INNOVATION & RESEARCH CAUCUS

GLOBAL ACCESS POLICY:

A Mechanism for Enhancing the Societal Impact of UK-driven Research and Innovation

IRC Report No: 064

REPORT PREPARED BY

Ezekiel Boro*

Ini Umoh*

Carolina Velasco*

Aaron Argomandkhah*

Chris Peters*

Becky Jones-Phillips*

*Liverpool School of Tropical Medicine

Delivered with ESRC and Innovate UK

Authors
The core members of the research team for this project were as follows:

- Dr Ezekiel Boro - Liverpool School of Tropical Medicine
- Dr Ini Umoh - Liverpool School of Tropical Medicine
- Dr Carolina Velasco - Liverpool School of Tropical Medicine
- Mr Aaron Argomandkhah - Liverpool School of Tropical Medicine
- Dr Chris Peters - Liverpool School of Tropical Medicine
- Dr Becky Jones-Phillips (PI) – Liverpool School of Tropical Medicine

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About the Innovation and Research Caucus
The Innovation and Research Caucus supports the use of robust evidence and insights in UKRI's strategies and investments, as well as undertaking a co-produced programme of research. Our members are leading academics from across the social sciences, other disciplines and sectors, who are engaged in different aspects of innovation and research systems. We connect academic experts, UKRI, IUK and the (ESRC), by providing research insights to inform policy and practice. Professor Tim Vorley and Professor Stephen Roper are Co-Directors. The IRC is funded by UKRI via the ESRC and IUK, grant number ES/X010759/1. The support of the funders is acknowledged. The views expressed in this piece are those of the authors and do not necessarily represent those of the funders.

Contact
You are also welcome to email us if you have any questions about this report or the work of the IRC generally: info@ircaucus.ac.uk

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Abbreviations and Acronyms

CARB-X	Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus disease 2019
DNDi	Drugs for Neglected Diseases Initiative
EDCTP	The European and Developing Countries Clinical Trials Partnership
FIND	Foundation for Innovative New Diagnostics
GAP	Global Access Policy
GARDP	Global Antibiotic Research and Development Partnership
G7	Group of Seven
HEI	Higher Education Institution
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
LMICs	Low- and middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
LSTM	Liverpool School of Tropical Medicine
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
mRNA	messenger ribonucleic acid
MPP	Medicines Patent Pool
PDP	Product Development Partnership
R&D	Research and Development
SHAPE	Social Sciences, Humanities and Arts for People and the Economy
UCL	University College London
UK	United Kingdom
UKRI	UK Research and Innovation
US NIH	United States National Institutes of Health
WHO	World Health Organisation

Executive Summary

The United Kingdom is a global leader in research and development (R&D), bolstered by substantial public and philanthropic funding investments. However, a persistent gap remains between innovation and equitable global access, particularly for populations in low- and middle-income countries (LMICs). Market-driven commercialisation models often prioritise high-income markets, limiting the reach of publicly funded innovations and undermining their potential societal impact, even in high-income countries like the United Kingdom.

Using a qualitative research methodology (literature review and interviews) and case studies, this report examines the role of a Global Access Policy (GAP) as a strategic mechanism for aligning R&D systems with global public health goals. Global access policies (also referred to as equitable access or socially responsible licensing policies) aim to ensure that innovations arising from publicly and philanthropically funded research are affordable and accessible worldwide.

Key Literature Review Findings

1. **Limited adoption of GAPs in the UK ecosystem**
   While some UK universities and funders have taken steps toward equitable access—particularly through socially responsible licensing and open science practices—formal, comprehensive GAPs remain uncommon. Notable institutions such as the University of Oxford and University College London have adopted elements of these approaches, but implementation is often inconsistent and context dependent.
2. **Limited evidence of effectiveness and impact**
   There is a need for more evidence to show that GAPs can significantly reduce prices and expand availability of health technologies globally.
3. **GAP pathways for scaling equitable access**
   The literature review identified three primary strategies for strengthening global access:

» **Equitable intellectual property management and socially responsible licensing**, including non-exclusive licensing, step-in rights, and access planning;

- **Open science and open access approaches**, enabling wider dissemination of knowledge and accelerating innovation;
- **Alternative R&D models and funding conditions**, which prioritise global public health outcomes over commercial returns.

Insights from Interviews and Case Studies

Interviews with leading universities and funders highlight that:

- GAP implementation is often pragmatic, flexible, and tailored to specific research disciplines, technologies and disease areas.
- Strong governance, internal coordination, and stakeholder engagement are essential for effective implementation.
- Key implementation barriers include limited industry engagement, insufficient policy alignment across research and funding institutions, limited accountability mechanisms, and low awareness of GAPs.
- Impact is constrained by limited enforcement mechanisms, and reliance on downstream commercial actors.

Funders such as Wellcome and Unitaid demonstrate advanced and systematic approaches, combining legal provisions with non-legal market shaping, partnership and capacity-strengthening mechanisms. Social Sciences, Humanities and Arts for People and the Economy (SHAPE) research funders like the British Academy lean more towards non-legal equitable partnerships, and capacity-strengthening mechanisms. However, challenges remain in monitoring long-term impact and coordinating broadly and effectively across the research and funding ecosystem.

Conclusions

GAPs represent a promising but underutilised policy tool for ensuring that publicly funded research delivers global public value. Realising their full potential will require stronger alignment between universities, funders, and industry; clearer standards and expectations; and improved monitoring and evidence of impact.

Key Recommendations

- **For Higher Education Institutions:**
  Strengthen governance and monitoring systems, enhance capacity within technology transfer offices, and improve transparency and consistency in licensing practices.

- **For Funders:**
  Establish minimum access requirements, improve coordination and transparency, invest in impact evaluation, and engage industry and investors to align incentives with equitable access goals.

Overall, advancing GAP adoption across the UK research ecosystem offers a critical opportunity to bridge the gap between innovation and access, ensuring that the benefits of scientific progress are shared more equitably worldwide.

1. Policy Context and Rationale

The United Kingdom (UK) is a global leader in research and development (R&D). It produced more academic publications than the United States or China, ranked fourth among G7 countries for total R&D expenditure, and fifth per capita for patent applications as of 2020. (Cambridge Industrial Innovation Policy, 2024) In 2022, 29% of UK R&D expenditure originated from non-commercial sources, including higher education institutions (HEIs) (23%), government (5%), and philanthropic organisations (1%). (Office of National Statistics, 2024) Despite this substantial public and charitable investment, many UK-generated innovations—particularly in pharmaceuticals and biotechnology—fail to reach low- and middle-income countries (LMICs), as commercial incentives continue to prioritise high-income markets.

Access to innovative medicines remains a critical challenge worldwide, even in high-income countries. (Morgan, Bathula and Moon, 2020) Rising drug prices, coupled with growing demand for healthcare services driven by demographic change and evolving health needs, are placing increasing strain on health system budgets and limiting patient access. (Morgan, Bathula and Moon, 2020) Historically, restricted access has been framed as an unavoidable trade-off required to sustain innovation. However, this narrative is increasingly being challenged. Policymakers and experts are now calling for new business models and policy approaches that ensure the benefits of innovation and R&D are accessible and affordable for all. (Morgan, Bathula and Moon, 2020; Suleman *et al.*, 2020) These approaches seek to realign innovation incentives with public health outcomes by reshaping the financial, legal, and policy frameworks that govern health innovation. (Suleman *et al.*, 2020)

Translating research into tangible societal benefit has long been a core objective of academic institutions and the public and philanthropic bodies that fund them. Many of the technologies that have transformed health outcomes globally originated within universities before being developed into marketable products. Yet gaps persist between discovery and access, particularly for populations in LMICs.

Closing these gaps is central to achieving the United Nations Sustainable Development Goals, especially Sustainable Development Goal 3 on ensuring healthy lives and promoting well-being for all. Target 3.8 calls for universal health coverage and access

to quality essential medicines, while Target 3.b emphasises support for R&D addressing diseases that disproportionately affect developing countries. Article 27 of the UN's Universal Declaration of Human Rights also asserts every human being's right "to share in scientific advancement and its benefits". Given the UK's strong R&D base and significant public investment, there is a clear opportunity to advance these goals by adopting policies that ensure innovations reach those most in need. (Walensky and Siedner, 2024)

Ensuring equitable access to research outputs has also become a key priority within the global health governance agenda. In 2025, countries concluded negotiations on a pandemic treaty under the World Health Organisation's constitution aimed at strengthening global health security. (DNDi, 2025) This pandemic treaty, officially endorsed at the World Health Organisation's 78th World Health Assembly, represents a significant shift in global health policy and once ratified, will constitute a landmark international legal instrument to safeguard the world against future pandemics. Notably, Article 9.5 mandates countries to adopt policies with public interest 'strings attached' to R&D funding. (DNDi, 2025) This is the first time an international health agreement has clearly recognised public R&D funding as a powerful lever to promote equitable access to health innovations. (DNDi, 2025) Additionally, World Health Organisation (WHO) Member States are negotiating an annex to the Treaty—the Pathogen Access and Benefit Sharing system—which, if adopted, will support rapid pathogen detection and sharing while ensuring equitable and timely access to medical countermeasures, including vaccines, therapeutics, and diagnostics. (DNDi, 2025)

Despite substantial public and philanthropic investment in early-stage UK academic research, late-stage development and global deployment of resulting innovations often falter. This is largely due to private-sector business models that prioritise high returns in wealthier markets. To ensure that publicly funded R&D delivers broad societal value—and that its outputs function as global common goods—UK academic research funders and institutions can adopt global access policies. These policies can mandate and operationalise plans for affordable, worldwide deployment of innovations, ensuring that public and philanthropic investments translate into equitable health outcomes both domestically and globally.

