Medicines Manufacturing Industry Partnership

abpi
Bringing medicines to *life*

BIA
UK BioIndustry Association

Innovate UK
Knowledge Transfer Network

Welcome and Introduction

Andy Evans, Chair, MMIP

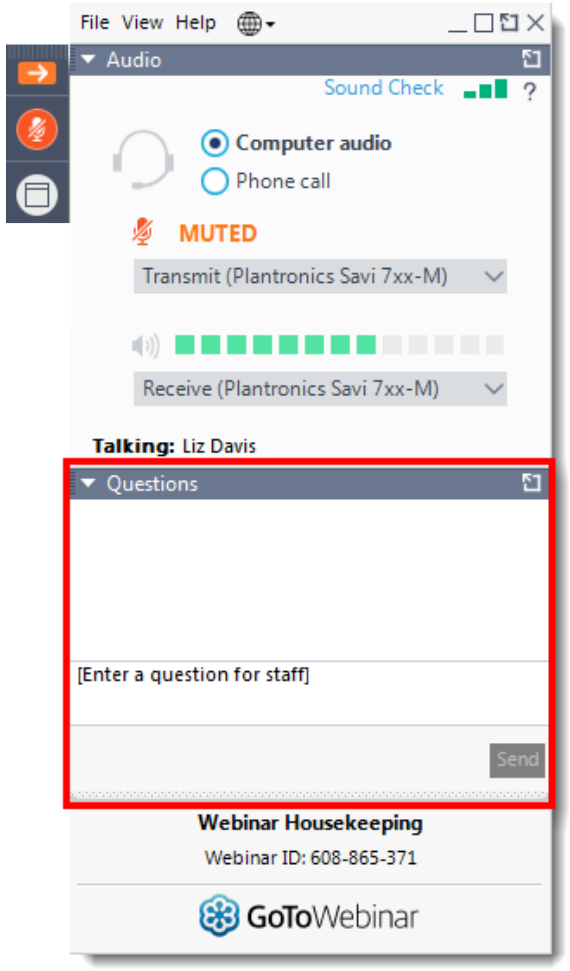
Welcome and Introduction

Professor Sir John Bell,
Life Sciences Council

Kristen McLeod
Director, Office for Life Sciences

Dr Richard Torbett
Chief Executive, ABPI

Housekeeping



Your Participation

- Please continue to submit your text questions and comments using the Questions panel we will try and get to as many as possible where time allows.

Note: Today's presentation is being recorded and slides will be made available after the webinar

MMIP

Trinity of academia, industry and government – driving manufacture of COVID-19 vaccines

Kate Bingham

Chair, UK Vaccine Taskforce

Managing Partner SV Health Investors

Andy Jones, Challenge Director: Medicines Manufacturing ISCF

Lucy Foley, Director of Biologics, CPI

Dr Catherine M. Green, Associate Professor, Head of the Clinical BioManufacturing Facility, University of Oxford

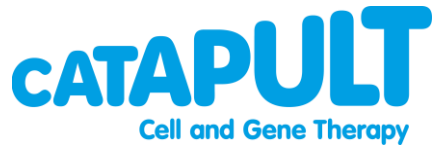
Prof. Daniel C Smith, Chief Scientific Officer, Cobra Biologics

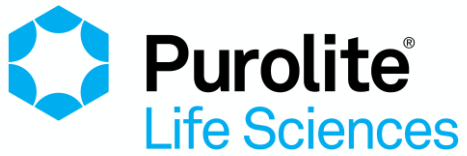
Mark Proctor, Global Supply & Strategy Snr. Director, AstraZeneca

Ian McCubbin OBE, Independent Pharmaceutical Professional

BIA COVID-19 Vaccine Taskforce members

BIA
UK BioIndustry Association





Blood and Transplant

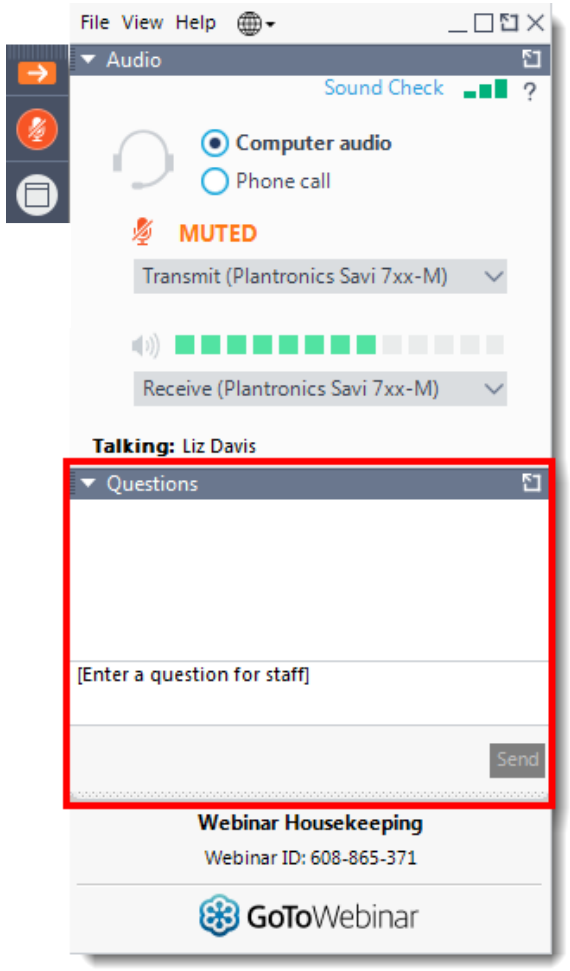
www.bioindustry.org

BIA COVID-19 Vaccine Taskforce members

UK BioIndustry Association

www.bioindustry.org

Housekeeping



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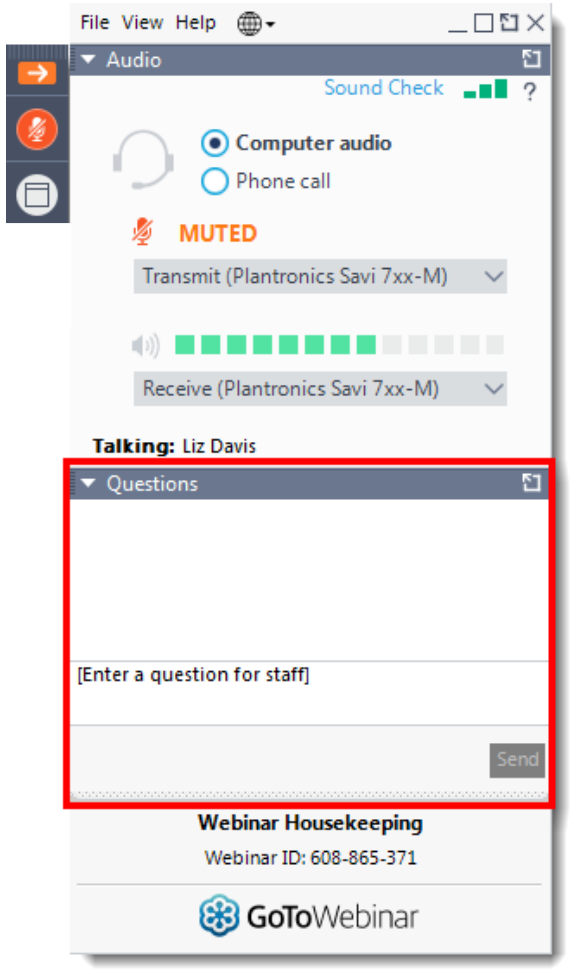
Questions?

