Wellcome Trust Frontiers Meeting

Precompetitive Drug Boundaries: Open Innovation in Drug Discovery and Development

Wellcome Trust, London
17–18 June 2010

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OVERVIEW

I. Background and aims

On 17 and 18 June 2010, the Wellcome Trust convened 50 leaders from academia, technology transfer, the biotechnology and pharmaceutical sectors and other professional bodies to discuss open innovation strategies for drug discovery and development.

At present, the cost of bringing new drugs to the commercial market is becoming increasingly unsustainable. Therefore, the market has been driven to develop alternative strategies for innovation, including partnerships with the biotechnology sector and academia and the outsourcing of chemistry, screening and lead-optimisation activities. There is some evidence that 'open source' science and public–private partnerships could energise the quest for new drugs. The Trust, in combination with a specifically constituted Scientific Steering Committee, developed this Frontiers Meeting to catalyse discussion on the specific challenges facing drug discovery and to suggest a framework by which the Trust can facilitate improvement.

The aims of the meeting were to:

- stimulate an open and inclusive discussion with stakeholders interested in the drug development process
- identify bottlenecks in the drug development process where precompetitive approaches could add value
- identify common ideas and alternative strategies for innovation that benefit all stakeholders
- stimulate pharmaceutical industry and academic partnerships
- stimulate collaborations for research
- facilitate networking and business connections
- develop ideas to influence government policy.

II. Structure of the meeting

Five discussion sessions were held over two days to address the key issues and lessons to be learnt within drug discovery and development. Sessions addressed varying perspectives on the precompetitive space, the role of intellectual property (IP) within this space, lessons from the not-for-profit sector and public–private partnerships, and the barriers to cross-sector working.

A list of the members of the Steering Committee can be found in Appendix 1, a full Agenda is included in Appendix 2 and a list of attendees can be found in Appendix 3.

III. Emerging themes

- Human capacity building is required to ensure that sufficient expertise is available, including a new generation of entrepreneurial scientists.
- Informatics infrastructures need to be developed to host, validate, curate, integrate and share heterogeneous and clinical data.
- There needs to be more research conducted in an IP-free environment and more flexibility with existing IP by both academia and industry:
    - metrics other than IP patents are required to evaluate researchers

    - practical guidelines for university technology transfer offices and standard formats for legal agreements would be useful.
- Regulatory incentives are required to encourage more cross-sector working and/or partnerships**.**
- Better communication is required, globally, to inform the community which activities are taking place and to identify best practice.
- New drug targets need to be identified and validated in partnership between academia and industry.
- Tools, compounds and failed drugs should be available to the whole community in centralised repositories.
- A successful example is required to showcase how open innovation and precompetitive research has led to the development of a drug. The whole community should target one disease and work together to realise this ambition.

IV. Recommendations

- Generate a white-paper-like publication of the meeting, stating how we could take this forward.
- Establish a 2020 initiative to elucidate a therapeutic entity for use in one or two diseases.
- Implement a cross-sector working group for the identification and validation of drug targets (possibly led by Bill Chin, Harvard University).
- Host an IP Frontiers Meeting, with university vice chancellors, technology transfer offices, biotech and pharma representation.
- Develop a communication strategy to ensure joined-up thinking between Europe, the USA and the rest of the world.
- Increase human capital in this area, ensuring the required skills sets and training are available.
- Establish repositories for – for example – targets and failed phase II drugs, or a library of key compounds with international availability, including in low-income countries.

MEETING REPORT

DAY 1

Session 1: Precompetitive space – perspectives

Jackie Hunter, Pharmivation, opened the meeting by setting the scene and describing the current issues facing the pharmaceutical industry. She described how pharmaceutical companies are changing the way they think and open innovation is being hailed as one solution. New models for precompetitive sharing are being established, and there has been an increase in academic and industry partnerships.

Bill Chin from the Harvard Medical School emphasised the need for the leaders of the pharmaceutical industry to step up and answer a 'call for sharing'. He highlighted that new and innovative models for drug development are required and that although there are many examples of successful precompetitive consortia, there is still much to do. Professor Chin highlighted the need for increased target knowledge and validation and that the explosion in our understanding of human and animal genomes – facilitated by epigenomics, whole genome sequencing, stem cell research, proteomics and metabolomics – will have an increasingly important role in determining appropriate targets.

Stephen Friend, the CEO of Sage Bionetworks, described its model of data sharing in an open, precompetitive space. He stated that data sharing is crucial to ensure successful disease modelling and that these data should be integrated correctly and not just compiled. These models could then inform our understanding of disease causality, as well as generate new mechanisms, targets and diagnostics.