A Global Access Policy (GAP), sometimes referred to as an equitable access policy/strategy or socially responsible licensing policy/strategy, comprises institutional guidelines adopted by research or funding organisations to ensure that publicly or philanthropically funded research outputs are made globally accessible and affordable. GAPs serve as instruments to balance incentives for innovation with equitable access to resulting products. They have most commonly been adopted by organisations working on diseases that disproportionately affect LMICs, where high prices pose significant barriers to access. GAPs are closely aligned with open science principles, which promote transparency and unrestricted access to research outputs and data. (DNDi, 2025) In practice, open access tends to be the most prominently implemented element of open science (Sikt, 2024), largely because funding organizations typically require publications to be made publicly available as a condition of funding.

While GAPs are well established among some global health funders (e.g. the Gates Foundation and Global Innovation Fund) and non-profit product development partnerships (e.g. Foundation for Innovative New Diagnostics [FIND], Drugs for Neglected Diseases Initiative [DNDi], and The Global Antibiotic Research & Development Partnership [GARDP]), most UK research funders and higher education institutions do not yet have formal GAPs or equivalent frameworks to ensure that innovations are affordably priced and globally accessible.

By addressing market failures that perpetuate inequitable access, GAPs offer a promising policy tool to ensure that publicly and philanthropically funded research is translated into healthcare technologies that are both affordable and widely available. Against this backdrop, this research project explored how GAPs can strengthen global access to UK-driven innovations and identified actionable strategies and recommendations to support their adoption and implementation across the UK research ecosystem.

Research Questions

This project sought to answer the following questions:

1. Which academic research institutions and funders in the UK currently have and/or implement GAPs?

2. Have GAPs been effective in ensuring global availability of publicly and philanthropically funded research outputs at affordable prices?
3. How can UK academic research institutions and funders create and adopt such policies to drive the global deployment of UK-driven innovations?

Research Objectives

The research objectives were to:

1. Identify exemplar GAPs developed and/or implemented by academic research institutions and funders;
2. Understand the impact of GAPs in promoting affordable global access to publicly and philanthropically funded R&D; and
3. Develop a practical framework to support UK academic research institutions and funders in adopting GAPs that ensure global deployment of their research and innovations.

2. Methodology

This study employed a qualitative research design, combining primary and secondary data collection methods. Specifically, we conducted a rapid review of scientific and grey literature on GAPs and related strategies, complemented by semi-structured key informant interviews with senior stakeholders from a diverse range of UK-based research funders and HEIs. This approach enabled triangulation of evidence and provided both contextual and practice-based insights into the development, implementation, and perceived effectiveness of GAPs.

2.1 Rapid literature review

A rapid review of scientific and grey literature was undertaken to map and synthesise existing evidence on the role, impact, and effectiveness of GAPs used by academic research funders and institutions in the UK to promote affordable and equitable global access to publicly or philanthropically funded research and innovation.

The scientific literature search was conducted in PubMed using a search strategy that combined terms related to global or equitable access policies and strategies (e.g., “global access policy,” “equitable access strategy,” “affordable access plan,” “socially responsible licensing”) with terms related to global health, access to medicines, LMICs, and institutional actors (e.g., academic institutions, research institutes, funders), alongside UK-specific geographic identifiers. *Please see Appendix I for a full description of the search terms and strategy*. The search was limited to English-language publications published between 1 January 2000 and 31 December 2024. This process yielded 2,751 records, which were screened using Rayyan.AI software. Title and abstract screening were conducted independently by one researcher, while full-text screening was conducted independently by a second researcher to enhance rigour and reduce selection bias. This resulted in a shortlist of thirteen articles that were subsequently reviewed in full.

In parallel, grey literature searches were conducted to capture relevant policy documents, reports, and publicly available materials produced by UK-based academic research funders and HEIs. These searches complemented the scientific literature and provided important contextual and practice-oriented insights.

2.2 Key informant interviews

Key informant semi-structured interviews were conducted to develop detailed case studies on exemplar GAPs or approaches being used by universities and funders involved in UK-led or supported research.

2.3 Recruitment and sampling

Primary data were collected through interviews with senior staff involved in the development and/or implementation of global access policies or related access strategies within their institutions. A multi-pronged recruitment strategy was used to identify and contact potential participants. This included leveraging professional networks, reviewing organisational websites and publicly available professional profiles (e.g., LinkedIn), and seeking referrals from previously identified key informants.

Participants were eligible for inclusion if they were able to communicate in English, were employed on a part-time or full-time basis (temporary or permanent contract) at a

managerial level or above within a relevant academic or funding institution and had worked at their institution for at least one year. Individuals below managerial level or with less than one year of institutional experience were excluded.

Using this approach, fourteen interviewees across five funders and three HEIs were identified and invited to participate. Each invitation included a detailed participant information sheet outlining the study's objectives, procedures, and ethical considerations. Five individuals ultimately consented to participate, representing the University of Oxford, the University of Cambridge, Wellcome, Unitaid, and the British Academy.

2.4 Data collection

Interviews were conducted virtually using Microsoft Teams at mutually agreed times. All interviews were conducted in English, lasted approximately 60 minutes, and were audio-recorded with participants' consent. Written informed consent was obtained from all participants prior to the interviews. To protect confidentiality, no personally identifiable information was collected during data collection.

2.5 Ethical considerations

The study was conducted in accordance with the *Declaration of Helsinki (2008)* and in compliance with the standard operating procedures of the Liverpool School of Tropical Medicine (LSTM) research ethics committee. Ethical approval was granted by the LSTM research ethics committee in June 2025 (protocol number 25–025). Only data relevant to the objectives outlined in the approved protocol were collected, and all information was handled in accordance with applicable legal and institutional requirements.

2.6 Data analysis and management

Findings from the rapid literature review were synthesised thematically to identify key trends, gaps, and illustrative examples relevant to GAP design and implementation. Interview data were analysed using inductive and deductive approaches. Key themes identified during the literature review informed the development of the interview guide (see Appendix II). This guide served as an analytical framework for the deductive coding of interview data and insights. In parallel, new themes that emerged from the interviews were inductively analysed, prioritised, and categorised according to the frequency with

which they were highlighted by participants. The NVivo 15 software was used to digitally transcribe the interview audio recordings and to support the data analysis.

Audio recordings and transcripts were stored securely on password-protected institutional systems (OneDrive and SharePoint) accessible only to the research team. Audio recordings were deleted immediately following transcription, and all study materials, including consent forms and transcripts, will be retained securely for up to five years before deletion, in line with LSTM Research Governance and Ethics Office data management requirements.

3. Literature Review Findings

The following is a narrative synthesis of key insights from the rapid literature review conducted.

3.1 Current UK Research Institutions and Funders with GAPs

a. UK academic institutions and their global access policies

Global Access

Socially Responsible Licensing and Equitable IP Management

In 2007, a group of American research institutions led by Stanford University developed a set of points or principles for Socially Responsible Licensing, advocating for university licensing policies and practices to balance commercialisation with the public good by ensuring broad access to research outputs and equitable access to resulting technologies. (Stanford University, 2007; González, Villarroel and Francicsca, 2026) Since their introduction, the Socially Responsible Licensing principles have been widely recognised and adopted by universities across multiple countries, forming the foundation for global access policies and practices in diverse geographical contexts.