Break

Back at 12:20

Housekeeping



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MMIP Workstream Updates

Technology & Innovation

Martin Wallace, GSK

Technology & Innovation Workstream

Name	Affiliation	Theme
Katie Murray	AZ/MMIC/HVMC	Small Molecule
Lucey Foley	CPI Biologics	Large Molecule
Julie Anderson	CPI Strategy	General/Secretariat
Martin Wallace	GSK	General/Lead
JP Sherlock	AZ	Small Molecule
Bob Docherty	Pfizer	Digital & Analytics
James Miskin	OxfordBiomedica	ATMP
Sarah Goulding	KTN	Large Molecule/AT
Stephen Ward Damian Marshall	ATMP/HVMC	ATMP
Kit Erlebach	Fujifilm **D**iosynth BIA/MAC	Large Molecule
Melissa Hanna Brown	Pfizer, Analytics (CAMS)	Small Molecule
Karen Wilkinson	KTN/Made Smarter	Digital
Nick Medcalf		
Anna Mereu	Innovate UK/Medicine Challenge	General
Patrick Hyett	GSK	Digital

Critical Questions to consider for technology Roadmapping

- What are the drivers we need to consider in the future?
- Where do we want to be in 2030?►
- What are the opportunities that will be afforded based on advances in science and technology?
- What are the current barriers to adopting this technology?

MMIP T+I Roadmap: Grand Challenges for 2021 and beyond

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

Infrastructure

Strategic Grand Challenges

Current

- Digitalisation
- Continuous Manufacturing
- ATMPs manufacturing & delivery

Potential Future

- Robust Agile Supple Chains
- Micro Flexible Factory
- A Net zero approach to medicines manufacture
- Modular, flexible Sterile Manufacture
- Advanced Bioprocess Manufacturing & Control
- Intracellular drug delivery

Technology opportunities

Digital Design – from Molecule to patient

On Demand Manufacturing

On Demand Sterile manufacturing capacity

Real time release for Advanced Therapies

Initial MMIP T+I Roadmap: Programmes and potential Projects that underpin the GCs

Deliver a more agile, adaptable, scalable, sustainable medicine manufacturing ecosystem that will deliver medicines to patients faster in a more sustainable way.

Robust Agile Supply chains

- Molecule to Patient
- Expanding the impact of process intensification

- API to DP Connectivity
- Drug Product Digital twins
- Small batch process intensification

Intracellular Delivery

- Lipidic & Polymeric Nanoparticles
- Targeted Delivery

Next Generation Biopharma manufacture

- Advanced bioprocess Control
- Cell free systems
- Industrialising Viral Vector Manufacture
- Development of a smart bioreactor

- Characterisation of processes in flow
- In process control and real time release.
- Downstream processes Digital twins – e.g. Lyo
- Shortening development and production times for stratified medicines and biologics to combat emerging threats (aka cell free).

Modular Flex Sterile Manufacturing

- Cleanrooms to meet future needs
- Digitisation of sterile operations

- Cleanrooms for complex therapies e.g ADCs
- Rapid Micro
- Miniaturisation of FF operations.

Micro Flex Factory

- Factory on Demand

- Modular and Mobile factory solutions
- Digitally enabled small volume/batch factory
- Plug & Play Automation Solutions

Net Zero Medicine Supply

- Delivering alternative green manufacturing processes for existing therapies
- Delivering Net Zero manufacturing processes for new therapies

- Alternative Oligo Manufacturing
- Delivering more sustainable manufacturing processes
- Net Zero supply chain of the future.

Roadmap refresh

- We are in the process of updating the technology roadmap
  - Last roadmap issued in 2017 (A lot has changed since then!)

- We will use this revised roadmap to help align all relevant stakeholders to deliver more agile, adaptable, scalable, sustainable medicine manufacturing ecosystem that will deliver medicines to patients faster in a more sustainable way.

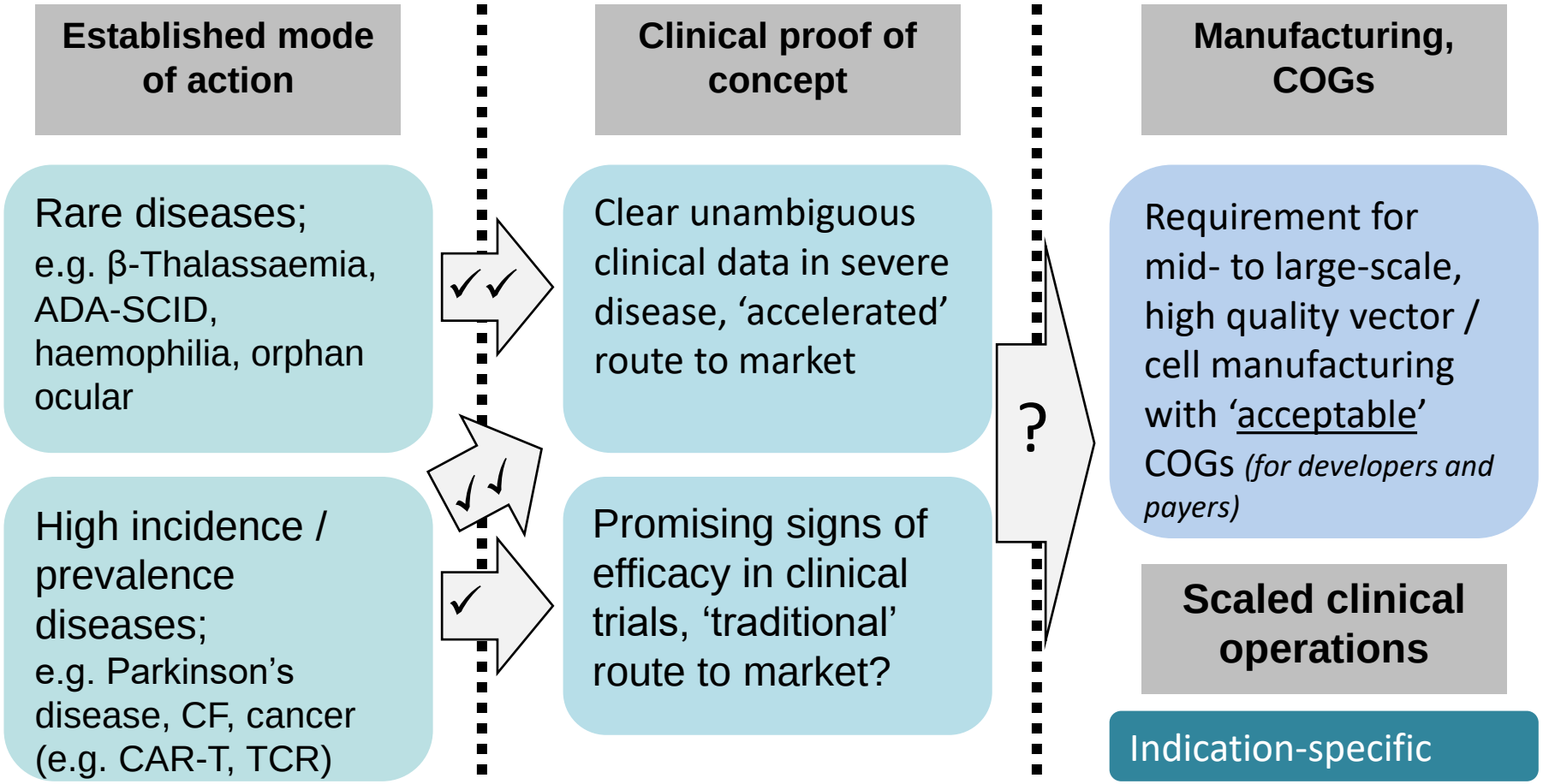
Advanced Therapies Workstream - update

James Miskin

MMIP Advanced Therapies Work Stream Lead

July 2020

Advanced therapies – a new treatment paradigm



ATMP CMC is extremely complex therefore manufacture is 'sticky'

