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Birmingham Health Partners
Collaboration. Innovation. Application.

DATED: 17th September **2019**

MEMORANDUM OF UNDERSTANDING

BETWEEN

BIRMINGHAM HEALTH PARTNERS

AND

THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY

MEMORANDUM OF UNDERSTANDING **dated** 17th September **2019**

Made between:

(1) The University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom ("UoB")
And

(2) University Hospitals Birmingham NHS Foundation Trust of PO Box 9551, Mindelsohn Way, Queen Elizabeth Medical Centre, Birmingham, B15 2PR ("UHB")
And

(3) Birmingham Women's and Children's NHS Foundation Trust of Mindelsohn Way Edgbaston Birmingham B15 2TG ("BWC")

together **"Birmingham Health Partners"** ("BHP")

And

(4) The Association of the British Pharmaceutical Industry (company number 09826787) whose registered office is at 7th floor Southside, 105 Victoria Street London SW1E 6QT ("ABPI")

together jointly referred to as the "parties".

1. Introduction

1.1 BHP and ABPI wish to enter into a co-operative relationship for the general purpose of exploring activities which seek to further align academic, NHS and industry capabilities, based on shared priorities, for the mutual benefit of all parties and ultimately the wider population (hereinafter jointly referred to as the "Purpose").

1.2 In order to achieve the Purpose, the ABPI and BHP share objectives to:

- Work together with integrity and probity for the benefit of patients and the public;
- Accelerate the discovery, development and delivery of innovative biomedical solutions, so that NHS patients are amongst the first to benefit from such medical solutions and scientific advances;
- Support social values and the economic development of Birmingham and the West Midlands through collaborative arrangements, research, infrastructure, and the transference of knowledge, skills and expertise, where such transfers do not conflict with the parties' legal or contractual obligations;
- Improve health outcomes through early collaboration on future advances in life sciences: for example, by evaluating the potential impact of research pipelines on healthcare system design to maximise the benefits for patients and realise system efficiencies where appropriate;
- Drive inward investment from the biomedical industry to the region, utilising Health & Social care as an economic driver;
- Enhance the value that Health & Social Care in Birmingham and the West Midlands derives from investment in medicines and technologies;
- Sustainably increase the adoption of biomedical innovation at pace and scale across the Birmingham and West Midlands footprint;
- Enhance the contribution of Birmingham and the West Midlands to the UK's life sciences industrial strategy and consequently the economic growth of the UK;
- Develop health and care data across the region to enable Birmingham and the West Midlands to become a world-leading site for the evaluation of biomedical innovation.

1.3 This Memorandum of Understanding ("MoU") sets out below the principles by which BHP and ABPI can continue discussions regarding the establishment of a formal arrangement in order to perform the Purpose.

2. Principles

2.1 BHP and ABPI propose to discuss the following:

- healthcare data informatics and systems;
- digitalisation of health care services;
- genomics medicine and diagnostics;
- medical technologies evaluation;
- patient-reported outcomes; and
- clinical trials.

2.2 This MoU is designed to facilitate an evolving relationship between the parties, and to signify the intention of the parties to pursue mutually beneficial co-operation. The MoU shall not interfere with or exclude the parties from forming relationships with any other institutions in similar areas, for pursuing the same Purpose. In exploring the principles at 2.1 above, the parties have set out the areas and challenges which they propose to explore in further detail at ***Appendix 1***. For the avoidance of doubt, this MoU (save for clause 5) and the Appendix 1 are not intended to be legally binding, but its content may be used by the parties to form the basis for future collaboration(s).

2.3 Any activity carried out within the broad framework of this MoU shall be subject to the mutual consent of the parties, taking into account any constraints of time, funding and other relevant resources.

3. Subsidiary Agreements

3.1 In addition, it is envisaged that each activity that the parties wish to pursue in accordance with the purpose of this MoU will be governed by terms and conditions to be separately negotiated and mutually agreed upon by the parties through the signing of one or more subsidiary agreements.