- Between 2012 and 2014, eight universities — University College London (UCL), University of Edinburgh, University of Manchester, Imperial College London, University of Oxford, University of Dundee, University of Bristol, and London School of Hygiene and Tropical Medicine (LSHTM, which pledged adoption

within a year) — made public commitments to Socially Responsible Licensing. (Gotham *et al.*, 2016a) University College London's technology transfer office reported that adopting Socially Responsible Licensing principles strengthened its negotiating position for affordability provisions. (Gold *et al.*, 2019)

COVID-19 Specific Mechanisms

- Oxford University initially issued non-exclusive, royalty-free licences for COVID-related IP but subsequently entered an exclusive licensing agreement with AstraZeneca, which included some price concessions for low-income countries. (Keestra *et al.*, 2022) Imperial College London established the social enterprise "VacEquity Global Health" to license its vaccine IP royalty-free in the UK and LMICs to promote equitable access. (Keestra *et al.*, 2022) Imperial College London also disclosed 10 patents for a variety of technologies including vaccines and ventilators. Regarding ventilators, University College London licenced its UCL-Ventura breathing aid design and manufacturing package on a non-exclusive basis to 122 countries. (Keestra *et al.*, 2022)
- Other UK universities also took steps, though often more limited, to address access concerns during the pandemic. The University of Edinburgh updated its Essential Medicines policy in 2020, broadening it to cover all health technologies and committing to greater transparency and access-oriented licensing. The University of Bristol distinguished itself as the only UK university to endorse the Association of University Technology Managers COVID-19 licensing guidelines, which encourage the use of time-limited, non-exclusive and royalty-free licences for pandemic-related IP. (Keestra *et al.*, 2022)

Open Access and Open Science

- Open Access Publication Policies: In one study, sixteen out of 25 surveyed universities – University College London, Imperial College London, LSHTM, Kings College London, Newcastle University, and Universities of Aberdeen, Bristol, Cambridge, Dundee, Edinburgh, Leeds, Leicester, Nottingham, Oxford, Southampton, Warwick – had formal open-access policies that ensure research findings are widely accessible, often with specific requirements for re-use. (Gotham *et al.*, 2016b) However only three — Imperial College London, Newcastle University, and University of Aberdeen — had dedicated institutional funds to cover open-access publication fees, according to the study. (Gotham *et*

al., 2016a) While 76% of health-related research articles published by these universities were available online, just 23% had a Creative Commons CC-BY licence, the gold standard for open access. (Gotham *et al.*, 2016a)

- Open Data Sharing Policies: Universities of Cambridge and Oxford have policies to make research data available for broader scientific scrutiny and re-use. (Gotham *et al.*, 2016b) For instance, Oxford University's policy (via the Structural Genomics Consortium) promotes open sharing of data (such as protein structures) to advance drug discovery. (So *et al.*, 2011; Gold *et al.*, 2019) Also, Cambridge University and the Wellcome Sanger Institute are part of the Global Alliance for Genomics and Health, contributing to the development and piloting of "registered access" models for sensitive genomic and health data. (Dyke *et al.*, 2018) This model enables access to data under agreed terms and conditions. The registered access model involves a Triple-A (Authentication, Attestation, Authorization) registration process to ensure user identification and agreement to data user terms.

b. Funders supporting Global Access, Open Science and Open Access[1]

Several UK-based and international funders such as the UKRI, Wellcome and research or product development partnerships (e.g., DNDi) supporting research in the UK play a significant role in driving global access to scientific research outputs, primarily through their funding conditions and direct support for open science and open access initiatives. *Please see Table 1 below for more information*.

The Global Healthcare Innovation Alliance Accelerator's Master Alliance Provisions Guide and database offer a comprehensive collection of information on equitable access policies, along with other resources published by global health R&D funders, PDPs, academic research institutions, and pharmaceutical companies. (GHIAA, 2026)

[1] Our first research question and objective when designing this project was initially to identify exemplar UK-based research institutions and funders using and implementing GAPs. We however were unable to find substantial information on UK-based funders from the literature review and interviews conducted, so we have expanded our findings to include other international funders, intermediary funders and product development partnerships (PDPs) funding research led or supported by UK research institutions.

Table 1: (Non-exhaustive) Examples of Global Access, and Open Access strategies used by Funder. Note: ✓ indicates which organisation utilizes the specific policy approach/access condition.

Type of Policy (Strategy)	Example of policy approach or access condition used	Public Funders			Philanthropic Funders			Intermediary Funders				PDPs		
		UKRI	MRC	US NIH	Wellcome	Gates Foundation	Unitaid	CEPI	CARB-X	EDCTP	DNDi	MMV	FIND	GARDP
Global Access	Target access profiles						✓(Unitaid, 2022)							
	Equitable access plans			✓ (NIH, 2025)	✓(Wellcome, 2026b)	✓(Gates Foundation, 2024)		✓(CEPI, 2018)	✓(Carb-X, 2021)	✓(EDCTP, 2025)			✓(FIND, 2018)	✓(Uniting Efforts, 2025)
	Socially responsible licensing/non-exclusive or partially exclusive licences				✓(Wellcome, 2025b)	✓(GHIAA, 2019)					✓(DNDi, 2004, 2025)			
	Non patent filing in LMICs				✓ (Wellcome, 2025d)									
	Humanitarian license					✓(GHIAA, 2019; Gates Foundation, 2024)								
	Royalty free licenses					✓(GHIAA, 2019)								
	Affordable access clause						✓(Unitaid, 2025)					✓(Justia, 2003)		
	Step-in rights				✓(Wellcome, 2026b)		✓(Unitaid, 2025)							
Open Science and Access	Gold open access	✓(UKRI, 2023)	✓(UKRI, 2022)	✓(Lenharo, 2025)	✓(Wellcome, 2025c)	✓(Gates Foundation, 2025)	✓(Unitaid, 2025)	✓(CEPI, 2018, 2023)		✓(Global Health EDCTP, 2024)	✓(DNDi, 2025)			
	Green open access	✓(UKRI, 2023)	✓(UKRI, 2022)											

3.2 Effectiveness of GAPs in Ensuring Affordable Access

The effectiveness of GAPs is often assessed in the context of how contractual provisions (such as at-cost sales and non-exclusive licensing) have been used to secure access in resource-poor settings. (Guebert and Bubela, 2014; Nguyen, Shazhad and Veras, 2018a)

Table 2: Examples of GAP measures used in practice and their outcomes

Measure	Example	Outcome
Affordability via "At-cost" commitments	University of Oxford partnered with AstraZeneca which committed to sell its COVID-19 vaccine at cost in perpetuity in the lowest income countries. (Keestra *et al.*, 2022)	While this was commendable, given the relatively low price of $4 per dose compared with other COVID-19 vaccine prices (UNICEF, 2025), and the delivery of three billion doses to 180 countries by the end of 2022 (University of Oxford, 2023b), it was constrained by a narrow definition of "developing countries," which excluded more than 30 countries that would otherwise have been eligible for affordable access through COVAX. (Keestra *et al.*, 2022)
Price reduction via Socially Responsible Licensing (SRL)/Non-exclusive licensing	Yale University renegotiated its licence for the HIV drug *Stavudine* with Bristol Myers Squibb, resulting in a 30-fold price reduction in sub-Saharan Africa. (Guebert and Bubela, 2014; Nguyen, Shazhad and Veras, 2018a)	Non-exclusive licensing enabled generic competition, reducing prices and improving global access. (Gotham *et al.*, 2016b; Keestra *et al.*, 2022)

3.3 Pathways for UK academic research institutions and funders to advance GAPs

Three main strategies were highlighted in the literature to support global deployment of UK-driven innovations:

a. Equitable IP Management and Socially Responsible Licensing

This involves institutional commitment to licensing technologies in a manner considerate of global needs, which influences downstream pricing, distribution and access. (Guebert and Bubela, 2014) Socially Responsible Licensing strategies define their aims around promoting the societal impact of university derived health innovation and ensuring equitable distribution in LMICs.

- **Non-exclusive licensing** fosters generic competition leading to rapid price reductions and improved global access. HIV and COVID-19 treatments are notable examples. (Guebert and Bubela, 2014; Gotham *et al.*, 2016b; Keestra *et al.*, 2022)
- **Incorporating march-in or termination rights** (also known as step-in rights) ensure compliance with equitable access provisions, and allow funders or research institutions to convert exclusive licence to non-exclusive licences if obligations are not met. (Nguyen, Shazhad and Veras, 2018a) Where exclusive licences are deemed necessary for development investment e.g. vaccines, they often result in higher prices and access issues.
- IP protection strategies utilising a "**minimally defensive patent**" strategy (e.g., patenting specific clinically useful molecules) combined with open licensing can secure development funding while guaranteeing affordable access. (Griffen *et al.*, 2024) **Including patent restrictions** like securing the licensee's agreement that they will not file patents in LMICs unless specifically requested, removes legal barriers to access. (Nguyen, Shazhad and Veras, 2018a) On the other hand, a lack of control can deter private sector investment needed to bring products to market. (Griffen *et al.*, 2024)
- **Differential pricing clauses/access provisions requiring licenses** to provide differential/tiered pricing or sell final products "at-cost" for sales in developing countries ensures greater affordability. (Nguyen, Shazhad and Veras, 2018a)
- **Equitable Access Plan** requirement for the submission of a plan when it is reasonably certain that the licensed product will be commercialised. This non-prescriptive approach

does not stipulate what the licensee's strategy or timeline should be for ensuring equitable access. It fosters conversation and requires thoughtful consideration of access issues. Licensees are to include their plan of achieving affordable access in LMICs with timelines, and to list countries where the product would not be commercialised. (Coller, 2025)