MMIP Advanced Therapies Work Stream

Priority areas for MMIP AT work stream, collectively aimed at **securing a significant UK position in ATMPs**:

- Skills – apprenticeships, AToMIC, LEAP, CATTS
- Future support for capability and capacity for ATMPs manufacture –

"Accelerating the Translation of the UK Academic ATMP Pipeline into Commercial Products that will be made in the UK"

- **Plus**: improving the UK fiscal environment for medicines manufacturing (including ATMPs)

The ATAC story

Life Sciences Industrial Strategy

INDUSTRIAL STRATEGY | UK Research and Innovation

Science Man Tech (L3), Senior Leader (L7)
Reg Affairs (L7)
& MA Scotland launched

Research Scientist (L7), Process Eng (L6) and Lab Tech Wales to be launched

MMIP

MMIP ATM Taskforce

Office for Life Sciences

BIA

Continued Gatsby and CGT interim funding

£1.5m funding – ATAC launched

Future Skills 2030 launch

2014 2015 | 2016 | 2017 | 2018 | 2019 | 2020

CGTC Skills and Training Survey

CATAPULT Cell and Gene Therapy

Action Plan

Gatsby Foundation interim funding

GATSBY

Delivery of Action Plan - skills to MAC

First AT Apprenticeship – 17 ATMP Technician Scientists (L5) from 8 orgs

ATAC Advanced Therapies Apprenticeship Community

Catapult Skills demand survey

CATAPULT Cell and Gene Therapy

Present skills strategy to BEIS

Department for Business, Energy & Industrial Strategy

ATAC - Securing the ATMP talent pipeline

Advanced Therapies Apprenticeship Community

- Established by CGT Catapult and MMIP
- £1.5M award from Industrial Strategy Challenge Fund
- First advanced therapies apprenticeship programme in England and Scotland
- Aims to provide the skills required to fuel industry growth
- First cohort recruited in September 2018

72 apprentices
Employed across ATMP industry

27 ATMP companies
Have hired apprentices & form the advanced therapies apprenticeship community

10 programmes launched
Addressing industry skills gaps

> 100 apprentices expected by end of 2020
Established processes gaining momentum

ATAC apprenticeships	Level
Laboratory technician for ATMPs	3
Science manufacturing technician for ATMPs	3
Team leader/supervisor across advanced therapies	3
Laboratory technician apprenticeship (Wales)	3
ATMP technician scientist higher apprenticeship	5
ATMP bio/chemical engineer degree apprenticeship	6
Regulatory affairs specialist for advanced therapies	7
Research scientist degree apprenticeship	7
Senior leader in advanced therapies	7
Modern apprenticeship in life sciences (Scotland)	SCQF 7

Purpose of vCATTS and nCATTS

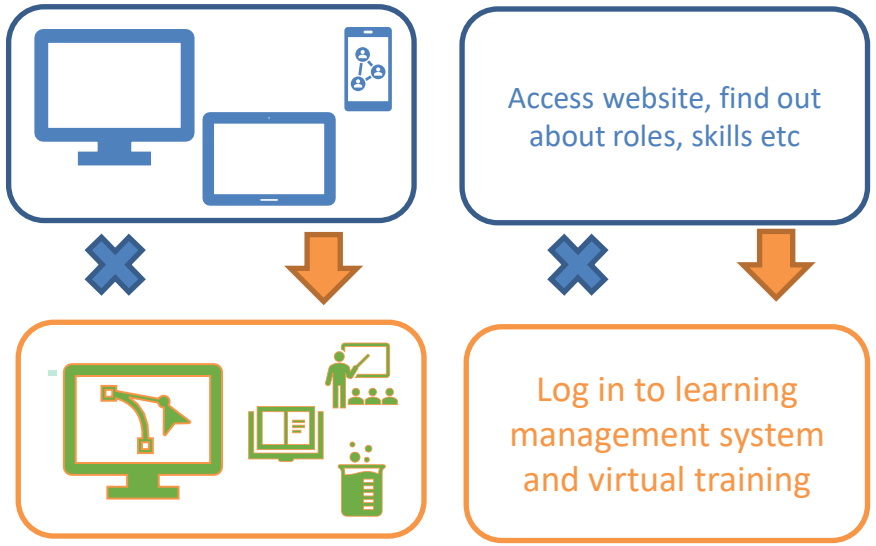
Purpose of vCATTS & nCATTS:

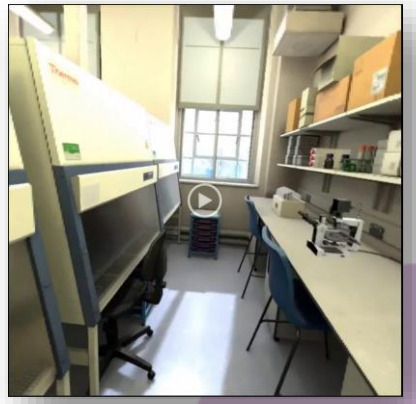
Virtual Training Centre:

- Accessible website, information on roles
- Learning management system
- Range of technical e-learning content
- VR & IR training modules

National Training Network:

- Geographical spread across UK
- Build on established/planned facilities
- GMP specialised training programmes
- Compliment vCATTS VR & IR modules





Increase in headcount by 2024

+3,387

(112% increase)

Initiation funding requested

£4.7m

Developing a Pan-UK Business Case to Improve Academic ATMP Manufacturing

MMIP

Viral Vectors for ATMPs-

Medicines Manufacturing Industry Partnership

abpi BIA Innovate UK Knowledge Transfer Network

British Society for Gene and Cell Therapy

cobra:bio

CATAPULT Cell and Gene Therapy

Oxford Biomedica

- Numerous stakeholders – academia, industry, funders etc.
- 6 contributory work streams led to delivery of business plan in Q4 2019

A UK Strategy for the Manufacture of Academic Advanced Therapies

MMIP

- MRC / LifeArc - £16m funding package announced (04May2020)
  - EOIs submitted by 01 June 2020
  - Compulsory workshop on 23 June 2020
  - Expected 03Sept deadline for applications and funding panel in Nov 2020

- Indirect support (not restricted to ATMPs)
  - Recently re-launched Biomedical Catalyst 2020 Round 1 Early & Late Stage Competition
  - Innovate UK competition for projects led by SMEs or RTOs
  - Grant funding (£250k to £4M total project costs); up to £30M available

Business environment for developing capability and capacity

MMIP

- Incentives matter for SMEs, to enable and de-risk capital investment

- **Target** - capture ATMP manufacture in the UK (as it matures from early clinical to larger phase trials and then commercial manufacture)

- **The need**: more established, long-term, consistent support in terms of fiscal approach to capital expenditure

'Why it works' case example *– Cobra and Oxford Biomedica both received IUK support for viral vectors – now actively contributing to ongoing AZD1222 COVID-19 vaccine candidate manufacturing* ***in the UK***

Concluding remarks

- There is a huge opportunity in the development of advanced therapy based medicines and the UK is doing well
  - See ARM/BIA UK report (link)

- ATMPs is a fast-growing field with significant investments evident globally ($9.8 billion globally) – source ARM sector report 2019 - link):

- There is still a real opportunity for the UK to secure an increased share of global ATMP manufacture for the long term, but more needs to be done ASAP (skills, capital grant support, etc) – ***ATMP work stream focus areas***

