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Bringing medicines to *life*

Collaborating for innovation

ABPI LINC: Library of Initiatives for Novel Collaborations

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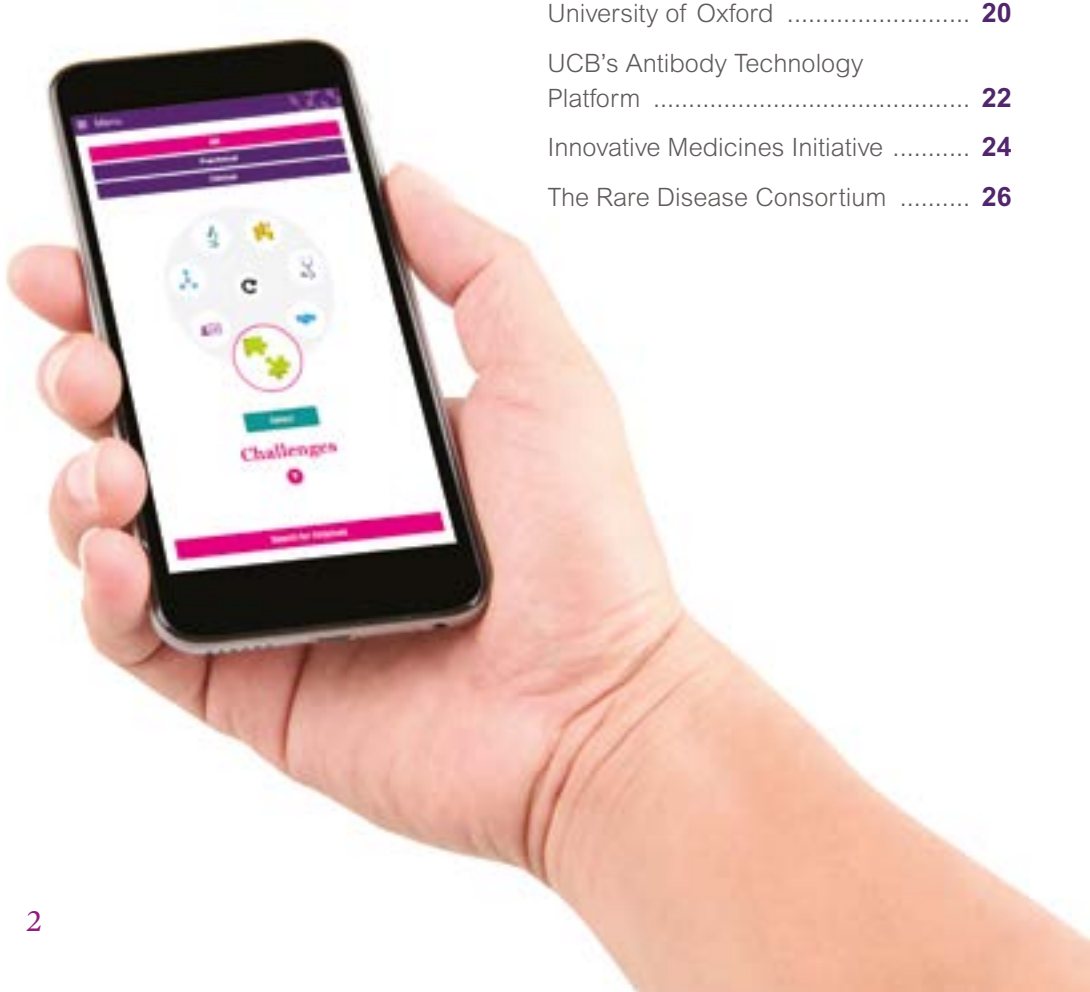

Foreword

Collaboration has never been more important for successfully delivering new therapies for patients. Innovation requires a vast range of skills, resources, and knowledge, which no single organisation can hold by themselves. Bringing together the capabilities found in universities, companies, the NHS, and patients themselves, can accelerate scientific progress and the discovery and development of new medicines. Collaboration also brings benefits to all partners involved, such as access to equipment, resources, or specialist knowledge, as well as an opportunity to develop new skills.

This booklet showcases just a few examples of the range and breadth of collaborations between the biopharmaceutical industry and academia in the UK. These range from one-to-one collaborations, sharing compounds, data, or funding, through to large-scale international consortia. We hope these provide inspiration for how you could get involved!