Main discussion points

- The precompetitive versus competitive space needs to be defined and agreed.
- Change will require bold initiatives and greater upstream collaboration; companies should compete in areas that offer a viable return on investment.
- Precompetitive consortia require:
    - strong project management
    - a consensus of direction of research, governance and culture
    - realistic goals and real-time evaluation of progress
    - a standardisation of methods and defined database formats.
- The protection of IP has a role in drug discovery and development, but it should not hinder open innovation.

Session 2: Lessons from the not-for-profit sector

Tim Hubbard from the Wellcome Trust Sanger Institute (WTSI) presented models for sharing in a precompetitive framework, highlighting open access in the not-for-profit sector. He acknowledged that both industry and academia face competitive pressures and the challenges of data protection and privacy. Dr Hubbard highlighted the WTSI data sharing policy and the benefit of early data release, which has led to many collaborative links and the development of novel diagnostic tests and vaccines that would otherwise not have happened.

Tim Wells, the Chief Scientific Officer for the Medicines for Malaria Venture (MMV), shared his views and experiences of product development partnerships in the not-for-profit sector. MMV is a not-for-profit foundation that was created to discover, develop and deliver new, affordable antimalarial drugs through effective public–private partnerships. The MMV model insists that ideas, data, expertise and best practice are shared between all collaborators.

The MMV also allows all members access to centralised pharmacology information. This model ensures that there is no funding monopoly or duplication of work.

Simon Croft from the London School of Hygiene and Tropical Medicine highlighted the lack of adequate or accessible therapeutics for neglected tropical diseases (NTDs). He stressed that a number of different approaches should be adopted to develop new drugs and improve those that are currently available for NTDs. In addition, for NTDs, there is a need to increase the capacity for good clinical practice within clinical trials conducted in low- or middle-income countries.

Samir Brahmachari from The Council of Scientific & Industrial Research (CSIR) in India described how open source and open innovation are part of the CSIR's strategy to develop innovative low-cost medicines, which are licensed cheaply to large pharma. Specifically, Professor Brahmachari described the CSIR's open source drug discovery model for infectious diseases, entitled 'Connect to Decode 2010' (C2D10). C2D10 is a large initiative to understand the biology of *Mycobacterium tuberculosis* to accelerate the discovery of novel drugs for tuberculosis, which is a disease neglected by pharmaceutical enterprises.

Main discussion points

- Precompetitive activities could occur at many stages of the pre-clinical space, but not once a drug or therapy is tested in a patient.
- Open access to data should reduce research costs and increase the speed of drug discovery.
- Academia and industry have similar issues with regards to competition and data protection. Publication embargoes to protect academic credit may be effective.
- Intellectual property:
    - patents may be useful for demonstrating credibility or measuring innovation or as a tool for partnering
    - filing patents hasn't made academia share their data more and can be a deterrent for industrial collaborations
    - academics tend not to be very knowledgeable about IP and often overvalue their research; however, academic researchers are under pressure to file for patents by their host institutions.
- Access to failed phase II drugs would benefit the whole community, especially if background data (including pharmacogenetics and toxicology information) were also available.
- PhD students need to be trained in enterprise and innovation. Unlike industry, academia does not currently have widespread project management expertise and skills to take large, international partnerships forward.
- There is a role for community annotation of large open access datasets.
- The Wellcome Trust could take on a facilitation role between industry and academia and define data sharing opportunities and best practice.

Session 3: Intellectual property within a precompetitive space

Tania Bubela from the University of Alberta introduced possible models for dealing with IP and described data commons, a model that encourages data sharing. The model is a self-organised and self-governed entity, which increases in value as more people use the resource. To follow this model, a cultural homogeneity needs to exist between all of the parties involved and shared practices need to be agreed in advance. Political pressures placed on universities to generate revenue conflict with this model because patents restrict innovative research. It was noted that universities should consider, in advance, whether they are likely to enforce any patents before filing them. If a university is not realistically going to pursue someone who has breached a patent, the effort and cost associated with filing it has been wasted and the patent is worthless. Open innovation would be encouraged if

alternative metrics, both economical and social, were used to evaluate research and development – for example, uptake by the community or the number of collaborations resulting from it.