- **Actively engage with voluntary licensing**, transfer of technical know-how, and pooling mechanisms for health technologies, including but not exclusive to initiatives by the MPP, Impact Licensing Initiative, and the WHO mRNA Hubs. (Eni-Olotu *et al.*, 2025)
- Ensuring access for more complex technologies like biologics will require further strategies that cover know-how, cell lines, and protocols, not just patents. Malhotra et al (2024) stress robust technology transfer, shared cell banks, and demand aggregation to lower costs and enable LMIC production. (Malhotra *et al.*, 2024)
- **Designing for access.** Commit to developing simpler, thermostable formulations with lower production costs. E.g. Monoclonal antibodies optimised for stability and ease of use are more suitable for LMICs (Malhotra *et al.*, 2024); new methods demonstrate that biologics can remain stable at ambient temperatures of up to 65 °C, thereby reducing cold-chain barriers, a key barrier in low-resource settings. (Marco-Dufort *et al.*, 2022)

Universities hold control over IP stemming from public research, which is a powerful legal instrument. The leverage is greatest in the upstream stage of technology development. (Nguyen, Shazhad and Veras, 2018a) Technology transfer offices can draw on established resources like the Association of University Technology Managers global health toolkit (Guebert and Bubela, 2014) for examples of Socially Responsible Licensing language. This approach also requires technology transfer offices to be versed in Socially Responsible Licensing practices and to be assertive with industry partners. (Guebert and Bubela, 2014) Success relies on transparent, thorough and unambiguous contractual clauses. It is important to note that publishing licensing agreements in full is rare; and the secrecy surrounding the commercialisation of publicly funded health research is a major barrier to global access in the bio innovation sector.

Adoption of Socially Responsible Licensing principles by leading UK research institutions like University College London and University of Oxford (Nguyen, Shazhad and Veras, 2018b) has stimulated investment from philanthropic foundations, generated positive spillovers in the societal reputation of these institutions and attracted more partnerships. Implementers of this

approach should however consider that technology transfer offices may prioritise patent counts and licensing revenues, leading to incentives that could conflict with public good goals. (Nguyen, Shazhad and Veras, 2018a; Gold *et al.*, 2019)

b. Open Science and Access

- This approach involves maximizing the timely and free sharing of research outputs like data, publications and software to increase efficiency, accelerate follow on innovation, and build public trust. (Gold *et al.*, 2019) Open science collaboration enables rapid data and idea transfer not hindered by lengthy contract negotiations. (Griffen *et al.*, 2024) This requires researchers and institutions to overcome incentives favouring closed research practices and prioritise producing quality, reproducible data over rapid publishing.
- Institutions have to invest in comprehensive data collection infrastructure and administrative systems for handling shared data.
- While openness is encouraged, it should be balanced against the need to protect IP strategically, to reduce the likelihood of uncontrolled experimentation and development delays.

Example: Both Universities of Oxford (University of Oxford, 2024) and Cambridge (University of Cambridge, 2026) possess formal commitments towards open science, which serves as an enabler for transferring knowledge on a local and international level.

c. New R&D business models

- Public and charitable funders can prioritise R&D models that align financial incentives with public health outcomes and impact for neglected populations/LMICs (So *et al.*, 2011; Gotham *et al.*, 2016b) rather than market potential. One way to achieve this could be through pull incentives that delink financial return from product sales volume. Examples of that incentive could be patent buyouts or prizes.
- Funders could also make access and transparency clauses a mandatory condition for receiving public funds (Keestra *et al.*, 2022) and can specify criteria to ensure compliance and positive outcomes.

This approach could sometimes be challenging to implement in practice, as in the case of the Health Impact Fund (So *et al.*, 2011), that was unable to secure long-term financing commitments. Valuing a health product's impact is also complex to measure. Notwithstanding,

supporting alternative R&D models like open innovation helps mobilise public and private resources to bridge the "valley of death" in translational research.

4. Case Studies

The two case studies[2] below are a narrative synthesis of the qualitative insights from interviews with Higher Education Institution stakeholders from the University of Oxford and the University of Cambridge and Funder stakeholders from Wellcome, Unitaid and the British Academy. *Please see a copy of the interview guide in Appendix II*.

4.1 Higher Education Institutions

Ensuring that research delivers tangible societal benefit is a core mission of most UK universities. This impact is pursued through multiple pathways, including the commercialisation of research outputs. Increasingly, universities are recognising that GAPs can serve as an additional mechanism to maximise societal value, particularly by supporting the equitable uptake of new medicines and therapies in LMICs.

At the same time, UK universities face growing expectations from research funders, academic researchers, advocacy and other types of organisations to demonstrate greater transparency and consistency in how they address affordability and access within IP licensing agreements. Institutional responses vary. Some universities, such as the University of Oxford, adopt a pragmatic approach to affordable access (University of Oxford, 2025) while others including the University of Edinburgh, University of Manchester, and University College London have made explicit public commitments to Socially Responsible Licensing. (Gotham *et al.*, 2016a) Outside the UK, Universities such as University of California Los Angeles have gone further by publishing standard licensing language used in biopharmaceutical agreements. (Nguyen, Shazhad and Veras, 2018b)

[2] As with all qualitative research, the interview findings carry certain limitations: they are not generalisable and may be influenced by various forms of bias, including researcher bias, confirmation bias, and selection or response biases. To minimise these risks, we incorporated reflexive practices throughout the research process, triangulated interview insights with verifiable data and external sources wherever possible and provided interviewees the opportunity to review and validate the findings to ensure their perspectives were accurately represented.

Conversely, some UK research institutions have been reluctant to require licensees to develop formal Equitable Access Plans, citing concerns that such obligations may deter commercial partners or downstream sub-licensees responsible for bringing products to market. It is unclear precisely how this reluctance squares with the reality of the access plan provision as utilised by University of California Los Angeles, University of California Berkeley, and others. The clause was specifically crafted in such a way as to be amenable to such concerns and gives significant latitude to the industry partner to craft their own strategies for LMIC access without prescribing any particular approach, and this flexibility has led to many universities on both sides of the Atlantic adopting it into their exclusive licenses for medical technologies. (Medicines Patent Pool, 2024)

4.1.1 Background and context for developing HEI GAPs: Oxford and Cambridge

The University of Oxford developed its GAP in the early 2000s, with licensing agreements and policy implementation managed by Oxford University Innovation (OUI). A key feature of the University of Oxford's approach is that it does not routinely file patents in LMICs. Oxford University's GAP is intentionally high-level, reflecting the fact that many technologies it develops, and licenses such as advanced monoclonal antibodies or cell and gene therapies are not immediately applicable to LMIC contexts. Where relevance does arise, however, the policy is designed to ensure that access to essential medicines is not impeded by pricing or patenting strategies.

In contrast, the University of Cambridge does not yet have a formal GAP, although it incorporates access-related terms within its IP licensing agreements and was in the process of developing a GAP during this project. Policy design at Cambridge University is shaped in part by the legacy concept of "Professor's Privilege" and its interaction with institutional IP frameworks. The University of Cambridge owns registrable IP generated by its researchers and academics, however these staff members retain discretion over whether and how to commercialise their inventions, including whether to work with the university's technology transfer office, Cambridge Enterprise. These decisions are also determined by funder requirements embedded within grant agreements.

Licensing and access provisions are typically tailored to the disease area or technology involved. At the University of Oxford, GAP-relevant cases have largely focused on vaccines and infectious diseases. For research assets/outputs where traditional IP protection is less relevant such as digital health tools, teaching materials, or research questionnaires, access is

often enabled through alternative non-commercial and/or non-profit models (because there's no IP to protect, exploit and/or commercialise) including through charitable organisations, social enterprises, crowd-funded initiatives, or equitable high-income country–LMIC partnerships.

A notable (registrable IP asset) example is the Oxford University-developed malaria vaccine, R21/Matrix-M™, which was licensed to the Serum Institute of India. (Serum Institute India, 2013) The patents for this technology were filed in the African Regional Intellectual Property Organization and the Organisation Africaine de la Propriété Intellectuelle jurisdictions, alongside other major markets, to prevent competitors from undermining manufacturing investments. This strategy was considered essential to sustaining R&D and ensuring reliable vaccine supply to LMIC populations. Another (non-registrable IP asset) example is Oxford University's patient reported outcomes. Patient reported outcomes, or clinical outcomes assessments, are condition-specific questionnaires designed to assess patients being treated for a variety of diseases. They are collected during clinical trials and used widely by clinicians (e.g., in the UK National Health Service), researchers, pharmaceutical companies and other public health stakeholders. The University of Oxford offers a portfolio of patient reported outcomes for licensing to commercial and non-commercial entities and many of Oxford University's non-commercial use patient reported outcome licences are free-of-charge, supporting wider societal benefit beyond commercialisation (Oxford University Innovation, 2026).