These case studies accompany the launch of ABPI LINC (Library of Initiatives for Novel Collaborations), a new research collaboration database tool. Aimed at academics, both within universities and hospitals, ABPI LINC is a user-friendly resource to help the UK community identify relevant opportunities for collaboration with the biopharmaceutical industry. Our ultimate hope for this tool is that it facilitates new collaborations, and accelerates medical research for the benefit of patients.

Malcolm Skingle

Malcolm Skingle

Director of Academic Liaison Worldwide Business Development, GSK, and Chair of the ABPI Academic Liaison Expert Network

Professor Jacky Smith investigates whether AstraZeneca's deprioritised gastrointestinal drug could be a new treatment for chronic cough

Pharmaceutical companies investigate thousands of compounds, but few become medicines. What happens to all the compounds judged unsuitable for their intended purpose? Increasingly, academic researchers are invited to consider these deprioritised compounds for their own research interests, leading to novel discoveries and potential new treatments.

The MRC-Industry Asset Sharing Initiative funds academic researchers to investigate new roles for deprioritised pharmaceutical compounds. Originally an agreement exclusively between AstraZeneca and the MRC, the initiative has expanded to include dozens of compounds from six major pharmaceutical companies (AstraZeneca, GSK, Janssen, Pfizer, Takeda, and UCB).

Through this scheme Professor Jacky Smith from the University of Manchester gained access to AZD3355, a GABA-B receptor agonist belonging to AstraZeneca. Previously investigated as a treatment for heartburn and gastroesophageal reflux, the compound had been deprioritised when it failed to produce the desired results.

Professor Smith is now investigating the compound as a treatment for chronic cough, a condition that affects an estimated 12% of the population. AZD3355 was well tolerated in healthy volunteers with experimentally induced coughing and is now being tested in a patient population.

For AstraZeneca, this scheme is about more than providing a compound. The company is keen to support researchers get the most value out of the compounds by sharing their knowledge of the drug. This may include information relating to its structure, pharmacodynamics, pharmacokinetics - even unpublished data from previous investigations.

"This project was born from our strong belief in the strength of UK science and in the important role that funding agencies like the MRC play in supporting the life sciences sector here."

Mene Pangalos, EVP, Innovative Medicines & Early Development biotech unit, AstraZeneca [1]

"Getting access to the compound means an enormous amount... There have been no new treatments for cough in over 50 years, so there is so much potential for patients."

Prof. Jacky Smith, University of Manchester [2]

As a result of the scheme's success AstraZeneca and other companies have increased access to their deprioritised compounds by creating their own compound-sharing initiatives. Through their clinical compound bank AstraZeneca has provided compounds for over 30 investigator-sponsored clinical research projects. Furthermore, academic researchers are invited to view their preclinical toolbox, which offers access to over 250,000 compounds from AstraZeneca's screening library.

For more information about the MRC-Industry Asset Sharing Initiative visit: https://www.mrc.ac.uk/funding/browse/mrc-industry-asset-sharing-initiative-2016/mrc-industry-asset-sharing-initiative-2016/#asset

For more information about AstraZeneca's clinical compound bank visit: https://openinnovation.astrazeneca.com/clinical-compound-bank.html

For more ways to gain access to compounds from pharmaceutical companies, both for pre-clinical and clinical studies, search "Compounds" in ABPI LINC: https://linc.abpi.org.uk

1 Source: https://www.mrc.ac.uk/ documents/pdf/mrc-astrazeneca- compound-sharing-case-study

2 Source: https://www.mrc.ac.uk/ documents/pdf/mrc-astrazeneca- compound-sharing-case-study/

Discovery Partnerships with Academia

Discovery Partnerships with Academia (DPAc) is a unique way for academic researchers to collaborate with GSK to translate their innovative ideas into transformative medicines.

DPAc seeks to partner with academics who have unique skills, insight or expertise and who want to be intimately involved in making a medicine. Academic researchers work with a dedicated DPAc Leader from GSK whose experience in drug discovery guides the project all the way from inception to, if successful, product launch. This close relationship between the academic researcher and the DPAc leader develops trust and openness and is critical to navigating through the challenges of medicines discovery and development. Each project is structured with defined milestones, and universities receive milestone payments as well as royalties if a medicine is commercialised. If the project terminates for any reason, the academic researcher is provided with key tools to enable them to continue their work.