Chas Bountra from the Structural Genomics Consortium (SGC) described the Consortium's successful open data sharing policy. The SGC is a public–private partnership, which promotes the development of new medicines by carrying out basic science of relevance to drug discovery. It has a no IP policy, reagents are given out freely and members of the consortium gain pooled resources and expertise. The Consortium is able to work closely with multiple private organisations, on the same project, in this IP-free arena and data can be released quickly into the public domain.

Main discussion points

- Patenting stifles innovation.
- Alternative metrics are required to judge people and their research, rather than the misguided emphasis on patenting.
- Data commons models should be encouraged.
- Rapid data dissemination and data sharing lead to increased efficiency and reduced duplications and costs.

Session 4: Wrap up for day 1 – open discussion

Key comments

- Further basic research to understand disease mechanisms and processes is required to identify biomarkers and drug targets to lead to more and efficacious drug leads and reduce drug development costs.
- It is possible to profit in a non-exclusive environment.
- Some metrics used to judge people and their research are probably not appropriate, and alternatives are required.
- IP restrictions should only be in place in the later stages of drug development; in the early stages, this leads to a lack of open access and innovation.
- Successful open innovation partnerships do not all fit one template. The needs of all parties involved should be taken into consideration and accommodated.

DAY 2

Session 5: Lessons from public–private partnerships

Paul Wyatt from the Dundee Drug Discovery Unit (DDU) described the Unit's successful model for innovative drug discovery. The DDU has all of the capabilities required for early-phase drug discovery: assay development, high-throughput screening, cell biology, medicinal chemistry, structural biology, computational chemistry, and drug metabolism and pharmacokinetics. The DDU also gains from being within a centre of academic excellence, with access to many outstanding scientists, support staff, *in vivo* models and reagents. The multidisciplinary unit conducts translational research, which falls between hypothesis-driven early research and commercialisation by a pharmaceutical company.

Michel Goldman from the Innovative Medicines Initiative (IMI) described the IMI's public–private partnership between the European Federation of Pharmaceutical Industries and Associations and the European Commission. The IMI's goal is to reinvigorate the biopharmaceutical sector in Europe by pooling and harnessing expertise and resources from the public and the private domain. The IMI identifies scientific challenges and – via competitive calls – funds academic and industry collaboration to address them.

Arthur Holden from the International Serious Adverse Event Consortium (iSAEC) described a generic model for establishing successful consortia and highlighted the lessons learned from the iSAEC. The iSAEC includes leading pharmaceutical companies, the Wellcome Trust, academic institutions, and scientific and strategic input from the US Food and Drug Administration (FDA) and other international regulatory bodies. The mission of the iSAEC is to identify biomarkers that predict the risk of drug-related serious adverse events.

Main discussion points

- New tools for target validation need to be developed.
- It is not necessary to establish drug discovery units within every university.
- Large-scale collaborations are required for the future progression of translational research; however, consortia fatigue can be an issue.
- New collaborations and partnerships can learn from the best practice developed by older, more established consortia.

Session 6: Barriers to cross-sector working – panel discussion

Members of the panel presented their views on what the barriers to cross-sector working are and stimulated discussions from all the attendees. The panel consisted of:

- Dr Tania Bubela, University of Alberta, Canada
- Dr Joseph Fleishaker, Pfizer Inc, USA
- Dr Sarah Garner, NICE
- Dr Lisa Green, Creative Commons, USA
- Dr Jo Martindale, Royal Society of Chemistry
- Dr Andy Merritt, MRC Technology
- Mr Rashik Parmar, IBM
- Professor Lars Sundstrom, Severnside Alliance for Translational Research, University of Bristol.

Session 7: Next steps – recommendations to the Wellcome Trust

- Generate a white-paper-like publication of the meeting, stating how we could take this forward.
- Establish a 2020 challenge to elucidate a therapeutic entity for use in one or two diseases.
- Implement a cross-sector working group for the identification and validation of drug targets (possibly led by Bill Chin).
- Host an IP Frontiers Meeting, with university vice chancellors, technology transfer offices, biotech and pharma representation.
- Develop a communication strategy to ensure joined-up thinking between Europe, the USA and the rest of the world.
- Increase human capital in this area, ensuring the required skill sets and training are available.
- Establish repositories for – for example – targets or failed phase II drugs, or a library of key compounds with international availability, including in low-income countries.

