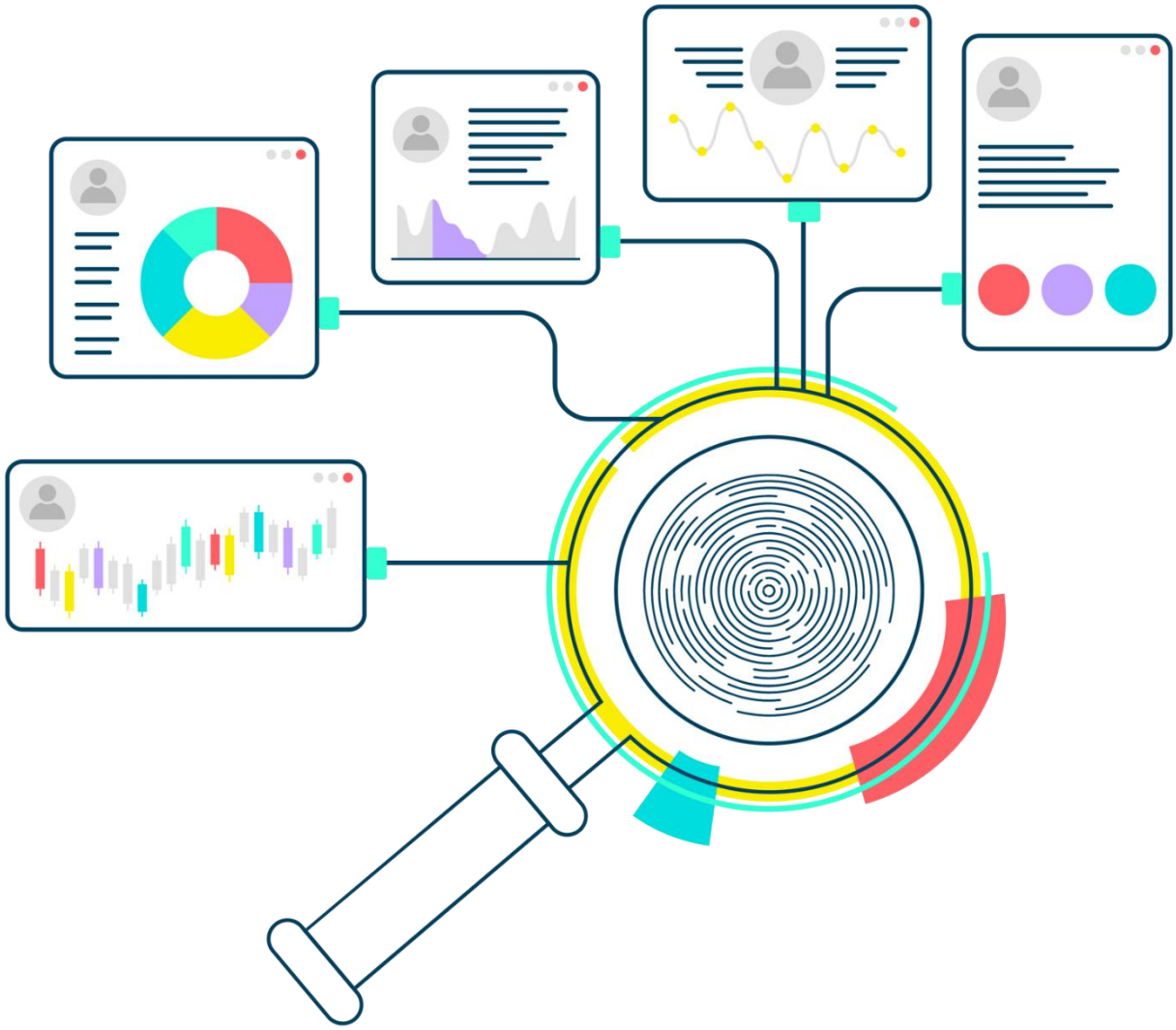
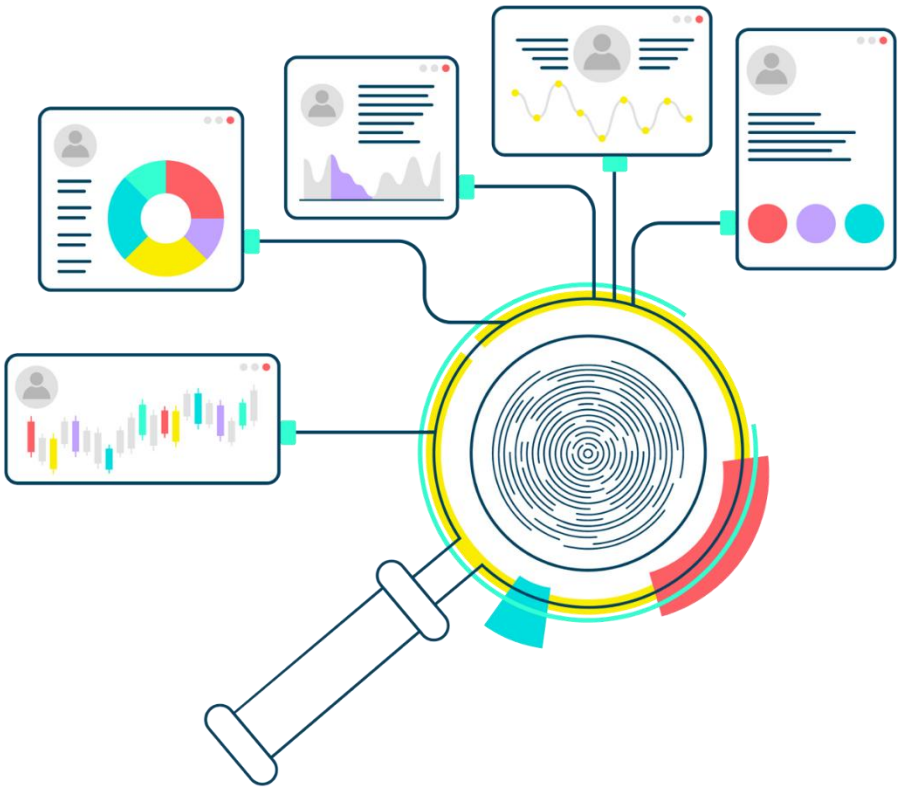
Understanding Patient Data



