



## Open Innovation in the NHS

April 2014

A FORUM Workshop



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### **CASMI**

CASMI is the Centre for the Advancement of Sustainable Medical Innovation, a partnership between Oxford University and UCL, created to develop new models for medical innovation. The centre aims to address the issues that have led to current failures in the translation of basic bioscience into affordable and widely adopted new treatments.

### **Disclaimer**

This document reflects the views of participants expressed at the meeting and does not necessarily represent the views of all participants or of the Academy of Medical Sciences. For further information, please contact Dr Naho Yamazaki, Head of Medical Science Policy ([naho.yamazaki@acmedsci.ac.uk](mailto:naho.yamazaki@acmedsci.ac.uk), (0)20 3176 2168).

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## Summary of key messages

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- Models of successful open innovation between industry, academia and the NHS do exist. These are characterised by trust and openness between partners, shared risk and reward, and the delivery of mutually beneficial outputs. Identification and effective utilisation of unique strengths within partner organisations is key.
- When collaborative partnerships are established on these principles, they can deliver outputs faster, better and cheaper than single sector working and can tackle clinical problems which defy the resources and skills of any one group working alone.
- Cultural differences between the three constituents may lead to mutual suspicion and misunderstanding, and confound the development of productive working partnerships. Education, communication and freedom of movement of individuals between industry, academia and clinical work places are required to break down these barriers.
- The size and complexity of the NHS may act as a barrier to collaboration and the dissemination of novel ideas throughout the healthcare community. Potential collaborators can struggle to identify a relevant and accountable individual within NHS organisations to make contact with regarding research partnerships.
- Differential understanding of what constitutes success and variable outcome measures between sectors can make it difficult to align goals. New metrics are required to measure the wider benefits of collaborative innovation for patient benefit.
- There is a failure to incentivise and reward innovation in the NHS. Action should be taken to embed the 'innovation for better outcomes' imperative within NHS incentive schemes.
- Existing NHS structures, Academic Health Science Networks (AHSNs) in particular, are currently poorly utilised as they need time to embed and build local relationships to fully realise their potential.
- Delegates were keen that cultures with the three sectors of industry, academia and the NHS were not caricatured. The diversity of skills and attitudes in each sector was recognised.

## Session 1 – Case Studies

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### 1.1 Introduction and objectives: Professor Richard Barker (Session Chair)

- Professor Barker introduced the meeting and its aim to explore the key challenges and opportunities surrounding open collaboration between the NHS, industry and academia. He noted that the linear process of discovery and innovation was being replaced by more complex models and suggested new metrics might be required to measure success and evaluate the UK's performance. Professor Barker outlined the significant potential of the NHS to act as a collaborator rather than passive recipient of innovation and invited delegates to consider the opportunities and problems from the point of view of all constituents.
- The **Academy of Medical Sciences' FORUM** was introduced, with discussion of its central aim of fostering closer links between academia, industry and the NHS.
- The **Centre for the Advancement of Sustainable Medical Innovation (CASMI)** project was described. It has been commissioned by the Wellcome Trust to review the scope, potential, challenges and barriers, and future of open innovation in life sciences, and to make recommendations to enhance its future success.

### 1.2. Case Study 1: Dr Richard Marshall, GSK R&D Fibrosis Discovery Performance Unit

- Dr Marshall started his presentation with a description of established models of industrial partnerships, which had been variably successful. He went on to detail an example of a 'bottom up' collaboration, initiated by a defined clinical problem: the need for novel therapeutics to target fibrosis, which is a common cause of mortality and morbidity in chronic inflammatory and metabolic diseases.
- From this starting point a network, CRAFT (CReative Advances for Fibrosis Therapies), of predominantly UK universities and the Royal Brompton & Harefield NHS Trust with an established interest in fibrosis was developed. These partners investigated the biology of fibrosis and fed into the GSK Fibrosis Drug Performance Unit (DPU), looking for established biomarker and surrogate outcome data as early markers of drug success for future trials.
- Dr Marshall described the successes of this network. Collaboration with the NHS had enabled the largest ever observational study of idiopathic pulmonary fibrosis (IPF) patients, with recruitment of 500 patients in two years, a participation rate unrivalled globally. All research output from this observational study will be published.