Appendix 1
STEERING COMMITTEE

- Jackie Hunter, Director, Pharmivation and Wellcome Trust Molecular and Physiological Sciences Strategy Committee member

- Tom Blundell, Professor in Structural Biology, Department of Biochemistry, University of Cambridge

- Rob Cooke, GSK, Structural Genomics Consortium Board Member and a previous Wellcome Trust Molecules, Genes and Cells Funding Committee member

- Garret FitzGerald, Professor in Translational Medicine and Therapeutics, University of Pennsylvania and Wellcome Trust Molecular and Physiological Sciences Strategy Committee member

- Tim Hubbard, Head of Informatics and Member of the Board of Management, Wellcome Trust Sanger Institute

Appendix 2
AGENDA

10.00–10.30	**REGISTRATION & COFFEE**	
10.30–10.45	**Welcome, Introduction and Aims** *Michael Dunn, Wellcome Trust;* *Jackie Hunter, Pharmivation*	
Session 1	**Precompetitive Space – perspectives** *Moderated by Jackie Hunter*	
10.45–11.15	**'A Call For Sharing'**	**Bill Chin** Harvard University
11.15–11.30	*Discussion*	
11.30–11.50	**Case Study: Sage**	**Stephen Friend** Sage Bionetworks
11.50–12.00	*Discussion*	
Session 2	**Lessons from the not-for-profit sector** *Moderated by Tim Hubbard*	
12.00–12.20	**Case Study 1: Medicines for Malaria**	**Timothy Wells** Medicines for Malaria Venture
12.20–12.30	*Discussion*	
12.30–13.30	**LUNCH**	
13.30–13.50	**Case Study 2: The Drugs for Neglected Diseases Initiative (DNDi)**	**Simon Croft** London School of Hygiene and Tropical Medicine
13.50–14.00	*Discussion*	
14.00–14.30	**Open Discussion** Lessons learned: Not-for-profit sector	
Session 3	**Intellectual property within a precompetitive space** *Moderated by Tom Blundell, University of Cambridge*	
14.30–14.50	**Setting the Scene – Models for dealing with IP**	**Tania Bubela** University of Alberta
14.50–15.00	Discussion	
15.00–15.20	**Case Study – Structural Genomics Consortium (SGC)**	**Chas Bountra** SGC
15.20–15.30	*Discussion*	
15.30–16.00	**COFFEE**	
16.30–17.00	**Open Discussion: IP within a precompetitive space**	
Session 4	**Wrap Up for day 1**	
17.00–17.30	*Moderated by Rob Cooke, GlaxoSmithKline* This session will highlight key outcomes and recommendations and identify any major issues for further consideration on day 2.	
17.30–19.00	**Drinks & opportunity to tour the Wellcome Collection's exhibitions:** **'Skin' –** the changing importance of skin, from anatomical thought in the 16th century through to contemporary artistic exploration. **'Medicine Man'** – examine medicine through the eyes of artists, scientists and patients. **'Medicine Now**' – delve into the treasure trove of Henry Wellcome.	
19.00	**Dinner**	

Day 2	**COFFEE available from 09.30**	
10.00–10.10	**Welcome and Recap** *Michael Dunn, Jackie Hunter*	
	Lessons from the not-for-profit sector (continued from Day 1) *Moderated by Tim Hubbard*	
10.10–10.30	**Case Study 2: What can we map across from the not-for-profit sector: Council of Scientific & Industrial Research (CSIR)**	**Samir Brahmachari** CSIR
10.30–10.40	*Discussion*	
Session 5	**Lessons from public–private partnerships** *Moderated by Jackie Hunter*	
10.40–11.00	**Case Study 1: Dundee Drug Discovery**	**Paul Wyatt** University of Dundee
11.00–11.10	*Discussion*	
11.10–11.30	**Case Study 2: Innovative Medicines Initiative**	**Michel Goldman** Free University of Brussels
11.30–11.40	*Discussion*	
11.40–12.00	**Case Study 3: International Serious Adverse Event Consortium (iSAEC)**	**Arthur Holden** iSAEC
12.00–12.10	*Discussion*	
12.10–13.15	**LUNCH**	
Session 6	**Cross-sector working** *Moderated by Garret FitzGerald, University of Pennsylvania*	
13.15–14.15	**Panel discussion: Barriers to cross-sector working** Discussion will highlight specific barriers. Panel to include representatives from technology transfer, industry, pharma, legal, academia.	
Session 7	**Next Steps** *Moderated by Jackie Hunter*	
14.15–14.45	**Open Discussion** (opportunity to revisit major issues and visit newly highlighted areas)	
14.45–15.00	**Wrap-up** *Jackie Hunter and Michael Dunn* **CLOSE**	

Appendix 3
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The Wellcome Trust

We are a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health.

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