Written evidence from Isomorphic Labs (PMA0109)

About Isomorphic Labs

Isomorphic Labs is an AI-first life sciences company founded in the UK, headquartered in London. We were spun out of DeepMind in 2021 following the AlphaFold breakthrough with an ambitious mission: to utilise AI to one day solve all disease. We are pleased to have the opportunity to respond to this inquiry on personalised medicine and AI, and welcome the Committee's focus on this area.

Executive summary:

- Isomorphic Labs' mission is to use AI to one day solve all disease. To advance our mission we are leveraging AI across the drug discovery and development process. This work supports the progression of personalised medicine. We are developing various capabilities to drive this progress which encompass the specific biological mechanisms underlying disease and an increased understanding of human biology. Our AI drug design engine (IsoDDE) can create drug candidates with greater pace and precision than conventional approaches, including for targets previously considered out of reach.
- Our approach aims to advance new drugs at greater speed, scale and probability of success, ensuring we can help more patients sooner. To accelerate our mission and support the potential of AI in personalised medicine, the UK Government should enhance human data access and connectivity (across genetic, 'omic, and cellular data, coupled with clinical outcomes) and improve regulation and clinical trials (addressing clinical trial set up and delivery, and regulatory innovation).
- The UK holds world-leading human data assets, but they do not yet work as a connected system. Realising that potential of this data for drug discovery requires the data ecosystem to work as a system: connected, accessible, and enriched with the novel data types that enable AI model performance. Single cell and spatial data are particularly significant: emerging evidence suggests that cell-specific genetic insights increase the probability of clinical trial success beyond what human genetics evidence alone delivers, yet these data types remain underintegrated into the national research infrastructure. At present, the connections between initiatives like HDRS, the Genomics Medicine Service, and NIHR Commercial Research Delivery Centres are not clearly defined enough to deliver the critical omics data needed to support novel treatments, for the right patients at the right time. The Government should also seek proactive alignment and formal membership of the European Health Data Space, to strengthen cross-border research opportunities. Whilst data access is crucial to drive progress for personalized medicine, public trust underpins all of this work: the Government has a central role in facilitating

open dialogue between patient groups, public bodies, and industry to ensure that the use of health data for AI drug discovery is transparent, ethical, and secures genuine public confidence.

- The UK's clinical trials infrastructure and regulatory frameworks must be optimised for AI-designed drug candidates. Successful personalised medicine trials depend on omics data collection and flow across the NHS that is not yet reliably in place, and on regulatory frameworks that are not yet ready for AI-designed drug candidates. Patient identification, stratification, and monitoring in trials requires connected data infrastructure across the Genomics Medicine Service, HDRS, and NIHR Commercial Research Delivery Centres. Once that infrastructure supports trial delivery, regulators must also be equipped to assess the evidence those trials generate. The Government should establish a dedicated National Commission for the Regulation of AI in Drug Discovery, to develop clear guidance on how computationally generated evidence, including structure predictions, binding affinity, and ADMET data, is treated in regulatory submissions. The Government should also look to international comparators: the FDA and EMA have already published joint guiding principles for good AI practice in drug development, covering discovery, trials, and safety monitoring.

Isomorphic Labs is a pioneering AI-first life sciences company headquartered in the UK, with a mission to one day solve all disease with the help of AI. Precision medicine has the potential to support this mission.

We were spun out of DeepMind in 2021 following the AlphaFold breakthrough with an ambitious mission: to utilise AI to one day solve all disease. Personalised and precision medicine have the potential to support our mission to solve all disease. To drive this, we are developing various capabilities that encompass the specific biological mechanisms underlying disease and an increased understanding of human biology.

Our drug design engine (IsoDDE) builds beyond the Nobel Prize-winning AlphaFold system. It unifies multiple proprietary AI models to predict biomolecular structures, binding affinities, and previously hidden drug-binding sites, working across therapeutic areas and drug modalities. The UK's life sciences ecosystem, research base, and data assets have been additive to our development, and are envisioned to be key drivers as we scale.

AI is already transforming how drugs are designed, not just how they are delivered

The inquiry's focus on personalised medicine rightly highlights the potential of AI across the full drug development lifecycle. The earlier stages of the lifecycle is a key area where significant near-term acceleration is possible, where AI is beginning to transform drug discovery itself: identifying biological targets, predicting molecular behaviour and accelerating progress of drug candidates. The process of identifying a disease target, and finding a potential drug candidate to act on it currently takes an industry average of six years. AI is capable of compressing that to months.

