EDGE/DM Whitepaper

EDGE/DM public documentation

EDGE/DM

Governed Data Space for Medical-Device Innovation

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A Governed Data Space for Medical-Device Innovation

A formal overview of the final EDGE/DM pilot, its value proposition, governed Data Products, trust model and responsible AI collaboration.

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Audience	Public stakeholders, providers, consumers, MedTech innovators, governance stakeholders

Publication note: *This document describes the final pilot operating model of EDGE/DM for public website download. It is not an implementation-status report and should not be read as a legal, medical or regulatory approval instrument.*

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Executive summary

Document control

Field	Value
Purpose	Provide a formal public overview of the EDGE/DM final pilot data space and its value proposition.
Audience	Executives, project stakeholders, providers, consumers, MedTech innovators, governance reviewers and public website visitors.
Classification	Public downloadable document
Final pilot assumption	The document describes the target/final EDGE/DM pilot operating model and deliberately omits implementation-progress indicators.
Clinical boundary	EDGE/DM documentation must not be interpreted as clinical decision support, medical diagnosis or regulatory clearance.

EDGE/DM is a governed data space for medical-device innovation. It enables organisations to describe, discover, request and reuse Data Products under participation rules, usage policies, evidence and traceability.

The final pilot model positions EDGE/DM as a trusted access point rather than an open repository. It supports the controlled publication of Data Products, transparent request pathways, policy-based usage conditions and responsible value creation for providers.

Core message
EDGE/DM turns data, services, model capabilities, evidence and AI-enabled workflows into governed Data Products that can be discovered and requested without implying uncontrolled access, unrestricted download or clinical decision-making.

The challenge addressed by EDGE/DM

Medical-device innovation increasingly depends on data, models, services and validation evidence distributed across organisations. Traditional bilateral sharing arrangements are difficult to scale

because they often lack consistent metadata, policy expression, identity, access conditions and auditability.

- Providers need a way to make selected assets discoverable while preserving control, sovereignty and usage conditions.
- Consumers need to understand relevance, permitted purposes and restrictions before investing in access requests.
- Governance stakeholders need evidence, traceability and clear rules for responsible reuse.
- MedTech innovators need mechanisms for benchmarking, validation, model evaluation and AI collaboration without uncontrolled movement of sensitive data.

What the EDGE/DM data space is

The EDGE/DM data space is not a single shared database. It is a governance and interoperability environment in which participating organisations publish and request Data Products through a controlled access model.

Data space building blocks

Building block	Public explanation
Participants	Organisations joining under approved roles such as provider, consumer, governance stakeholder or technical operator.
Catalogue	The discovery layer where public, non-sensitive Data Product summaries are listed.
Usage policies	Conditions defining permitted purposes, prohibited uses, obligations and constraints.
Access request	A structured request containing organisation, role, purpose, action and acceptance of applicable terms.
Access decision	A traceable policy outcome that records whether the requested use is compatible with applicable conditions.
Evidence	Documentation supporting publication, validation, audit, model governance and traceability.

Data Products in the final pilot

A Data Product is a governed, reusable asset described with metadata, usage conditions, evidence and responsibilities. It may be a dataset, service, AI capability, workflow or traceability asset.

Data Product types

Type	Description
Curated or composite dataset	A structured dataset or collection prepared for governed discovery and controlled reuse.
Inference service	A model capability exposed as a controlled service without exposing model weights or underlying datasets.
AI Agent	A governed AI capability with defined task, permitted use, input/output constraints, evidence and logging obligations.
Validation workflow	A benchmarking or evaluation workflow supporting model, device or process validation.
Traceability service	A capability for explanation, compliance review, evidence retrieval or audit support.
Federated task	A learning, evaluation or knowledge-sharing task performed across participants under governance.

