Academic – NHS – Industry Collaboration in Experimental Medicine

Innovative partnering
## Contents

3  Foreword

5  Benefits of collaboration

6  **Collaboration 1: NIHR National Cancer Research Network - AstraZeneca**  
**Early-stage drug development**

8  **Collaboration 2: The University of Cambridge - GlaxoSmithKline**  
**An Academic Discovery Performance Unit**

10 **Collaboration 3: NIHR Biomedical Research Centre, Moorfields Eye Hospital NHS Trust - University College London - The Automation Partnership**  
**Regenerative medicine applications in ophthalmology**

12 **Collaboration 4: NIHR Biomedical Research Centre, Newcastle University - Multiple Industry Partners**  
**A collaborative training programme in translational research**

14 **Collaboration 5: The University of Brighton - The Brighton and Sussex University Hospitals NHS Trust - Neater Solutions**  
**Improved assisted living technology**

16 **Collaboration 6: The University of Edinburgh - NHS Lothian - Pfizer**  
**Generation of a well-characterised patient cohort**

18  Appendix

19  Postscript from the Managing Director of the NIHR Office for Clinical Research Infrastructure (NOCRI)
Foreword

Innovative partnering can accelerate the development of new treatments, devices and diagnostics to tackle complex healthcare needs. Creative engagement between the NHS, universities and industry forms a powerful alliance to drive translational medicine in the UK. This alliance is vital. It ensures that advances in basic science progress swiftly into benefits for patients and the economy.

The National Institute for Health Research and Medical Research Council have compiled this booklet in order to share six examples of innovative research that involve successful partnering between the NHS, universities and industry. These examples show different sorts of collaboration, supported by a range of funders.

A variety of approaches have brought about successful collaborations. Many involve a commitment of material, funding or expertise. Industry has been willing to share unique compound libraries. Shared risk-reward models have been created to fund programmes of work. Training programmes, secondments and joint posts have helped share expertise and best practice.

We hope that reading these examples will inspire you to explore ideas for collaboration adapted to your own area of interest.

Professor Dame Sally C. Davies
Director General of R&D, Department of Health

Professor Sir John Savill
Chief Executive of the MRC
Benefits of collaboration

The ability of academia, the NHS and industry to collaborate in more productive ways will speed translation of scientific ideas and observations into therapeutics and benefits for patients.

Collaboration is effective when it teams complementary scientific skills, knowledge and technologies to tackle a complex research issue. It is most pertinent when undertaking the early clinical phase in the development of a new healthcare product. At a recent workshop involving the directors of academic experimental medicine centres and industry scientists, a number of complementary strengths and resources were highlighted:

- The pharmaceutical, biotechnology and medical technology industries could adopt more informed approaches to drug, device and diagnostic design and development through collaboration. UK academia hosts a strong cohort of investigators with innovative discoveries and ideas arising from detailed explorations of specific diseases.

- Accurate disease biomarkers developed and validated by academia can improve study protocols, stratify patient populations and ultimately ensure therapy development is more targeted and efficient.

- Partnering with the UK’s world class NHS, including its clinicians, healthcare professionals and dedicated experimental medicine research infrastructure, fosters engagement with patients and their carers. Operating in the context of a unified care system ensures product design is better informed and potentially stratified by patient disease.

- Early access to industry compounds and technologies presents academics and clinicians with the opportunity for unique first-in-human clinical research studies. These provide a platform for further research and development, as well as expand the knowledge base and publication record. Industry can also share its wealth of experience in negotiating the regulatory pathways to first-in-human studies.
Within translational medicine, stronger collaboration between universities, the NHS and industry will become a powerful platform for engaging and influencing other important stakeholders, such as national and international regulatory authorities.

Personal contacts, showcases, workshops and conferences remain fertile ground for initiating collaboration. Research funders provide a range of support both for events to kick-start partnering and through a variety of funding streams to support collaborations at all levels, from individual projects to large scale consortia. The model Industry Collaborative Research Agreement (mICRA), streamlined regulatory approvals and guidance with route maps for intellectual property agreements all aim to simplify partnering.

Against a backdrop of high rates of phase II candidate compound attrition, and an increasing emphasis on open innovation by the life sciences industries, the time is ripe to encourage early stage collaboration between industry, academia and the NHS.
Collaboration 1

A pioneering collaboration offering academic investigators an opportunity to research promising molecules that rest outside industry’s core programme for the benefit of cancer patients.

