

MediWales & BIVDA: Diagnostics Industry Update

A Review of the Stratified Medicine Innovation Platform – Innovate UK

Stratified Medicine Innovation Platform

*Alasdair Gaw, Sophie Dale-Black, Loic Lhuillier
Chris Rowe, Penny Wilson*

Innovate UK

- The UK Innovation Agency
 - set up in 2007 to support UK economic growth
- We look at the challenges that offer market opportunities
- Identify where the UK has real capability
 - and where the timing is right
- We work with communities and other organisations
 - finding the right form of support for companies in these areas



In 6 years....

Over 2800 active CR&D projects

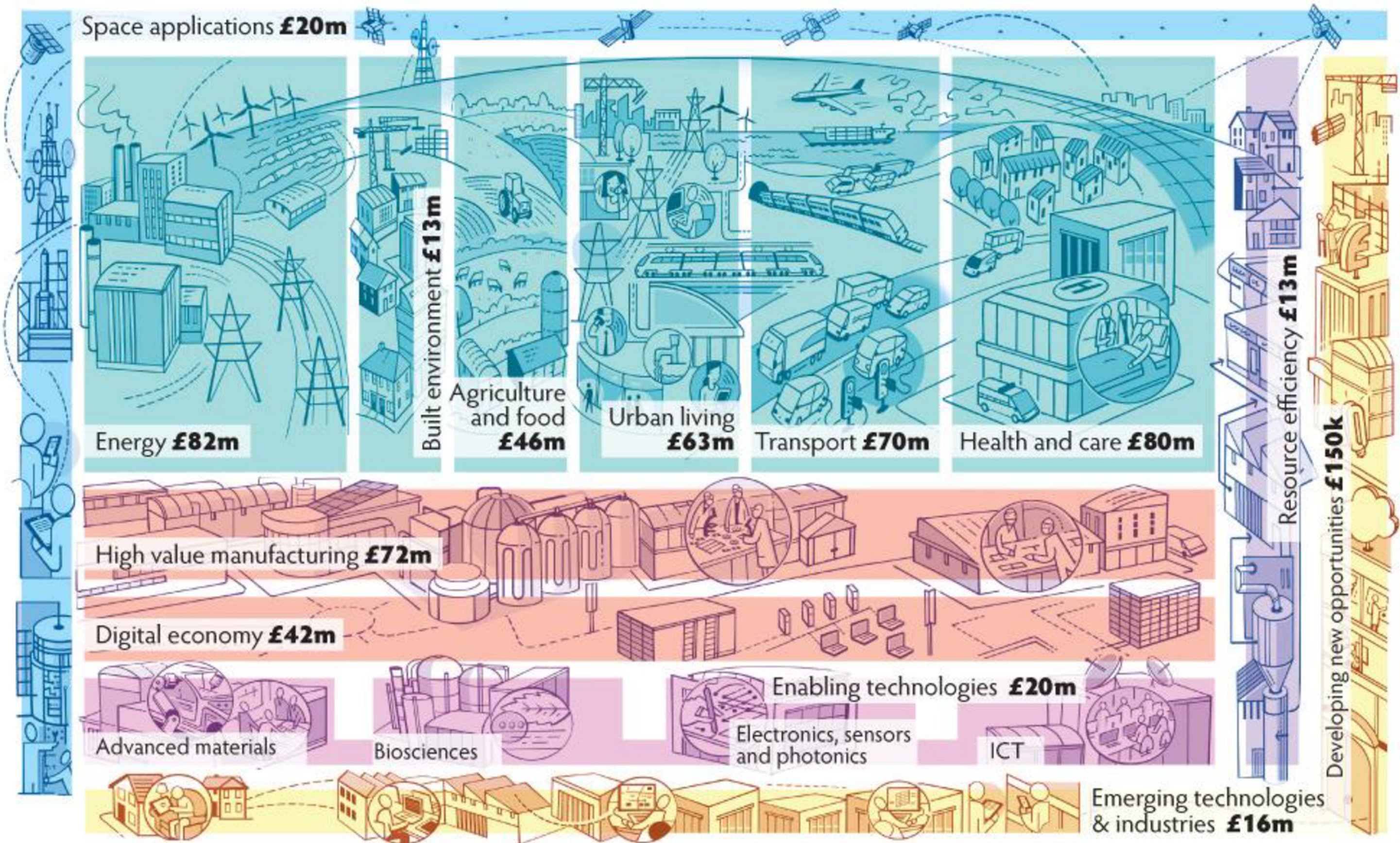
>4000 business partnerships and almost all the UK's universities