In 2011 DPAc collaborated with Damian Mole, a clinician scientist fellow and consultant surgeon at the University of Edinburgh (UoE), to discover a treatment for severe acute pancreatitis (SAP), a devastating condition with no available therapy. Damian's initial clinical observations indicated the tryptophan pathway is increased in patients with SAP compared to those whose disease spontaneously resolves. Genetic knockdown of a key enzyme of this pathway prevented SAP in rodent models, suggesting inhibition of kynurenine monooxygenase (KMO) in patients with acute disease could prevent the progression to severe disease, thus reducing morbidity and mortality.

The UoE team provided a deep understanding of the disease biology, pathway biochemistry and structural biology of the target and this was combined with the assay development, pharmacology, synthetic, computational and medicinal chemistry expertise from GSK. A series of KMO inhibitors designed and synthesised within GSK were profiled in biochemical and cellular assays by both partners. Lead compounds showed clear efficacy when dosed in a therapeutically relevant manner in a rodent model of SAP, demonstrating pharmacological inhibition of KMO protects against organ damage. This work was published in Nature Medicine and led to the filing of a patent application.

"It's great working with a DPAc team that always keeps the goal very much on the middle of the table. It's extremely rewarding to be part of this collaboration with GSK and it's a great working environment. Everyone on our DPAc team is really good at what they do. I feel privileged to be part of it."

Mr Damian Mole, MRC Senior Clinical Fellow and Honorary Consultant Surgeon, University of Edinburgh[1]

The project is now progressing to clinical development with potential to significantly reduce the incidence of SAP, thereby dramatically improving patient outcomes and decreasing the major healthcare burden associated with this disease.

For more information about DPAc visit http://www.dpac.gsk.com/

For more opportunities to partner with pharmaceutical companies search "Non-specific partnering" in ABPI LINC: https://linc.abpi.org.uk

1 Source: http://www.dpac.gsk.com/case-studies-uedinburgh.html

Cancer Research UK MedImmune Alliance Laboratory

Cancer Research UK (CRUK) is collaborating with MedImmune, the global biologics research and development arm of AstraZeneca, to empower the discovery of new ways to diagnose and treat cancer. The Cancer Research UK-MedImmune Alliance Laboratory (CMAL), based in Cambridge, combines academic insight and industrial drug development expertise to accelerate the discovery of novel diagnostic and therapeutic antibodies that will benefit cancer patients.

Within this unique collaboration, MedImmune brings its experience and expertise in discovering biologic medicines, and its proven human antibody platforms and technologies; CRUK and its extensive network of cancer researchers bring understanding of cancer biology and oncology expertise, together with an understanding of disease mechanisms and models.

CMAL is actively engaging with both academic investigators and the wider oncology research community: cancer researchers in the UK and Europe, who are focusing on potential drug targets, are encouraged to work in partnership with CMAL's multidisciplinary team to maximise the opportunity for the identification of potential biologic medicines and diagnostics for cancer therapy.

The CMAL collaboration has been operating since late 2015 and the combined team of two MedImmune and 12 CRUK expert scientists work together to generate antibodies to establish proof of concept for the Principle Investigators' original ideas. The initial projects are progressing well and the first publication describing a collaborative piece of work around one of the novel therapeutic targets should be published late 2017/early 2018. This will be followed by the first candidate antibody therapeutic, which could be ready for onward development as early as during 2019.

The CRUK-MEDI Alliance Laboratory invites researchers interested in accessing this unique laboratory, whether they have a novel insight into the disease biology, a well-validated target, or relevant expertise in immunology to visit: http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/our-research-partnerships/cruk-medimmune-alliance-laboratory.
For more information, or to express an interest in working with the alliance, email: AllianceLab@cancer.org.uk.

1 Source: http://www.cambridgecancercentre.org.uk/research/cancer-research-uk-medimmune-alliance-laboratory

Eisai - UCL – a long term strategic partnership

Neurodegenerative diseases present one of the major medical, scientific, societal, and financial challenges of our time. In the UK, the number of people currently affected is close to 1 million and this is expected to double in the next 20 years. Japanese pharmaceutical company Eisai has partnered with University College London (UCL), a world-leader in dementia research, to address this urgent need for effective treatments.

The collaboration encompasses several early stage research projects aiming to identify and validate novel drug targets across key processes involved in neurodegeneration. Eisai benefits from UCL's world-class research into the mechanisms underpinning neurodegenerative diseases and expertise in clinical translation and in return contributes its drug discovery experience and state-of-the-art resources.