In addition, AI can support enhanced discovery of causal human biology, relevant to novel precision medicine. It is widely acknowledged within the industry that new drugs with human genetic evidence are over 2.5x more likely to succeed in clinical trials, and recent evidence suggests this is further enhanced with cell-specific genetics insights.[1][2] This highlights the role of causal human biology data in supporting AI enabled drug discovery of future precision medicines.

Data accessibility is critical infrastructure for AI-driven drug discovery

[1] Minikel, E.V., Painter, J.L., Dong, C.C. et al. Refining the impact of genetic evidence on clinical success. Nature 629, 624–629 (2024). https://doi.org/10.1038/s41586-024-07316-0

[2] Harrison G. Zhang, Peter Eckmann, Jiacheng Miao, Andrew B. Mahon, James Zou. The Virtual Biotech: A Multi-Agent AI Framework for Therapeutic Discovery and Development. bioRxiv 2026.02.23.707551; doi: https://doi.org/10.64898/2026.02.23.707551

Isomorphic Labs responsibly uses diverse data sources and approaches to data access, including pre-competitive consortia (e.g. OpenBind), national research cohorts (UK Biobank), patient cohorts, and commercially licensed dataset. The quality and accessibility of these data sources directly impact model performance and insights to inform what drugs we design and for what diseases. The UK ecosystem offers important data partners for Iso. To maintain and extend its global competitiveness, the UK must invest in critical novel data types that are representative of UK society as a whole. This would unlock drug discovery, while also helping to address historical underrepresentation in health data.

To drive forward our mission to solve all disease, we must unlock novel insights about causal human biology and how to deliver the right drug, to the right patient, at the right time (a core premise of personalised medicine). This mission relies on access to the right data, and there is strong evidence of what data types are critical. The data that underpins these insights are human genetic and cellular data, along with wider understanding of disease.

The Health Data Research Service is an important new addition to sources of human data to support personalised medicine, with the potential to add distinct value in the UK alongside UK Biobank, Our Future Health, Genomics England, and other academic and charity research cohorts. It is essential that HDRS and the wider ecosystem support and prioritise access to rich multimodal NHS data (incorporating genomics, labs, diagnostics, outcomes and prescribing data) but critically also the ability to further enrich NHS patient data with novel single cell, spatial and other data types that are key to unlocking personalised medicine discovery and development. The Committee should consider how the wider health research ecosystem can collaborate to unlock the potential of these novel 'research' data types, and integrate these with NHS data. This could leverage existing University/NHS biobanks, NIHR Bioresource and other resources that can access samples to support drug discovery. The Committee should also consider how and who can bring together this diverse ecosystem with clear roles to deliver this integration, and how these novel data types can be progressed alongside unlocking access to structured NHS data.

The Government should also consider how it can develop stronger cross-border research opportunities, particularly with the European Union. The European Health Data Space aims to optimise the secondary use of health data for research and development, and the UK should actively pursue formal routes to participation as a third country. In the interim period, the Government should work to ensure proactive alignment with EHDS standards to enable continued cross-border research, and put the UK in a strong position to seek EHDS participation.

Patient trust is fundamental to the successful development of responsible AI and the ethical use of health data for AI. The Government has a key role to play in

fostering public confidence, and should facilitate cross-sector dialogue: bringing together patient advocacy groups, public bodies and industry. By enabling open, transparent discussions, the Government will help demystify AI applications in drug discovery and ensure the development of ethical and responsible AI standards that are truly fit for purpose. The ICO and MHRA should also develop clear regulatory guidance on the secondary use of omics and clinical trial data for AI-based drug discovery, including clarity on lawful bases and requirements relating to transparency, pseudonymisation and anonymisation.

AI-designed drugs will only reach UK patients if the UK's regulatory and clinical trials infrastructure is ready

The Government's ambition to use AI to accelerate the development of trial-ready drugs to within 100 days by 2030 is referenced in the inquiry's background. Companies like Isomorphic Labs are already advancing AI-designed drug candidates towards clinical trials. The policy question increasingly centres on whether the UK's clinical trials infrastructure is well positioned to receive them.

MHRA reforms are moving in the right direction. Clinical trial applications rose 9% in 2025, the new clinical trial regulations taking effect from April 2026 include a fast-track notification route for lower-risk studies and a 14-day assessment route for Phase I trials, and the Government has now reached an average of 122 days for commercial clinical trials, reaching its target of 150 days.