Together with partners and business, over £2.5bn invested in UK innovation

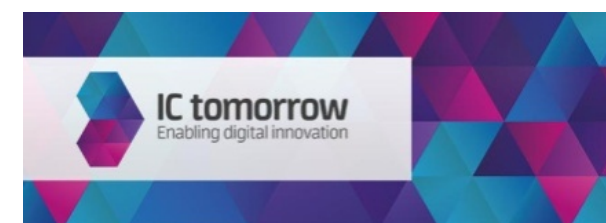
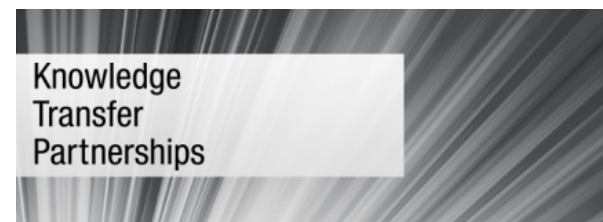
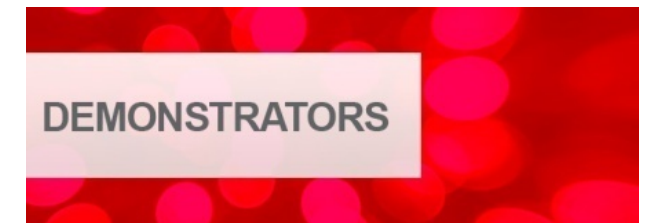
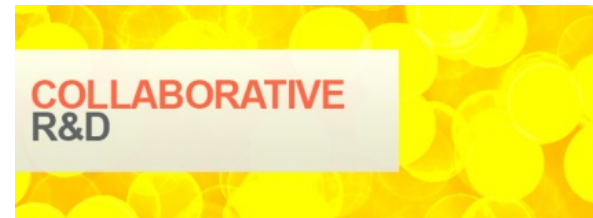
How we stimulate innovation

- We enable people and companies to **collaborate** and share ideas
- We **break down barriers** to innovation
- We help business understand future markets and **innovation opportunities**
- We **bring together partners** to maximise innovation investment and work on common goals
- We offer **funding** through competitions, to de-risk development of new products and services

Anticipated commitments in priority areas, during 2014-15



Joining up the Toolset



Stratified Medicine Innovation Platform

- Launched October 2010
- Accelerate Development and Uptake of Stratified Medicine
 - Improve Patient Outcomes
 - Provide Cost Benefit to the NHS and The Healthcare Industry
 - Deliver wider UK economic benefit
- Key Partners
 - Department of Health, Scottish Government Health Directorate
 - NICE, Medical Research Council, Technology Strategy Board
 - Arthritis Research UK, Cancer Research UK
- Consultation and Advice
 - MHRA, NIHR
- The combined 5 year Investment amounts to £200 Million

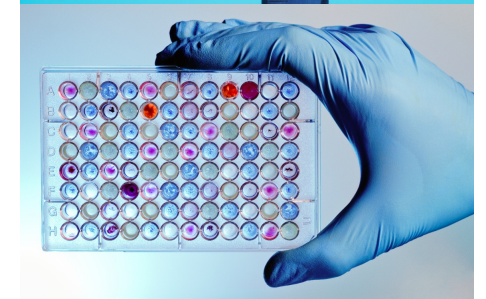


Putting UK healthcare at the heart of a revolution
in the diagnosis and treatment of disease

SMIP UK Roadmap Key Themes

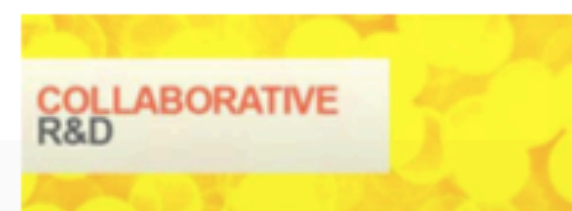
- Incentivising adoption
- Increasing awareness
- Patient recruitment – consents and ethics
- Clinical trials
- Data – collection, management and use
- Regulation and standards
- Intellectual property
- Bio-banks and biomarkers
- Increasing the impact of R&D investment