This strategic partnership, agreed in 2012, is a central part of Eisai's 'Open Innovation' strategy to accelerate the development of new therapies by sharing knowledge and resources with academic partners. Eisai received the UCL Enterprise Corporate Partner of the Year award in 2014 in recognition of their commitment to the partnership.

Importantly, the collaboration is generating results. Researchers are publishing their findings and presenting at international conferences. UCL receives milestone payment when projects reach significant objectives, the first of which has already been completed.

"This is a unique and innovative partnership which we have taken care and time to establish such that it will provide a truly enabling platform for joint working. I am sure that this model will be seen as an exemplar and will be highly productive going forward."

Professor Alan Thompson, Dean of the Faculty of Brain Sciences, UCL

"Eisai is extremely proud of the 'Open Innovation' strategy that is exemplified by our long-standing partnership with UCL. Through this collaborative effort, we bring together leading scientists to help us discover new solutions for people with these life-changing illnesses. In particular, new treatment options are needed for people with dementia where one new case is diagnosed every 3.2 seconds."

Dr Teiji Kimura, Chief Discovery Officer,Neurology Business Group, Eisai

The university will also receive royalties if a medicine is commercialised as a result of the collaboration.

A unique partnership model ensures both parties are equally represented at every level. Overseeing the entire collaboration is a joint committee co-chaired by Professor Alan Thompson (UCL) and Dr. Teiji Kimura (Eisai). A Therapeutic Innovation Group (TIG) comprised of senior scientists from both parties is responsible for operational management, and individual projects are co-led by scientists from each organisation. Project teams are supported by a group of TIG scientists (funded by Eisai but employed by UCL) who work across projects and move between UCL laboratories and Eisai's UK-based Neurology Innovation Centre as appropriate.

The European Paediatric Formulation Initiative

The European Paediatric Formulation Initiative (EuPFI) is a consortium of organisations working together to deliver better and safer medicines for children. Established in 2007, the consortium now has 14 members from the pharmaceutical industry, academic research institutions, and hospital pharmacies, with the European Medicine Agency as an observer.

The consortium identifies challenges in formulating medicines for children, facilitates discussion between relevant partners, and supports the implementation of solutions with funding, resources, and expertise. EuPFI members work together in a pre-competitive way, sharing their experience and expertise through interactive discussions. The consortium supports new technologies emerging from academic research and encourages pharmaceutical companies to consider paediatric formulations at an early stage of medicine development.

One major aim of the consortium is to improve the availability of information relevant to paediatric formulations. Medicines are created by mixing the active ingredient with other ingredients known as excipients, which can help ensure that the drug reaches the desired concentration, facilitate drug absorption, and improve long-term stabilization. Some excipients are less well tolerated in children than adults, as their physiological systems are still developing. Despite extensive excipient safety data for adults, there is very limited paediatric data for the development of medicines for children. EuPFI developed the Safety and Toxicity of Excipients for Paediatrics (STEP) database which provides the drug development community with readily accessible safety information for excipients used in paediatric formulations, and is freely available on the EuPFI website.

Membership of EuPFI is open to anyone with an interest in paediatric formulation development to advance the delivering of medicines for children.

To find out more about the consortium, visit: http://www.eupfi.org/

GSK-Cambridge Alliance for clinical research

GSK, the University of Cambridge, and Cambridge University Hospitals NHS Foundation Trust, have established a strategic partnership, combining their complementary skills and resources for clinical research, aiming to jointly deliver new medicines to patients in the next 5-10 years.

The collaboration is based around a clinical trials unit owned by GSK and located within Cambridge's main hospital. GSK's Clinical Unit Cambridge (CUC) is a research facility specialising in innovative Phase 1 and early Phase 2 studies. The research undertaken at the centre spans a broad range of therapeutic areas, with approximately half of the current portfolio involving experts from the University of Cambridge.

Academic researchers provide specialised disease knowledge while the pharmaceutical company maintains high standards of regulatory compliance and operational efficiency, as well as compounds and resources. GSK also provides an 'Entrepreneur in Residence' to promote translational thinking among academic researchers at the University, encouraging scientists to consider possible clinical applications of their work. In addition, GSK provides support to academics submitting applications to translational funding programmes.

The partnership includes a Varsity Funding Programme, which directly funds collaborative projects aiming to develop new medicines across the breadth of GSK research areas of interest, as well as supporting research addressing clear gaps in our understanding of disease and drug mechanisms.