However, for companies using AI in drug design rather than in diagnostics or clinical decision-making, the regulatory questions arise earlier in the pipeline prior to clinical trials. IsoDDE is a research and design tool, not a medical device or clinical AI system. As AI-designed drug candidates move towards trials, questions will arise about how regulators treat computationally generated evidence (e.g. in silico predictions of toxicity and computational binding data) in regulatory submissions. The emergence of New Approach Methodologies offers an opportunity to generate AI training data in translational bench-to-bedside assays that could one day lead to in silico toxicity predictions made in the earliest phases of drug discovery, significantly cutting the timeline to clinic and increasing probability of success. The UK needs clear guidance on AI-designed drug candidates before the first wave reaches the clinic. The Committee should recommend that the Government, through MHRA and the Regulatory Innovation Office, develop a National Commission for the Regulation of AI in Drug Discovery, complementing the National Commission for the Regulation of AI in Healthcare. Separate questions remain about whether MHRA has the capacity and expertise to assess AI-designed drug candidates, and whether the UK's clinical trial setup processes are competitive with the US.

For precision medicines in particular, timely and standardised access to data to support biomarkers for trials will be key. Omics data (biological datasets covering genomic sequencing, protein expression profiles, and tissue analysis) from patients will be essential to support novel treatments being assessed in the right patients and at the right time, supporting patient recruitment, stratification and monitoring. This will require both the development of infrastructure and regulatory clarity. Infrastructure must not only support data needs for discovery but also the collection of this data within clinical trial infrastructure. The NHS Genomics Medicine Service (GMS) provides promising early infrastructure to enable this, with the planned unified genomic record (UGR) and bioinformatics standardisation workstream announced in the England Rare Diseases Action Plan. These will support the interoperability and sharing of omics data across the NHS and between diagnostics and clinical trials. To bolster AI-enabled drug discovery, we urge the Government to link the UGR with other data sources across the broader health data research infrastructure.

There is an opportunity to enhance links between data services (like HDRS) and clinical trials delivery infrastructure in the NHS, to support adoption of tests for novel biomarkers for both trials and discovery. This will require better connection and flow of data (i.e. across NHS systems, the Genomics Medicine Service, NIHR Commercial Research Delivery Centres) to support patient identification, recruitment and ongoing monitoring in trials, and the integration of data into future discovery research.

The UK is a clear leader in AI for drug discovery, but stands to benefit from adopting a clearer regulatory approach to AI drug development as we are witnessing in other jurisdictions.

The UK's life sciences ecosystem, research base, and data assets (including the UK Biobank) have been additive to Isomorphic Labs' development, and we are deeply committed to the UK.

We would urge the Committee to make the case to the Government that it should take heed of peers internationally, who are adopting clear regulatory positions needed to enable AI drug discovery companies to thrive. For example, the US Food and Drug Administration and European Medicines Agency have jointly published "Guiding Principles of Good AI Practice in Drug Development", providing early regulatory guidance on the use of AI across drug discovery, clinical trials, manufacturing, and safety monitoring.

We would welcome similar initiatives here in the UK, to provide the regulatory certainty needed to scale our impact.

Annex - Recommendations to the Committee

We would welcome the Committee considering the following recommendations:

- The Government should work to strengthen links between health data initiatives, including the Health Data Research Service, the NHS Genomics Medicine Service, NIHR Commercial Research Delivery Centres, and the forthcoming Unified Genomic Record to deliver the critical omics data needed to support novel treatments and drug candidates.
- The Government should consider how the wider health research ecosystem can collaborate to unlock the potential of novel 'research' data types (e.g. novel single cell and spatial data), and integrate these with NHS data (e.g. genomics, labs, diagnostics, outcomes and prescribing data). The Government should consider who is appropriately empowered to bring together the diverse ecosystem players with roles to deliver this.
- The Government should pursue formal routes to participating in the European Health Data Space as a third country, with proactive alignment with EHDS standards in the interim period.
- The Government should facilitate cross-sector dialogue, bringing together patient advocacy groups, public bodies and industry, to build patient trust, demystify AI applications in drug discovery and ensure the development of ethical and responsible AI standards that are truly fit for purpose.
- The Government, through MHRA and the Regulatory Innovation Office, should consider setting up a National Commission for the Regulation of AI in Drug Discovery to complement the National Commission for the Regulation of AI in Healthcare, to develop clear guidance on how computationally generated evidence, including preclinical toxicity and clinical predictions, is treated in regulatory submissions.
- The ICO and MHRA should develop clear regulatory guidance on the secondary use of omics and clinical trial data for AI drug discovery, including clarity on lawful bases and requirements relating to transparency, pseudonymisation and anonymisation.