EHDS Teach-in

Third country involvement and collaboration framework

June 2026



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Understanding Patient Data

Forward

The report reflects collaboration between Understanding Patient Data (UPD) and Health Connect Partners (HCP) to strengthen UK understanding of the of the European Health Data Space Regulation (EHDS) and the data sharing framework it creates. With generous Wellcome funding, UPD commissioned HCP for its legal expertise to clarify EHDS developments and implications, supporting informed engagement among UK stakeholders and future policy considerations.

HCP undertook a detailed synthesis of current policy and guidance on the implementation of the EHDS Regulation, distilling complex legal and regulatory frameworks into accessible insights. This overview was presented to a UK audience of health data experts convened by UPD, enabling a structured teach-in on the potential implications for the UK.

This teach-in provided a forward-looking overview of how the EHDS Regulation is likely to shape secondary use of health data, cross-border research, third-country participation and public trust. It draws on emerging TEHDAS2 implementation guidance and UK expert discussion to identify the policy, governance and technical issues that UK organisations should understand now, regardless of whether or when the UK pursues formal participation in the EHDS ecosystem as a third country.

Although the EHDS Regulation provides two routes for third country participation – one with potential application from March 2027 and one with potential application from March 2031 – decisions being made now on governance, standards, public engagement and technical infrastructure will affect potential future UK engagement in EHDS. The relevant questions are therefore not only how the UK should respond to current guidance, but what capabilities and relationships the UK should seek to build over time to ensure that the EHDS has a favourable impact for the UK.

Together, UPD and HCP have shaped the following report to support ongoing UK dialogue and strategic preparedness.

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Background

TEHDAS2 — the Second Joint Action Towards the European Health Data Space — is the EU supported programme developing practical guidance and technical specifications for the harmonised implementation of the EHDS provisions on secondary use of health data. It began in May 2024, involves the 27 EU Member States with Norway and Iceland, is coordinated by the Finnish Innovation Fund Sitra, and is due to conclude in December 2026. The EHDS Regulation entered into force in March 2025 and becomes generally applicable in March 2027, making the TEHDAS2 outputs an important bridge between the legal framework and practical implementation.