4. Renewal Amendment and Termination

4.1 This MoU shall be effective for an initial period of three (3) years from 17th September 2019 ("the Initial Term").

4.2 A review of this MoU will be initiated at least twelve (12) months before the end of the Initial Term to review the effectiveness of the co-operation and to consider whether to enter into a further MoU for a further period ("Renewal Term").

4.3 A party to this MoU may request an amendment to this MoU at any time, provided such amendment is with the prior written consent of the authorised representatives of all parties.

5. Confidentiality

5.1 For the purposes of this clause "Confidential Information" shall mean all information of a commercially or sensitive nature including (but not limited to) strategic plans, specifications, electronic or digital media, documents, and communications which are disclosed by one party to another, irrespective of the medium of disclosure, for use in or in connection with the subjects covered by this MoU.

5.2 Subject to clause 5.4 each party undertakes that it shall ensure that during the Initial Term:

5.2.1 Confidential Information disclosed by one party ("Disclosing Party") to another ("Receiving Party") shall be kept secret and will only be disclosed in the manner and to the extent expressly permitted by this MoU;

5.2.2 It restricts Confidential Information to its own employees, representatives, and agents (who are under obligations of confidentiality to their employer no less onerous than those set out in this MoU), who need to know the information for the Purpose for which it was supplied;

5.2.3 It uses the Disclosing Party's Confidential Information solely for the Purpose of this MoU and as otherwise permitted by this MoU and/or any subsequent written agreement;

5.2.4 It only makes copies, summaries, extracts, transcripts, notes, reports, analyses, and recordings (in any form of media) that use, contain, or are based on or derived from the Disclosing Party's Confidential Information as are reasonably necessary to fulfil its obligations under this MoU; and

5.2.5 It keeps the Disclosing Party's Confidential Information safe and secure and applies to it documentary and electronic security measures that match or exceed those the Receiving Party operates in relation to its own confidential information and will exercise reasonable care in doing so.

5.2.6 Unless otherwise agreed, the Receiving Party shall not during the Initial Term, and for a period of 5 (five) years after the termination or expiry of this MoU for any reason, use any other party's Confidential Information for any purpose other than the carrying out of its obligations under this MoU or other than in accordance with this clause.

5.2.7 Pursuant to the preceding clause, after the termination or expiry of this MoU, the Receiving Party undertakes to destroy or return to the Disclosing Party all the Confidential Information, including the copies, summaries, extracts, transcripts, notes, reports, analyses, and recordings, as described in clause 5.2.4.

5.3 The undertakings in clause 5.2 above shall not apply to Confidential Information:

5.3.1 Which, at the time of disclosure, has already been published or is otherwise in the public domain other than through breach of the terms of this MoU;

5.3.2 Which, after disclosure to the Receiving Party, is subsequently published or comes into the public domain by means other than an action or omission on the party of the Receiving Party;

5.3.3 Which the Receiving Party can demonstrate was known to it or subsequently independently developed by it and not acquired as a result of participation in this MoU, nor used, derived from, referring to or in any way relating to the Confidential Information;

5.3.4 Lawfully acquired from third parties who had a right to disclose it with no obligations of confidentiality to the Disclosing Party;

5.3.5 Disclosed pursuant to the requirement of any law or regulation other than the Freedom of Information Act 2000 ("FOIA"), provided that written notice of such requirement is give without undue delay to the Disclosing Party (to the extent legally permissible) so as to give the Disclosing Party an opportunity to intervene and further provided that the Receiving

Party uses reasonable endeavours to obtain assurance that the Confidential Information will be properly treated in a confidential manner;

5.3.6 In the case of a disclosure under FOIA, provided the relevant party has previously obtained appropriate legal advice that no exemption to disclosure under FOIA is likely to be upheld if the matter were to be referred to the Information Commissioner or the Information Tribunal or the order of any court of competent jurisdiction or relevant regulatory body.

6. General

6.1 The parties to this MoU shall not be deemed to be in breach of this understanding or otherwise liable to any other party in any manner whatsoever for any failure or delay in performing or initiating the activities proposed in this MoU or in Appendix 1.

