talent it needs to keep pace with novel technologies.



Working with our expert group (Futures Group) and industry groups (including MMIP).



## At the life sci growth moment, we secured £6.5m to support medicines manufacturing skills

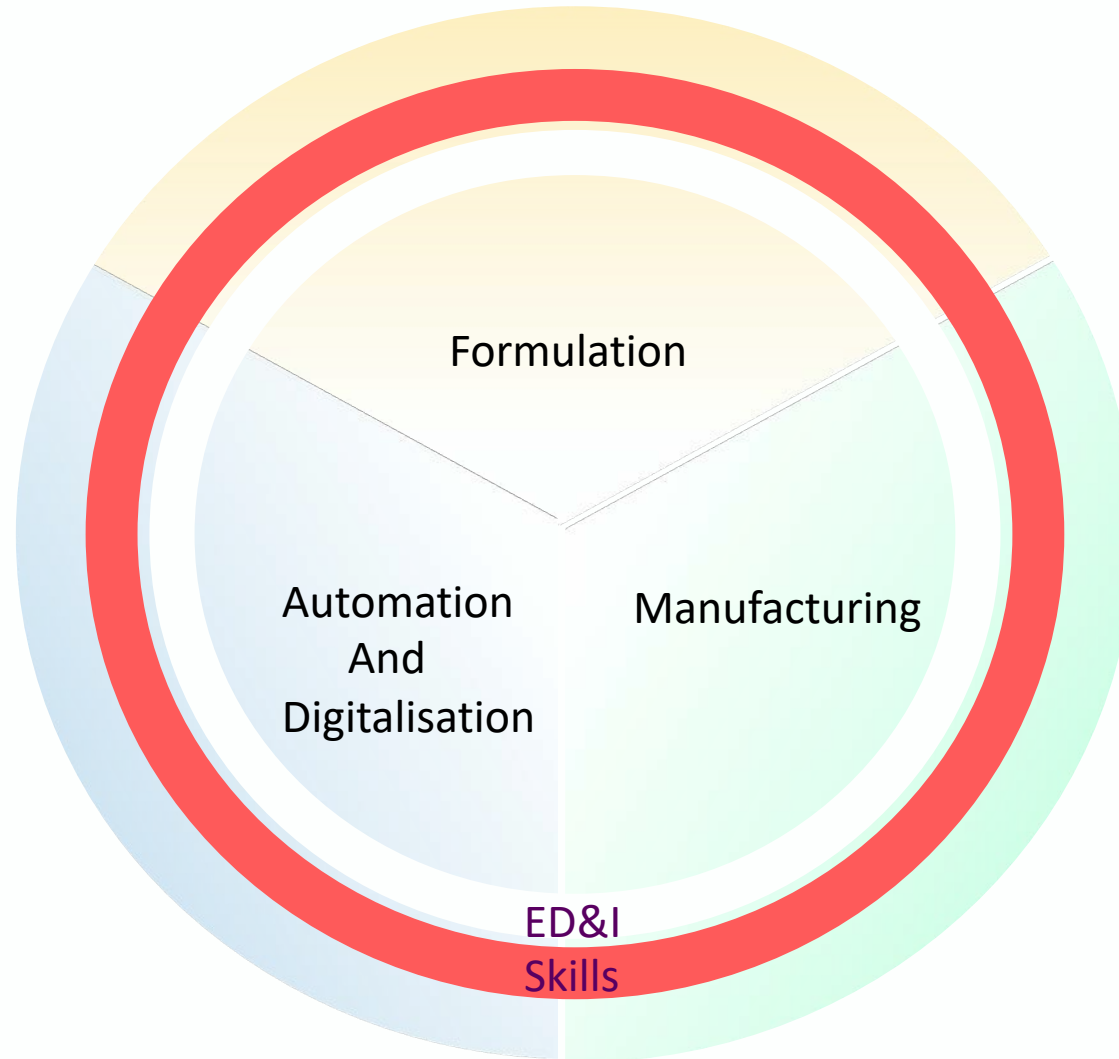
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- At the Chancellor's Life Sciences Growth moment in May, we secured £6.5m for Medicines Manufacturing Skills.
- On 5 September we announced £5.5m of our life sciences growth funding would be used to establish a medicines manufacturing centre of excellence.
- The competition is now live and closes on the 22<sup>nd</sup> November 2023 at 11:00am
- Key considerations for the CoE and our work:
  - Clarity for the sector through coordination
  - Growing the marketplace
  - Targeting key challenges that exist across the talent pipeline



# Skills have been put at the heart of the community of practice

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## Looking forward

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- There are a wealth of industry groups and trade associations who are very active in this space already– MMIP, SIP Futures Group, BIA, ABPI for the CoP to engage with.
- The Medicines Manufacturing Skills Centre of Excellence will be a key partner in this space once established.