The TEHDAS2 consultation process has been carried out in three waves: January–February 2025, September–November 2025, and May–June 2026. The current and final wave is open until 28 June 2026 and covers seven draft guidance documents relevant to this teach-in: collaboration, international and third-country access, data enrichment, catalogue navigation, dataset linkage, citizen information points and handling research outcomes. While this creates an immediate consultation window, the purpose of this document is broader: to use the consultation drafts as a prompt for longer-term UK learning, alignment and engagement.

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Third country involvement and collaboration framework

Teach-in: what the guidance says

Participation in secondary use of health data

One of the most complex areas of the EHDS is how organisations outside the EU — including those in the UK — can participate in secondary use of health data. The regulation creates two distinct routes, with different timelines and requirements:

Route 1 — Authorised Participant	Route 2 — Reciprocity
• Full integration into HealthData@EU infrastructure • Third country must comply with all EHDS Chapter IV requirements — mirrors the EU framework • Requires a designated national contact point and an EC implementing act • EU users must be granted equivalent access to the third country's data • Not available until 26 March 2035 at the earliest	• Access based on functional equivalence — conditions 'not more restrictive' than EHDS (not identical) • Third country must offer EU applicants equivalent access to its health data • EC issues an implementing act confirming equivalence; EC can revoke if equivalence lapses • No HealthData@EU infrastructure integration required • Can be operational from March 2027 — considerably earlier than Route 1

What's needed to be an 'authorised participant' under Route 1?

For third countries seeking full authorised participation in HealthData@EU under Route 1, the EHDS Regulation establishes three cumulative pillars of compliance. Route 1 is not available until 26 March 2035 and requires an assessment conducted by the European Commission of the country's models and processes for providing access to data for research. When the respective country's processes are found to be adequate an 'implementing act' is adopted by the EU which authorises the participation of that county in the EHDS. The table below sets out the three pillars and their core requirements.

PILLAR 1 **National Contact Point** *Art. 75(1), (12)*	PILLAR 2 **EHDS Chapter IV Compliance** *Art. 51–81*	PILLAR 3 **Equivalent Access for EU Users** *Art. 75(5)(c)*
• Designate a national contact point for secondary use • Technical capability to connect to HealthData@EU • Act as joint controller of processing operations • Meet minimum criteria set by EC implementing act (by 26 March 2027) • Communications in at least one official EU language	• Minimum EHD categories available; IP & trade secret protection (Arts. 51–52) • Permitted purposes only; prohibited purposes excluded (Arts. 53–54) • Heath Data Access Bodies (HDABs) designated with full tasks & powers (Arts. 55, 57–59, 63–64) • Data holder & user obligations enforced (Arts. 60–61) • Opt-out mechanism & secure processing environments (Arts. 71, 73)	• EU-based data users granted access to third-country EHD • On terms equivalent to HealthData@EU conditions • Data transfers of personal data: General Data Protection Regulation (GDPR) applies, in particular Chapter V which concerns transfer of data to third (non-EU) countries • Adequacy decision required for the use of a Secure Processing Environment (SPE) and data storage outside EU (Art. 87)

Route 1 (Authorised Participant) not available until 26 March 2035 (Art. 105) — EC assessment and implementing act required.

These requirements are relevant to UK policy planning now, not only after 2035. Decisions on health data legislation, HDAB designation and SPE infrastructure taken today will determine whether Route 1 participation is achievable in a realistic timescale. Possible areas for future UK engagement include mapping gaps against the three pillars as part of longer-term capability planning.

TEHDAS2 recommendations for reciprocity assessment under Route 2

The TEHDAS2 draft guideline (M4.3) sets out a detailed reciprocity assessment framework. Equivalence is judged against six dimensions:

- **FAIR principles:** datasets must be Findable, Accessible, Interoperable and Reusable, with standardised metadata in searchable catalogues
- **Data quality and traceability:** equivalent standards of documentation, completeness and fitness-for-purpose

- **Secure management:** equivalent IP and trade secret protections, controlled access, authentication mechanisms
- **Permitted purposes:** third country must observe EHDS's permitted secondary uses and prohibited purposes
- **Fees and timelines:** non-discriminatory fee structures; data supplied within three months of request (extendable to six)
- **Pseudonymised access:** critically, the third country must permit access to pseudonymised individual-level data — access to fully anonymised data only would not meet the threshold

Data transfer and storage rules

Regardless of which route applies, data transfer is governed by a layered set of rules:

- **Personal health data:** GDPR Chapter V continues to govern all transfers. Even remote access to an SPE may itself constitute a transfer. Data users must not extract personal data from SPEs; outputs must be anonymised.
- **Non-personal derived data:** Treated as 'highly sensitive' under the EU Data Governance Act when transferred to third countries. Re-identification risk must be assessed, accounting for small population sizes and near-future technological capabilities.
- **SPE storage:** More restrictive than standard GDPR — Standard Contractual Clauses and Binding Corporate Rules are not sufficient. Only adequacy-decision countries qualify.