- A further success from the fibrosis network was in the development of Positron Emission Tomography (PET) studies in IPF, in which academics from the network discovered a new application of imaging and were able to publish the novel finding. GSK took on this technique and performed a reproducibility study, validating the academics' findings and establishing the technique as an effective means of tracking disease progression. Dr Marshall described a further collaborative effort in this area, this time with Cancer Research UK (CRUK), to develop a peptide discovered by CRUK as a novel PET ligand to be used as a tool for further research into IPF.
- Dr Marshall summarised the network's achievements and showed how they had succeeded in the ground-up build, from basic science to clinical application, of a PI3K inhibitor as a novel anti-fibrotic agent. Because of this success, there are future plans to create a leading integrated translational research centre for fibrotic disease with closer collaborations focused around two academic centres. Dr Marshall questioned whether the funding models within these collaborations might change from one funded solely by industry, with universities contributing to overhead costs, academic time or PhD studentships.
- Dr Marshall observed that the key to success of this network was the production of "*mutually beneficial science*", as well as having motivated clinicians and patients willing to engage with research into this disease with a high unmet medical need. He also stressed the importance of geographical proximity to the success of the collaboration, allowing movement of people between centres: all except one of the networks are UK based.
- Dr Marshall went on to present a list of keys to success that he had learned through his collaborative experiences with academia and the NHS.
  - Trust: barriers between sectors have broken down but trust does take time to develop
  - Mutual scientific objectives and joint ownership
  - Sharing of risks and rewards
  - Delivering outputs of value to all parties
  - Recognition of when intellectual property (IP) is of value and when it is not
  - Continual dialogue with proximity and transfer of personnel
  - Training with the recognition that translational science is a specialist area in its own right
  - Effective utilisation, with minimal overlap, of collaborators' areas of expertise: the different sectors must not try to do each other's job, they should recognise where in the collaboration task-specific expertise lies and use it to its full potential.
- Dr Marshall discussed the challenges of open innovation to academia and industry. He questioned whether academia was ready for open innovation: despite the addition of the 'Impact' assessment in the Research Excellence Framework (REF), current university and national systems of recognition and reward need to better recognise translational research. Open innovation also does not chime with

the traditional academic 'ownership' of research, including over-protection of ideas with IP; securing funding from 'traditional' sources that are not always geared towards supporting translational research; and publication of translational research deemed less attractive to most high impact journals.

- He then questioned whether industry was sufficiently prepared for open innovation either despite some key shifts in attitude and working practices that had already been made including: the recognition that open innovation was key to survival; that publication of all clinical data was increasingly becoming accepted practice; and that movement of personnel between sectors was improving. He acknowledged that collaborations across pharmaceutical companies could be improved to better drive open innovation whilst thought needs to be given to the 'reward' structure for academics.

### **1.3. Case Study 2: Professor Andy Cope, the MRC/ABPI Rheumatoid Arthritis Consortium**

- Professor Andy Cope shared his experiences of developing a large-scale collaboration with partners in industry, academia and the NHS. The motivation for developing the partnership was the clinical need to develop stratification tools in rheumatoid arthritis (RA) to identify early those people at risk of disease and progression and to provide accurate prognoses for patients suffering from RA.
- The starting point of the collaboration was a brainstorming session between academia and industry. From this point a consortium was forged with a detailed plan of works and shared responsibilities. Professor Cope identified a number of challenges that the consortium needed to overcome to progress including: the need for all parties to 'buy in' to the consortium; a lack of willingness by industry to share patient-level data from previous trials; identifying and exploiting the available know-how across partners; developing infrastructure for sample and data collection; and ethical issues around data handling.
- Professor Cope detailed the importance of having a steering committee to drive the project forward, in conjunction with a smaller consortium management group that allowed quick decision making.
- Professor Cope's positive impressions of working with industry were detailed. He felt that the industrial partners made a significant commitment and truly recognised the value of the collaboration. He highlighted the impressive informatics and analytical power within industry. The consortium made an attempt to quantify the monetary value of the industrial partnership, and estimated they had received 'in kind' support of £111,000 in the first year, though recognised this may be an underestimate, due to unseen internal work.
- Professor Cope went on to describe the Towards a Cure for Early Rheumatoid Arthritis (TACERA) study that had been conducted by the consortium. The

complex logistics of sample collection, transport and analysis across 25-40 centres was highlighted as one of the major challenges of the trial. Professor Cope explained that a further challenge was formalising contractual arrangements between the centres and industry partners, which significantly delayed the start of the study. He recommended these should be light touch, broad and non-prescriptive, and based on the model Industry Collaborative Research Agreement (mICRA) developed by the National Institute of Health Research (NIHR)<sup>1</sup>.