# Equality, Diversity and Inclusion

Karen Souza

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# EDI in Medicines Manufacturing



Innovate UK

**Businesses consider diversity  
and inclusion in their approach  
to innovation**

**A connected, more inclusive  
innovation system**



# Why does inclusion in innovation matter?

McKinsey  
& Company

Companies with executive teams in the top quartile for gender diversity are 25% more likely to outperform their competitors on profitability than those in the lowest quartile. This rises to 36% for ethnic diversity.

<https://www.bcg.com/publications/2018/how-diverse-leadership-teams-boost-innovation>

BCG  
BOSTON  
CONSULTING  
GROUP

In both developing and developed economies, companies with above-average diversity on their leadership teams leads to more and better innovation and improved financial performance.

<https://www.bcg.com/publications/2018/how-diverse-leadership-teams-boost-innovation>

Deloitte.

Organisations with inclusive cultures are 2 times as likely to meet financial targets, 3 times as likely to be high performing, 6 times more likely to be innovative and agile and 8 times more likely to achieve business outcomes.

[https://www2.deloitte.com/content/dam/insights/us/articles/4209\\_Diversity-and-inclusion-revolution/DI\\_Diversity-and-inclusion-revolution.pdf](https://www2.deloitte.com/content/dam/insights/us/articles/4209_Diversity-and-inclusion-revolution/DI_Diversity-and-inclusion-revolution.pdf)



# What are the consequences of exclusion in innovation?

**THE CONVERSATION**  
Academic rigour, journalistic flair

COVID-19 Arts + Culture Business + Economy Cities Education Environment + Energy Health + Medicine Politics



**Gender bias in medicine and medical research is still putting women's health at risk**

March 7, 2021 7.09pm GMT Updated March 9, 2021 8.29pm GMT

**Forbes**

PERSONAL FINANCE

## A.I. Bias Caused 80% Of Black Mortgage Applicants To Be Denied

Kori Hale Contributor @  
*I'm the CEO of CultureBanx, redefining business news for minorities.*

Sep 2, 2021, 07:48am EDT

## Silent and deadly? The electric car debate



Pedestrians are 40 per cent more likely to be hit by a hybrid or electric car than by one with a petrol or diesel engine in the UK ([Guide Dogs, 2015](#)).



## There can be financial implications too!

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- 1 in 5 potential customers have a disability
- 73% of potential disabled customers experienced barriers on more than a quarter of websites they visited
- Businesses loose approximately £2 Billion a month by ignoring the needs of disabled people
- 70% of disabled people will NOT return to a business after receiving poor customer service