Collaboration framework

The M4.2 Collaboration Framework guideline sets out the conditions under which health data can be shared and used across borders within the EHDS. The guideline addresses three topic areas – ethical governance, collaboration models and coordination, and IP rights and trade secrets – and examines how research infrastructures and networks fit into the formal EHDS role structure.

Key challenges identified across these three areas include:

- **Ethical governance:** fragmented national ethics procedures that risk becoming a multi-country bottleneck
- **Collaboration models and coordination:** Member States are at different readiness levels with uneven catalogue maturity
- **IP Rights and Trade Secrets:** difficulty identifying IP-protected elements in complex datasets, the tension between metadata transparency and confidentiality

UK expert reflections

These reflections summarise points raised by a select group of UK experts. They should be read as prompts for future discussion and engagement, rather than as a comprehensive or representative UK position.

Value proposition and UK engagement

A key question raised in the UK expert discussion was whether there is a sufficiently compelling case for UK-based organisations to engage with EHDS at this stage. The value proposition needs to be made explicit and credible before meaningful engagement can be expected.

One area with clear strategic relevance is the link to EU Framework Programme 10 (FP10). The current Horizon Europe Health Workplan already focuses on tools, technologies and digital solutions for health and care, including personalised medicine. If this focus expands in FP10, EHDS alignment could become a prerequisite for competitive UK participation in EU-funded health research.

Governance and the case for a specialist supranational body

The absence of harmonised Research Ethics Committee (REC) approaches across EU jurisdictions was identified as a significant barrier to coherent secondary data governance. UK experts drew on the UK's experience with the Health Research Authority Confidentiality Advisory Group (CAG) as a transferable model.

Core features identified as potentially transferable to supranational EHDS governance included:

- A clearly defined framework centred on proportionality and the paramount importance of public benefit, rather than categorical rules.
- Explicit consideration of precedents – whether a decision sets a new precedent and how it can be justified – supporting transparency and consistency over time.
- A deliberative committee structure that allows for debate, acknowledges evolving data uses, and enables adaptation while maintaining consistency.
- Mandatory evidence of public involvement from applicants, assuring the proposed use of data without consent is acceptable in each case.

Third-country divergence and the interoperability risk

UK experts highlighted a structural risk for EHDS design: while EU mechanisms can enforce Member State alignment with interoperability standards, they do not extend to third countries. Without structured alignment pathways, these countries may unintentionally diverge, reducing the effectiveness of cross-border data sharing. This is not a case for enforcing uniform standards globally, but for ensuring alignment decisions are deliberate and informed. The key risk to avoid is accidental divergence caused by exclusion from governance processes. The UK's limited participation in international standards forums

underscores this challenge and signals the need for more proactive engagement using existing representation.

Associate participation: a practical path forward

A possible response to the third-country challenge is to offer a meaningful role in EHDS design and governance without requiring regulatory alignment or political union. An "associate participation" model – with defined rights and responsibilities, but no formal vote – could provide visibility, influence, and engagement. Political framing is critical, particularly in the UK, where EU alignment carries sensitivities; participation should be presented in terms of practical benefits rather than political integration. A strong value proposition would include access to larger datasets, reduced cross-border complexity, improved competitiveness, decreased regulatory divergence, expanded markets, and the ability for suppliers to help shape emerging standards.

Raising awareness through trusted channels

Awareness of EHDS among UK stakeholders remains low. Possible channels for raising awareness include established, non-political bodies with existing trust relationships, including health data research organisations, patient advocacy groups, professional bodies and supplier associations. There may also be a role for identified EHDS champions or 'consulates' in third countries: individuals or organisations with a specific remit to raise awareness, connect interested parties with relevant EHDS processes, and represent third-country perspectives back into governance.