- In summary, Professor Cope listed the lessons he had learned through his experience:
  - Project management is key and lessons can be learnt from industry in this regard.
  - A pragmatic contractual framework is required.
  - There is a need to define the role of the NHS and identify individuals to contact.
  - Budget flexibility is essential.
  - A robust review process keeps the project on track.
  - In the pre-competitive domain, everything is shared.

#### 1.4. Case Study 3: Dr Anne Mandy, University of Brighton

- Dr Mandy started her presentation describing a very real clinical problem: a lack of wheelchairs suitable for use by patients with hemiplegia, a condition where one side of the body is totally or partially paralysed. She went on to describe the development of a new wheelchair that could be propelled and steered by patients with hemiplegia, offering them greater mobility and independence and reducing the need for carer input. Despite this innovative solution to address an important clinical need, the project has faced a series of hurdles.
- The first issue that Dr Mandy addressed was a vicious cycle that blinded people to the real clinical need for an innovative solution. Because wheelchair provisions were inappropriate for users with hemiplegia, these individuals were not using or seeking wheelchair services. The wheelchair services had therefore failed to notice the unmet need in this patient population.
- Dr Mandy then described challenges in seeking industrial partners with whom to develop her product. Larger manufacturers were not interested because of they failed to recognise the unseen need. Dr Mandy found a smaller specialised manufacturer with interest and enthusiasm, however they struggled to cash match her Health Technology Devices (HTD) funding, which was a requirement of the grant, but were able to match the funding in other ways including through the contribution of free time.

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<sup>1</sup> The model Industry Collaborative Research Agreement (mICRA) was developed by the NIHR to support clinical research collaborations between academia, pharmaceutical and biotechnology industries, and the NHS across the UK. <http://www.nihr.ac.uk/infrastructure/Pages/micra.aspx>

- Engagement with the NHS proved to be another barrier to accessing patient users with whom to discuss and trial the product. Dr Mandy described frustrated attempts to go through NHS clinical services, in which progress could not be made due to the services being too busy, understaffed or not organised for appropriate engagement. Dr Mandy eventually worked with voluntary groups to recruit the users to test the product.
- Despite the success of the product in trials, with patient groups and with the NHS, the frustrations continued. Dr Mandy's industrial partners were recognised on the academic papers validating the wheelchairs use, however this precludes the papers from being considered by NICE, which may delay or limit the widespread application of this new technology.
- Dr Mandy commented that the NHS is critical for success but overly bureaucratic. She called for greater flexibility and transparency of the process of getting new products onto prescribing lists/adopted for use.
- It was suggested that changes are required in the measurements of success in order to incentivise collaborations. Among other factors, consideration should be given to the savings a product makes, the patient's perspective on the value of the product and the bigger picture, including patient and carer quality of life improvements.

#### **1.5. Case Study 4: Professor Tony Young, Anglia Ruskin University**

- Professor Young started his presentation with a description of his role as a clinician, academic, innovator and entrepreneur. He emphasised the difference an enthusiastic and determined individual could make and provided three examples to demonstrate what can be achieved with cross-sector input.
- He first described his efforts to improve medical device decontamination, which were inspired by his awareness of a case where patients had come to harm through improper sterilisation of surgical equipment. Professor Young identified a deficiency in the training of staff that were involved in decontamination and proposed improved training and education. Despite challenges making others recognise this as a problem, Professor Young was able to set up a foundation degree course and start raising expectations of training within this group of staff. Following on from these efforts, the UK now recognises medical devices decontamination staff as scientific support staff, rather than auxiliary grade staff, and training is mandatory. This has raised standards, quality of care and patient safety.
- Professor Young's second example was the development of a MedTech campus at Anglia Ruskin University, which brings together in one place the essential components of innovation. He described the process of engaging public and

private enterprise to secure the funding for a medical science innovation campus across three sites in Essex.