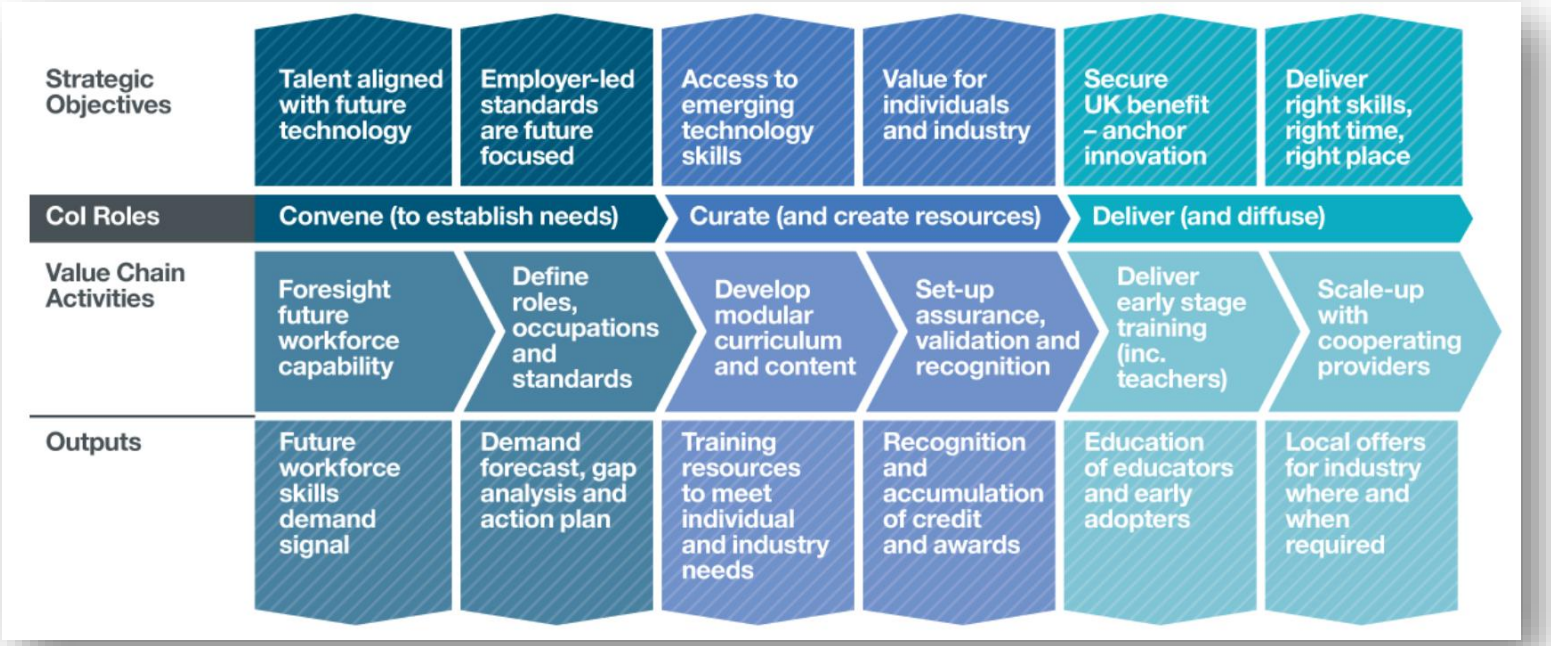
Skills Workstream

MMIP Conference – 15 July 2020

Dr Kate Barclay MBA CEng FIChemE

Future Skills Landscape: Then & Now !!

Then: 1Q2020 skills based value chain approach



Now: 2Q2020 pandemic response and economic recovery

Future Skills 2030 Action Plan: CSR
- Global Operating Environment
- Sector Attraction & Perception
- Apprenticeships
- Integrated Skills

Immediate Skills Response
- Continued supply of medicines
- Vaccine Taskforce response
- Retaining/retraining UK skills
- Alternative ways of working

Skills Based Recovery
- Innovative medicines – ATMPs
- Attraction from declining sectors
- Vocational training delivery
- Life Sciences Recovery Roadmap

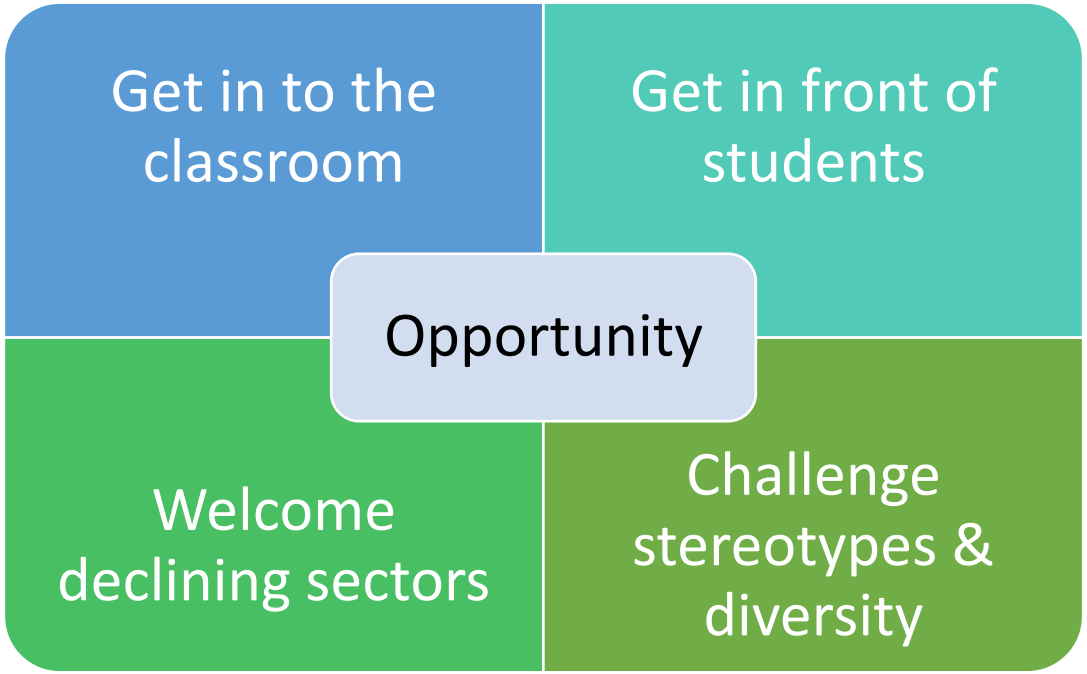
Global Operating Environment

Points Based Immigration System – effective 31 Jan 21

- Free movement will end
- EU and Non-Eu migration will be treated the same
- Single system for the UK
- PBS focussed on attracting talent – STEM focus