## Spending power of disabled consumers

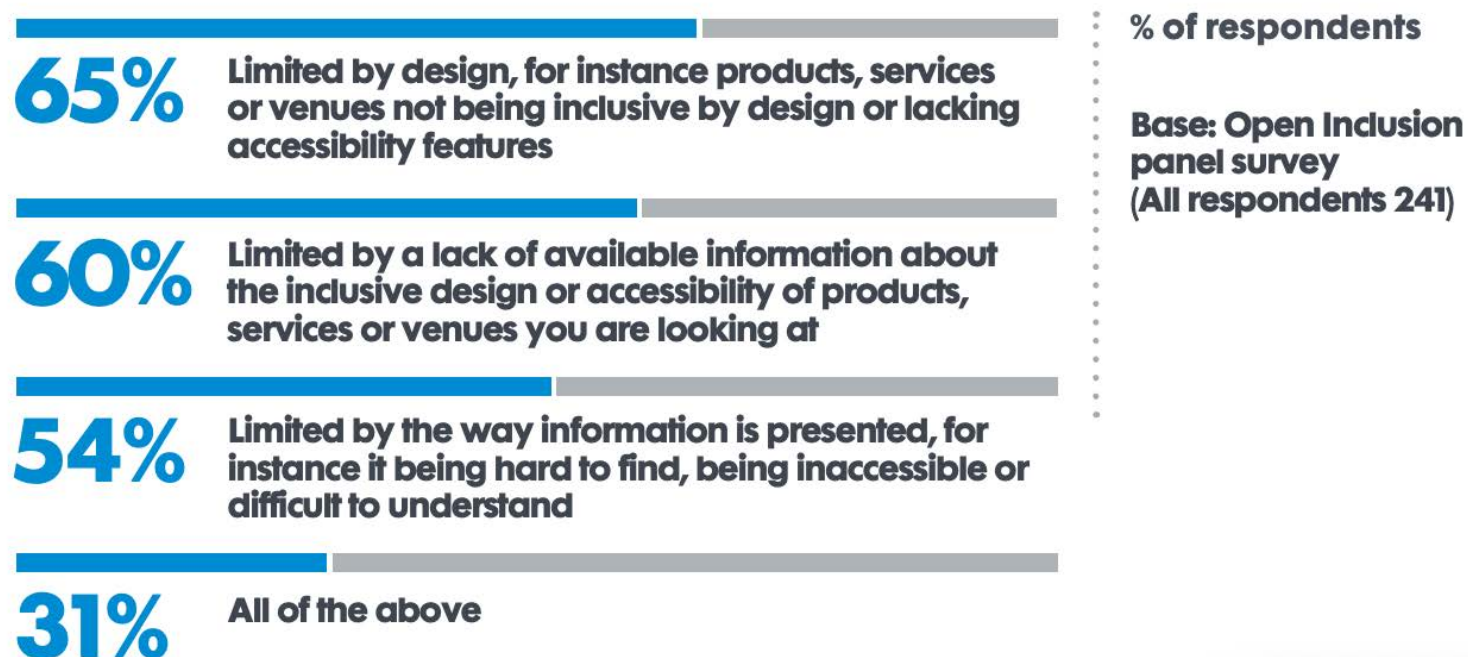
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- In the UK, it's thought that some seven million people of working age have a disability.
- They have a spending power, known as the "purple pound" worth around £274bn, and they want to spend on technology.
- This includes hardware such as TVs and phones, software such as video games, and streaming services.
- As technology has become an ever-greater part of our lives following the COVID-19 pandemic, businesses have more and more to gain from demonstrating that they are willing to meet disabled consumers' technology and customer support needs.

# Some more facts from the Business Disability Forum

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**Chart 1: Limitations for disabled customers when considering purchase of products and services**