<https://connect.innovateuk.org/documents/2843120/3724280/Stratified+Medicines+Roadmap.pdf>



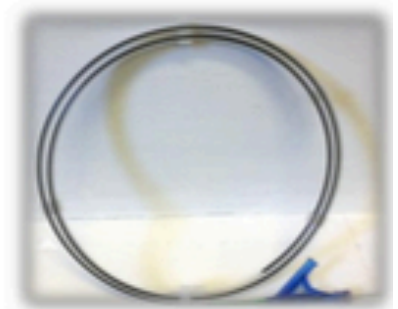
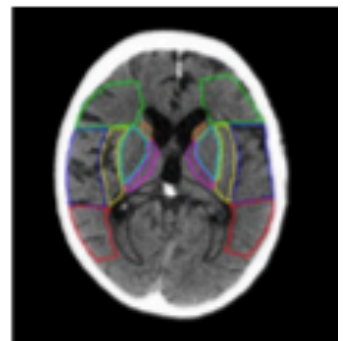
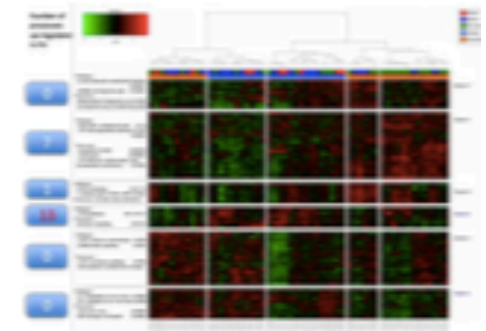
Stratified Medicine Innovation Platform

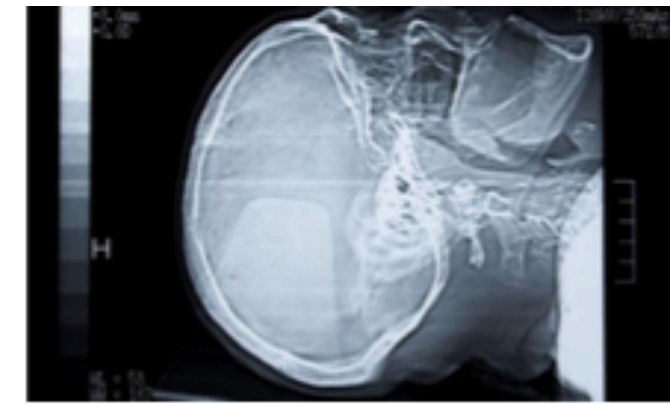
- Round One:
- 3 Competitions £9.5 million:
 - Development Business Models
 - Bio-banking: Funding policy ethics SOPs etc
 - Point of need diagnostics for hepatitis
 - Companion Diagnostics, integration and implementation
 - Inflammatory Biomarkers
 - Rheumatoid arthritis: 2 projects: TNF non responders
 - Osteoarthritis: aggrecan breakdown
 - COPD: functional biomarkers, muscle & cv
 - Tumour Profiling
 - 4 projects: Oncology multi screen assays
 - 2 projects: IT database systems



2: Determining Patient Response

- Using Health Economics to drive adoption
 - Identifying non-responders or adverse events
 - £6.5million TSB +£1Million DH
- Stage 1: Health Economics Assessment
 - 11 projects funded (£1m)
- Stage 2: Product Development 4 funded
 - **Almac Diagnostics** Development of a test to guide breast cancer treatment
 - **Brainomix**: An electronic system for early diagnosis of type of stroke enabling fast appropriate therapy.
 - **Philips Healthcare**: Home based monitoring for early detection of severe neutropenia in patients receiving chemotherapy
 - **DIASOLVE**: Catheter allows combined infusion of local vasodilator and measurement of Fractional Flow Reserve through intrinsic pressure probe (diagnostic)