- The third example was the use of big data analytics to predict falls risk in elderly people. Professor Young described a new collaboration of interested parties, including the local council, commissioning groups, Anglia Ruskin University and private enterprise, who were working together to direct care towards elderly people most at risk of falling at home.
- Entrenched cultural differences were highlighted as a major barrier and challenge to effective open innovation. Professor Young suggested incentives needed to be provided for innovation and new measures of success developed.

## Sessions 2 and 3 – Working Group discussions

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- The case study presentations were followed by two discussion sessions. The first, chaired by Professor John Tooke PMedSci, explored the opportunities and challenges of open innovation for all parties of the tripartite partnership. In the second and final session, chaired by Dr Amanda Begley, delegates considered practical measures that could be taken to address the three key challenges identified: metrics and incentives, culture and structure.

### 2.1 Metrics and incentives

#### Challenges and opportunities

Delegates highlighted the following issues:

- The huge pressures of clinical service provision mean that it is not always possible for NHS staff and management to prioritise innovation and external collaborations. There are limited metrics and rewards to incentivise the development and adoption of innovation, both at the individual and organisational level. It was commented that within the NHS there is a perception that *“innovation comes from elsewhere”* and that there is distrust of disruptive innovators and little reward for mavericks.
- The traditional measures of academic success, namely publication record, do not do enough to encourage open, collaborative working. These academic success metrics do not match those of industry or the NHS, so the partners have very different goals and universities can under-value collaborative or cross-sector working. We need further details of the impact assessment exercise of the REF to determine whether this could facilitate collaboration. For example, it is not clear which university would claim ‘impact’ credit in a REF exercise for a collaborative piece of work.
- There was agreement that we need to define new measures of success for the promotion of open innovation. In the NHS and academia in particular, these new success metrics could enable reward structures to be put in place that incentivise risk-taking, collaboration and innovation.

#### Practical steps

- It was considered that metrics and outcome measures should be designed to focus on value to the end user. There should be a measure of one’s partnerships and the impact the partnerships have on delivering objectives. There was discussion about whether entirely new metrics were required, or whether those recognising collaboration could be layered on existing frameworks. It was agreed that the experience of the REF exercise’s attempts to measure impact would be instructive in this area. A key point was that outcome measures and metrics were only of value if they helped to drive behavioural change.
- The group discussed the need to provide incentives to both individuals and organisations. These incentives should recognise continuous improvement and not take the form of one-off payments. Peer recognition was seen as an important

incentive and it was commented that organisations such as the Academy of Medical Sciences and learned societies should reward individuals who have made significant impact and produced demonstrable improvements in healthcare.

- It was suggested that protected research/innovation time could be used to facilitate innovation and also act as a reward for it. It was recognised that career progression was one of the most powerful incentives to behavioural change.
- The group identified that NHS Chief Executives are sometimes driven by service delivery endpoints and can consider some collaborations to be disruptive to their main aims. They need to be able to see the local rewards of innovation and enterprise. Localism was emphasised, both in terms of allowing the rewards for innovation to be seen and retained locally, but also allowing flexibility for local variation in incentive structures.

The following actions were proposed by delegates:

- Profits from innovative enterprise should be kept within the NHS Trust and available for local investment in areas of need without central direction.
- A personal recognition framework should be in place, across all sectors, to reward individuals involved in (collaborative) innovative ventures. In the NHS, Clinical Excellence Awards should recognise collaboration and innovation. In academia, the possibility of developing 'impact scholarships' and 'impact sabbaticals' was suggested.
- Lessons should be learned from the assessment of 'Impact' in the REF exercise. A formal debrief should be arranged and successful aspects of REF exercise applied to rewards within the NHS and universities.
- Other innovative ways of quantifying meaningful clinical impact within partnerships should be sought.

## 2.2 Culture

### Challenges and opportunities

The following issues were noted by delegates:

- Conflicting cultures within academia, the NHS and industry present significant barriers to collaborative working. Cultural barriers can arise from people's assumptions, stereotypes, preconceived ideas and misunderstanding.
- The focus on patient safety in the NHS can inhibit innovation and research. There needs to be a shift in the balance between risk and benefit. It is rarely recognised that there is a risk associated with not doing something. There is disconnect between official policy that states innovation is central to the NHS and what drives the system on a day-to-day basis.
- Academic and industry sectors can often view the NHS as a 'junior partner' in a collaborative venture, or as a necessary means of accessing patients, which is unhelpful and discourages NHS engagement. They can also fail to make clear the incentives to NHS involvement.
- Academia and NHS, on the other hand, can often view industry as a sponsor rather than a collaborative partner. It was mentioned that some NHS staff do not feel permitted to speak to potential collaborators, particularly industry.