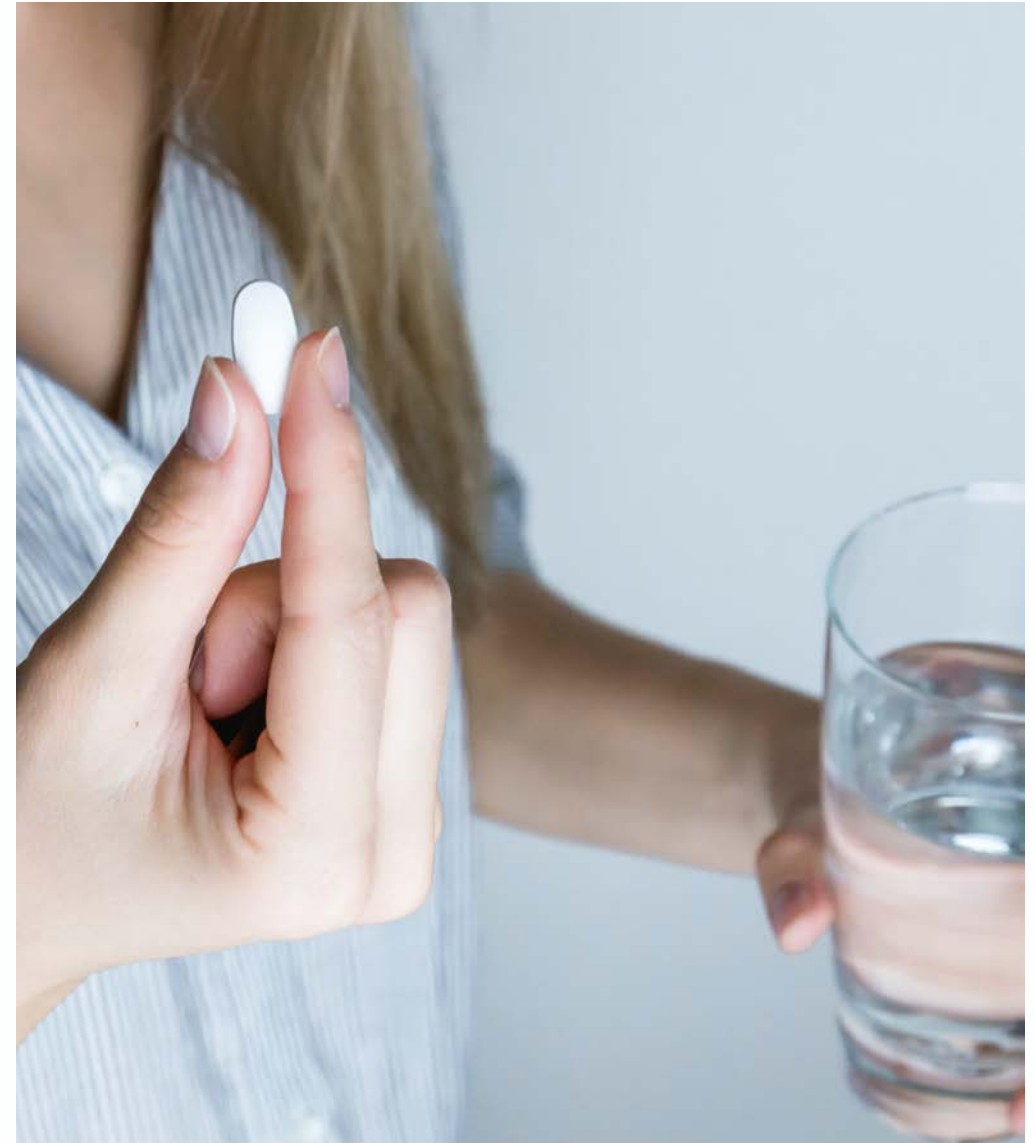
# What are the consequences of exclusion in medicines manufacturing?

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- The size of a pill may be dictated by the amount of drug and other ingredients required but is the ability to consume the product considered?
- If patients need to interfere with the construction of the drug – could this impact how effective it is?

## **Why so many pills are TOO BIG to swallow: And why it's safe to crush or cut up some - but not others**

- Drug manufacturers have total control over pills' shapes, sizes and colours
- 'They may not consider how difficult it may be to swallow a medicine'
- It is dangerous to assume you can break up big pills
- Sometimes coatings are needed for the drug to function properly



# What are the consequences of exclusion in medicines manufacturing?

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- Prescribers need to consider religious beliefs when prescribing.
- If manufacturers could mitigate this by trying to eliminate some of the main dietary restrictions could the medications be more widely accessible?



**Religious constraints on prescribing medication**

# What are the consequences of exclusion in medicines manufacturing?

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- It was reported that users experience challenges with packaging when using in non-hospital environments
- It is estimated that around a third of medication errors occur due to confusion triggered by product packaging and labelling. Such mistakes can be harmful to patients, but also costly to the health service and potentially time-consuming for pharmacists.



**Paramedic interactions with the packaging of medications and medical supplies: Poor package design has the potential to impact patient outcomes**

# What are the consequences of exclusion in medicines manufacturing?

- Some devices employing infrared light or imaging may not perform as well with patients with darker skin pigmentation, which has not been accounted for in the development and testing of the devices when patients with only a limited range of lighter skin tones were recruited
- Research suggests the way some medical devices are designed and used may be failing to account for differences related to ethnic background, gender or other characteristics - potentially exacerbating existing inequalities in healthcare.

## Views being sought to tackle inequality in medical devices

Call for evidence launched to discover if and how medical devices and technologies may be exacerbating inequalities in healthcare.