4.1.2 Essential Components of an HEI's Global Access Policy

Interviewees identified several core elements that should underpin an effective HEI GAP:

- A development plan that explicitly includes regulatory approval pathways for LMICs.
- Clear pricing provisions, such as caps on vaccine prices relative to cost of goods sold. During the COVID-19 pandemic, Oxford University's agreement with AstraZeneca included a temporary pricing cap linked to costs of good sold—an exceptional arrangement. This is because manufacturers rarely disclose cost of goods sold data to protect their competitive advantage, ensure flexibility in pricing their products and negotiating with suppliers, and reduce transparency regarding product-specific profit margins.

- Requirements for licensees to articulate a global access plan upon first regulatory approval, including strategies for LMIC access or sub-licensing where appropriate.
- Provisions allowing universities to revise licensed territories or seek alternative partners if access commitments are not met in specific LMICs.

While these represent minimum expectations for registrable IP assets, access requirements are often adapted on a case-by-case basis depending on the technology (e.g. vaccines, drugs, diagnostics) and disease area (e.g. infectious diseases versus non-communicable diseases).

4.1.3 Governance, Accountability, Transparency of HEI GAP Implementation

Internal coordination, Senior Executive oversight, standardised M&E frameworks

At the University of Cambridge, global access provisions are implemented and monitored internally by Cambridge Enterprise through standard licensing templates and internal review processes. Oversight by senior university committees is limited, reflecting the long-term and contingent nature of access clauses, which may only become relevant years after licensing. Licensees are required to submit annual development reports detailing progress, use of the technology, and territorial exploitation, enabling termination where technologies are not actively developed.

At the University of Oxford, all licensees are obliged to provide certain Sustainable Development Goals-related metrics that is used in impact case studies. Oxford University Innovation has also used some of this information for their impact reports over the last three years. (University of Oxford, 2023a) Oxford University Innovation monitors compliance across all IP licensing agreements, including GAP-related provisions.

Joint internal and external governance committees

There are unique situations, such as during the COVID-19 pandemic, where Oxford University established governance structures to steer the partnership with AstraZeneca and others in the right direction, through joint committees with representatives from Oxford University, AstraZeneca and the UK Government.

4.1.4 Enablers of and Barriers to HEI GAP Implementation

Enablers

- **Institutional buy-in** typically through a research policy committee or equivalent governance body is essential for policy adoption and enforcement.
- **Tracking impact over time** is increasingly recognised as important, particularly in relation to contributions to the UN Sustainable Development Goals.

Barriers

- **Poor industry engagement** emerged as the most significant barrier. Commercial partners may delay or resist engagement in LMIC markets, effectively stalling access. This has led some universities to adopt lighter-touch policies. Nonetheless, GAPs can exert important pressure on multinational pharmaceutical companies to engage meaningfully on access and, where they do not, to enable alternative routes to market.
- **Holding licensees accountable** remains challenging. Many agreements are executed at early R&D stages, where access terms are embedded within funder grant conditions rather than commercial licences. Industry partners often resist GAP clauses, viewing them as onerous, duplicative, or inconsistent across HEIs, funders, PDPs, and organisations such as the MPP. In some cases, companies have objected to GAP provisions already covered by donor funding agreements.
- **Lack of awareness of GAPs in HEIs**: GAPs are not always widely communicated within and outside HEIs. Awareness is typically concentrated within technology transfer offices, particularly legal and contracts teams, and among research groups working on LMIC-relevant technologies. This information asymmetry further limits the use, effectiveness or impact of these policies even when they exist.

4.1.5 Impact and Sustainability of HEI GAPs

For infectious disease vaccines developed at the University of Oxford, access impact is commonly assessed through metrics tracked by WHO and other global health organisations, including doses procured, delivered, and administered in LMICs, regulatory approvals, and estimated lives saved. Long-term sustainability of GAPs will depend on greater alignment between HEIs and funders, clearer guidance on implementation, and improved sector-wide consistency. Several UK and European Union funders currently lack explicit equitable access policies, contributing to uncertainty and uneven expectations.

Improving awareness and understanding of GAPs remains a priority, as some industry and small and medium-sized enterprises continue to question the rationale for embedding access obligations within licensing agreements and seek to renegotiate such terms directly with funders.

4.2 Funders

4.2.1 Background and context for developing GAPs: Wellcome, Unitaid and British Academy

Wellcome, Unitaid and the British Academy represent distinct funder archetypes within the UK and global health research landscape, each engaging with global access in ways that reflect their missions, funding models and portfolios.

Wellcome first publicly articulated its approach to equitable access through the publication of its Equitable Access Statement in 2018. While the statement formalised Wellcome's position, its access-oriented practices long predated this publication. The statement aligns with Wellcome's mission to support research in areas such as infectious disease and mental health and outlines the principles underpinning its efforts to maximise societal impact and access to the health innovations it funds. (Wellcome, 2025d) At the time of this project, Wellcome was consulting on a refreshed version of the statement. (Wellcome, 2025a)

The updated statement is expected to clarify Wellcome's definition of equitable access and to move beyond a primary reliance on legal agreements to secure access. It will place greater emphasis on structured, non-legal support for grantees to help translate funded innovations to their intended populations and beneficiaries. This includes collaboration with regional and national actors such as the Africa Centres for Disease Control and Prevention, WHO African Regional Office and Clinton Health Access Initiative, and support for activities including cost-effectiveness evaluation, market shaping, innovative financing mechanisms, and locally appropriate care and delivery models. Wellcome also aims to standardise minimum access conditions across all funded projects, with additional or more stringent conditions applied to projects further along the development pathway.

Wellcome's policy necessarily remains high-level and flexible, reflecting the fact that it primarily funds early-stage research. For such research, access outcomes often materialise many years after funding is awarded and are frequently delivered by downstream commercial partners that have no direct contractual relationship with the funder. As a result, Wellcome's equitable

access approach operates in close alignment with its intellectual property and commercialisation policy (Wellcome, 2026b), using a combination of legal and non-legal levers to influence long-term outcomes.

Unitaid has also embedded equitable access into its mandate since its inception nearly two decades ago. Its mission is explicitly focused on accelerating equitable access to health products, which it defines as ensuring that quality-assured products are made widely available as quickly as possible, on a continuous basis, at affordable and sustainable prices for LMICs. Unitaid's current strategy spans HIV, tuberculosis, malaria, maternal and child health, oxygen access and cervical cancer, alongside cross-cutting investments in areas such as the MPP, regional manufacturing, climate and health, and pre-pandemic preparedness.

Unitaid's portfolio covers a wide range of product classes—including diagnostics, vaccines, therapeutics and medical devices—and spans the full development continuum, from early R&D to pre-commercialisation and products that have been on the market for several years. This breadth has allowed Unitaid to develop deep, practice-based insights into how access strategies must be tailored to different product archetypes, disease areas and stages of development, and what works differently for, for example, originator products versus generic formulations.

Although the British Academy does not have a formal Global Access Policy, many of the underlying principles of GAPs align closely with its funding ethos. As a major funder of Social Sciences, Humanities and Arts for People and the Economy (SHAPE) research, the British Academy funds and fosters equitable international research partnerships and seeks to ensure that non-UK partners are treated fairly and as equals. (The British Academy, 2026b) The Academy supports open access principles (The British Academy, 2026a), particularly for journal articles through green open access routes, but takes a more cautious approach to open access for books and monographs due to the prohibitive costs of book processing charges. As the British Academy does not fund open access (with limited exceptions, such as monographs produced under its postdoctoral fellowship scheme) it does not mandate open access in its funding agreements.

4.2.1 Essential Components of a Funder's Global Access Policy

Funders typically adopt bespoke approaches to global access, aligning access conditions with organisational strategy, portfolio characteristics and available levers.

For Wellcome, key (and aspirational) components of its approach include:
i) clearly defined intellectual property ownership and exploitation rights and responsibilities;
ii) access planning, including consent to access plans where applicable;
iii) reporting obligations that may extend beyond the formal end of a grant;
iv) step-in rights;
v) limited financial return mechanisms (e.g. convertible loans or revenue-sharing), used strategically as negotiating levers to waive the financial revenues in exchange for access conditions or activities that advance the funder's access objectives.
vi) consent-to-commercialisation requirements, with waivers often granted to trusted, mission-aligned entities such as higher education institutions.

In certain cases, particularly for later-stage projects, larger awards or interventions targeting high-burden populations, Wellcome may layer additional conditions onto funding agreements. These may include due diligence requirements, pricing commitments (e.g. cost of goods plus a defined margin), or obligations to ensure access in disease-endemic countries. While Wellcome's overall approach is product-agnostic, the specific terms applied are determined on a case-by-case basis.

Unitaid's access approach is structured around its overarching access strategy, which aims to secure equitable access for 30 products by 2030. Within this framework, Unitaid sets explicit access targets and deploys multiple mechanisms to achieve them. These include legal access commitments, commercialisation strategies and the development of target access profiles for funded product classes.

Target access profiles articulate a shared vision of what success looks like across the entire value chain, from funders and manufacturers to implementers, policymakers, procurers and end users. Developed through extensive stakeholder engagement, target access profiles specify desired outcomes related to use cases, evidence generation, regulatory approval, quality assurance, supply chains, demand generation and pricing, etc. They also inform practical decisions such as training requirements and procurement strategies.

Target access profiles are translated into roadmaps and, where leverage permits, into binding contractual commitments. Where direct leverage is limited, Unitaid adopts an end-to-end strategy, working with other funders and partners to collectively secure desired outcomes. Commitments vary by development stage and information availability and may include royalty-

free licensing and step-in rights for early-stage products, multi-country registration commitments for commercialised products, access plans and affordable pricing commitments informed by cost, willingness-to-pay and benchmark analyses.

The British Academy focuses on open research practices rather than product access. It advocates for datasets to be deposited in open repositories, while recognising that some datasets require restricted access due to sensitivity. The Academy assigns IP ownership to the host institution and therefore does not actively manage IP arising from its grants.

4.2.2 Governance, Accountability, Transparency and Resource Allocation of Funder GAP Development and Implementation

Governance, accountability and resourcing mechanisms vary across funders but are central to effective GAP implementation.

Internal consultation & coordination, Senior Executive oversight, Board review/approval

Wellcome's 2018 Equitable Access Statement was developed through internal consultation and engagement with Wellcome-funded public–private partnerships such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator. As a statement of existing practice, it was approved by the Senior Leadership Team without requiring board approval. Implementation is coordinated through informal cross-functional working groups spanning innovation and access, funding, legal and policy teams. The access and legal teams work together to ensure appropriate access terms are used in funding and commercialisation agreements.

Unitaid reports progress against its target access profiles to its board, with strategic oversight provided by senior leadership, including the Director of Strategy and the Legal Director. A dedicated, multidisciplinary access team covering legal, technical, procurement and industry engagement expertise supports funding teams to design and operationalise access strategies, negotiate agreements, capture lessons learned and adapt approaches as leverage and partnerships evolve.

External consultation

Wellcome's refreshed access statement is expected to be shaped through extensive external consultation, incorporating feedback from a broad range of stakeholders, including private

sector actors, universities, civil society and advocacy organisations, Ministries of Health, and health workers. The revised statement will then proceed through an internal engagement and approval process broadly consistent with that used for the original statement.

In developing its target access profiles, Unitaid similarly adopts a consultative approach, mapping the roles and contributions of other funders and partners in achieving shared access objectives and clearly situating its own role within the broader access ecosystem. The target access profile strategy was co-developed with a wide range of stakeholders, including countries, donors, procurers, implementers and affected communities. Input from country and civil society representatives on Unitaid's board was particularly influential, prompting the further development of detailed roadmaps and practical toolkits to complement the target access profiles.

The British Academy convenes an Open Access Advisory Group that informs policy discussions within the Social Sciences, Humanities and Arts for People and the Economy funding ecosystem.

Standardised Monitoring, Evaluation and Learning frameworks

Wellcome uses standardised internal templates and systems to track access-related progress, with all systems auditable. As part of its refreshed policy, Wellcome is considering mechanisms such as expert review committees for access plans or public disclosure of plans to enable external feedback.

Unitaid has developed detailed guidelines and reporting frameworks for implementers, aligned with its access strategy and target access profiles.

The British Academy requires grant holders to provide links to open-access outputs as part of reporting and to describe how equitable partnerships have been implemented. It has recently introduced overseas assurance visits to better understand projects from international partners' perspectives and is exploring the use of DOIs and ORCIDs to track citations and impact.

Community of Practice and External Advocacy

Unitaid, Wellcome, and other global health funders have established a community of practice to facilitate knowledge exchange, share portfolio-level lessons learned, and collectively refine and strengthen their GAP strategies. Through this collaborative forum, funders also explore

opportunities to jointly implement equitable access approaches across the full innovation and access pathway. In addition, Unitaid supports the MPP to advance advocacy efforts and promote best practices for improving equitable access worldwide.

As part of its wider knowledge systems strengthening programme, the British Academy has been running a series of workshops and conferences on equitable partnerships to enable multistakeholder perspectives and advocate for best practice on equitable partnerships. (The British Academy, 2024a, 2024b, 2025)

4.2.3 Dissemination of Funder GAPs

Internal resources: publications, in-person learning series

Wellcome provides a range of internal publications to support staff and partners, accessible via its intranet. Unitaid complements this with internal learning initiatives, including all-staff sessions designed to build understanding of its access strategy through interactive discussion and knowledge sharing, as well as dedicated technical working groups involving domain experts. The British Academy primarily communicates its approach externally through a publicly available open access policy webpage.

External resources: website, social media, multimedia, in-person workshops

Externally, Wellcome disseminates its access strategy through publications, videos and other resources shared via its website and social media channels (e.g. LinkedIn). Knowledge generation and dissemination are likewise central to Unitaid's approach, exemplified by initiatives such as the *Access Is Not an Afterthought* publication series. (Unitaid, 2024, 2023a, 2023b, 2023c) In addition, Unitaid, in collaboration with the Geneva Graduate Institute, has developed a workshop and simulation game aimed at non-practitioners seeking to better understand equitable access challenges, with a massive open online course version of the workshop planned for launch soon.

4.2.4 Impact and Sustainability of Funder GAPs

Attributing access outcomes directly to specific access conditions is inherently challenging, particularly given long development timelines and complex R&D and innovation delivery ecosystems. However, internal and external reporting mechanisms enable funders to capture lessons learned and refine future approaches.

Examples of innovations supported through global health funding and GAPs that have achieved impact in LMICs include[3]:

- **Hillchol® (BBV131)**, a next-generation oral cholera vaccine licensed to Bharat Biotech and developed with Hilleman Laboratories, an MSD–Wellcome joint venture. (Hilleman Laboratories, 2024; Wellcome, 2024)
- **Arise**, an affordable standing wheelchair, and **SmartCane**, an electronic travel aid for visually impaired individuals, funded through the Affordable Healthcare in India programme supported by Wellcome and the Government of India. (Wellcome, 2010, 2026a; Phoenix Medical, 2017, 2024)
- **Rifapentine**, a tuberculosis drug whose global access was expanded through Unitaid-supported evidence generation, WHO guideline development, generic entry and coordinated procurement, leading to availability in 142 countries.

4.2.5 Enablers of and Barriers to Funder GAP Implementation

Enablers

- **Strong governance and M&E mechanisms**: Robust internal processes, clear structures, effective communication channels, and adequate resourcing across teams involved in GAP implementation are essential to ensure alignment and consistency in interpreting and applying access conditions and strategies. Certain provisions such as “consent to access plans” may also require dedicated governance arrangements to ensure they are implemented effectively.
- **Close, collaborative relationships with award-holders**: Regular communication, constructive engagement, and clear feedback loops with award-holders enable early identification of risks and timely resolution of issues as they arise.
- **Fostering market competition through proportionate and practical access agreements**: Effective equitable access depends on competitive markets. This requires a pipeline of multiple products reaching the market within similar timeframes. Introducing

[3] While these innovations were commercialised in LMIC contexts, apart from rifapentine, it is unclear how widely accessible and available the other products are across LMICs, as insufficient information was shared during interviews or is available in the public domain.

the first market-ready product too rapidly, or at an unsustainably low price, can create significant financial barriers for follow-on innovators and limit country uptake, potentially resulting in entrenched monopoly conditions that undermine long-term access and innovation.

- **Aligning value across key stakeholders**: Ensuring equitable access requires alignment among all actors across the ecosystem, including donor countries and funders, recipient countries and Ministries of Health, global health policymakers, procurers, civil society organisations, and industry partners.
- **Leveraging funders' convening power and influence**: Funders can use their convening authority and strategic influence both independently and in collaboration with other funders and global health procurers to generate interest, align incentives, and secure meaningful commitments from industry and commercial partners.

