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How can EHR system clinical users make the best of algorithm-based tools?

This working paper has been prepared for

EHR @dataspace

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1 Introduction and objectives

The **European Health Data Space** (EHDS)[1] provides an essential first step towards the establishment of a FAIR (Findable, Accessible, Interoperable, Reusable) and interoperable algorithmic-ready ecosystem by formalising data exchange standards across Europe, particularly for the six priority categories of personal electronic health data for primary use (Article 14 of the EHDS Regulation).

Fully realising the promise of algorithm-based tools – for predictive care, clinical decision support, personalised interventions, and more applications – will demand going further. This is what this working paper explores.

The paper serves as a document to feed into discussions on how to prepare future communication between **Electronic Health Record (EHR) systems** and **algorithm-based tools**. Ultimately, these discussions will inform strategies and concrete actions to enable the healthcare sector to fully leverage the transformative power of algorithmic tools.

The paper draws on the **FAIR data** principles and EHDS objectives. Ensuring that the data which fuels algorithmic-based tools (i.e., "AI-based tools" or AI tools) is of high quality, is meaningfully structured, and is easily sharable requires comprehensive, **multi-level strategies** – which range from local hospital workflows to European semantic frameworks – with human beings and AI working 'hand-in-hand' to progressively refine data ecosystems.

The eventual aim of the group working on this working paper is to produce a conclusive briefing paper to be used for advocacy purposes with a policy audience. The final briefing paper is meant to set European-level expectations for data structures that facilitate the integration of interoperability and algorithm-based tools. Ultimately, this **integration** will support better healthcare delivery, continuity of care, patient safety, resource optimisation, and personalised medicine.

In preparing this paper, two on-line workshops took place with stakeholders who reflected together in depth on the practicalities involved in building multi-level strategies on algorithm-based tools in the context of the EHDS.

[1] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

2 Key components of any future EHR data roadmap

The key components of an eventual **roadmap** are foreseen to be: FAIR data and interoperability; data fluidity; data quality assurance; user-centred design; and the role of the EHR industry. They correspond to the kinds of barriers to data fluidity that have been identified. Furthermore, the technical model selected for AI clinical decision support systems (AI-CDSS) deployment[2] has also direct implications for the EHR-systems.

2.1 FAIR data and interoperability: A crucial role

This working paper underscores the fact that **high-quality, FAIR[3]-compliant data is fundamental** to unleashing the potential of algorithm-based tools. Without standardised, interoperable, and well-curated data, the effectiveness of algorithm-based tools collapses, risking the making of inaccurate predictions or unsafe recommendations. (This challenge can be termed the "garbage in, garbage out" problem.)

The 2025 EHDS regulation introduces for the first time a unified legally binding framework aiming to ensure health data interoperability across Europe by specifying content, coding systems, and technical specifications for data exchange. However, the scope of the EHDS still leaves some important aspects under-addressed – notably **data quality assurance and user-centred design**. Article 78 of the EHDS mentions a data quality and utility label but mostly in the context of secondary use.

2.2 Data fluidity: A core requirement

The concept of **data fluidity** is central to the roadmap. (Data fluidity implies the seamless, timely movement and integration of data across systems for informed decision-making.)

Achieving data fluidity requires:

1. **Standardisation of data formats and protocols** that use standards like HL7 (FHIR®) DICOM, and OMOP,
2. **Interoperable systems architectures** that support plug-and-play integration,
3. **Data quality assurance** processes that ensure completeness, validity, timeliness, and accuracy,

[2] See section 3.1 below.
[3] Article 92(8) of the EHDS describes the EHDS Board's role - together with a range of other bodies - in moving towards FAIR data implementation in research and innovation.

4. **Compliance with legal frameworks** like the General Data Protection Regulation (GDPR)[4] or HIPAA[5],
5. **User-centred design** that tailors systems to real user needs,
6. **Data harmonisation** through the use of controlled vocabularies and mapping tools to integrate diverse sources.

With the exception of data quality assurance and user-centred design, most of these requirements for data fluidity are explicitly addressed by the EHDS regulation. The missing elements are therefore tackled in this working paper as two core components on which further work is needed.

This wide coverage also requires, however, that all health data producers accept the principle of co-responsibility in the development of an integrated ecosystem where core data has, in essence, been created to support diverse purposes.

2.2.1 Data quality assurance: An area of underdevelopment

Data quality is a persistent challenge; its quality assurance also. In terms of quality assurance, the EU-funded **QUANTUM project**[6] is expected to provide guidance. The project is shaping methodologies for labelling datasets with quality and utility markers, covering concepts like:

- **Quality** (e.g., accuracy, completeness, consistency),
- **Fit-for-use** (potential utility of data),
- **Fit-for-purpose** (actual utility for a specific need),
- **Maturity** (the sophistication of an organisation's data management).

While the QUANTUM project mainly targets data for secondary use, many principles are equally vital for primary clinical applications (primary data use), especially where algorithmic tools rely on these datasets for decision support.

In February 2025, QUANTUM released two deliverables[7] covering aspects related to the "specification of the data sets' quality and utility label". The label specification aims to cover the provisions of Article 78 in Chapter IV of the EHDS regulation.

2.2.2 User-centred design: An overlooked element

This paper points out a critical gap: **few initiatives meaningfully implement user-centred design** to ensure that EHR systems produce data which is structured and reliable enough for algorithmic integration. This lack of user-centred design not only reduces clinician engagement

[4] https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng
[5] HIPAA stands for the Health Insurance Portability and Accountability Act of 1996. It is a federal law in the United States of America that aims to protect sensitive patient health information from being disclosed without a patient's consent or knowledge.
[6] https://quantumproject.eu/
[7] Specification for the assessment of data holders maturity and Specification of the data sets' quality and utility label

but also undermines the quality of data generated, which in turn limits what algorithms can safely process.

For example, despite growing mentions of "co-creation" with users, actual studies show **only ~50% user satisfaction with EHR systems**[8], with frequent usability issues arising from customisations which are made to fit local workflows. Often, certification does not even cover the site-specific implementation that user-centred design approach would require, and, likewise, iterative improvement cycles are neglected.

AI-CDSS also requires:

- Pathway-aligned triggers (based on national clinical guidelines),
- Clear override workflows ensuring meaningful human oversight,
- Clinician feedback loops contributing to post-market surveillance datasets,
- User interface and user experience (UI/UX) standards enabling explainability without disrupting workflow.

3 Linking AI-CDSS, FAIR data, and data fluidity

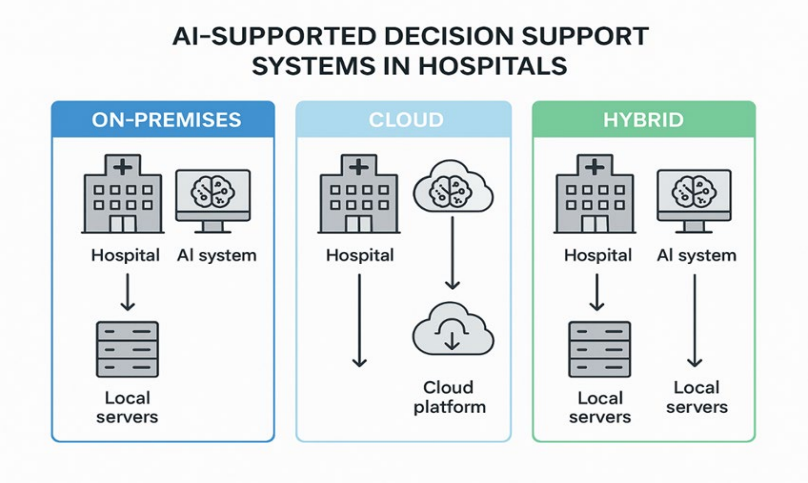
The capacity of AI-CDSS systems to provide their expected value is directly related to both the level of FAIRification and the level of fluidity of data within and between systems.

3.1 Three different models of deployment of AI-CDSS

Hospitals increasingly deploy AI clinical decision support systems (AI-CDSS) using three technical models:

- **On-premises systems** tightly integrated into local EHR/PACS infrastructure (used when data-localisation or GDPR constraints are strong).
- **Cloud-based systems** delivering scalable AI inference via secure APIs (common for imaging, risk scoring, and Natural Language Processing (NLP)).
- **Hybrid systems** combining local data retention with cloud-executed models. The implications for data governance and interoperability differ across these models.

[8] See, for example, https://pubmed.ncbi.nlm.nih.gov/31735343/ and https://pubmed.ncbi.nlm.nih.gov/33871018/. See also this report from CPME: https://www.cpme.eu/news/implementing-a-user-friendly-and-intuitive-electronic-health-record-is-the-only-way-forward



AI decision support systems used by individual healthcare providers often tend to rely on cloud or hybrid models due to scalability and processing requirements, though on-premises implementations remain common where privacy, latency, or regulatory constraints apply.

3.2 The EHR industry: Both an enabler and a bottleneck

EHR vendors have a crucial role to play to ensure the necessary data fluidity to feed AI-DCSS.

Large EHR vendors increasingly offer built-in algorithmic modules for applications like clinical decision support and predictive analytics. However, these capabilities often remain locked in by **insufficient local data quality**, **lack of interoperability**, **or heavy implementation burdens**. Thus, EHR vendors may also act as **gatekeepers** who resist the disruptive integration of external AI tools for various reasons e.g., to preserve market control or to avoid the costs of major system reengineering.

4 Key barriers to data fluidity identified

To date, **five barriers** to data fluidity have been identified: incomplete semantic standardisation and interoperability of data; some aspects of human-driven coding; the absence of high-quality data; a lack of continuous data governance/iterative design; and a lack of openness to third-party design.

These main barriers are presented as statements, below (statements 1-5). These descriptions were meant to trigger discussions with workshop participants on the basis of concrete use cases.

4.1 Incomplete semantic standardisation and interoperability

While the EHDS regulation pushes for interoperability, **semantic standardisation is still incomplete**. Many local systems depend on implicit conventions or partial coding schemes (which are often tied to reimbursement), and not on robust clinical semantics. Initial steps are, however, foreseen by the EHDS regulation, such as the use of codes for primary diagnostics from 2029 onwards.

If they are not based on shared, integrated standards or structured terminologies (like SNOMED CT, LOINC, ICD, FHIR® resources with semantic profiles), algorithm-based tools cannot reliably interpret or process data. Even where these standards exist, operationalisation remains patchy. There can be difficulties with e.g., translations, validated subsets, or alignment with national requirements.

4.2 Heavy reliance on human-driven coding in non-clinical silos

Human-driven coding often occurs in non-clinical settings, and **may currently be relied on heavily**. In many EU countries, substantial financial and human resources are used to code data often in relationship to reimbursement optimisation. The hard coding of data (using structured terminologies) is often handled by administrative teams, whose members may operate in a disconnected way from clinicians. Clinicians often view data entry as a burden with unclear benefits, which reduces their motivation to ensure the capture of structured, high-quality data that algorithms could later use.

4.3 Risks from algorithm-based tools requiring quality data

AI tools (examples include predictive risk models, natural language processing, and image analysis) rely on **high-quality, harmonised, context-rich data.** Unfortunately, they rarely draw on such high-quality data.

Local data heterogeneity, a lack of traceable mappings, and evolving clinical language mean that:

- AI tools trained in one context may underperform or mislead in another context,
- Even minor data misinterpretations can have large clinical impacts.

When AI models trained in one institution are deployed elsewhere, model drift and performance degradation occur if data definitions, population characteristics, or workflows differ – therefore, reinforcing the need for robust data-quality governance.

4.4 Limited progress on continuous data governance and iterative design

Interoperability is **not a one-shot technical procedure**, but an ongoing process supported by a governance process which combines at least three elements:

- **Automated tools** (e.g., extract-transform-load (ETL) processes, terminology servers, and ontology mappings),
- **Human oversight** (e.g., by knowledge managers/data managers),
- **Iterative design and validation** which adapts to local workflows and data evolution.

Many organisations, however, still lack agile, well-resourced forms of governance to support this iterative lifecycle.

Although implementation success relies on addressing all key factors listed above, clearly defined roles (Chief Information Officer (CIO), Chief Medical Information/Informatics Officer (CMIO), IT lead, clinicians, compliance, vendors) play a major role in reducing implementation failures.

4.5 EHR-centred ecosystems can exclude disruptive external innovation

Many EHR vendors prefer integrating their own AI modules over opening their interfaces to third parties. This approach can be referred to as an EHR-centred ecosystem or a "closed ecosystem". Such an approach can slow or stifle innovative algorithm adoption.

This barrier to innovation is compounded by regulatory ambiguities — for example, under the EU Medical Device Regulation (MDR)[9], many algorithm-based tools qualify as medical devices (Class 2b or higher) which adds heavy burdens of compliance for IT vendors.

The AI Act[10], MDR, and the EHDS will increasingly require interoperable audit logs, standardised APIs and full traceability of data exchanged with AI-CDSS – indirectly limiting vendor closed ecosystem strategies.

5 Recommendations and strategic directions: Towards a calibrated and carefully governed approach

To date, seven potential recommendations have been formulated which could lead to a calibrated and carefully governed approach to algorithm-based tools that are relevant to the EHDS and EHRs. Each potential recommendation is accompanied by the question(s) posed to October and December 2025 workshop participants and the responses or feedback that the question(s) received.

5.1 Implement deep semantic interoperability strategies

Move beyond superficial data exchange towards **semantic interoperability "by design"** i.e., intentionally. This means to:

- Adopt international standards like FHIR® for structuring clinical resources,
- Use robust ontologies and coded vocabularies (e.g., SNOMED CT, LOINC, ICD),
- Invest in national terminology servers (as has been done in Austria, France, and the Netherlands) to ensure alignment, translation, and dynamic updating of standards.

Semantic strategies must also increasingly cover multimodal inputs: imaging, omics, signals, and unstructured text, aligning with DICOM, whole slide imagining (WSI), and national exchange formats.

This deeper approach to semantic integration will not only ease the integration of AI tools but also support cross-border care continuity.

[9] Regulation (EU) 2017/745 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20250110)
[10] https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng

Question:

1. Do current semantic standards (e.g., SNOMED CT, LOINC, ICD) sufficiently meet the needs of AI integration. Or do we need new approaches? The relevance of these issues was evaluated as mixed by the October 2025 workshop panel.

5.2 Prioritise data quality assurance as a foundation

Use principles emerging from the QUANTUM project to establish **comprehensive data quality frameworks** covering:

- Technical attributes (e.g., accuracy, completeness, timeliness, consistency),
- Operational maturity (automated processes under human stewardship),
- Fit-for-use and fit-for-purpose assessments tailored to both clinical care and algorithm readiness.

This approach will require dedicated data governance teams, systematic quality labelling, and adaptable frameworks that evolve with local needs.

High-risk AI systems (such as AI-CDSS) must demonstrate:

- Representative, relevant, error-minimised datasets,
- Transparency on data provenance, metadata, and documentation,
- Ongoing bias and fairness monitoring,
- Continuous quality tracking as part of post-market surveillance (cf. the MDR and AI Act).

Workshops' participants agreed that robust data-quality assurance (including quality labels, auditability, and dataset readiness reviews) is a priority prerequisite for safe AI deployment.

Questions:

2. Given the "garbage in, garbage out" dilemma, how can we ensure that the data used by AI tools is of sufficient quality and context? This question was evaluated as highly relevant by the October 2025 workshop panel.
3. What governance models can support continuous data quality improvement and iterative algorithm design in clinical settings? This question was evaluated as highly relevant by the October 2025 workshop panel.
4. Should the certification of AI-based tools include assessments of the quality and structure of local datasets where they will be deployed? This question was evaluated as **absolutely relevant** by the October 2025 workshop panel.

5.3 Integrate user-centred design and continuous co-creation

Shift from static "one-time" EHR rollouts to **iterative co-design processes** involving clinicians, nurses, and even patients and their carers — whether formal or informal.

Incorporate tools like:

- Usability logs and user feedback loops,
- Adaptive interfaces that evolve with clinical needs,
- Human-in-the-loop reviews of AI outputs to maintain trust and safety.

User-centred design is also crucial to ensure that structured data capture becomes effortless and meaningful, by embedding it seamlessly into clinical workflows.

Feedback from the December 2025 workshop reinforced that user-centred design must address clinical alert fatigue, ensure intuitive verification loops, and make structured data capture effortless for clinicians.

Question:

5. Why does co-creation with clinicians often fail in practice despite being part of project rhetoric? This question was evaluated as highly relevant by the October 2025 panel.

5.4 Leverage AI for progressive FAIRification

FAIRification of EHR data is a stepwise approach. Hence, once a baseline level of data structure is achieved, AI can help accelerate it. For instance:

- NLP tools can semi-automatically structure free-text clinical notes,
- Learning systems can iteratively improve data extraction by replacing human validation,
- Hybrid approaches can balance pre- and post-coordination of complex concepts (by e.g., combining simpler SNOMED codes at runtime instead of forcing rigid up-front definitions).
- Federated learning setups that preserve data locality while enriching model quality are important facilitators.

Question:

6. Is the deployment of AI decision support tools conditioned by the use of AI data FAIRification tools? What would be the risks? This question was evaluated as highly relevant by the October 2025 workshop panel.

5.5 Invest strategically at multiple levels

Full FAIRification is not achieved by an individual healthcare organisation alone. FAIRification also requires:

- National/regional investments in core infrastructures (terminology servers, validated medicinal product datasets under the ISO IDMP, sovereign cloud services, and semantic frameworks[11]),

[11] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview

- Organisational strategies for the staffing of expert data stewards and setting up agile data quality teams,
- EHR vendors evolving to support open, modular integration with external algorithmic tools.

Question:

7. Are current EHR vendors enablers or blockers of innovation in AI-driven healthcare? How can this dynamic be modified? This question was evaluated as relevant by the two workshops' attendees, but the audiences needed more information to form a more precise opinion.

5.6 Balance transparency, explainability, and seamless AI

There are paradoxes to resolve:

- To be **trusted and adopted**, AI must be explainable and keep clinicians "in the loop".
- To ensure **daily operational acceptance**, however, AI must also disappear into the background ("be invisible") through having removed administrative burdens without providing distracting details.

Designing for both explainability and transparency ("invisibility") will be key. To achieve this, high-risk AI systems must provide:

- Clear explanations of logic (appropriate for clinicians),
- Communication of uncertainty,
- Full traceability of inputs/outputs,
- User awareness when interacting with AI (transparency obligation).

EHR vendors must support:

- Open integration with third-party AI tools via standardised APIs,
- Model versioning, traceability, and rollback capabilities,
- Privacy-preserving deployment setups (often preferring EU-sovereign clouds),
- Change management processes consistent with MDR "significant change" rules.

Questions:

8. Which AI tools are meant to be deployed the quickest? To support which type of process? By whom and where? This question was evaluated as being of moderate relevance by the October 2025 workshop panel.
9. Can AI be both explainable and "invisible" in clinical workflows? Or are these goals inherently contradictory? This question was evaluated as highly relevant by the October 2025 workshop panel.
10. Should there be regulatory mechanisms to compel EHR vendors to open up interfaces for third-party AI tools? This question was evaluated as being of moderate relevance by the October 2025 workshop panel.

5.7 Recognise that advanced AI algorithm integration is still nascent

While some advanced health systems (examples which originated largely from the USA, including Mount Sinai, Kaiser Permanente, Mayo Clinic, and EPIC and Cerner clients) have begun embedding AI into their systems, they are exceptions and are often aided by having integrated ecosystems. Many European settings still face foundational hurdles with interoperability and data quality.

AI-CDSS must support drift detection, incident reporting, and periodic performance reviews aligned with the MDR and AI Act post-market surveillance requirements.

Thus, a phased approach is essential – starting with improving fundamental data structures and quality before adding additional layers of complex AI tools.

Questions:

11. What can we learn from early adopters like the Mayo Clinic? And how transferable are their models to European contexts? This question was evaluated as being of moderate relevance by the October 2025 workshop panel.
12. How do we address the risks of AI tools misinterpreting data when they are moved across institutions or countries with different data practices? This question was evaluated as highly relevant by the October 2025 workshop panel.

6 Input from the EHTEL membership workshops

Input came from two workshops: an EHTEL Implementers Task Force workshop (October 2025) and an extended Xt-EHR workshop (December 2025) The recommendations were broadly supported by the participants of the workshops, and some messages were especially reinforced.

During the first workshop, the representative of the EHR industry stated that "AI integration is only as strong as underlying data quality" and that EHR vendors must act as bridges, not gatekeepers. He also emphasised that agile change management, rapid data model evolution, and clinician engagement are key success factors.

The AI-CDSS developer representative insisted on the complementarity and the need for EHR producers to be "structurally" open to innovation.

Both confirmed that AI needs to be seen both as consumer and catalyst (in terms of predictive analytics, NLP structuring, automated coding, data harmonisation). They mentioned the following major challenges: data quality gaps, semantic interoperability, vendor dynamics, user-centric design, regulation compliance, and fragmentation of national systems and legacy interfaces.

Most importantly, there was a strong consensus in the first workshop on the fact that one should start first with solid data governance which is compliant with the concept of data fluidity (described in chapters 2 and 3 of this working paper). In this respect, the EHDS and the European EHR

format (EHRxF) are both an opportunity and a systemic transformation challenge. The three main messages from this first workshop were:

- **Data quality** is the primary limiting factor.
- Vendors must act as **enablers**, not gatekeepers.
- **Governance, role clarity, and compliance** (with the AI Act, MDR, and EHDS) are becoming core operational requirements.

During the second workshop, which reflected on two use cases to support the discussions, participants:

- Emphasised that **data quality** is not simply an "operational" requirement but **a safety prerequisite** for any AI-CDSS. They highlighted the need for tiered data verification frameworks, dataset readiness checks at AI deployment sites, continuous monitoring for bias and drift, and the inclusion of provenance metadata. Participants also emphasised that certification of algorithm-based tools should include **assessments of the quality and structure of the local datasets** where the tools are deployed.
- Reinforced the importance that **user-centred design** plays in minimising alert fatigue, aligning with real clinical workflows, and supporting explainability without adding cognitive burden. AI-CDSS should therefore offer stratified alerts, workflow-aligned triggers, and human-in-the-loop feedback mechanisms enabling clinicians to verify, reject, or correct AI outputs.
- Confirmed that EHR vendors often operate as structural gatekeepers, either intentionally or unintentionally slowing down third-party innovation. Participants emphasised the importance of **mandatory open APIs**, semantic transparency, and governance mechanisms to ensure that EHR vendors act as enablers rather than blockers of algorithmic innovation.

Workshop discussions confirmed the validity of these barriers and added that several of them – especially data quality gaps, vendor lock-in, and insufficient clinical usability – remain the primary reasons why AI-CDSS are difficult to deploy at scale.

Participants also highlighted the need to have deeper discussions on the following two aspects:

- Appropriate prioritisation of AI-use cases for deployment,
- Trade-offs between explainability and "invisible automation" in workflows.

7 Suggestions for a future working paper

This entire topic is complex and has multiple implications. The initial scope of this working paper was to focus on the FAIR requirements for data to be consumed by AI-CDSS. Workshop participants proposed the following as future possible additions to this working paper:

- **AI training and digital literacy:** to reflect on the need to rely on standardised training and awareness frameworks for the health workforce aligned with EU strategy and EHDS requirements. The frameworks should be adapted to each main category of stakeholder. The inputs from the SUSA project[12] would be very valuable here, together with standardised factsheets adapted to each stakeholder, workflow, and context.
- **Extended legal, ethical, and regulatory considerations:** to reflect on an extended allocation of liability for agentic or semi-autonomous AI tools and the impact of the Digital Omnibus[i13], legitimate-interest provisions[14] or integration of vertical healthcare regulation (MDR, clinical safety rules). Lifecycle impacts on AI-CDSS (e.g., update cycles, significant change assessment) would also deserve specific attention.
- **Privacy-preserving data interoperability:** to enable further reflection on pseudonymisation methods and identity-management requirements, the use of synthetic data for safe experimentation and model validation and validated approaches for anonymous cross-organisational data exchange should be considered.
- **Data access and data catalogues:** the need to access a large volume of quality data for AI-CDSS systems also raises the issue of the use of data collected for secondary use and which will be made available through healthdata@eu by Health Data Access Bodies (HDABs). A revised paper might thus seek clarification of primary versus secondary data access pathways, focusing specifically on the use of data catalogues for research and AI model development.

Some of the proposed additions to this working paper are already covered by other working papers developed in 2025 and produced by EHTEL. The need to rely on foundational definitions across papers was, however, identified as important. Hence, an upcoming Xt-EHR document from the Xt-EHR Joint Action (deliverable D8.1) will describe four core functional profiles: one for EHR systems and three for non-EHR system types (i.e., wellness apps, medical and in-vitro diagnostic devices, and AI high risk systems).

[12] https://susacampus.eu/about-susa/

[13] [13] Digital Omnibus" refers to the European Commission's late 2025 proposal to bundle and streamline existing EU digital laws (like the GDPR, AI Act, Data Governance Act) into one coherent package, aiming to simplify compliance, reduce fragmentation, and update rules for new tech, particularly around data, AI, and cybersecurity.

[14] To rely on legitimate interest as a legal basis, an organisation must meet the following three cumulative conditions. The organisation has an actual **legitimate interest**. the processing of personal data is **necessary** for the legitimate interest, and the interests of the data subjects do not outweigh those of the organisation (**balancing of interests**).

8 Conclusion: Towards a FAIR, interoperable, algorithm-ready ecosystem

The EHDS provides an essential **first step towards the establishment of a FAIR and interoperable algorithmic-ready ecosystem by formalising data exchange standards across Europe**, particularly for six critical health information domains[15].

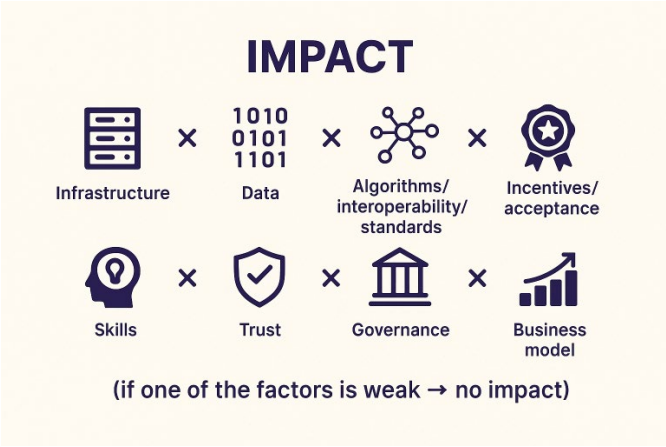
Fully realising the promise of AI-CDSS and other algorithm-based tools – for predictive care, clinical decision support, personalised interventions, and more applications – will demand to go further. These are the four actions that the task force considers to be most important:

- Investing in deep semantic interoperability,
- Building robust, quality-centric data governance,
- Ensuring user-centred design from the outset,
- Enabling both national infrastructures and local agile methodologies.

Importantly, AI is not just an endpoint; it is also becoming a key **enabler of the FAIRification process.** By leveraging automated learning systems under careful human oversight, health systems can progressively elevate their data maturity, and open the door to safer, more effective, algorithm-based care.

The AI Act and the MDR create new expectations of traceability, explainability, and post-market monitoring that must be integrated into the broader FAIRification and EHDS processes.

The workshops themselves demonstrated that, while the four foundations of FAIR, data fluidity, interoperability, and governance remain valid, additional considerations – including data-quality inspections, dataset readiness assessment, AI literacy, privacy-preserving interoperability, and clearer regulatory alignment – must be integrated to ensure a robust European framework for safe, effective and future-proof algorithm-based tools.



Finally, impact matters! It must be remembered that real impact can only achieved if these **eight factors are successfully and simultaneously addressed**: infrastructure, data, standards, incentives, skills, trust, governance, and an appropriate business model.

[15] Article 14.1 defines six priority categories of personal electronic health data for primary use (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical imaging studies and related imaging reports; (e) medical test results, including laboratory and other diagnostic results and related reports; and (f) discharge reports.

9 List of questions selected to support discussions

This is the full list of questions used to support discussions held in the 2025 workshops.

Theme	Questions assessed	Average relevance rating
Certification	Should the certification of AI-based tools include assessments of the quality and structure of local datasets where they will be deployed?	Very high
Cross-border	How do we address the risks of AI tools misinterpreting data when they are moved across institutions or countries with different data practices?	Very high
Data Quality	Given the "garbage in, garbage out" dilemma, how can we ensure that the data used by AI tools is of sufficient quality and context?	High
AI in for AI output	Is the deployment of AI decision support tools conditioned by the use of AI data FAIRification tools?	High
Governance	What governance models can support continuous data quality improvement and iterative algorithm design in clinical settings?	High
Co-creation	Why does co-creation with clinicians often fail in practice despite being part of project rhetoric?	High
EHR vendors	Are current EHR vendors enablers or blockers of innovation in AI-driven healthcare? How can this dynamic be modified?	High
Early Deployment	Which are the AI tools which are meant to be deployed the quickest? To support which type of process? By whom and where?	High
Explainability	Can AI be both explainable and 'invisible' in clinical workflows? Or are these goals inherently contradictory?	High
Regulation	Should there be regulatory mechanisms to compel EHR vendors to open up interfaces for third-party AI tools?	Mixed
Early Adopters	What can we learn from early adopters like the Mayo Clinic? And how transferable are their models to European contexts?	Mixed
Semantic Standards	Do current semantic standards (e.g., SNOMED CT, LOINC, ICD) sufficiently meet the needs of AI integration. Or do we need new approaches?	Mixed