Initiated by a chance discussion between Professor David Cameron of the NIHR National Cancer Research Network (NCRN) and Professor Andrew Hughes of AstraZeneca (AZ), this collaboration offered mutual benefits. AZ were looking to evaluate their compounds in a broader range of cancers, and the Network (comprising multiple clinical investigators) would gain access to novel molecules for improved oncology research and patient benefit.

<table>
<thead>
<tr>
<th>Academia</th>
<th>Initiation</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professors Rick Kaplan &amp; David Cameron (NCRN) brought previous experience of industry engagement from the National Cancer Institute, USA.</td>
<td>Professor Andrew Hughes, a senior VP at AZ, held a joint position as Chair of Translational Medicine at the University of Manchester and had enthusiasm for working with academia.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Offer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Research infrastructure</td>
<td>• Defined collaboration budget</td>
</tr>
<tr>
<td>• NHS patient access</td>
<td>• Portfolio of novel molecules</td>
</tr>
<tr>
<td>• Novel protocol development</td>
<td>• Patient support costs</td>
</tr>
<tr>
<td>• Objective molecule evaluation</td>
<td>• Drug development expertise</td>
</tr>
<tr>
<td>• Integrated disease knowledge</td>
<td></td>
</tr>
</tbody>
</table>

**Collaborative functions**

- Joint protocol sign-off
- Early-stage data sharing
  - Collaborative choice of lead candidate molecules
  - Systematic collaborative support including model agreements
  - Combinational therapeutic approaches

**Outcome**

- R&D of drugs for cancers outside company’s core programme
  - Earlier patient access to new and more innovative drugs
    - 14 Phase II Clinical Studies
  - An established model of collaborative working that could be rolled out in other disease areas and with other industry partners
Key success factors

• Access to and engagement of AstraZeneca decision makers in the company’s UK Cancer Division Headquarters

• Effective workshops involving industry product & disease teams and academic study groups generated ideas and opportunities for the development of drug candidates

• Long-term support for the collaboration was established in the form of model contracts, clear roles and responsibilities, active management and organisational understanding

“You need to simply sit down with companies and find common areas. Perhaps look at 1 or 2 molecules and disease areas where a company may wish to broaden their activity. Emphasise the need for long-term collaboration and establish the systems to ensure this.”

Professor Rick Kaplan
Associate Director of the National Cancer Research Network

“This really is a win-win situation. We can provide data about our development pipeline and compounds that allow academic researchers to pursue interesting areas of science, whilst we gain a vital external perspective, and research data that may point towards new indications for a particular drug.”

Chris Wilks
Coordination Director & Head of Partnerships, AstraZeneca
Collaboration 2

An academic-industry engagement to enable academic development of novel drug candidates in a range of therapeutic areas.

Cambridge University, Cambridge University Hospitals NHS Trust and GlaxoSmithKline have built upon a strong history of collaboration. As a GSK ‘Academic Discovery Performance Unit’, Cambridge academics work as stakeholders on the clinical development of proprietary GSK drug candidates, while GSK gain the cross-themed expertise of international experts.

<table>
<thead>
<tr>
<th>Academia</th>
<th>Initiation</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>The secondment of Professor Ed Bullmore from Cambridge to work half-time as head of the GSK Cambridge Clinical Unit, based in Addenbrooke’s Hospital, greatly facilitated this collaboration. Building on a foundation of previous Cambridge-GSK pre-competitive collaboration, there was a mutual desire for greater academic input in the clinical development activities of GSK.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Offer</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Non-compartmentalised and imaginative thought to a research question that cut across two GSK disease teams, neuroscience and metabolism</td>
</tr>
<tr>
<td>• Objective judgement of a candidate drug’s potential</td>
</tr>
<tr>
<td>• Project management focused on delivery</td>
</tr>
<tr>
<td>• Structural and strategic model of a GSK project team</td>
</tr>
<tr>
<td>• Specialist drug-development knowledge</td>
</tr>
<tr>
<td>• Commercial analysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collaborative functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Embedded academic teams</td>
</tr>
<tr>
<td>• Programme-level agreements to cover IP, publication rights, and other rules of engagement</td>
</tr>
<tr>
<td>• A shared risk-reward structure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>• One candidate drug for obesity successfully progressed through a phase I programme and is now undergoing phase II trials.</td>
</tr>
<tr>
<td>• Preclinical studies on a candidate drug being analysed primarily for obesity have identified an additional therapeutic activity for addiction</td>
</tr>
<tr>
<td>• A greater appreciation of the issues facing the two partners has brought academia and industry closer in this setting</td>
</tr>
</tbody>
</table>
Key success factors