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Data enrichment, linkage and cataloguing

Teach-in: what the guidance says

Data enrichment

Data enrichment is a process by which an existing dataset is enhanced by adding new information, context, or derived value to increase its analytical usefulness. Enrichment is not legally defined in the EHDS Regulation, which means the guideline is non-binding and Member States may take different approaches. However, the EHDS Recital 57 states:

"Health data users may enrich accessed datasets with corrections, annotations and other improvements. Member States may establish rules for use of enriched data."

Enrichment is distinct from data preparation (cleaning, formatting) and from data linkage (which is managed by the HDAB before data reaches the user).

The TEHDAS2 draft guidelines identify three distinct pathways through which enrichment outputs may be handled once a data user has completed work within a Secure Processing Environment (SPE). These pathways are not mandatory under the EHDS Regulation – national discretion applies – but they provide a structured framework for HDABs and data holders to adopt consistently. The choice of pathway depends on the quality of documentation, the generalisability of the enrichment, and whether national rules permit dataset transfer.

THREE FEEDBACK PATHWAYS — National discretion applies; no pathway is mandatory		
PATHWAY A **Project-specific only**	**PATHWAY B** **Methods/code sharing (most common)**	**PATHWAY C** **Exceptional dataset transfer**
Enrichment documentation is inadequate, the scope is too narrow, or methods are insufficiently generalisable to be of value beyond the original project. The process ends without notification to the	The enrichment is well-documented and potentially reusable. The HDAB may share methods, code, and documentation with the data holder without any dataset transfer taking place. The data holder	An exceptional-value enrichment, combined with an explicit data holder request and national rules that permit transfer, may justify a full dataset transfer. This pathway requires formal controller-to-controller

data holder. The enrichment remains confined to the original project and is not shared.	independently applies the methodology to its own data, retaining full control.	legal agreements and adequate data holder infrastructure to receive and manage the enriched dataset.

The guideline suggests that Pathway B – methods and code sharing rather than dataset transfer – is both the most common and the most appropriate default in the majority of cases. It preserves data minimisation principles, and avoids the legal complexity of controller-to-controller transfer agreements.

Dataset linkage

Data linkage in the EHDS context refers to connecting records from different sources at the individual level before the data is made available to the user in an SPE. Data users do not have access to identifiers and do not perform linkage themselves. Data users may propose a linkage plan in their application, but it is executed by the HDAB, data holder or trusted data holder. Four methods are described in the guideline, in order of preference they are deterministic direct, deterministic indirect, Probabilistic, and Privacy-preserving record linkage (PPRL).

Navigating the catalogue

The EHDS infrastructure for primary use of health data, HealthData@EU, operates a federated governance model, whereby health data remains in Member States. Under the EHDS there is a two-level cataloguing system:

- **National Dataset Catalogue:** Each Member State collects dataset descriptions from national data holders (registries, hospitals, public authorities). The national dataset catalogues will feed metadata to EU level via HDAB/National Contact Point (NCP).
- **EU Dataset Catalogue:** Central catalogue on HealthData@EU platform. Aggregates metadata from Member State national catalogues, EU institutions, authorised third countries & authorised participants.

The catalogue uses HealthDCAT-AP, a harmonised metadata standard. Users can search by clinical keywords, data category (aligned to EHDS Article 51 categories — EHR, genomics, registries etc.), coding systems (ICD-10, SNOMED CT, OMOP), population characteristics, quality label and update frequency.

The catalogue is publicly accessible without a login. A basket function (requiring EU Login) allows shortlisting datasets for comparison before submitting a formal application.

UK expert reflections

These reflections summarise points raised by a select group of UK experts. They should be read as prompts for future discussion and engagement, rather than as a comprehensive or representative UK position.

Enrichment through code rather than modified datasets

Some UK experts noted that their enrichment model differs from TEHDAS2 draft guidance, which treats enrichment as separate from analysis. In "bring code to data" models, such as OpenSAFELY, researchers create enrichment methods as executable code within a Trusted Research Environment (TRE), rather than modifying underlying datasets. Phenotypes, code lists, derived variables, and analytical pipelines are shared as code, embedding enrichment within the analytical process. This removes the need for separate decisions about sharing enrichment methods. The discussion highlighted several advantages of this approach and suggested that the EHDS framework should recognise and support it alongside more traditional dataset-level enrichment models.

Incentives, system design and enrichment quality

UK experts emphasised that large-scale sharing of enrichment methods depends on system design and incentives. If sharing requires significant additional effort after project completion, uptake will be limited. The EHDS should therefore integrate documentation and code-sharing into standard research workflows, rather than treating them as post-project tasks.

A key long-term challenge is maintaining the quality, provenance, and usability of shared methods. To ensure reuse, documentation must be clear, assumptions explicit, and methods maintained as data structures evolve. Possible future actions include HDABs providing standard templates to support high-quality documentation, enabling reuse and preventing default reliance on less transparent approaches due to inadequate record-keeping.

Data linkage: governance and technical controls matter as much as method

On dataset linkage, UK experts drew on direct operational experience to emphasise that robust governance and technical controls are at least as important as the specific linkage method employed.

Universal requirements for both linkage and enrichment activities should include clear provenance, standardised documentation, transparent methods and strong auditability. These are not optional good practice; they are the foundation on which trust in shared data infrastructure is built.

Transparency as a foundation for data sovereignty

Countries contributing health data are concerned about external actors extracting value without leaving reusable knowledge or benefit to local populations.

The EHDS guidelines should explicitly address how value generated through EHDS-facilitated research is shared with contributing communities — a condition for sustaining the public trust on which EHDS depends.

Interoperability standards and the catalogue

UK experts noted that the value of the HealthData@EU catalogue for third-country users depends substantially on the interoperability standards underlying dataset descriptions. Where third countries adopt standards that diverge from those used in EHDS – for example, country-specific FHIR Core profiles inconsistent with the European profile – their datasets may not be discoverable or comparable within the catalogue. This reinforces the case for proactive engagement with third countries on standards alignment, as a precondition for meaningful catalogue participation rather than an afterthought.

Understanding Patient Data

Citizen involvement and research outcomes

Teach-in: what the guidance says

Citizen Information Points (M8.3)

Article 58 of the EHDS requires HDABs to make information about secondary use publicly available, easily searchable, and accessible. The TEHDAS2 guideline focuses on how this information should be delivered.

Mandatory information HDABs must provide:

- Legal basis for granting access to health data
- Safeguards protecting individuals' rights
- Applicable rights: opt-out, right to be informed, right to receive clinically significant findings, right to complain
- How individuals can exercise their rights and contact the relevant HDAB
- Details of who has accessed data, for what purposes (data permit details)
- Results obtained by health data users

The guideline recommends structuring citizen-facing information around six areas: rights; who is using health data; how data is protected; project results; the dataset catalogue; and complaints and contact. Visual explainers, layered information for different audiences, and feedback mechanisms are encouraged as good practice.

A landscape analysis of existing portals within the guideline highlighted the UK's NHS National Data Opt-Out (NDOO) as a good example of comprehensive secondary use information. The analysis found that EU portals currently provide substantially more information about primary use (patient care) than about secondary use (research).

Handling research outcomes (M8.4)

Once results are generated within an SPE, they leave the GDPR framework and come under EHDS-specific rules on transparency, reporting and accountability. Key obligations for secondary data users include:

- Report outcomes to the HDAB that granted access, in line with the conditions of the data permit (Art. 61(4))
- Comply with output controls when exporting results from the SPE — no information may be disclosed that could enable identification of data subjects (Art. 73(2))
- Ensure dissemination remains within the authorised scope of the data permit

- Ensure reported outcomes are clear and accurate enough to support the HDAB's own transparency obligations

Important nuances: the EHDS does not define ownership of research results — this remains governed by EU and national law and by contracts. Outcomes may be subject to limitations arising from pre-existing IP rights in the datasets used. The regulation creates a meaningful distinction between use of data under a permit (strictly within the SPE, for authorised purposes) and downstream use of knowledge derived from those results (broader, but still constrained by the permit scope and output controls).

UK expert reflections

These reflections summarise points raised by a select group of UK experts. They should be read as prompts for future discussion and engagement, rather than as a comprehensive or representative UK position.

Co-design as the foundation

UK experts emphasised that public trust cannot be retrofitted. It must be built from the outset, through genuine co-design that treats members of the public as stakeholders who can shape the process – not simply as audiences to be informed or consulted after decisions have been made.

NHS England's experience was cited as a practical model. Co-designing communications with a dedicated public advisory panel produced significantly better outcomes than communications developed by professionals alone. The panel was not consulted on outputs; it was involved in shaping the approach. This distinction matters and is directly transferable to EHDS communications and information design.

Transparency around public involvement

Being transparent about the involvement work undertaken – what the public was asked, what they said, and what difference it made – is more powerful than asserting that engagement occurred. Demonstrating that public input has genuinely influenced decisions builds trust in a way that general statements about public involvement cannot. Outputs of engagement processes should be published and accessible, not filed internally.

Representativeness and inclusion

Public deliberations must include representative samples of the population, with particular attention to groups that are seldom heard and who may have different perspectives on data use, opt-out, and the purposes of health research. Engagement processes that draw predominantly from engaged, educated, or already-informed publics are unlikely to surface the concerns and priorities of those with the most at stake. The EHDS citizen information portal and opt-out mechanisms should be designed with these groups in mind from the outset.

Policy deliberation

UK experts noted that decisions about health data policy – including opt-out mechanisms, permitted purposes, and the terms on which commercial organisations can access data – are well-suited to deliberative public processes that go substantially beyond information provision. The public has legitimate views on these questions, and those views should be sought and taken into account through structured, facilitated processes. The EHDS framework should incorporate public deliberation as a standard part of policy development at both EU and national levels, not as an optional enhancement.

UK learnings relevant to EHDS citizen information design

The NHS NDOO was highlighted within the TEHDAS2 landscape analysis as a good example of comprehensive secondary use information – a recognition that reflects years of iterative development. Key learnings include: invest more in secondary use information; use layered content for different audiences; deploy visual explainers and plain language; and embed feedback mechanisms to build ongoing trust.

Research outcomes and transparency obligations

UK experts noted the importance of closing the loop with citizens on research outcomes. The EHDS framework creates transparency obligations for data users in relation to HDABs; the spirit of those obligations should extend to the public. Where research using health data produces results of public significance, those results should be communicated accessibly and proactively – not left to chance discovery through academic publication.

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Summary of UK expert responses

The following summary draws together themes raised through limited UK expert input. It should be read as an indication of issues that merit further exploration, rather than as a comprehensive sector-wide response.

The value proposition for UK-based organisations to engage with EHDS **remains unclear** in the **absence of a clear UK Government signal** on participation and without binding legal obligations.

Many of the **challenges being addressed across the four nations** of the UK, **reflect the challenges of cross-border collaboration** which the EHDS seeks to address at the European level. In particular, it was noted that the UK Health Data Research Service is trying to address many of the same issues as the EHDS.

Much **detail remains in tertiary legislation** (implementing and delegated acts), creating **significant uncertainty** for organisations seeking to prepare for EHDS or develop a compliance position.

The UK health data research community has substantial **experience in governance, public engagement, and cross-border data collaboration** that could offer **valuable learnings for EHDS** implementation.

Strong, specialist, transparent governance – along the lines of the UK's Confidentiality Advisory Group (CAG) model – is essential at the supranational level in order to address issues around ethics.

Without deliberate mechanisms for third-country inclusion, divergent national interoperability standards **risk fragmenting the global health data ecosystem** and reduce the value of the EHDS.

An **'associate participation' model** – offering third countries a structured role at the EHDS design table, with rights and responsibilities but without a vote – could unlock significant value for the research community, life sciences industry, and health technology suppliers.

The **definition of AI** within the EHDS requires expansion to cover **drug development and precision medicine** applications, where **data depth, breadth and multimodality** are critical.

Public trust must be built through genuine **co-design, representative public involvement, and transparency** at every stage – not as an afterthought.

Looking ahead: future opportunities for UK–EU health data alignment

Realising the full potential of the EHDS now presents a clear opportunity to move towards implementation, ensuring sustained alignment, collaboration, and shared system development. Rather than the development of a regulatory framework, the next phase can establish lasting ecosystem and relationships that strengthen connections between the EU, the UK, and the wider global health data community.

Three priority opportunities stand out for enabling long-term impact:

1. Give the UK a practical way to stay involved

The UK is not part of the EU, but it has a strong interest in how the EHDS develops. One opportunity is to create a practical route for the UK and other non-EU countries to stay close to EHDS discussions — for example through observer roles, working groups, implementation forums or other structured engagement.

This would help UK organisations understand what is coming, share relevant UK experience, and avoid being surprised by standards or governance decisions that may affect future research, innovation or data partnerships.

2. Keep UK systems ready to work with EHDS

The UK does not need to make an immediate decision about formal participation. However, it can keep its options open by regularly comparing UK law, governance arrangements, data access processes and technical standards with the direction of EHDS.

This would make it easier to identify where the UK is already aligned, where gaps are emerging, and what would need to change if closer UK–EU health data collaboration becomes desirable in future.

3. Shape common technical standards before they become fixed

Many of the most important EHDS decisions will be technical: how datasets are described, how data is linked, how research code is reused, how results are checked, and how secure environments operate. These choices will affect whether and how UK and EU systems can work together in practice.

The UK can add value by engaging early in standards discussions and sharing practical experience, including approaches such as ‘bring code to data’, strong documentation and clear provenance. Early engagement would reduce the risk that UK and EU systems drift apart and become harder to connect later.

Conclusion

The EHDS represents more than a regulatory initiative—it is an opportunity to build a long-term, collaborative infrastructure for health data use and innovation. For both the EU and the UK, the focus now should be on capturing this opportunity by embedding durable governance, continuous alignment, and structured partnership models.

Equally, it should be recognised that for the UK, whether or not formal participation is pursued, EHDS interoperability standards, governance frameworks and data access conditions will shape the environment in which UK researchers, life sciences companies, health technology suppliers and patients operate.

Approached in this way, the EHDS can serve as a foundation for enduring cooperation, shared standards, and strengthened relationships, positioning both the EU and the UK within a more connected and resilient global health data landscape.

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Appendix 1: Engaging with the TEHDAS2 consultation

Seven TEHDAS2 draft guidelines are currently open for public consultation. The deadline is **28 June 2026**. Responses are reviewed by the document authors and reflected in the final versions, which will support Member State EHDS implementation and feed into European Commission implementing acts.

The seven draft guidelines are:

- **M4.2 — Collaboration framework:** ethical governance, coordination models, IP rights protection for research infrastructures
- **M4.3 — Third-country access and transfer:** two-route framework, reciprocity assessment criteria, storage rules
- **M5.4 — Data enrichment:** definitions, feedback pathways, roles of user, HDAB and data holder
- **M5.5 — Navigating the catalogue:** platform structure, search methods, dataset records, basket function
- **M7.5 — Dataset linkage:** linkage methods, who performs linkage, cross-border considerations
- **M8.3 — Citizen information points:** mandatory information, additional good practice, portal landscape
- **M8.4 — Handling research outcomes:** reporting obligations, output controls, IP and transparency

How to submit an effective response

The TEHDAS2 consultations are structured in two parts: Part A for general feedback and Part B for specific article-by-article commentary. All questions marked as mandatory have a 'Not applicable' option. One may respond to as many of the seven documents as they wish.

What carries most weight:

- **Concrete operational examples:** a real scenario where guidance is unclear, creates a bottleneck, or conflicts with national law is more useful than abstract criticism
- **Identified gaps:** 'this scenario is not covered' is more actionable than 'this is wrong'

- **Specific legal conflicts:** if a recommendation conflicts with GDPR, the European Data Governance Act, or the Artificial Intelligence Act, cite the specific provision
- **Evidence-backed comments:** link to published studies or position papers in open text fields; authors prioritise these
- **Distinguishing blockers from improvements:** flagging which issues are implementation blockers helps authors triage
- **Cost and resourcing implications:** flag budget implications, particularly for SPE and HDAB infrastructure, given active scrutiny of these in comitology
- **Position papers, data points and broader reflections**: these can be submitted via links or document uploads

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Acknowledgements

Wellcome Trust is kindly supporting UPD's engagement with the EHDS, including the shaping of *EHDS Teach-in: Third country involvement and collaboration framework*. We are grateful for their support in convening UK stakeholders to explore inclusive, responsible, and innovative approaches to exploring the alignment to the EHDS, and implications for the UK. We would also like to thank the UK experts who joined us to strengthen UK understanding of the of the EHDS and the data sharing framework it creates, and share their respective thoughts.

About UPD

Understanding Patient Data (UPD) is the UK's trusted independent voice on patient data. We make the use of patient data more visible, understandable and trustworthy, so it can be used well, responsibly and for public benefit. UPD is a hosted organisation of the NHS Alliance in London. UPD's core work is funded by Wellcome, the Medical Research Council, the National Institute for Health and Care Research, NHS England, the Department of Health and Social Care, and the Office for Life Sciences.

About HCP

Health Connect Partners (HCP) is a boutique consultancy focusing on healthcare policy and legal issues, in particular regarding digital health, medical devices and pharmaceuticals.