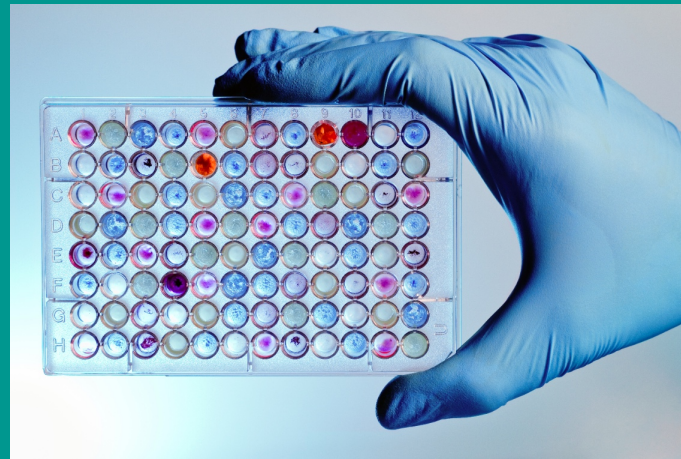


3: Advancing in-vivo imaging for Stratified Medicine

- 46 applications, 12 funded (£8.6m)
- **GE Healthcare Ltd** – imaging agent for PCa
- **Intelligent Ultrasound Ltd** - automating quality assessment of B-mode ultrasound scans
- **IXICO Ltd** - dementia diagnosis
- **Lightpoint Medical Ltd** - molecular imaging camera and laparoscope for PCa surgery
- **Lightpoint Medical Ltd** - intra-operative molecular imaging fibrescope for BCa surgery
- **Marchbanks Measurement Systems Ltd** - continuous non-invasive intracranial pressure monitoring device
- **Mirada Medical** - Stratification of pulmonary nodules in lung cancer screening
- **Optos plc** - Functional optical coherence tomography ophthalmoscope
- **Perspectum Diagnostics Ltd** - LiverMultiscan with MRI – replacing liver biopsy
- **Philips Electronics UK Limited** - Atherosclerosis stratification
- **National Physical Laboratory Management Limited** - piUCT for the diagnosis of breast disease
- **Siemens Healthcare** - Guide cardiac resynchronisation therapy

Stratified Medicine Innovation Platform

- Round Four: £3.5million TSB
 - Enabling tissue sampling handling analysis and storage
 - 5 projects funded
- Round Five: £4.6 million Neurodegenerative Disease
 - Diagnostics and care management: 3 consortia
 - Business models and Data integration: 3 consortia
 - 10 companies and 10 academic institution
- KTP: Modelling for Stratified Medicine £1.0m
 - Developing new modelling approaches across bioinformatics, systems biology, health economics and analytical algorithms to support the use of stratified medicine in the UK



Stratified Medicine Innovation Platform: Sixth Competition Round

Connecting the UK Infrastructure

Two 2-phase SBRI competition

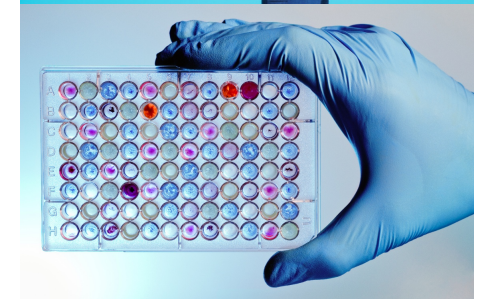
Total investment: £10m

Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

Challenge

- Slow adoption rate of new innovations by healthcare providers a national challenge to growth of stratified medicine
- Resources within NHS under greater pressure
- Stratified medicine can improve cost effectiveness of healthcare, improve health efficiency & effectiveness, and reduce burden on the patient

