EDGE/DM Participation Guide

EDGE/DM public documentation

EDGE/DM

Governed Data Space for Medical-Device Innovation

EDGE/DM Participation Guide

How Organisations Join and Operate in the Data Space

A participant-facing guide explaining roles, onboarding, Data Product publication, access requests, responsibilities and participation boundaries.

Document code	EDGEDM-PUB-PG
Version	v1.0 - Final pilot public edition
Date	9 June 2026
Owner	Idneo Technologies S.A.U.
Audience	Potential participants, providers, consumers, governance stakeholders, technical integrators

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.*

Table of contents

Overview

Document control

Field	Value
Purpose	Guide eligible organisations through participation in the EDGE/DM final pilot data space.
Audience	Potential participants, data providers, consumers, MedTech innovators, governance stakeholders and technical integrators.
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.

This guide explains how an organisation participates in EDGE/DM, what roles are available, what documentation applies and what responsibilities follow from participation.

Participation principle
Participation in EDGE/DM is a governed onboarding pathway. It is not open account registration and does not imply unrestricted access to Data Products.

Participant roles

Participant roles

Role	Description	Typical responsibilities
Data Provider	Publishes Data Products or services.	Defines usage conditions, provides evidence, maintains

		asset descriptions.
Data Consumer	Discovers and requests governed use.	Declares purpose, accepts policies, respects obligations.
MedTech Innovator	Uses EDGE/DM to support research, validation and product development.	Frames use cases, follows permitted purposes, contributes evidence where required.
Governance Stakeholder	Reviews participation, evidence and policy alignment.	Supports accountability, rule interpretation and issue handling.
Technical Integrator	Supports interoperability and access workflows.	Implements connectors, metadata mapping, identity, policy and traceability interfaces.

Participation journey

The participation journey is designed to ensure that organisations enter the data space with a clear role, clear responsibilities and a shared understanding of usage conditions.

1. Initial discovery through the public website and documentation.
2. Expression of interest through the participation request form.
3. Organisational role and intended-use review.
4. Review of governance documents, Rulebook and participation agreement.
5. Credential, identity and technical readiness checks where applicable.
6. Data Product publication or access-request preparation.
7. Governed collaboration with traceability and evidence.

Provider preparation

Providers prepare governed assets for catalogue visibility and controlled reuse. They should define what is being offered, under which conditions and with which evidence.

- Data Product title, description and type.
- Provider and contact responsibility.
- Allowed purposes and prohibited uses.
- DUA/DUP usage-policy terms.
- Evidence such as anonymisation, minimisation, Model Card, validation or traceability references.
- Commercial or value-creation expectations where applicable.

- Technical integration requirements for service, connector or API-based Data Products.

Consumer/requester preparation

Consumers should prepare access requests that are specific, purpose-bound and compatible with applicable usage conditions.

- Organisation identity and role.
- Data Product of interest.
- Declared purpose and requested action.
- Intended use and expected outputs.
- Geography of processing and data-handling approach.
- Acceptance of DUA/DUP terms and obligations.
- Evidence or justification required by governance review.

Participation agreement

The participation agreement formalises participation, role assignment, acceptance of the Rulebook and obligations relating to data sovereignty, confidentiality, security, traceability, incidents and offboarding.

Participation agreement topics

Topic	Meaning
Role	The approved participant function within EDGE/DM.
Rights	What the participant may publish, request or review.
Obligations	Confidentiality, permitted use, traceability, security and evidence duties.
Data Product terms	Specific usage conditions linked to each Data Product.
Economic conditions	Pilot participation and future value models, where applicable.
Offboarding	Cessation, revocation, termination and continuing duties.

Governance documents

Document framework

Document	Purpose for participants
Governance Model	Explains roles, responsibilities, decision processes and controlled evolution.
Rulebook	Defines operational rules for publication, access, use, security, audit and incidents.
Participation Agreement	Formalises the participant's role and acceptance of the framework.
DUA/DUP	Defines product-specific permitted purposes, prohibitions and obligations.
Technical Guide	Explains interoperability, policies, connectors and evidence concepts.

What participation does not mean

- It is not permission to download all available data.
- It is not permission to use Data Products for clinical decision-making.
- It is not transfer of provider ownership or control.
- It is not authorisation to redistribute assets.
- It is not a waiver of data protection, security or contractual obligations.

Readiness checklist

Participation readiness checklist

Area	Provider	Consumer
Organisation	Legal/entity details and contact points.	Legal/entity details and contact points.
Role	Provider role and asset responsibility.	Consumer/requester role and intended use.
Policy	Allowed purposes, prohibitions	Declared purpose and

	and obligations.	DUA/DUP acceptance.
Evidence	Anonymisation, minimisation, Model Card or validation evidence.	Justification and usage commitments.
Technical	Connector/API/service readiness where applicable.	Secure access and auditability readiness where applicable.
Commercial	Value model and participation terms.	Commercial/legal basis for requested use.