• An approach that prioritised scientific engagement as an incentive for individual academics

• Financial risk-sharing model

• The on site GSK clinical unit in Cambridge helped to build bridges and enable the partners to realise each other’s value to the collaboration

• Cambridge academics successfully presented an organised, coherent and compelling offer to GSK in a therapeutic area in which they excelled in an international context

“[A driving force behind this collaboration was the realisation that the existing GSK unit on the Cambridge campus was not in itself enough to establish strong collaborations. There had to be an arrangement that allowed academics to be in control of the drug development work in order to motivate them on a scientific level.”

Professor Ed Bullmore
Cambridge University/GSK

“This collaboration with Cambridge has had a very positive effect on GSK scientists. The innovative nature of the collaboration has stimulated more innovative thinking from our teams and liberated their ‘academic within.’”

Dr Pauline Williams
Head of GSK’s Academic Discovery Performance Unit, Cambridge
Collaboration 3

A collaboratively-funded project to develop a novel substrate on which to grow stem cells for regenerative ocular therapy.

A method for growing transparent tissue, developed by academics at University College London (UCL), was licensed to The Automation Partnership. Collaboration with the NIHR Biomedical Research Centre (BRC) at Moorfields Eye Hospital brought therapeutic applications to cure blindness through the proposed generation of a complete ocular surface. The technology ultimately has applications in many areas of regenerative medicine.

<table>
<thead>
<tr>
<th>Academia</th>
<th>Initiation</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Robert Brown of UCL patented technologies for membranes supporting cell growth. Dr Julie Daniels of the NIHR BRC at Moorfields joined the Technology Strategy Board-funded collaboration to develop clinical applications for the technology in ocular therapy.</td>
<td>The Automation Partnership were interested in licensing this technology for commercial development, and were awarded a grant to this end from the Technology Strategy Board (TSB).</td>
<td></td>
</tr>
</tbody>
</table>

**Offer**

- Translational research expertise in the field of ocular therapy
- Patented technologies
- Academic contacts in further therapeutic areas
- NIHR-funded research infrastructure

- Experience in automated cell culture systems
- Robust protocols and technique standardisation
- Funding
- Lead applicant on the Technology Strategy Board grant

**Collaborative functions**

- The Automation Partnership won a collaborative grant from the Technology Strategy Board
- Appropriate patents are filed in open negotiation between the partners
- Twenty individuals from both academia and industry are involved in the project

**Outcome**

- A patented automated workstation capable of producing consistent 3D tissue structures
- Publications and conference presentations from both academic and industry partners
- Grant applications submitted for spin-off projects in further areas of regenerative medicine
Key success factors

• Enthusiasm and commitment of the partners towards a common goal

• Availability of collaborative funding to kick start development of a commercially higher-risk technology

• A protected academic idea developed by commercially-aware scientists

• A ‘Collaboration Steering Committee’ to quickly escalate issues and keep the project on track

• The cell therapy unit hosted by the NIHR Biomedical Research Centre at Moorfields

“The establishment of core infrastructure in the form of the NIHR BRC’s cell therapy unit was crucial in attracting The Automation Partnership to specifically enter the area of corneal regeneration. The project has really benefited from the expertise of the individuals in this unit.”

Dr Julie Daniels
Reader, NIHR BRC, Moorfields Eye Hospital

“An deep relationship has developed between the collaborators and much has been learnt in the field of tissue engineering from working with world-class researchers. The successes already realised in this project would simply not have been seen outside of this collaborative model.”

Dr Rosemary Drake
Chief Scientific Officer, The Automation Partnership
Collaboration 4

A training programme developed and delivered collaboratively between academia and industry to improve the translational knowledge of clinical academics.

The Wellcome Trust has supported a training programme developed collaboratively between Newcastle University and several industry partners. It has proven very popular with both clinical fellows and industry, and acted as a catalyst for greater industry engagement at Newcastle.