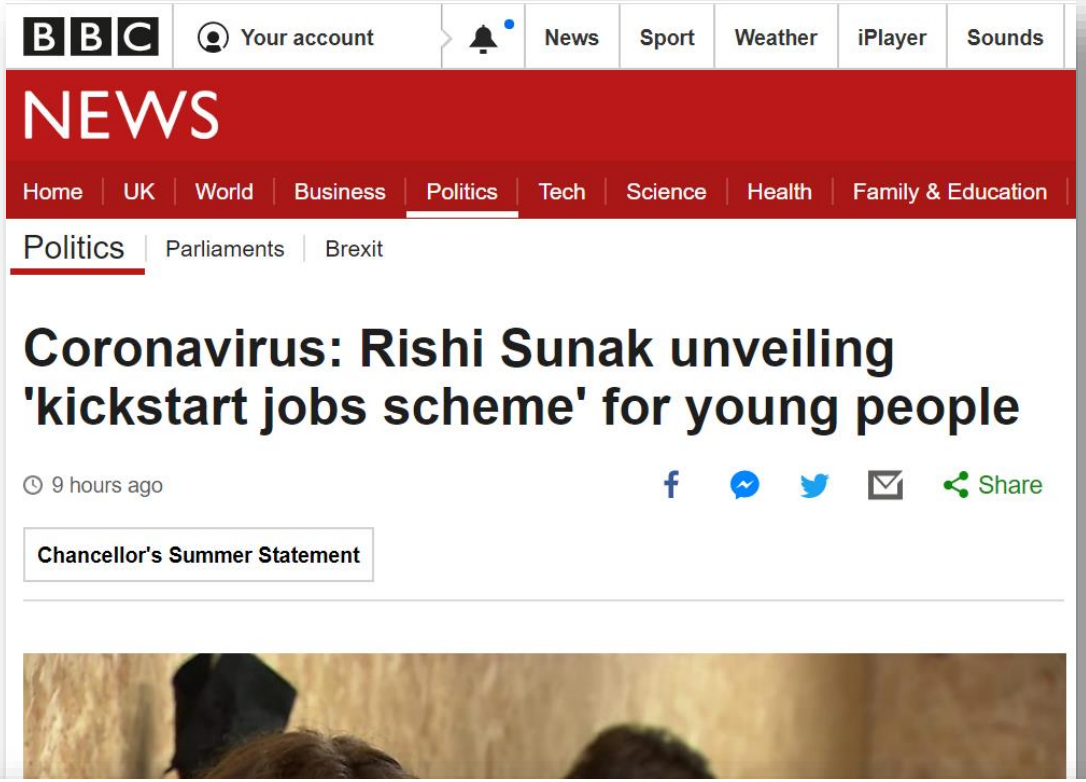
Un-skilled	Skilled
• End free movement across EU for all inc. unskilled • No route for low or un-skilled visa • Reduce reliance on low skills outside UK	• Skills threshold reduced to RQF3 (from RQF6) • Salary threshold decreased to £25,600 (20pts). SOL * • No RLM test • No cap (was 21k) • PBS (STEM first app.) – 70
Highly skilled	**Students**
• Global Talent (EU/non-EU) • Changes to endorsement bodies – more STEM focus • Broader unsponsored route within PBS without job offers* • PBS/cap/take time	• Biggest category by far • EU treated same as RoW • Offer in place • English, ££, ability • From summer 2021 remain 2 years (was 4 months)

Sector Attraction & Perception



- Who does not know about viruses & vaccines ?
- Everyone is an epidemiological expert
- Science is constantly in the news, social media
- Who we are is really visible across sectors
- It is a really good time to shout about what we do

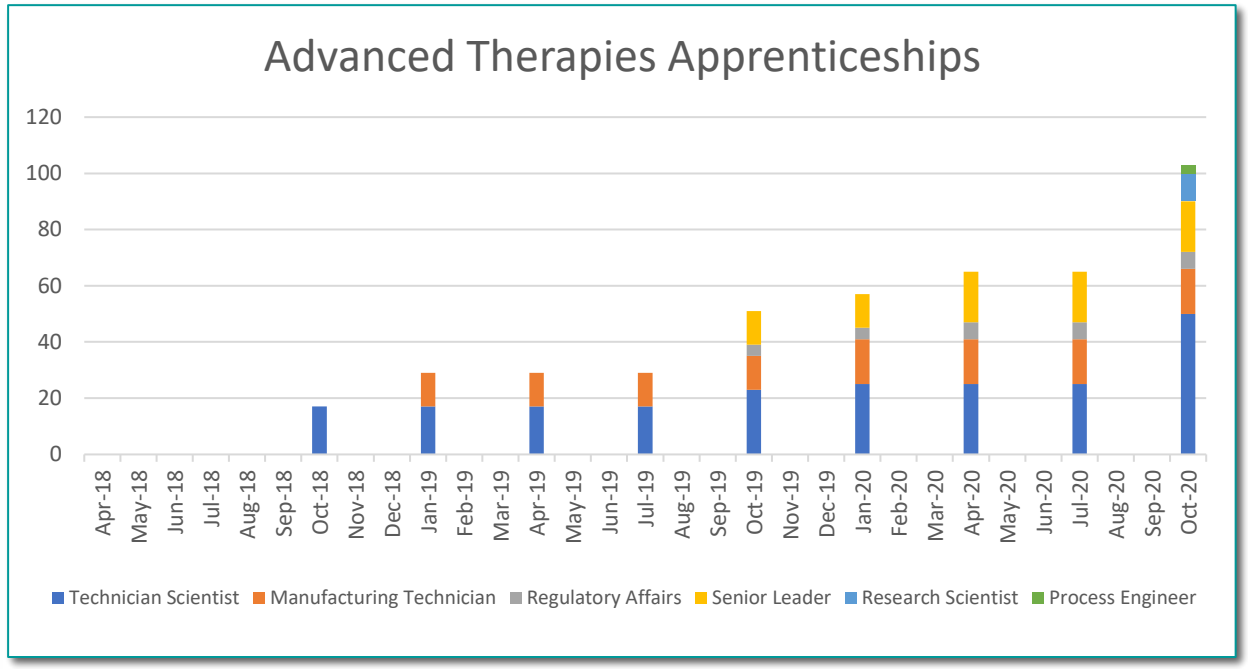
Apprenticeships:



'Skills, skills, skills' for recovery, says Halfon

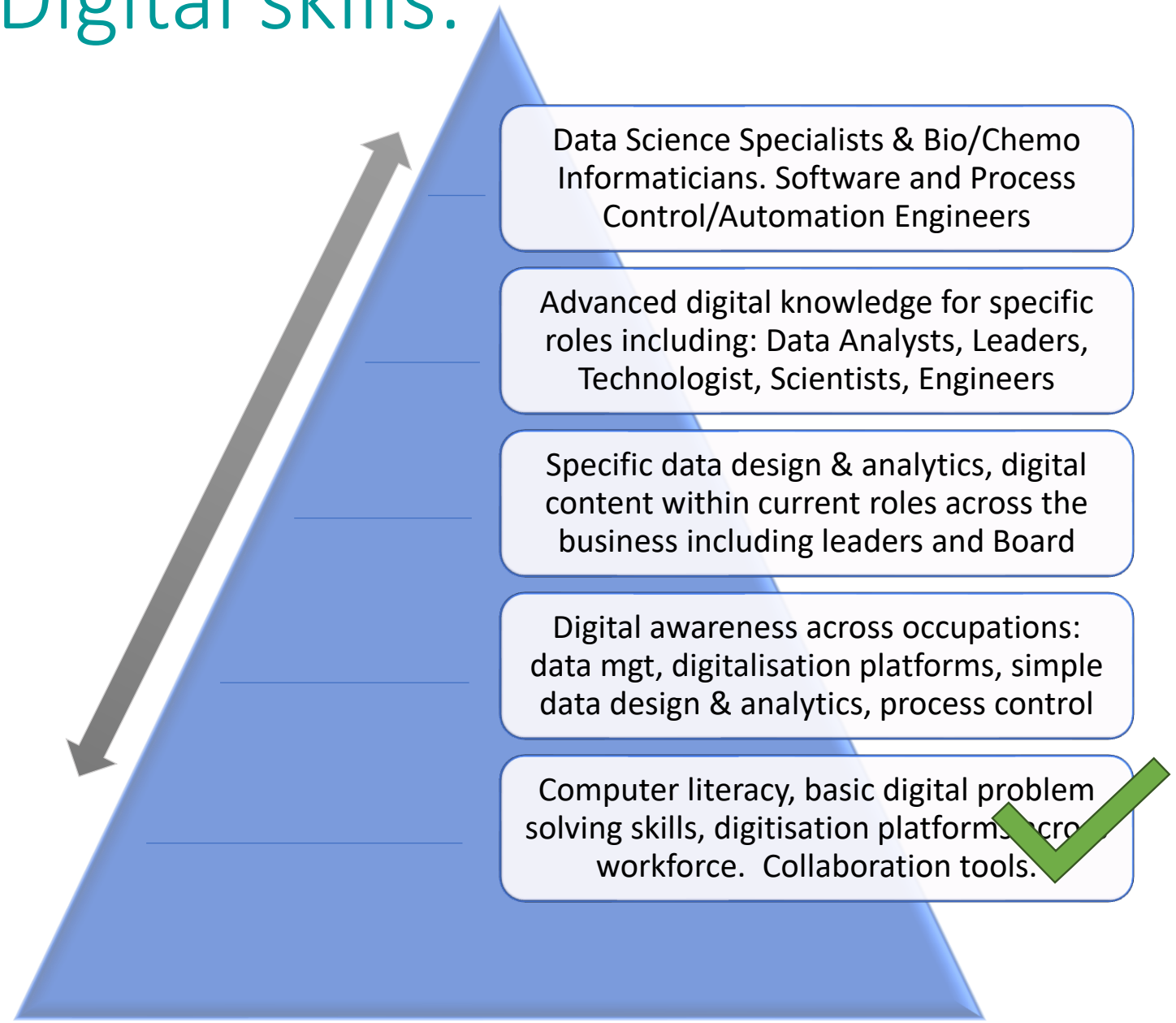
Apprenticeships must be "front and centre" of training plans, says chair of education select committee.