6.2 This MoU records the understanding between the parties and is not intended to be a legally binding document and shall not be enforceable in any Court of Law, with the exception of clause 5 relating to Confidential Information.

6.3 Each party shall be responsible for its own costs associated with this MoU and neither party shall have the authority to authorise or incur financial liability on behalf of the other.

6.4 No party to this MoU shall be permitted to use the other's name, crest, logo or branding without first having obtained the other's prior written consent to such use and fully complying with the user guidelines and both parties shall immediately cease use of such name, crest, logo or branding upon termination, withdrawal from, or expiry of this MoU.

For the purposes of this MoU the nominated BHP contact is:

Dr Emma Robinson

Director of Operations, College of Medical & Dental Sciences; Chief Operating Officer, Birmingham Health Partners

The University of Birmingham, Edgbaston, Birmingham, B15 2TT, United Kingdom.

Telephone: 0121 414 4047

Email: e.robinson.1@bham.ac.uk

The nominated contact for ABPI is:

Su Jones

NHS Engagement Partner

The Association of the British Pharmaceutical Industry, 7th Floor Southside, 105 Victoria Street, London, SW1E 6QT

Telephone: 02077477178

Email: SuJones@abpi.org.uk

This MoU is executed on behalf of the parties by their respective duly authorised signatory as set out below:

Signed:	**Signed:**
.....	.....
By	**By**
Prof. Sir David Eastwood	**Mike Thompson**
Vice Chancellor & Principal	**Chief Executive Officer**
For The University of Birmingham	**For The Association of the British Pharmaceutical Industry**

Signed:	**Signed:**
.....	.....
By	**By**
The Rt. Hon. Jacqui Smith	**Sarah-Jane Marsh**
Chair	**Chief Executive Officer**
For University Hospitals Birmingham NHS Foundation Trust	**For Birmingham Women's and Children's NHS Foundation Trust**

Appendix 1 - Areas of Focus

BHP and the ABPI intend to work together to address *four key regional health challenges* that:

- have national and international relevance;
- create sufficient critical mass of interest to ABPI membership;
- take advantage of the region's combination of expertise, capabilities and integrated translational eco-system to create a genuinely differential offering and potential for significant economic impact.

Challenge 1: Improving Cancer Outcomes:

There are more than 360,000 new cancer cases a year in the UK, with over 50% in breast, prostate, lung and bowel. Although cancer incidence in the region is broadly in line with the national average, the regional cancer mortality rate is significantly higher than for England and cancer prevalence is steadily growing.[1]

Building on our high-performing Genomics Medicine Centre (GMC) and development of our multi-disciplinary tumour boards in establishing joined up cancer pathways, we have the critical mass of research, clinical and commercial expertise to develop a pragmatic real-world platform to accelerate new treatments for cancer and rare diseases. We have the opportunity to integrate genomics, other diagnostic and healthcare record data to provide well-characterised patient populations. We will leverage our expertise and leadership in the design and delivery of high-value, complex precision medicine trials to support patient-focussed drug development and targeted treatments, and respond to the industry's need for novel and more efficient trial designs as reported in Life Sciences Industrial Strategy Sector Deal 2. Example areas targeting research with clinical trials include blood (TAP), brain (BRAIN-MATRIX), breast and lung (National Lung Matrix) cancers, hepatocellular carcinomas (Immunotace) and paediatrics (PHITT).

How, in collaboration with the pharmaceutical industry, do we maximise the benefit to our region's population through earlier diagnosis, better-targeted treatment pathways and earlier access to novel therapies, and create an agile, internationally relevant[2] test bed for new approaches to cancer treatment and diagnostics?