<table>
<thead>
<tr>
<th>Academia</th>
<th>Initiation</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>There was a mutual realisation between industry and academia that, although many people discussed the topic of ‘translational research’, few within academia actually understood how to effectively develop the results of research into therapies and technologies for patient benefit.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Offer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• NIHR Biomedical Research Centre with dedicated infrastructure funding to support research translation</td>
</tr>
<tr>
<td></td>
<td>• An experienced group of clinical academics</td>
</tr>
<tr>
<td></td>
<td>• Updated ‘Real World’ course content</td>
</tr>
<tr>
<td></td>
<td>• PhD programmes in translational research hosted at industry sites</td>
</tr>
<tr>
<td></td>
<td>• Expert experience in therapy development</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collaborative functions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Newcastle University engaged multiple industry partners</td>
</tr>
<tr>
<td></td>
<td>• Collaborative development of a first year Masters course entitled ‘MRes in Medical and Molecular Biosciences’</td>
</tr>
<tr>
<td></td>
<td>• Partners agreed to use real experimental data to enrich the course content</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• University, NHS and industry partners found themselves on the same side of the table when designing and delivering the training programme</td>
</tr>
<tr>
<td></td>
<td>• University-NHS-industry interactions in Newcastle are more common, rich and diverse as a result of this collaboration</td>
</tr>
</tbody>
</table>
Key success factors

• Senior industry figures from the partner companies work alongside academics to deliver the Masters programme

• A strong translational research environment within the Newcastle NIHR Biomedical Research Centre

• The course tackles a very real gap in translational knowledge within the clinical academic community

• Broad profiles of the companies involved, which include Sanofi-aventis, Roche, AstraZeneca, PTC Therapeutics, Sirtris and GSK

“Collaborative translational medicine programmes provide a unique opportunity for early stage research to progress and transition into advanced development. In the near term, programmes in translational medicine will benefit both academia and industry. Looking to the future, global healthcare and overall quality of life will be the beneficiaries.”

Professor David Jones
Newcastle NIHR Biomedical Research Centre

“Collaborative translational medicine programmes provide a unique opportunity for early stage research to progress and transition into advanced development. In the near term, programmes in translational medicine will benefit both academia and industry. Looking to the future, global healthcare and overall quality of life will be the beneficiaries.”

Dr Zvi Loewy
Vice President of Research for Dental Care at GlaxoSmithKline

“The success of the course has meant that we are on target for it to be self-funding within the planned 5 year timescale. There are big plans to roll modules out nationwide in specific disease areas, or to aid in continuing professional development for industry profiles.”
Collaboration 5

A collaborative development of a life-changing wheelchair assembly for people with hemiplegia, a total paralysis of one side of the body.

The collaborative development of this wheelchair, involving academics at Brighton University, NHS clinicians and their patients and engineers at Neater Solutions offers patients more freedom than the standard NHS wheelchair. A crucial grant was awarded from the National Institute for Health Research (NIHR) Health Technology Devices Programme.

<table>
<thead>
<tr>
<th>Academia</th>
<th>Initiation</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engineer Samuel Lesley began developing the foot-steered wheelchair during a student project. In 2002 he approached Dr Anne Mandy at the University of Brighton with the idea.</td>
<td>Jon Michaelis, Managing Director of Neater Solutions, signed up to develop the technology in a collaborative deal with the academic partners.</td>
<td></td>
</tr>
</tbody>
</table>

**Offer**

- The involvement of rehabilitation teams, care home teams and stroke professionals
- Effective patient engagement
- Grant application expertise
- Trial protocol design
- Commercial acumen
- Engineering design experience
- Production feasibility

**Collaborative functions**

- IP ownership and publication issues were addressed at the beginning of the collaboration
- The trialling of prototypes in NHS patients' homes was crucial to resolve early-stage design problems
- Open channels of communication were maintained and quarterly meetings held between the collaborators

**Outcome**

- The product has been showcased at international conferences and exhibitions
- The reputations of all partners benefited from a number of publications
- Neater Solutions are looking to engage with other academic partners in other device areas as a result of this work
Key success factors

- Data were published from well designed trials that demonstrated the benefits of the design over standard wheelchairs. This was key to securing further grant funding for the project.

- Extensive patient and carer involvement for each trial and further engagement via newsletters.

- Strong coverage of progress through scientific publications, conference presentations, local press coverage and patient comment.

- Clear areas of leadership and responsibility were established in the collaboration.

Dr Anne Mandy
University of Brighton

“Following trials of the prototype, it was vital that a commercial partner was engaged in order to attract further funding. The NIHR Health Technology Devices programme became available to us and launched the next phase of development.”