"Our collaboration with GSK ... gives our academics access to the technologies and molecules that only industry can provide while giving GSK access to the world-leading research knowledge at Cambridge, delivering valuable impact for both partners."

Professor Patrick Maxwell, Regius Professor of Physic at the University of Cambridge

Source: https://www.cam.ac.uk/news/gskcambridge-strategic-partnership-aims-to-develop-next-wave-of-game-changing-medicines

2/3 ABPI member companies have an open innovation initiative accessible to academic researchers through the public domain

18 ABPI member companies have publicly available initiatives offering compounds for research

The pharmaceutical industry published over 16000 publications in collaboration with UK scientists between 2006 and 2015[1]

27 ABPI member companies have publicly available initiatives offering support for Investigator Initiated Studies

On average publications with industry collaboration are cited more highly than those without[1]

1/2 ABPI member companies have publicly available funding initiatives for academic research

14 ABPI member companies have set challenges open to academics, with prizes of up to £1 million

1 ABPI Sourcebook 2016: Open for Innovation. Data provided by Clarivate Analytics

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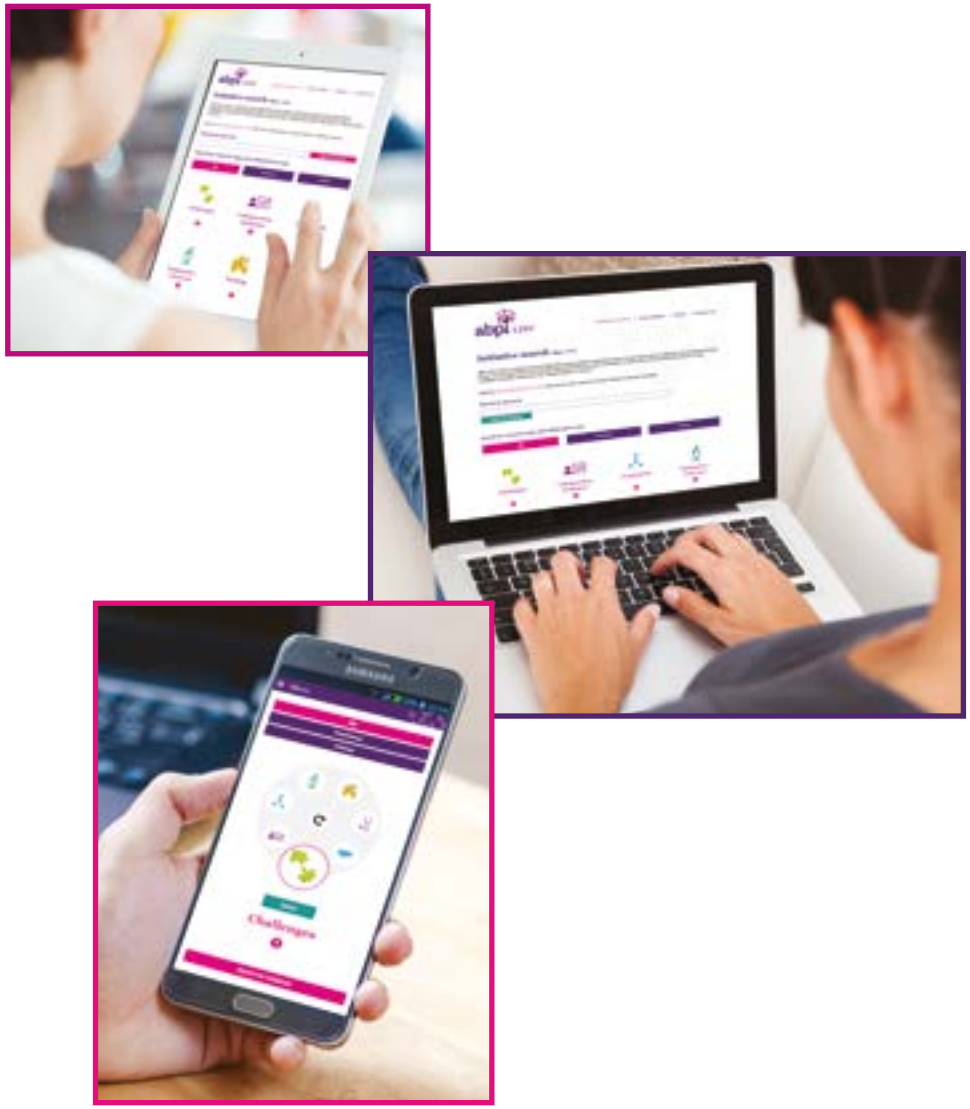

ABPI LINC website and icons designed and developed by Starbit

The Cambridge Pharmaceutical Cryo-EM Research Consortium

The Cambridge Pharmaceutical Cryo-EM Research Consortium brings together partners from academia and industry to share access to a Titan Krios™ cryo-transmission electron microscope, an advanced technology used to produce 3D images of complex structures at the near-atomic scale.