- There is a tendency for academics to place much greater value on experimental medicine than late phase studies. It was thought that this hampers translation of ideas into clinical practice and discourages individuals from conducting translational studies.
- In general, there is a lack of understanding in academia and the NHS about how drugs and devices are developed, and in academia and industry about how the healthcare system operates. The importance of education and training was highlighted.

### **Practical steps**

- Communication is key in challenging cultural issues. There should be a clear vision outlined from the top - a mandate to innovate and encourage commercialisation and entrepreneurship. The 'innovation champion' proposed earlier can play a key role. There was a note of caution, however, that top-down dictation will be counterproductive. Communicating success and rewarding innovation needs to be embedded in every level of the organisation.
- The importance of nurturing a small number of 'innovation advocates' to drive change and foster a culture of innovation was raised.
- Academic Health Science Networks (AHSNs) and Academic Health Science Centres (AHSCs) could work with Trusts to identify such individuals from the NHS.
- There was enthusiasm for the promotion of success stories and celebration of the benefits of open innovation. It was also acknowledged that risk taking should be encouraged by not penalising failure. A delegate commented, we need to *"provide a safe place where failure is accepted"*. Another suggestion was wider public engagement over the value of innovation and catalysing their enthusiasm as a 'pull' factor.
- Specific areas may need tailored action to address cultural barriers. For instance issues over trust relating to use of patient data.

The following actions were proposed by delegates:

- Use 'champions' in all sectors to model and incentivise a culture of innovation. Every NHS Board should have a named individual responsible for innovation to ensure that innovation and collaboration are given appropriate priority.
- Facilitate secondments and placements to promote movement between sectors.
- Showcase concrete examples of innovation in all three sectors to demonstrate that success is possible.

## **2.3 Structures**

### **Challenges and opportunities**

- There can be conflict and confusion about which public body to approach when industry is seeking to establish collaborations with academia and/or the NHS. Finding a point of contact within the NHS can be particularly difficult for external agents. This complexity has the potential to dilute the perceived impact of collaboration.

- The NHS, rather than being a single organisation, consists of many separate entities with competition between them, which poses a barrier to collaboration and uniform dissemination of ideas.

### **Practical steps**

- Rather than develop new institutions to promote innovation, existing structures should be better utilised. AHSNs offer a potential solution to translation of innovation into service, but they are still nascent and need to become more established with appropriate support. The opportunities of industrial partnerships are not consistently being fully exploited and there is scope for improvement.
- Development of holistic cross-sector initiatives focused on improving a particular condition may be one way of addressing the lack of alignment of priorities across the three sectors. The Prime Minister's Dementia Challenge<sup>2</sup> may act as a useful model that aligns objectives and focuses efforts.

The following actions were proposed by delegates:

- A workshop to define the way in which incentives could be applied in the complex adaptive system of the medical science ecosystem to encourage open innovation and collaboration. This workshop should harness expertise from beyond the biomedical sciences and include the perspectives of social scientists, anthropologists and entrepreneurs.
- A rigorous academic exercise to evaluate the impacts and successes of the dementia initiative. This should form the basis for recommendations to inform future cross-sector initiatives
- AHSNs should come together to argue with a single voice, for increased security, as well as a clear five year mandate.

### **2.4 General comments and closing thoughts**

- It was suggested that future workshops on collaboration between academia, industry and the healthcare sector may benefit from wider NHS engagement if it were to examine innovation opportunities in specific disease states, or to focus on innovation as a means to improve specific outcomes.
- There was agreement that in all sectors, change was required and that the NHS should not singularly shoulder current failures to exploit collaborative working opportunities.