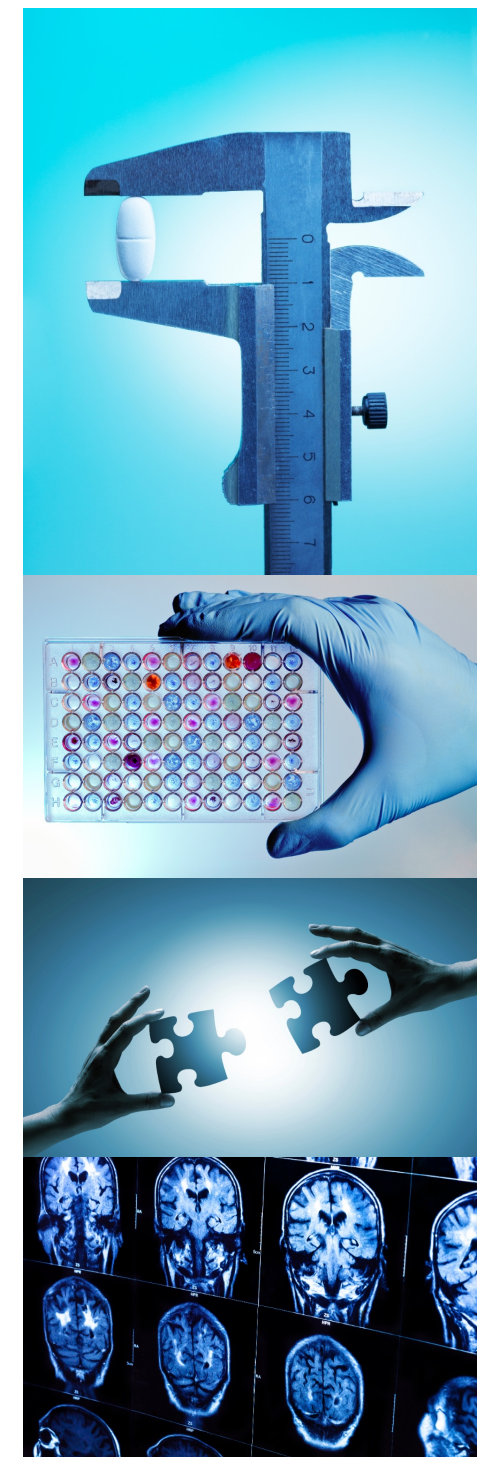


Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

UK Infrastructure

- New organisations and capabilities within the UK Infrastructure to enable early access to researchers, regulators, NHS and payers
- Strategic engagement with these organisations allow companies to determine best approach to implementation, establishing clinical value chain, commercialisation and uptake of tests



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

- Innovate UK's Stratified Medicine Innovation Platform investing £10m in 2 phase SBRI competition
- Challenge to accelerate the uptake of innovative diagnostics for Stratified Medicine with UK healthcare system
- Demonstrate the benefit of companies working with the UK enabling infrastructure



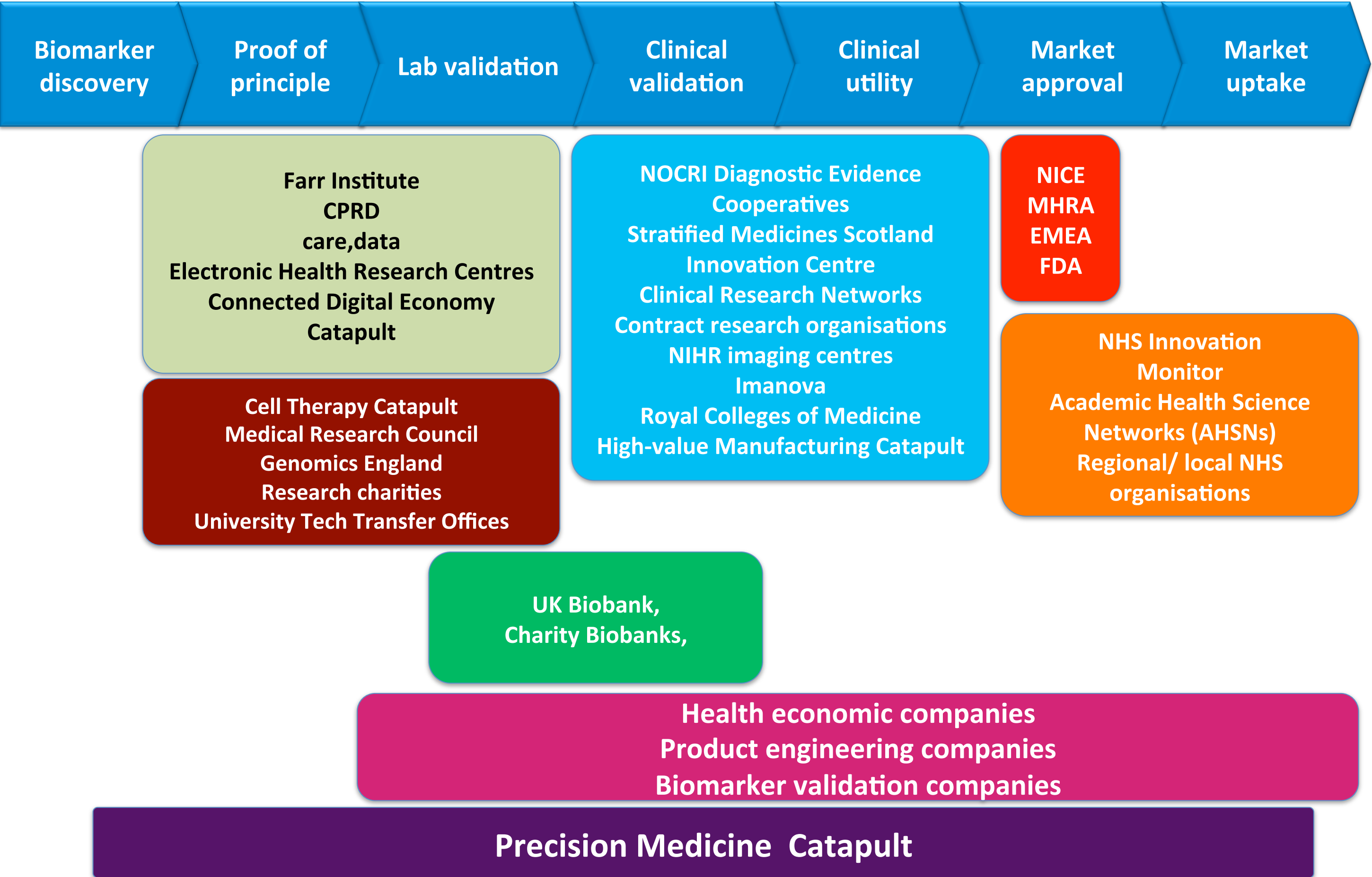
Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