Barriers

- **Industry engagement**: Small and medium-sized enterprises especially may be reluctant to engage due to concerns that access-related grant terms could limit future partnerships with large multinational pharmaceutical companies. However, this concern is often not supported by evidence. Funder experience and available data suggest that biotech small and medium-sized enterprises can still successfully enter mergers and acquisitions with multinational firms and raise follow-on venture capital despite the presence of equitable access provisions.
- **Post-grant data and information gaps**: Obtaining timely and accurate information from award-holders and partners after grant completion remains challenging. This is less problematic for products with shorter development timelines such as diagnostics or medical devices or where award-holders are directly responsible for commercialisation but remains a barrier for longer-term or more complex product pathways.
- **Accountability and enforcement challenges**: Holding companies and implementers accountable for access commitments is difficult, particularly where funders are unable to publicly disclose key contractual terms. Nonetheless, engagement with communities and civil society, alongside advocacy around access commitments, can play an important role in monitoring progress and maintaining pressure for successful implementation.

- **Limited coordination among funders**: A lack of alignment and coordination across funders can undermine access strategies, create inefficiencies, and complicate engagement with industry partners, ultimately weakening efforts to achieve equitable access.

5. Future Directions for GAPs

More robust evidence and evaluation methods are needed to assess the effectiveness and impact of GAPs, including comparative analyses of access outcomes for innovations developed with and without GAP requirements. Strengthening the evidence base will be critical to informing future policy design and implementation.

There is also a need to better articulate the public value and impact of GAPs to policymakers and the wider public, particularly in the context of increasing financial pressures on UK universities and funders. These constraints often result in global access considerations being deprioritised, especially where research outputs lack a clear or immediate pathway to global deployment. Even where GAPs exist, insufficient resourcing can limit follow-through, rendering access provisions largely symbolic rather than impactful.

Applying GAPs to SHAPE research presents additional complexity, as these outputs do not typically follow linear commercial translation pathways. While some universities and funders are supporting entrepreneurship and business formation around SHAPE research including in LMIC contexts it remains unclear how GAPs could systematically promote access for these outputs. Further experimentation and learning will be required.

Greater integration between biomedical product development and SHAPE research is also needed to maximise impact. These domains are complementary rather than separate: SHAPE research can address behavioural, cultural, and social factors that influence acceptability, uptake, and effective use of health technologies. For example, antivenom products developed for Indian snake species are often the mainstay treatments for snakebite envenoming in African markets despite being ineffective against African snakes. This mismatch undermines trust in modern medicine and can drive communities toward traditional healers, worsening health outcomes. Addressing such challenges requires stronger attention to social and behavioural dimensions alongside biomedical innovation.

The global implications of recent US drug pricing reforms particularly policies pursuing “most-favoured-nation” pricing remain uncertain. While intended to reduce US drug prices, early evidence suggests mixed effects: as of early 2026, although sixteen major pharmaceutical companies had entered agreements with the US government, all continued to raise list prices for some brand-name medicines. (Jacobus, 2026) The downstream spillover effects of these policies on global access warrant close monitoring.

Finally, as part of this project, we have developed a model GAP template and framework to serve as a guide for prospective UK research institutions and funders to adapt and develop their own global access policies. *Please see Appendix III for the GAP template*.

6. Recommendations

6.1 For Higher Education Institutions

- Strengthen governance, monitoring, and evaluation systems to more systematically track GAP implementation and impact.
- Better resource and empower technology transfer offices, especially in smaller or specialist HEIs, to operationalise GAP commitments, through dedicated internal funding allocations/mechanisms or public and/or philanthropic funding schemes.
- Improve alignment and consistency across universities and funders on access expectations and contractual terms.
- Ensure equitable research partnership agreements are supported by clear publications, data management, and IP policies. Making standard templates and examples of best practice publicly available would significantly support more equitable collaborations.

6.2 For Funders

- Agree on a minimum set of non-negotiable equitable access conditions to be included in funding and licensing agreements, alongside shared definitions of “access” and “access planning.”
- Increase transparency around key access-related terms and conditions among funders to support coordination and alignment with broader access strategies.

- Invest in strengthening the evidence base on the effectiveness and impact of GAPs. This includes supporting the development of more robust monitoring and evaluation frameworks, as well as comparative analyses examining access outcomes for innovations developed with and without GAP requirements. Building a stronger empirical foundation will be essential to inform future policy design, refine implementation approaches, and demonstrate the value of GAPs to policymakers, partners and the wider public.
- Engage industry more proactively through structured dialogue to align access obligations with commercial incentives and R&D investment priorities. Broader access debates should more fully incorporate private-sector perspectives to support sustainable, multi-stakeholder solutions. Pharmaceutical companies should also be encouraged to publicly share access plans, which may offer reputational benefits alongside transparency.
- Work with private investors to make access planning a mandatory requirement for investment decisions and reporting by pharmaceutical and biotech companies.

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Now that you have read our report, we would love to know if our research has provided you with new insights, improved your processes, or inspired innovative solutions.

Please let us know how our research is making a difference by completing our short feedback form via this link.

You are also welcome to email us if you have any questions about this report or the work of the IRC generally: info@ircaucus.ac.uk

Thank you

The Innovation & Research Caucus

Appendix I

Search Terms and Strategy

‘equitable access policy’ OR ‘global access policy’ OR 'equitable access strategy’ OR ‘global access strategy’ OR ‘equitable access plan’ OR ‘global access plan’ OR ‘affordable access plan’ OR ‘stewardship and access plan’ OR ‘socially responsible licensing (SRL) policy’ OR ‘equitable licensing policy’ OR ‘global access licensing’

AND

‘Global health’, OR ‘global public health’, OR ‘tropical medicine’, OR ‘infectious disease’ OR ‘low and middle-income countries’ OR ‘access to medicines’

AND

‘Academic institution’ OR ‘research institute’ OR ‘public research organisation’ OR ‘funder’ OR ‘donor’

AND

‘United Kingdom’ AND ‘Britain’ AND ‘England’ AND ‘Wales’ AND ‘Scotland’ AND ‘Ireland’

AND

Filtered by date: 1 Jan 2000 – 31 Dec 2024

Appendix II

IRC Project Interview Guide

Background/Context

1. When was your institution's Global Access Policy (GAP) developed, and what prompted its creation?
2. What are the primary goals and challenges the GAP aims to address?
3. How does the GAP align with your institution's mission?

GAP Development Framework

4. What are the essential components of a GAP? (probes/e.g., conditions of use in LMICs, IP exploitation, licensing, partnerships, SRA/LMIC regulatory approvals, manufacturing, pricing, supply chain, marketing and sales, access monitoring).
5. How does your GAP take into account the wide variety of scenarios that may be encountered, such as different technologies, different public health needs, different stages of development, *etc.?*

Governance, Accountability, Transparency and Resource Allocation

6. How was the GAP developed? (probes/e.g., internal drafting, stakeholder groups, staff or senior leadership buy-in, external consultations with HIC & LMIC partners, CSOs, or consultants)
7. What governance structures or processes oversee the GAP's implementation? (probes/e.g., Equitable Access Committee, Governance Board oversight, EDI, Partnerships strategy)
8. What monitoring and accountability mechanisms are in place? (probes/e.g., independent reviews, compliance checks, partner reporting, responsible department)
9. How is the GAP communicated internally and externally? (probes/e.g., staff awareness, website publication/explainer documents/summaries, social media)
10. How are institutional resources allocated to support GAP implementation?
11. How important/valuable is your institution's GAP implementation to driving your organisation's strategy?
12. What is the connection between your institution's GAP and your institution's technology transfer office, if it has one? How does your institution ensure that the GAP is translated into contractual obligations with partners and/or licensees?

Implementation: Enablers and Barriers

13. What does successful implementation of a GAP look like to your organisation?
14. What factors enable successful GAP implementation? (probes/e.g., how was this demonstrated/evidenced – quantitative/qualitative outputs?)
15. What barriers hinder effective GAP implementation?
16. Has your institution run into any challenges with industry partners that limit the effectiveness of the GAP? If so, how has your institution addressed these challenges?

Impact and Sustainability

17. Has your institution's GAP improved global equitable and affordable access to publicly/philanthropically funded research? (probes e.g., how was this demonstrated/evidenced – quantitative/qualitative outputs?)
18. If a funder, can you share examples of product developers successfully or unsuccessfully implementing your institution's global access policy or strategy for global accessibility?
19. If an HEI, can you share examples of research outputs that became (or failed to become) globally accessible due to your institution's global access policy or strategy?
20. How do GAPs impact or influence private sector engagement in health research? (probes/e.g., change in private sector ways of working, change in private sector policy/process) What actions could promote engagement while mitigating disengagement risks?
21. How can GAP approaches be promoted/advocated for and sustained amid changing R&D funding landscapes in high-income countries?

GAP Future Directions

22. Should GAPs extend beyond biomedical research to fields like Social Sciences, Humanities, and Arts (SHAPE)? How could they drive global access beyond traditional dissemination methods?
23. How do we ensure more advocacy and support for GAPs through policy engagement, public engagement, etc.