Challenge 2: Addressing maternal and paediatric health:

As the youngest and one of the most diverse cities in Europe, Birmingham also harbours many of the health challenges prevalent in younger population. Notably over 24% of Birmingham children are overweight or obese when they start school and this rises to 40% by the time they leave primary school.[3]

Enabled through the only single specialist Foundation Trust for both women and children in England and supported by a nationally leading "ageless" experimental medicine infrastructure and globally leading paediatric trials capability:

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[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/639592/Cancer_in_theWest_Midlands.pdf

[2] *BHP has ongoing work in identifying BRCA mutation prevalence in the BAME population linking clinical, genetic, pathology information across the West Midlands (with a parallel pilot cohort study in Punjab, India). This will identify a population that could potentially benefit from PARP inhibitors in the UK, but has direct relevance to populations of origin and areas of growing affluence across India/Pakistan/African countries.*

[3] https://www.birmingham.gov.uk/downloads/file/8104/birmingham_childhood_obesity_scrutiny_report

How can we work with ABPI members to unlock opportunities to address the growing challenges around health outcomes associated with childhood obesity (e.g. diabetes), cancer and mental health, developing paediatric-specific interventions to improve life outcomes?

Working with our leading clinical and research centres in areas such as miscarriage treatments (TABLET, MifeMiso), identifying genetic-related developmental problems (e.g. PAGE) and uncommon conditions in early pregnancy, what areas might deliver a significant step-change in maternal health outcomes?

Challenge 3: Tackling Multimorbidity in an Ageing Population

With around 15-20% (a rapidly increasing figure) of our population already past working age, we face major challenges in the rapid accumulation of multi-morbidity across cancer, dementia, cardiovascular and respiratory disease, diabetes and other conditions, with costs of care for >85s up to 8 times higher [4,5].

A prerequisite to investigating the socio-economic, behavioural, environmental and biomedical factors underling the aetiology of multimorbidity is an understanding of which diseases tend to cluster and which disease clusters have the greatest prognostic significance. Our recent MRC-NIHR grant in collaboration with University of Cambridge puts us at the forefront of developing methodology to understand multimorbidity clustering and its epidemiology through analysis of large datasets.

Working on the development of methodologies to understand multimorbidity clustering and its epidemiology provides new understanding of which diseases tend to cluster and which disease clusters have the greatest prognostic significance. Leveraging this understanding alongside our biological and translational expertise in biogerontology, neurosciences, and the mechanisms driving multimorbidity, and strong clinical-academic collaborative infrastructure across acute and chronic care populations, we can develop, deploy and evaluate new therapeutic interventions.:

How can we collaborate with industry to tackle the biological, clinical and regulatory challenges presented by an increasingly complex multi-morbidity and aged population to allow us to rapidly validate preventative, stabilising and potentially regenerative solutions as well as develop optimal, personalised, treatment regimen?

Challenge 4: Rapid, Validated Assessment of Biological Endpoints of new, patient-focussed drug development

There is a need to more rapidly validate the efficacy of new drugs through capturing of the biological endpoints of treatment interventions and, in turn, utilise this knowledge to inform new treatment regimes. There is a pressing need for standardisation of monitoring and assessment in delivery of major clinical trials in order to definitively validate new therapies[6]*. This is especially true in the move toward patient-focussed drug development and personalised medicine, and to support reimbursement.*

Through the enabling capabilities in patient and disease characterisation across our BHP eco-system, as well as our pioneering work around use of novel technologies to track infectious disease and

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[4] https://www.birmingham.gov.uk/downloads/download/2122/how_the_council_is_changing

[5] *A recent analysis of 2017 data from the UHBFT revealed that 75% of the 29,000 unplanned admissions were for patients aged over 50 and 85% of those had 3 or more co-morbidities.*

[6] e.g. https://cimac-network.org/

understand chronic conditions through deep phenotyping, we can develop exemplar, innovative, integrated clinical studies that bring together complex diagnostic techniques to accelerate understanding and efficacy of new therapeutic interventions. By looking at diseases with shared mechanisms/pathways and marry these up with biological outcomes we can understand more quickly whether a compound(s) is having the desired quantifiable impact on a blood cell/tissue marker and through appropriate complex trials design test efficacy of drugs across a number of diseases with similar underlying mechanisms.

How, through a catalysing focus on e.g. inflammatory-related disorders, immuno-oncology and infection, can we co-create and firmly establish internationally recognised platforms for the standardised assessment of disease in order to underpin rapid validation of new therapies and diagnostics?