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<sup>2</sup> <http://dementiachallenge.dh.gov.uk/>

## Appendix 1: Programme

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<b>09:30 – 10:00</b>	<b>Registration</b>
<b>Session 1 – Case studies</b> <b>Chair: Professor Richard Barker OBE</b>	
10:00 – 10:15	Introduction and objectives <i>Professor Richard Barker</i>
10:15 – 10:30	Case study 1 GSK R&D Fibrosis Discovery Performance Unit, <i>Dr Richard Marshall</i>
10:30 – 10:45	Case study 2 The MRC/ABPI Rheumatoid Arthritis Consortium, <i>Professor Andy Cope</i>
10:45 – 11:00	Case study 3 University of Brighton, <i>Dr Anne Mandy</i>
11:00 – 11:15	Case study 4 Anglia Ruskin University, <i>Professor Tony Young</i>
<b>11:15 – 11:30</b>	<b>Tea/coffee break</b>
<b>Session 2 – Discussion</b> <b>Chair: Professor Sir John Tooke PMedSci</b>	
11:30 – 12:15	Discussion of the key challenges and opportunities of openly partnering with the NHS
12:15 – 12:45	Feedback
12:45 – 13:00	Summary session and identification of the three key issues to tackle in the afternoon working group session
<b>13:00 – 13:45</b>	<b>Lunch</b>
<b>Session 3 – Working groups</b> <b>Chair: Dr Amanda Begley</b>	
13:45 – 14:45	Discussion in groups of the three key issues of openly partnering with the NHS
14:45 – 15:30	Feedback
15:30 – 15:45	Summary session
<b>15:45 – 16:00</b>	<b>Tea/coffee break</b>
<b>16:00</b>	<b>Close</b>

## Appendix 2: Delegate list

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- Professor Richard Barker OBE (Chair Session 1)**, Director, Centre for the Advancement of Sustainable Medical Innovation
- Dr Amanda Begley (Chair Session 3)**, Director of Innovation and Implementation, UCL Partners
- Professor Chris Brightling**, Clinical Professor in Respiratory Medicine, University of Leicester and member of the MRC/ABPI COPD consortium
- Mr Ian Busby**, Project Leader - The Open Innovation Initiative, SETsquared Partnership
- Professor Andrew Cope**, Head of Academic Rheumatology, King's College London and member of the MRC/ABPI Rheumatoid Arthritis consortium
- Professor Andy Hall**, Associate Dean of Translational Research, Faculty of Medical Sciences, Newcastle University
- Dr Kurt Hertogs**, Head Platform Innovation & Incubator Strategy, Johnson & Johnson Innovation Centre
- Professor Andrew Hughes**, VP Head of Early Clinical Development, AstraZeneca
- Professor Graeme Laurie FRSE FMedSci**, Professor of Medical Jurisprudence, University of Edinburgh
- Dr Louise Leong**, Director of R&D Policy, Association of the British Pharmaceutical Industry
- Dr Anne Mandy**, Reader and Director of Post Graduate Studies, University of Brighton
- Dr Richard Marshall**, Head of the R&D Fibrosis Discovery Performance Unit and Senior Clinical Lead in Respiratory R&D, GSK
- Dr Linda Maxwell**, NHS Partnership Leader, ISIS Innovation Ltd, University of Oxford
- Mr Jason Miller**, National Account & HTA Policy Manager, Pfizer
- Dr Alan Moodie**, Vice President, UK External Engagement, GSK
- Dr Nicola Perrin**, Head of Policy, The Wellcome Trust
- Dr Martino Picardo**, Chief Executive Officer, Stevenage Bioscience Catalyst
- Dr Ravi Rao**, Vice President, Medicines Development Leader and Head of Clinical Development, Immuno-inflammation, GSK & member of the MRC/ABPI Rheumatoid Arthritis consortium
- Mr Michael Smith**, Commercial and IP Manager (Research & Development), Queen Elizabeth Hospital Birmingham
- Dr Tony Soteriou**, Research Infrastructure and Growth Senior Manager, Department of Health
- Professor Sir John Tooke PMedSci (Chair Session 2)**, President, Academy of Medical Sciences
- Dr Louise Wood**, Deputy Director, Head of NHS Research Infrastructure and Growth, Department of Health
- Ms Louise Wren**, Policy Adviser, Strategic Planning and Policy Unit, The Wellcome Trust
- Professor Tony Young**, Director of Medical Innovation, Postgraduate Medical Institute, Faculty of Health, Social Care & Education, Anglia Ruskin University

### Secretariat

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