Located in the University of Cambridge's Nanoscience Centre, the microscope is used by researchers from the university, the Medical Research Council Laboratory of Molecular Biology (MRC-LMB), and five pharmaceutical companies (Astex Pharmaceuticals, AstraZeneca, GSK, Heptares Therapeutics, and UCB). As part of a three year agreement with this consortia, the company who designed and produced the microscope, FEI, part of Thermo Fisher Scientific, is providing expert guidance on the use of cryo-EM, including sample preparation and data collection services.

Designing effective treatments for disease often requires detailed knowledge of the structure of molecular complexes, such as pathogens or the potential therapeutic targets. Historically, determining these structures has relied on x-ray crystallography and NMR spectroscopy. However, the sample preparation these methods require can affect the conformation of proteins, altering their 3D structure.

"Cryo-EM 3D models allow us to see and understand the workings of protein-based molecular machines that we could not analyze before... The technique was rapidly adopted by leading academic researchers and is now finding its way into early stage discovery and development in the pharmaceutical industry."

Peter Fruhstorfer, vice president and general manager of the Life Sciences business, FEI

The advantage of cryo-EM is that samples can be visualised without the need for chemical fixation or crystallisation, ensuring the shape observed is the true structure of the protein in its native environment.

Multiple cryo-EM images can be integrated together using a software developed by MRC-LMB scientist Sjors Scheres to generate 3D models. This allows researchers to visualise, and so better understand, the structure of complex, dynamic molecular assemblies down to the scale of individual atoms. Cryo-EM has already been used to produce 3D images of viruses, ribosomes, mitochondria, and enzyme complexes, and is informing our understanding of these proteins and their actions in the body.

Through this consortium members are learning how cryo-EM can be used to advance our understanding of key molecular complexes and thus aid the discovery and development of new therapeutic agents across a range of disease areas.

Source: https://www.mrc.ac.uk/news/browse/pioneering-lmb-research-behind-new-cryo-em-consortium/

GSK's Immunology Catalyst

GSK's Immunology Catalyst is an innovative opportunity for academic researchers to pursue their independent research whilst on sabbatical in a major pharmaceutical company. By inviting academic scientists to work alongside top industry scientists at their site in Stevenage, GSK intend to stimulate scientific conversations, foster new collaborations, and catalyse breakthroughs in immunology.

The Catalyst supports selected academic researchers with access to the company's research tools and equipment, drug discovery experts, and financial support. This provides researchers experience of working in industry, whilst they remain employed by their university and are encouraged to continue publishing their work.

Interaction between Catalyst members and GSK scientists is key. Catalyst scientists are hosted in existing GSK laboratories with aligned research, scattering them throughout the company.

Catalyst members are invited to GSK seminars and project meetings where their alternative perspective is welcomed. By participating in scientific and strategic discussions the academic researchers deepen their knowledge of drug discovery and translational research and set the foundations for long-term collaborative relationships.

The programme offers flexibility to suit individuals, with the current six participants (and their nine postdocs and students) spending 20-80% of their time at GSK for up to three years. This team is set to expand with the recruitment of three more postdocs and students in 2017.

In addition to promoting day-to-day interactions, GSK hosts Immunology Network summits twice yearly. These meetings bring together Catalyst members, the GSK immunology community, and a board of internationally renowned academic immunologists for high-level discussions about advancements in the field.

This pioneering model for collaboration is building a world-class network of key experts in the field of immunology, an area where breakthroughs could potentially impact all of GSK's therapeutic areas.

For more information about Immunology Catalyst, visit: http://www.gsk.com/en-gb/careers/postgraduates/immunology-catalystpostdoctoral- training-programme/

"I believe bringing top class academics in-house will change the way GSK and academia interact. As an ex-academic, I know that the academic world does not always see what big pharma has to offer: amazing science, world class research tools and facilities, and opportunities to achieve excellence in project management and development as a leader."