30 Jun 2020 | News | Family & Education



- Financial incentives for new apprenticeships
- For new talent (18-24) and upskilling (>25)
- Upskill from declining sectors
- Diversity of talent & skills
- ATAC applications have doubled/tripled
- Support across SMEs to take on apprentices
- ATAC will reach over 100 apprentices
- Mainly SMEs in ATMPs/Vaccine manufacturing

Digital skills:



DECODED

The Alan Turing Institute

CAMBRIDGE SPARK

- Upskilling in data analytics
- CPD in basic programming & tools
- Attracting new data science talent
- Data science for managers
- Senior leadership bootcamps
- VR/IR training and assessments

Fiscal Workstream Update

Andy Evans, Chair, MMIP

Fiscal Workstream Update – Andy Evans

- An enduring focus area for MMIP has been on improving the fiscal landscape in the UK to support industry and to help incentivise investment in new manufacturing facilities and upgrades

- Whilst the UK has an attractive overall corporate tax position, MMIP has prioritised the provision of effective capital grants scheme as the key step needed to make the UK more globally competitive

- A paper asking for the introduction of a capital grants scheme was presented to the Life Sciences Council in 2019 and was progressed with the Office for Life Sciences and discussed with Treasury

- The recent challenges with Covid 19 have reinforced the importance of UK Medicines Manufacturing both from its inherent economic value and also its key role in the resilience of the medicines supply chain for the UK. This is fully recognised by Government.

- MMIP presented again to the Life Sciences Council in June on the need for capital grants, effective collaborative R&D funding for manufacturing, and investment in skills. The paper was fully endorsed.

- MMIP and the Office for Life Sciences are now building the full business case and an operating model for a capital grants scheme, with the ambition of this being accepted by Treasury for implementation in 2021

Regulatory Workstream update

Adam McLennan

MMIP Regulatory Workstream Lead

July 2020

MMIP Regulatory Work Stream

Objectives:

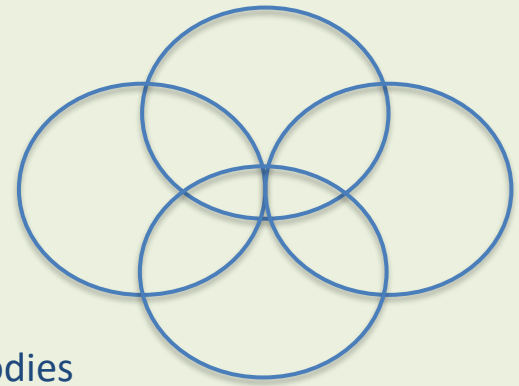
- ✓ **Connect and promote UK's regulatory environment as a core asset for medicine manufacturing and investment**
- ✓ **Make innovation operational; expediting investment through to realisation by multi-party partnership**
- ✓ Represent the views and objectives of opportunity areas like ATMPs and nearly approved vs experimental manufacturing technologies. Including new areas of challenge (eg. Environmental sustainability, AI)
- ✓ Awareness, preview and cascade of Brexit/Regulatory impacts

Scope:

- Manufacture of drug substance, drug product and new technologies
- Pre-clinical, Clinical and Commercial products.
- Medical devices that form part of a medicinal product, combination products, software, CE mark vs medical use, 3D printing (point of care manufacture - POC) and bio-printing
- Proprietary, OTC & generic product
- Innovation Centres / MHRA engagement