Appendix III

A model GAP template and framework for UK research institutions and funders

1. Purpose

The purpose of this Global Access Policy (GAP) is to balance incentives for innovation and commercialisation with the social responsibility to ensure that research outputs (the knowledge, technologies, and products arising from research) supported or conducted by (--organisation/university/institution name--) that are intended or have potential to address essential needs and/or with potential for significant health, subsistence, or wellbeing impact in low- and middle-income countries (LMICs) ("Covered Outputs"), are accessible, affordable and/or made available to the populations who need them the most.

This Policy outlines a set of strategies in support of Global Access objectives. The University/Organisation will implement internal measures within its remit to promote equitable access, while partners, licensees, and collaborators are expected, where appropriate, to propose strategies to enable and support progress toward achieving Global Access goals for Covered Outputs.

Definitions

Global Access:

a) Covered Outputs resulting from research and development activities undertaken by the University/Institution are promptly and broadly disseminated; and

b) Products, technologies, and innovations developed from such research are made available and accessible at an affordable price to the people most in need, particularly in low- and middle-income countries (LMICs), in ways that ensure acceptability, quality, and sustainability over time.

Equitable Access: A principle ensuring that populations in LMICs and other resource-limited settings can obtain and benefit from the outcomes of publicly or philanthropically funded research on fair, reasonable, and non-discriminatory terms, considering local purchasing power, infrastructure, and health system capacity.

Tailored Access Plan: A document developed by a licensee, collaborator, or partner, outlining how access will be achieved for a research outcome in LMICs.

It should describe intended pricing strategies, licencing strategies (if any), local manufacturing (if applicable), supply models, regulatory pathways, technology transfer plans, and LMIC availability timelines.

Relevant sex- or gender-related access considerations may be addressed within the Tailored Access Plan where material to equitable access.

Global Access Objectives: Are the intended access outcomes for a Covered Output, as defined and documented in the Tailored Access Plan (TAP), describing how the Product or research outcome is expected to be made available and accessible to populations in need in LMICs.

Global Access Milestones: Are indicators of progress, as set out in the Tailored Access Plan (TAP), used to assess advancement toward the Global Access Objectives.

Low- and Middle-Income Countries (LMICs) are defined in accordance with the World Bank's annual income classification or equivalent regional designations.

2. Scope

This Policy applies to all Covered Outputs, including, but not limited to, products such as new molecules, compounds, combinations, biological materials, diagnostic devices, digital tools, processes or methods, including manufacturing, formulation, and data and information such as research data, protocols, methodologies, and software.

Where, if such outputs are further developed or licensed to third parties, the university/institution will seek to ensure that Global Access obligations flow down to all subsequent agreements.

3. Institutional Commitments and Strategies

This section outlines a set of strategies the University/Institution will follow within its own operations and practices to support the implementation of GAP principles.

3.1 Equitable Access Principle

The university will embed equitable access objectives across its research, licensing, and partnership activities, supporting the following dimensions to ensure access:

a) ***Affordability:*** pricing and cost structures that do not prevent use;
b) ***Availability:*** adequate and timely supply in relevant geographies, and taking into account practical barriers to access;
c) ***Acceptability:*** suitability for local context, culture, gender-related considerations, and regulation;
d) ***Sustainability:*** long-term continuity of access and quality.

These principles apply across the research and innovation lifecycle, including preclinical and clinical development, and where research is conducted in LMICs, should inform considerations of post-trial access and sustainable local availability.

The University/Institution acknowledges that approaches to equitable access must be flexible and adapted to each technology and context. It will work collaboratively with partners to identify suitable equitable access mechanisms while ensuring that people's benefit objectives are met, as outlined in section 5.

3.2 Responsible Intellectual Property Management

The university may utilise a number of approaches to ensure responsible IP management for Covered Outputs. These may include, as appropriate:

a) Filing patents selectively, only where necessary to attract partners or investment;
b) Avoiding filing or enforcing patents in LMICs when such protection could restrict local manufacturing or use;
c) Including humanitarian licensing provisions in contracts to permit the University/Institution to further license relevant Covered Outputs for non-exclusive use during emergencies or unmet need;
d) Preferring socially responsible licensing (SRL)/non-exclusive or partially exclusive licences over fully exclusive agreements;
e) Royalty-free licences to LMICs territories or regions, where appropriate to support affordability and access objectives.
f) Retaining step-in rights, such as march-in and/or termination rights to ensure equitable access commitments are upheld.

3.3 Voluntary Licensing and Participation in Access Initiatives

The university recognises that public-health oriented voluntary licensing can be an effective means of promoting equitable access, particularly for health and essential technologies.

Where appropriate, the university should:

a) Offer voluntary, non-exclusive licences to qualified manufacturers or implementers based in or focusing on LMICs
b) Participate in recognised global or regional access initiatives
c) Include clauses allowing, encouraging, and/or mandating future voluntary sub-licensing intended to achieve equitable access objectives.

3.4 Early Planning and Integration into Research

The University/Organisation recognises that achieving equitable access requires early planning, open knowledge-sharing, and alignment with partners.

Accordingly, the University/Organisation will seek to integrate Global Access considerations into research and development activities at appropriate stages of the research and innovation lifecycle, including project conception.

a) Access Consideration at Project Conception

While certain aspects of equitable access may not always be knowable from the start, Principal Investigators and research teams should, to the extent possible, evaluate potential access pathways as part of project design with the support of their respective technology transfer office, including:

» Anticipated affordability and manufacturing feasibility;

- Regulatory and market access pathways in LMICs;
- Potential public-health impact and sustainability.

b) Design for Access and Scalability

Researchers are encouraged to adopt “design-for-access” principles, such as:

- developing technologies suitable for low-resource settings (e.g., thermostable, low-cost, easy to use) and incorporating acceptability into the project design so as to make best efforts not to inadvertently exclude important populations from eventual use;
- selecting materials, processes, and suppliers that facilitate downstream local production, where possible; and
- planning early for quality, regulatory, and supply-chain considerations.

c) Regulatory and Market Pathways

Researchers and partners should plan early engagement with National Regulatory Authorities (NRAs) and relevant public-health procurement bodies to ensure that development of a Covered Output considers relevant aspects that may impact timely registration and access in LMICs. Where applicable, development should align with the WHO Essential Medicines Lists or equivalent regional guidelines.

d) Local Manufacturing and Technology Transfer

Where relevant and feasible, the University will encourage collaboration with local or regional CMO/CDMOs to promote technology transfer, strengthen local capacity, and enable sustainable in-country/regional end-to-end or fill and finish local production for LMIC markets.

3.5 Open Access and Data Sharing

Where research publications, data, or knowledge are reasonably expected to support equitable access to Covered Outputs, the University/Organisation will seek to promote timely and responsible open access, in accordance with applicable institutional policies, funder requirements, and legal and ethical obligations.

In such cases, and where appropriate**,** the University may:

- Encourage open-access publication of research results that are necessary to enable downstream development, regulatory review, or implementation in low- and middle-income countries (LMICs); and
- Promote proportionate sharing of data, protocols, or research tools that are material to enabling follow-on research, manufacturing, or access pathways.

4. Partner / Licensee Commitments and Responsibilities

To translate the University/Organisation’s Global Access principles and commitments into practical outcomes, collaborators, licensees, and partners may be required to support equitable access through the following mechanisms:

a) Access Planning

The University/Organisation will require Partners/Licensees to prepare a Tailored Access Plan (TAP) describing how equitable access will be achieved.

The TAP should outline strategies and timelines for achieving equitable access. While every Covered Output may have its own set of issues to consider, some of the items that should be accounted for in an access plan may include:

- Target LMICs and launch plans, as well as areas where there are no intentions of commercialising;
- Supportable pricing and affordability strategies, such as differential, tiered, or cost+ models for LMICs;
- IP management strategies, including voluntary licensing and technology transfer. Where appropriate, commitments to limit or refrain from patent filing or enforcement in LMICs or specified territories in support of equitable access objectives
- Supply and Distribution to LMICs with Access Plans considering early demand forecasting for the initial years of market introduction, including anticipated volumes from public-health purchasers, to support sustainable supply;
- Manufacturing and technology transfer provisions; including whether and how regional or local manufacturing capacity may be supported over time
- Regulatory and quality plans; including plans for registration, quality assurance, and alignment with relevant national or international standards.
- Distribution and supply strategies; taking into account practical considerations affecting access and uptake in LMIC settings.
- Reporting milestones and transparency measures; proportionate to the stage of development, to track progress against agreed access objectives.
- Where Sex- or gender-related considerations are material factors to equitable access in LMICs, an indication of whether and how such factors are identified and, where appropriate, reflected in access planning.

b) Monitoring and Reporting

Partners are expected to:

- Participate in reasonable and proportionate monitoring, reporting or Access reviews to assess the progress towards achieving the Global Access milestones defined in TAP.

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