Dr Paul Peter Tak, Senior Vice President R&D Pipeline, Chair of the Development Steering Team and Chief Immunology Officer, GSK

Novo Nordisk and the University of Oxford partnership for diabetes research

Diabetes affects an estimated 4.5 million people in the UK and when poorly managed can result in complications such as heart disease, stroke, blindness, and premature mortality. To accelerate the discovery of new treatments for both the disease and its complications, the University of Oxford has partnered with Novo Nordisk, a Danish pharmaceutical company with over 90 years of experience in developing medicines for diabetes.

The decade long commitment will see the company invest £115 million into a new Novo Nordisk Research Centre Oxford, a university-based research facility focussing on early stage research into type 2 diabetes. This will be located within the University of Oxford's biomedical campus, bringing Novo Nordisk scientists into close contact with 2,500 university researchers. To promote cross-institutional working Novo Nordisk has also committed funding for collaborative projects involving researchers from both organisations.

World-leading academics with insight into the disease biology and mechanisms will inspire Novo Nordisk employees with new directions for their work. In turn, academic researchers will benefit from the drug discovery resources and expertise of a pharmaceutical company with extensive experience developing medicines in this therapeutic area.

This partnership builds upon 15 years of successful collaboration between the two organisations. Novo Nordisk was a founding partner of the Oxford Centre for Diabetes, Endocrinology and Metabolism, a tripartite organisation connecting the university with industry and the NHS. The company also supports the development of the next generation of leaders in the field through its postdoctoral fellowship programme for basic scientists and clinicians based at the University of Oxford.

Through sharing their complementary skills and expertise, Novo Nordisk and the University of Oxford hope to generate new, innovative treatments for the growing number of people with diabetes.

"Our vision is that the **unique combination of industrial and academic know-how** will eventually lead to a new generation of treatments to improve the lives of people with type 2 diabetes"

Mads Krogsgaard Thomsen, Chief Science Officer
and Executive Vice President of Novo Nordisk

Source: http://www.ocdem.ox.ac.uk/ novo-nordisk-enters-collaboration-with-university-of-oxford

UCB's Antibody Technology Platform Access programme: A collaboration with the University of Oxford

UCB's core Antibody Discovery Platform represents a highly efficient method to sample a natural immune repertoire, and the application of automation to some of the early stages of the process has improved reproducibility, accelerated timelines and increased capacity.

In order to enhance its collaborative networks and to stimulate research for the academic community, UCB subsequently launched a 'Technology Platform Access' programme, offering researchers the opportunity to access the platform to generate potential therapeutics or proof-of-concept tool reagents to further their research on potential antibody targets.

One of the first projects to enter the programme was a collaboration between two leading groups at the University of Oxford, one of UCB's long-standing academic partners: the research groups of Alain Townsend, Professor of Molecular Immunology at the Weatherall Institute; and Simon Draper, Professor of Immunology and Infectious Disease at the Jenner Institute.

"UCB is committed to increasing our collaborative networks to accelerate scientific discovery. The Ebola partnership with the University of Oxford demonstrates the potential of our Technology Platform Access programme to facilitate industry-academia interaction, generating tools and potential therapeutics to benefit patients suffering with severe disease."

Dr Neil Weir, Head of Discovery Research, UCB NewMedicines™

"Gaining access to UCB's antibody discovery technology allowed us to investigate a broader spectrum of Ebola antibodies than would have previously been possible. By identifying a significant amount of antibodies we have been able to expand our research efforts, including sponsoring a PhD student, to try and identify a therapy for Ebola"

Professor Simon Draper, Professor of Immunology and Infectious Disease at University of Oxford

Following recent ebola virus outbreaks in West Africa, there has been considerable interest in generating new therapies, both vaccines and monoclonal antibody mixtures, directed against the ebola virus glycoprotein (EGP). UCB have been working with the teams at Oxford to produce large and diverse panels of anti-ebola virus neutralising antibodies.

Together more than 80 anti-EGP antibodies have been identified, from which a number of 'cocktails' are being tested with the help of Public Health England. The success of the project has led to further research into the discovery of antibodies which exhibit enhanced and broader strain neutralisation activity. This is being explored as a joint Oxford-UCB PhD.

For more information about the Technology Access Platform, visit: http://www.ucb.com/our-science/our-science/tpap

For more information about accessing equipment belonging to a pharmaceutical company, search "Equipment/Resources" in ABPI LINC: https://www.linc.abpi.org.uk

Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is the world's largest public-private partnership in the life sciences, with half of the €5 billion budget provided by the EU Commission and the other half by pharmaceutical companies. The overall objective is to accelerate the discovery, development, and delivery of innovative medicines for patients.