Jon Michaelis
Managing Director, Neater Solutions

“Working with academia was crucial to secure grants for the development work. It also ensured our design optimally met the needs of both patients and carers. For instance, trials in patients’ homes triggered a design change in the steering system that was not predicted at the start of the project. Future studies into the impact on patient health and care will be important to secure funding of the equipment for the individuals who need it.”
Collaboration 6

Multidisciplinary working with cohorts of well-phenotyped patients offers a clear opportunity for academia and industry to work together to provide broader disease insight.

This collaboration evolved from an academically-led cohort study investigating the complications of diabetes in older patients. Pfizer's involvement significantly expanded the range of baseline information collected on the participants, explored biomarkers and provided a platform for broader studies.

<table>
<thead>
<tr>
<th>Initiation</th>
<th>Academia</th>
<th>Offer</th>
<th>Industry</th>
</tr>
</thead>
</table>
| An MRC-funded study was collecting clinical data on inflammation and microvascular disease in older diabetes patients with a focus on the development and progression of cognitive impairment. A chance discussion by one of the clinical co-investigators with his local area drug representative stirred interest. Pfizer were interested in opportunities for complementary investigations on liver dysfunction, another complication of diabetes. | • Multidisciplinary team  
• Protocol design  
• Cohort of 1000 senior diabetic patients  
• Dedicated research infrastructure | • Interest in liver function in diabetes  
• Funding  
• Specialist biomarker methodologies | |

<table>
<thead>
<tr>
<th>Collaborative functions</th>
</tr>
</thead>
</table>
| • Expanded biomarker investigations on participants allowing a more comprehensive understanding of diabetic complications  
• Comparison of different measurement techniques  
• Cross validation of novel biomarkers |

<table>
<thead>
<tr>
<th>Outcome</th>
</tr>
</thead>
</table>
| • An intensively phenotyped cohort  
• Expanded datasets giving a strong platform for future studies on a suite of diabetic complications  
• Publications and conference presentations  
• Validated techniques to be used for future data collection  
• A solid platform for future grant submissions |
Key success factors

- A multidisciplinary academic team
- Top class research infrastructure
- UK-based lead scientist at Pfizer

“Alignment of our interests with that of Industrial partners was valuable. It also helped having a key person here in the UK to talk to and build a more personal working relationship, as sometimes collaboration at a distance can be difficult.”

Dr Jackie Price
Clinical Senior Lecturer in Epidemiology and Public Health, The University of Edinburgh

“From a Pfizer perspective, access to a well phenotyped patient cohort was key. It is often very difficult to be able to access longitudinal data and clinical samples that will allow a better understanding of disease emergence and progression.”

Dr Geoff Johnston
Director of Molecular Medicine, Pfizer
Appendix

Useful links:

**Medical Research Council (MRC)**
- Industry Collaboration Award (MICA)
  www.mrc.ac.uk/Fundingopportunities/Grants/MICA/Specification/index.htm

**National Institute for Health Research (NIHR)**
- Invention for Innovation Programme (i4i)
  www.nihr-ccf.org.uk/site/programmes/i4i/

**Technology Strategy Board (TSB)**
- Collaborative Research and Development
  www.innovateuk.org/deliveringinnovation/collaborativeresearchanddevelopment.ashx

**The Wellcome Trust**
- Collaborative translational funding streams
  www.wellcome.ac.uk/Funding/index.htm

**UKCRC Experimental Medicine Resources Website**
- Online database of the UK’s experimental medicine infrastructure and expertise
  www.ukcrcexpmed.org.uk
This booklet highlights six innovative models of early phase partnerships between industry, the NHS and universities. These show a variety of ways by which collaborations can arise to benefit all parties.

A number of the collaborations build upon previously established relationships. Others began from chance interactions or personal relationships. The NIHR Office for Clinical Research Infrastructure (NOCRI) aims to make this process more streamlined by linking industry with the country’s leading academic experimental medicine experts in a coordinated way, as well as by providing a forum for early collaborative discussions.

Additionally, NOCRI is providing the tools to support these interactions. For example, the recently developed model Industry Collaborative Research Agreement (mICRA) can shorten the contracting process for collaborative relationships. If you would like to know more about how NOCRI can help you to establish academic-NHS-industry collaborations, please contact us at: nocri@nihr.ac.uk.

For further information or support with research collaborations, contact: nocri@nihr.ac.uk

Postscript from the Managing Director of the NIHR Office for Clinical Research Infrastructure (NOCRI)

Mark Samuels, Managing Director, NOCRI