- Addressing the leading healthcare challenges of the UK.
- Aim to provide exemplars of working across UK landscape to reduce time to adoption
- Linking companies with NIHR DECS, MRC Path Nodes, AHSN, Devolved government structures etc.
- Drive adoption by early engagement with UK Infrastructure



Potential partners across Diagnostic test commercialisation pathway



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

- PHASE 1 of the competition: £2 million
 - Amount available up to £150,000 per project
 - Aim to provide exemplars of working across UK landscape to reduce time to adoption
 - Up to 9 months duration:
 - Fund organisations to develop economic case to evidence the value of the proposed product or service



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

- PHASE 1 of the competition: £2 million
 - Production of detailed project plan to develop and trial the product in the healthcare service
 - Elements of feasibility tests to generate further evidence of ability to stratify patients into sub-groups
 - Address issues surrounding adoption of product into NHS
 - At 9 months a report of the results and proposed value must be submitted
 - Successful applicants may then apply for Phase 2 funding



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

All projects should, where appropriate:

- Describe the use and development path of diagnostic product or service
- Explain how it will enable patient stratification
- Review the unmet clinical need
- Describe the new clinical care pathway
- Review required interactions with UK Infrastructure



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

IN SCOPE:

- Projects seeking to develop tests capable of stratifying patients
- Clinical treatment(s) currently available in the UK
- Broad definition of 'Tests', includes in-vitro & in-vivo diagnostic tests, physical measurements, intelligent use of data to guide clinical decisions.
- Test carried out in hospitals, clinics, GP's surgeries and in the community



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

OUT OF SCOPE:

- Diagnostic tests that don't give rise to patient stratification
- Diagnostics for treatments still in development
- Novel Biomarker discovery



Stratified Medicine Innovation Platform Round 6

Stratified Medicine: Working with the UK Infrastructure

- PHASE 2 of the competition: £8 million
 - For projects up to 3 years duration:
 - Opens September 2016
 - Successful applicants from Phase 1 only
 - Applicants will submit a full development plan up to commercialisation
 - After submission applicants will pitch to a board of assessors
 - Expectation of up to 4 projects being funded.



Stratified Medicine: Connecting the UK Infrastructure

Phase 1: £2.0m Up to £150,000 per project max length 9 months

| | |
|---------------------------|-----------------------------|
| Competition opens | 7 September 2015 |
| Briefing event | 15 September 2015 |
| Registration deadline | 28 October 2015 noon |
| Deadline for applications | 4 November 2015 noon |
| Contracts awarded | 08 January 2016 |

Stratified Medicine Innovation Platform: Sixth Competition Round

Connecting the UK Infrastructure

For more information Contact:

alasdair.gaw@innovateuk.gov.uk

christopher.rowe@innovateuk.gov.uk