IMI seeks to achieve this through facilitating large-scale cross-sector collaborations between universities, pharmaceutical companies, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. Currently, the IMI is operating over 50 projects, each comprising a consortium of partners from both the public and private sectors across Europe. Public organisations and SMEs receive funding for the research, whilst pharmaceutical companies provide in-kind contributions to the consortia. The UK has played a significant role in the IMI to date, having received the highest proportion of funding both for academic and SME partners of any country.

Organisations are encouraged to submit suggestions for future IMI projects through a simple online form, and consortia seeking funding are invited to respond to regular calls for applications.

To find out more about the IMI, visit: http://www.imi.europa.eu.

See across for information on two examples of IMI projects.

OrBiTo

The development of most medicines involves optimising the formulation to ensure they reach their target in the body. The Oral Biopharmaceutics Tools (OrBiTo) project aims to enhance our understanding of how orally administered drugs are absorbed from the gastrointestinal tract.

It combines *in vitro* and *in silico* approaches to produce a biopharmaceutics toolkit, which will then be validated using clinical data. This toolkit could accelerate the development of pharmaceutical products across a wide range of therapeutic areas.

Thirteen ABPI member companies are partners of the OrBiTo project, as well as two UK universities and two UK-based SMEs. The project began in October 2012 and is due to be completed in autumn 2017. So far, the project has delivered more than 50 publications.

To find out more about OrBiTO, visit: http://www.orbitoproject.eu

SAFE-T

One of the first IMI projects, SAFE-T addressed the lack of sensitive and specific clinical tests to diagnose and monitor drug-induced injury to the kidney, liver, and vascular system. The SAFE-T project identified biomarkers in patients' blood and urine that allow us to better predict, detect, and monitor these unforeseen drug side effects. In addition, these biomarkers will improve diagnosis and treatment decisions for chronic disease patients.

Some of the biomarkers generated by the project have received letters of support from the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), which will facilitate their use in the clinic.

The success of the project led to the creation of a spin-out company, SIGNATOPE, dedicated to cross-species immune assay technology, which plays a key role in the pre-clinical phase of drug development. The company benefits hugely from interaction with members of the SAFE-T consortium, such as the Critical Path Institute and 11 ABPI member pharmaceutical companies.

To find out more about SAFE-T, visit: http://imi-safe-t.eu

The Rare Disease Consortium

The Rare Disease Consortium (RDC) is a joint undertaking of Pfizer and six leading UK universities, known collectively as the Global Medical Excellence Cluster (GMEC). The RDC provides a framework for world-leading academic investigators from GMEC, who have unrivalled scientific insight into specific diseases, to collaborate with scientists at Pfizer, who are often also disease experts and who have extensive experience in developing medicines for patients with rare diseases. The resulting collaborations between GMEC and Pfizer have the potential to accelerate the development of new treatments for patients suffering with some of the most debilitating and often life-threatening illnesses.

Collectively, rare diseases affect more than 3.5 million people in the UK, yet less than 5% of these diseases have any approved treatments. This unmet medical need is in part due to the vast number of diseases and the diversity of underpinning biochemical pathways. The RDC aims to address this by facilitating collaborations in early stage discovery, focussing on rare hematologic, neuromuscular, and pulmonary diseases.

For GMEC academics, participating in the RDC presents the opportunity to potentially translate their hard work and biological expertise into a real benefit for patients. Approximately 70% of the estimated 7000 rare diseases have a monogenic origin, and the RDC is seeking to build on recent discoveries linking diseases with specific genetic defects to drive forward drug discovery.

GMEC comprises six leading UK research institutions (University of Oxford, University of Cambridge, UCL, King's College London, QMC, and Imperial College London). Academic researchers from these universities are invited to submit project proposals to the RDC, and successful proposals are fully funded by Pfizer, including staff and research costs. Pfizer also provides access to their molecules, tools, drug discovery platforms, and/or expertise in an effort to accelerate the translation from research to patient benefit.

> These types of initiatives provide an excellent opportunity to ensure that our research and findings make their way into real treatments to improve patient outcomes."
>
> Professor Jonathan Weber, Director of Imperial College Academic Health Science Centre (AHSC)

The following ABPI member companies are involved in the collaborations described in this booklet:

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