Team

- Industry
- Academia
- MHRA
- Generics
- QPs
- MMIC
- Professional bodies



MMIP Regulatory Work Stream

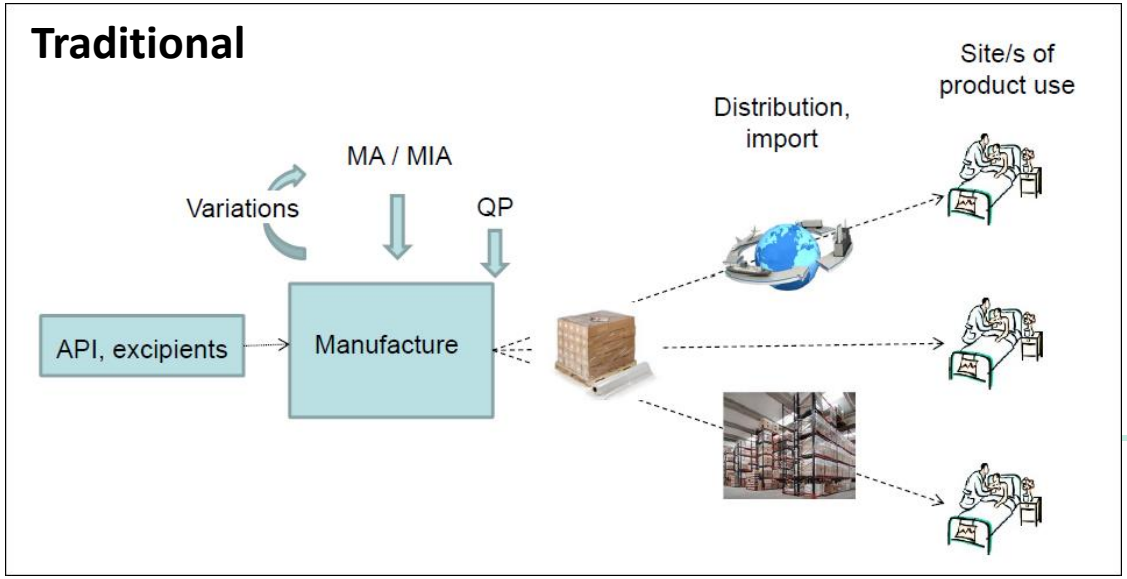
Sector Deal 2 – innovative regulation

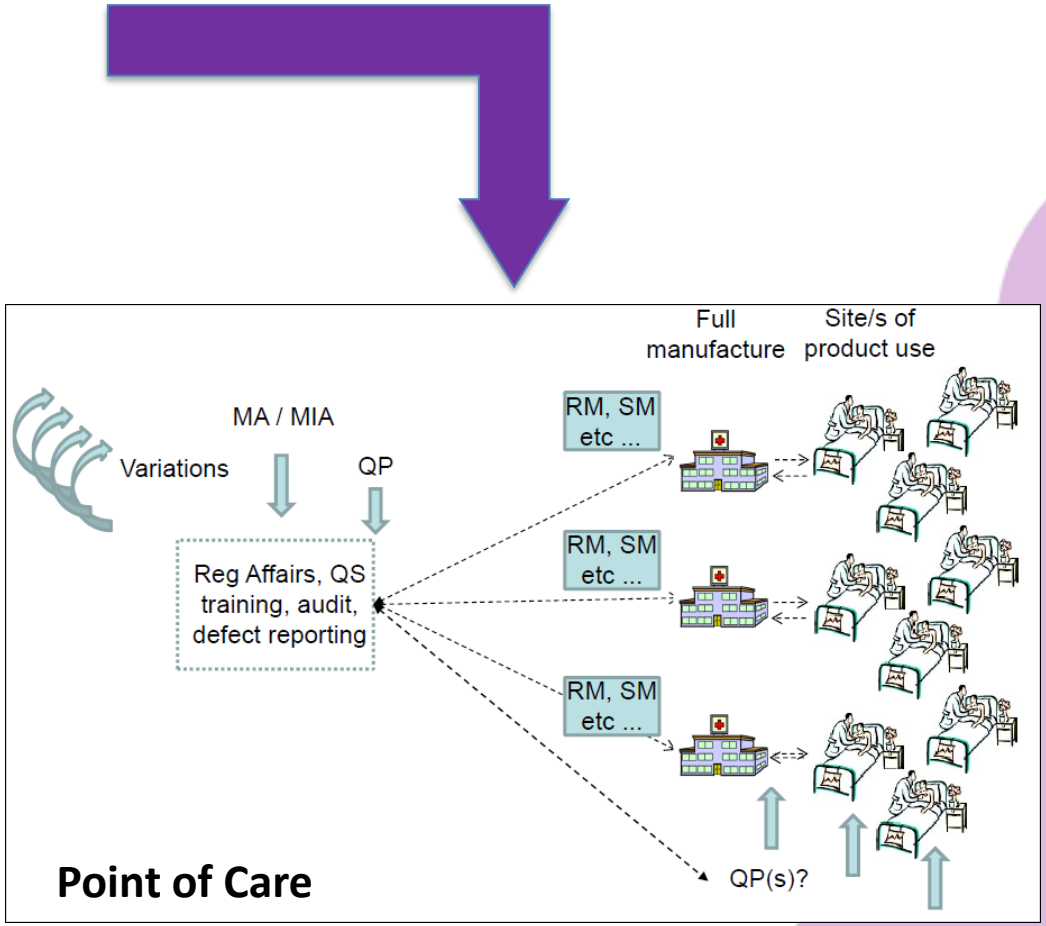
`A commitment to innovative regulation that ensures the UK framework keeps pace with emerging technology developments, such as artificial intelligence, and supports their entry into the NHS'

1. Enabling access to advice that supports innovative trial design
2. Developing a regulatory pathway for genomic medicines and tests
3. Earlier and better signal detection for devices and medicines
4. Establish a Yellow Card Biobank to capture genetic information from patients experiencing ADRs
5. Develop synthetic datasets which mimic real-world data to enable testing and validate of algorithms and other AI used in medical devices
6. Further develop CPRD services to include secondary care data
7. Develop a framework for POC manufacture in medicines and devices
   - Project ends 31 March 21
   - 2 workshops planned for 2020

Key focus points working with MHRA in 2020

MMIP Regulatory Work Stream
Point of Care



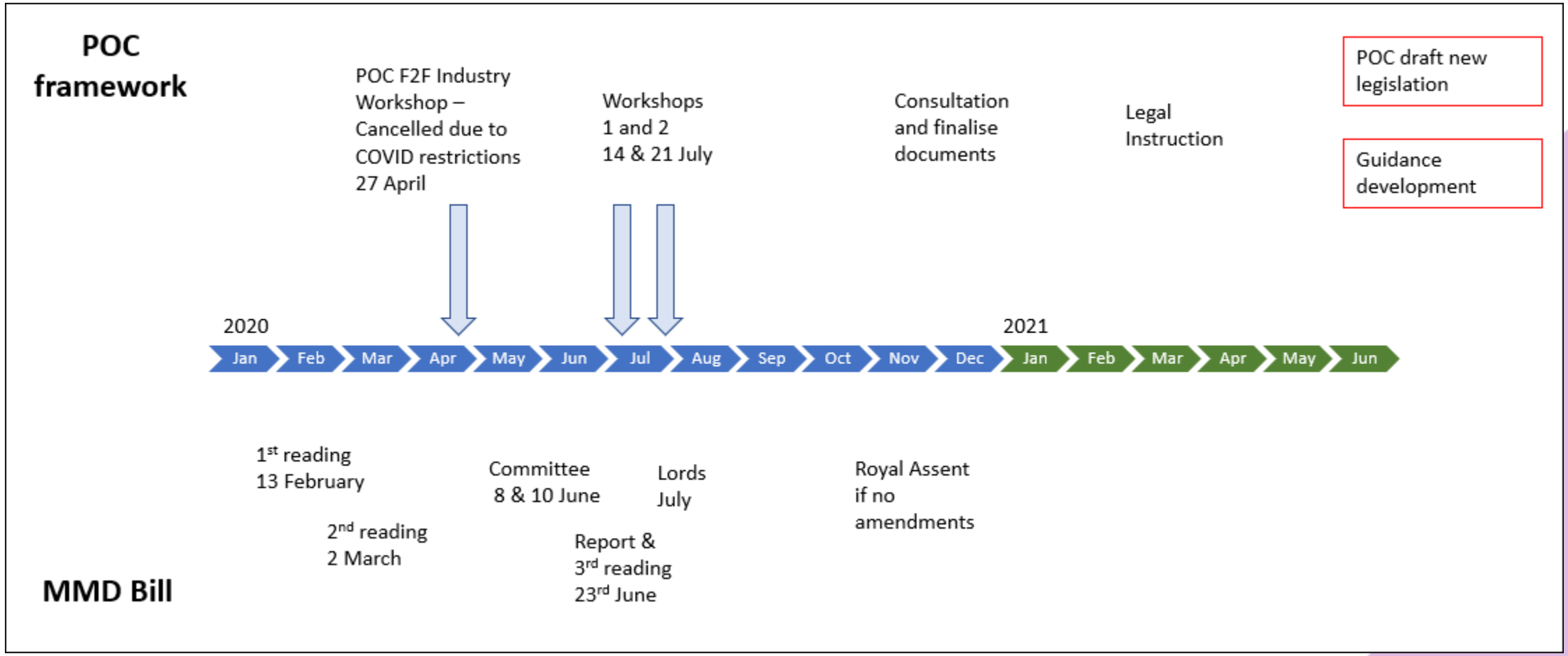


Application examples

ATMPs
Bloods (eg. modified platelet rich plasma)
Medical Gases (eg. ambulances)
3D printed medicines and devices
The next technological advances ??

MHRA Contact:
Ian Rees

MMIP Regulatory Work Stream
Point of Care



MHRA Contact: Ian Rees

MMIP Regulatory Work Stream
Innovative Trial Design

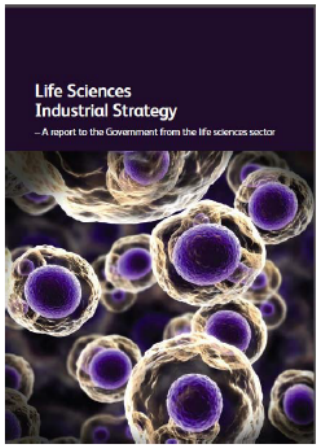
MMIP

Life Sciences Industrial Strategy 2017 report to the UK Government:

Our goal

"As the UK seeks to do more **complex and innovative trials**, MHRA needs to continue engaging with sponsors to **assist with innovative protocol designs** and should facilitate efficient approval of complex trials and amendments to such trials, for example, to add new arms.

The **UK should attempt to lead the innovation** in clinical trial methodology, such as basket trials, and should also attempt to embed routine genomic analysis to make trials more targeted, smaller and more likely to deliver high efficacy."



MHRA implementation plan for novel trials

- Key outcome: Strengthened UK environment for clinical research that provides support for innovative trial design
- Includes
  - Engagement with stakeholders on novel trials and our advice services
  - Workshop(s)
  - Internal training
  - Possible guidance/report for industry
- Already engaging with NIHR and NICE
  - NIHR workshop December 2019 and March 2020

MHRA Workshop (Innovative Trials & Innovation Office) planned to line up with POC workshops End 2020

MHRA Contact:
Dr Kirsty Wydenbach

MMIP Regulatory Work Stream – Electronic PIs

Electronic Leaflets (ePI) - update

EFPIA – multiple sessions on framework for introduction within EU in 3 - 5 years

Previous work done and documented (EMA view 2017)

- USA / Canada examples / post approval
- History EU – PIM, XEUMPD, IDMP
- Austrian system for reading PI's available (not preferred for EU)

Dec 2019 – Technical design and functionality webinar

- ePI creation tool, simple lightweight, regulator-hosted
- high level impact assessment, user stories

Plan 2020 – Phase I – standards and technical solution to be agreed
– EU implementation within 3 – 5 years

Potential opportunity for Sector Deal 3

– digital / patient safety / environmental sustainability
– speed to market
– UK jump ahead or align with EU ?

Concluding remarks

We have a great opportunity working together between Industry and Government to deliver the Life Sciences Industrial Strategy

New technologies, medicines, innovation, competition and a globalised supply chain

needs

an Innovative, Enabling and Consultative Regulatory Environment (MHRA)

We can align new medicines / patient safety / regulation / sustainability to ensure the **UK's regulatory environment is a core asset for medicine manufacturing and investment**

Questions?

MMIP Achievements and Strategy for the Future

Andy Evans, Chair, MMIP

MMIP Mission and Vision

MMIP represents the voice of medicines manufacturers in the UK and was established jointly by Government and the Biopharmaceutical industry in 2014

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.

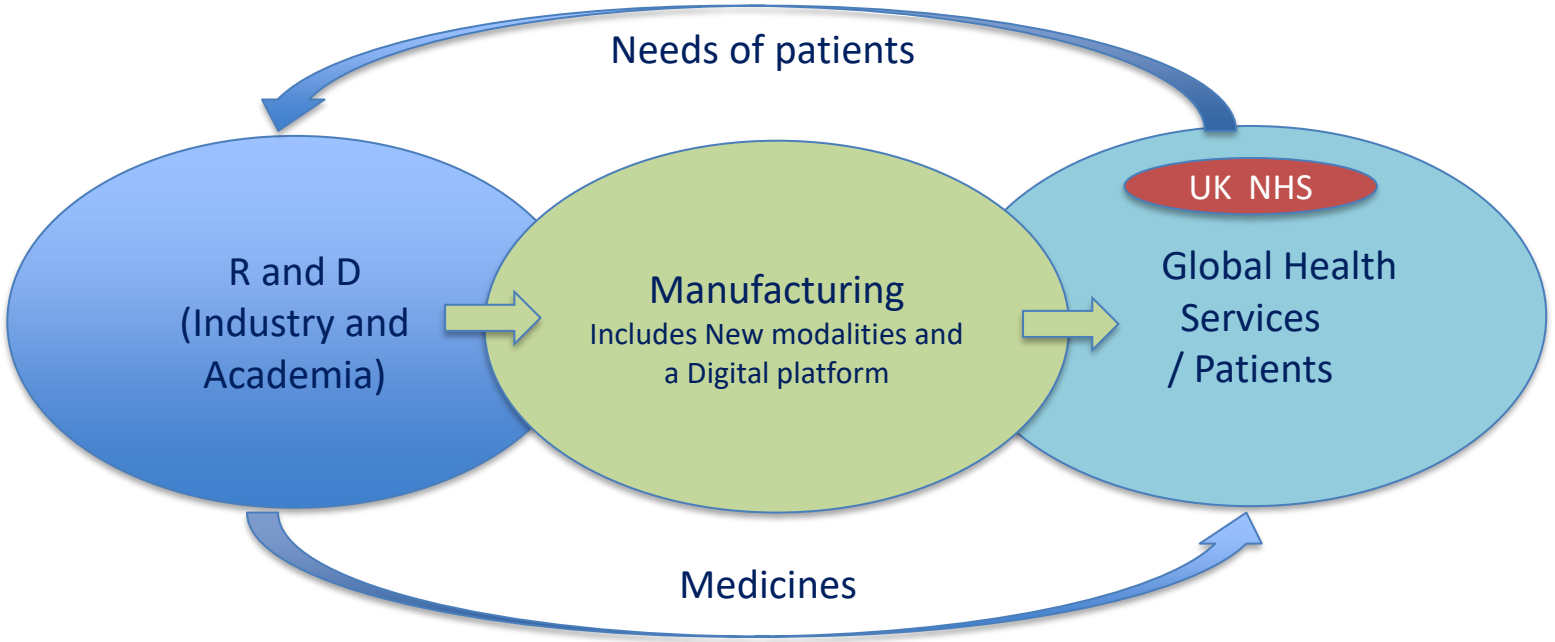
Vision for MMIP:
Focusing on technology and Innovation leadership to make the UK the best place in the world for medicines manufacturing through:

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.

MMIP Strategy Overview

2 core themes to the MMIP Strategy:

1) Optimise the whole value chain by working at the interfaces to add value
2) Improve the overall functional effectiveness and efficiency of manufacturing



MMIP achievements created a platform for UK Medicines Manufacturing to contribute in the Covid 19 crisis - now need to focus on supporting economic recovery and securing future resilience

Strategy for delivering Growth and Resilience

ATTRACT: Clinical and Commercial manufacturing of new types of medicines such as ATMPs and other Complex medicines and likely to need investment in new sites, or new facilities on current sites, and use of innovative process and analytical technologies.

BUILD and ANCHOR: Clinical and Commercial Manufacturing of established types of medicines through securing investment in current capabilities and likely investment in current Sites.

Focus Areas:

1. **Securing Capital Support preferably in the forms of grants**
2. **Sustaining Collaborative R&D in Manufacturing Technology (Process and Digital) building on our world class innovation infrastructure to speed adoption into Industry.**
3. **Developing the Skills we need for the future**
4. **Regulatory framework that supports Innovation**

Closing remarks

Steve Bates, Chief Executive Officer, BIA

Medicines Manufacturing Industry Partnership

abpi
Bringing medicines to *life*

BIA
UK BioIndustry Association

Innovate UK
Knowledge Transfer Network