# Inclusive Innovation

All innovations are designed at the outset with diversity, and diverse users, in mind

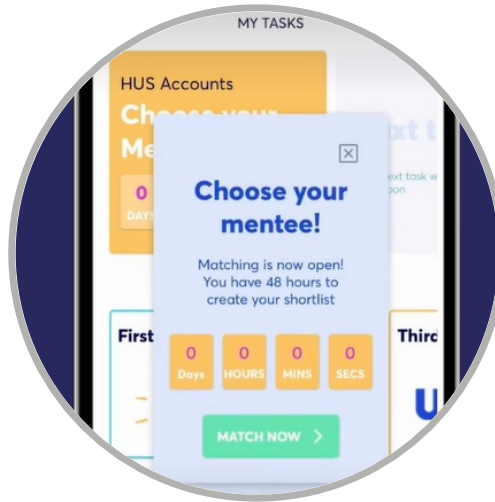


# Defining “Inclusive Innovation”

It is a **product, process, service** or **technology** that centers on **Equality, Diversity** and **Inclusion**.



Designed to support  
a specific  
demographic



Developed to be  
specifically  
accessible to all



Scaling existing  
practices to venture  
into a new market or  
to develop  
something new

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# £2.5 million investment

Supporting businesses who are role models in developing innovations that centre on equality, diversity and inclusion in their design and development.



# Get involved

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Please join our new Linked In group  
“Inclusive Innovation – Innovate  
UK”

<https://www.linkedin.com/groups/12775315/>





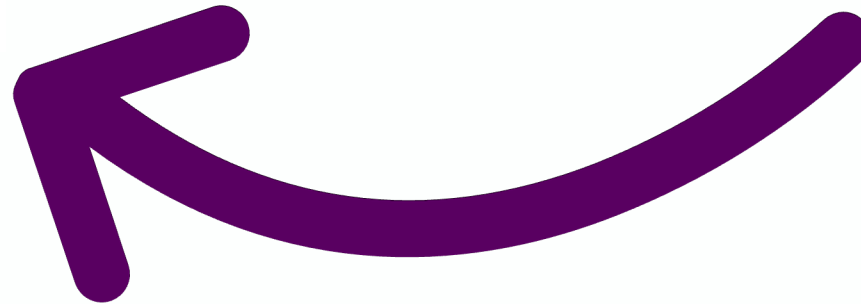
# Karen Souza

Diversity & Inclusion Partner  
Inclusive Innovation

**Innovate UK KTN**

[Karen.souza@iuk.ktn-uk.org](mailto:Karen.souza@iuk.ktn-uk.org)

Or find me on **LinkedIn**



# 11:15-11:30 Break

If you haven't already done so please sign up to the TMM CoP mailing list to hear about upcoming activities, events and outputs.

<https://info.ktn-uk.org/p/2VFU-F2M/medicines-manufacturing-cop>

Or alternatively scan the QR code



# 11:30-12:15

## Interactive session

Chair: Owen Burbidge

Go to [menti.com](https://menti.com) and use the code 3778 4691

**12:15-12:30**

# Looking to the Future and Closing Remarks

**Hari Markides and Mark Talford**

**Add your ideas onto the mural board:  
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# What you can expect going forward

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- TMM CoP face to face launch event (possibly January - date TBD)
- Series of face-to-face or online workstream led events at interesting sites across the country
- Workshops
- Monthly webinar series
- Monthly/fortnightly newsletter
- This CoP is for the community!
- Our offerings will evolve as the CoP progresses – suggestions welcome



# What's happening currently

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## Industry news/events

- Advanced Therapies Manufacturing Community – Edinburgh 8 November
- Bioprocess UK - Brighton 28-30 Nov 2023
- BioProNet – Manchester Jan 2024

## TMM/IUK News

### Flexible, Agile, Scalable and Sustainable Technologies for Medicines Manufacturing (FASST)

[https://bit.ly/TMM\\_FASST](https://bit.ly/TMM_FASST)

Opens: 26th Sept

Closed: 22nd Nov 2023

### Medicines Manufacturing Skills: Centre of Excellence

<https://bit.ly/TMMSkills>

Opens: 26th Sept 2023

Closed: 22nd Nov 2023

### Flexible, Agile, Scalable and Sustainable Technologies for Medicines Manufacturing – Grand Challenge

[https://bit.ly/TMM\\_GrandChallenge](https://bit.ly/TMM_GrandChallenge)

Opens: 16th Oct 2023

Closed: 15th Nov 2023



# Contact Us

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Roya Esat-Dabestani

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