Final pilot Data Product catalogue summary

Data Product	Type	Allowed purposes	Key prohibited purposes	Class
AI Interpretability And Traceability Service	TraceabilityService	Compliance, Interpretability, TechnicalValidation	ClinicalDecisionSupport, MedicalDecisionMaking, RealClinicalDiagnosis	Class0
Early Sepsis	InferenceService	ControlledInferen	ClinicalDecisionS	Class1

Timeseries Inference Service		ce, TechnicalValidation	upport, DatasetDownload, MedicalDecision Making, ModelWeightDownload, RealClinicalDiagnosis	
Malaria Microscopy Inference Service	InferenceService	ControlledInference, TechnicalValidation	ClinicalDecisionSupport, DatasetDownload, MedicalDecision Making, ModelWeightDownload, RealClinicalDiagnosis	Class1
Smartdx Lateral Flow COVID-19-19 Composite Dataset	CompositeDataset	Benchmarking, ModelEvaluation, Research	ClinicalDecisionSupport, MedicalDecision Making, RealClinicalDiagnosis	Class1
Smartdx LFT Decoding Inference Service	InferenceService	ControlledInference, TechnicalValidation	ClinicalDecisionSupport, DatasetDownload, MedicalDecision Making, ModelWeightDownload, RealClinicalDiagnosis	Class1

Trust, governance and traceability

Trust in EDGE/DM is created through a combination of participation rules, a Rulebook, Data Product specifications, DUA/DUP usage policies, semantic interoperability, evidence and traceability.

- Participation is role-based and governed by defined responsibilities.
- Data Products carry usage conditions rather than being exposed as unrestricted assets.

- Sensitive uses such as real clinical diagnosis, medical decision-making and unauthorised redistribution are excluded unless a future approved framework explicitly supports them.
- Evidence, logs and access decisions support accountability.
- Processing and collaboration are governed under defined geography, purpose and access constraints.

Provider value and responsible monetisation

EDGE/DM supports responsible value creation for providers. The final pilot model should be understood as a foundation for sustainable Data Product services, not as an open sale of sensitive medical data.

Provider value pathways

Pathway	Description
Governed access licensing	Controlled access to a Data Product under agreed purpose, scope and obligations.
Subscription data services	Recurring access to curated, updated or maintained Data Products where appropriate.
Benchmarking and validation	Datasets, metrics, protocols or services used to evaluate models, devices or workflows.
AI service access	Inference services, AI Agents or evaluation workflows exposed under governance.
Federated collaboration	Learning, evaluation or knowledge distillation while data remains under participant control.
Evidence services	Traceability, model cards, validation reports and compliance-support artefacts delivered as part of a trusted offering.

AI collaboration and federated patterns

AI collaboration is treated as a governed capability within the data space. AI Agents, inference services, federated learning tasks and federated distillation tasks can become Data Products when their purpose, input/output boundaries, limitations, obligations and evidence are defined.

Federated AI collaboration

Pattern	Role within EDGE/DM
Federated learning	Participants train or evaluate locally and share controlled updates or results.
Federated distillation	Participants share derived knowledge such as predictions, logits, embeddings or metrics rather than raw data.
Federated benchmarking	Participants evaluate models or workflows against agreed protocols without necessarily centralising data.
AI Agent as Data Product	A governed AI capability exposed with policy, traceability and evidence requirements.

Federated learning and federated distillation are not the data space itself. They are technical collaboration patterns operating inside the governance, identity, catalogue, policy and traceability layers of the data space.

Participation pathway

Participation follows a governed pathway: explore, express interest, role review, agreement, Data Product or request preparation, governed collaboration and traceability.

1. Explore the catalogue and public documentation.
2. Express organisational interest and intended role.
3. Complete role and eligibility review.
4. Accept the participation agreement and applicable governance framework.
5. Publish or request Data Products under DUA/DUP conditions.
6. Operate with evidence, access decisions and traceability.

Responsible-use boundaries

- EDGE/DM does not present sensitive medical data as an uncontrolled commodity.
- Catalogue visibility does not grant access to data, models or services.
- Participation does not override provider-defined usage conditions.
- AI capabilities are positioned for innovation, evaluation, benchmarking, traceability and governance support, not autonomous clinical decision-making.

- Formal contractual, legal, data-protection and regulatory obligations remain subject to participant agreements and applicable law.