



## Public Participation Agreement Model

EDGE/DM public documentation

# EDGE/DM

Governed Data Space for Medical-Device Innovation

## EDGE/DM Participation Agreement

Public Draft for Eligible Participants

A formal public draft participation agreement for preliminary review, assuming the final pilot operating model.

<b>Document code</b>	EDGEDM-PUB-PA
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<b>Audience</b>	Eligible participants, legal/procurement reviewers, providers, consumers and governance bodies

**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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## Notice and document status

### Document control

Field	Value
<b>Purpose</b>	Provide a formal public draft participation agreement for organisations considering participation in the EDGE/DM final pilot.
<b>Audience</b>	Eligible participants, legal/procurement reviewers, providers, consumers and governance bodies.
<b>Classification</b>	Public downloadable document
Final pilot assumption	The document describes the target/final EDGE/DM pilot operating model and deliberately omits implementation-progress indicators.
<b>Clinical boundary</b>	EDGE/DM documentation must not be interpreted as clinical decision support, medical diagnosis or regulatory clearance.

#### Legal notice

This public draft is intended for website download and preliminary review. It becomes binding only when completed, reviewed and executed by the relevant parties under the applicable legal process.

## Parties

This Participation Agreement is entered into between the EDGE/DM governance authority or designated operator and the participating organisation identified in the signature block or onboarding record.

### Agreement fields

Field	Description
Participant legal name	Name of the organisation joining EDGE/DM.

<b>Approved role</b>	Provider, consumer, governance stakeholder, technical operator or other approved role.
<b>Contact point</b>	Authorised representative and operational contact.
<b>Effective date</b>	Date on which participation begins.
<b>Applicable annexes</b>	Role, Data Product, DUA/DUP, security and economic annexes.

## Definitions

### Key definitions

Term	Definition
<b>Data Space</b>	The governed EDGE/DM environment for discovery, participation, policy-based requests and controlled reuse.
<b>Data Product</b>	A governed asset, service or capability described with metadata, usage conditions and evidence.
<b>Participant</b>	An organisation admitted to EDGE/DM under an approved role.
<b>Provider</b>	A participant that publishes or exposes Data Products.
<b>Consumer</b>	A participant that requests governed use of Data Products.
<b>Rulebook</b>	The operational rules governing participation, publication, access, use and evidence.
<b>DUA/DUP</b>	Data Usage Agreement / Data Usage Policy attached to a Data Product.

## Scope of participation

The Agreement governs participation in the EDGE/DM final pilot and the participant's rights and obligations in relation to discovery, publication, request and use of Data Products.

- Access to public catalogue information.
- Participation in governed workflows according to assigned role.
- Publication or request of Data Products subject to specific policies.
- Compliance with Rulebook, governance decisions, DUA/DUP terms and security requirements.
- Traceability, evidence and audit obligations.

## Admission and onboarding

Participation requires admission by the governance authority or designated operator. Admission may depend on role, organisational identity, technical readiness, legal review and acceptance of the applicable framework.

- Provide accurate organisational and contact information.
- Identify requested role and intended use.
- Accept the Rulebook and governance framework.
- Complete security and credential requirements where applicable.
- Maintain updated participant records.

## Rights and obligations

### Participant rights and obligations

Area	Participant right	Participant obligation
<b>Catalogue</b>	Discover public Data Product summaries.	Respect that discovery does not imply access.
<b>Publication</b>	Publish Data Products if approved as provider.	Maintain metadata, policies and evidence.
<b>Requests</b>	Request governed use if approved as consumer.	Declare purpose, action and intended use truthfully.
<b>Policies</b>	Receive clear usage terms.	Comply with DUA/DUP and Rulebook obligations.
<b>Traceability</b>	Access appropriate evidence or decision records.	Permit logging and audit within agreed scope.

## Data Products and usage policies

Data Products remain governed by product-specific terms. The provider defines proposed usage conditions and evidence; the governance framework ensures alignment and traceability.

- No Data Product is unrestricted by default.
- Each Data Product may have its own DUA/DUP.
- Access decisions are purpose-bound and action-specific.
- Redistribution, re-identification, clinical decision-making and extraction of protected assets are prohibited unless explicitly approved in a future framework.
- Providers maintain ownership or control subject to applicable agreements.

## Economic conditions

Economic conditions may be defined in annexes or Data Product-specific terms. EDGE/DM supports controlled value creation without representing sensitive data as an uncontrolled commodity.

### Potential economic models

Model	Description
Pilot participation terms	Conditions applicable to participation in the final pilot.
Governed access licensing	Access under purpose, scope, time and obligation constraints.
<b>Service access</b>	Use of inference, AI Agent, benchmarking or validation services.
<b>Subscription model</b>	Recurring access to governed Data Products or services where appropriate.
Federated collaboration	Commercial or collaborative terms for federated evaluation, learning or distillation.

## Security, confidentiality and incidents

- Participants must protect credentials and confidential information.
- Participants must not attempt to bypass approved connectors, policies or access pathways.
- Participants must comply with applicable data protection and security obligations.
- Participants must report incidents, suspected misuse or policy breaches.

- Participants must respect offboarding, revocation and cessation-of-use requirements.

## Term, suspension and offboarding

The Agreement remains in force for the period defined in the executed agreement or onboarding record. Participation may be suspended, restricted or terminated for breach, incident, offboarding, governance decision or expiry.

- On termination, access rights cease unless expressly preserved.
- Ongoing confidentiality, audit, non-redistribution and data-protection obligations may survive.
- Credentials and access paths must be revoked or deactivated.
- Participants may be required to confirm cessation of use or deletion of controlled outputs where applicable.

## Annexes

### Suggested annexes

Annex	Purpose
Annex I - Participant role	Approved role and organisational details.
Annex II - Rulebook acceptance	Acknowledgement of governance and Rulebook terms.
Annex III - Security requirements	Identity, credential, connector and operational controls.
Annex IV - DUA/DUP model	Minimum Data Product usage-policy terms.
Annex V - Economic conditions	Pilot, licensing, service or value model terms.
Annex VI - Offboarding	Cessation, revocation and continuing obligations.

## Signature block

### Signature block

For EDGE/DM	For Participant
Name:	Name:

Title:	Title:
Date:	Date:
Signature:	Signature: