

Project Charter



eOSC Node

BBMRI-ERIC

Health & Food

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1. SUMMARY

EOSC Node | BBMRI-ERIC (the BBMRI-ERIC EOSC Node) is the thematic EOSC Node for biobanking, biomolecular resources and sensitive health data. BBMRI-ERIC operates across 25 member and observer countries and WHO/IARC, and connects approximately 500 biobanks at universities and university hospitals. The BBMRI-ERIC Directory, which served close to 7,000 users in 2025, is the world's largest biobank catalogue. The wider BBMRI-ERIC federated research infrastructure handled almost 15,000 access requests in the same year. Its services are quality-managed, operate at TRL 9 and are designed for the lawful and secure use of sensitive health data.

The Node connects BBMRI-ERIC's established discovery and access services with capabilities available across the EOSC Federation. Researchers can discover samples and data through the Directory and the privacy-preserving Federated Platform, request access through Negotiator and, after approval, analyse authorised data in a suitable secure environment. This supports FAIR research while keeping sensitive data as open as possible and as closed as necessary.

The MCVAL use case - multicentric validation of an AI model for prostate cancer screening - demonstrated the first cross-Node implementation in 2025 with EOSC Node | Italy (ICSC/INFN). From 2026 onward, BBMRI-ERIC is extending the Node through RI-SCALE and EOSC Mesh, including Node governance, catalogues, federated identity, secure data processing and reproducible cross-Node workflows. BBMRI-ERIC also co-chairs the EOSC Health Data Task Force and contributes to alignment between EOSC, the European Health Data Space (EHDS) and other health-data infrastructures.

2. VALUE PROPOSITION

Participation in the EOSC Federation is a strategic step in implementing BBMRI-ERIC's 2025-2035 Roadmap: Biobanking for a Healthier World. It strengthens interconnectivity across sectors and communities, supports incentives for data generation, sharing, reuse and return, and advances the datafication of biobanks. Federating existing services also supports more efficient use of scarce expertise, storage and compute capacity in a fragmented and rapidly evolving funding and policy landscape.

2.1 Value for medical research communities

BBMRI-ERIC provides a pathway from discovery to authorised analysis. Researchers can discover resources through the BBMRI-ERIC Directory, representing approximately 9.9 million patients and donors across 33 countries, and perform real-time, privacy-preserving queries at source through the Federated Platform, including Locator and Finder, which currently covers approximately 460,000 donors across 10 countries. Negotiator then facilitates access requests and communication between researchers and the biobanks or other data holders responsible for the requested resources.

Through developments in RI-SCALE and cross-Node work in EOSC Mesh, BBMRI-ERIC aims to extend this pathway into an end-to-end workflow. After the relevant access decision has been made, the workflow should support selection and provisioning of an appropriate secure analysis environment, controlled availability of the authorised data, deployment of analytical software or reproducible workflows, execution of the analysis and controlled return of authorised outputs. Depending on the applicable permissions and technical architecture, data may be transferred to an authorised environment or analysis may be brought to the data.

Secure compute capacity may be provided through other EOSC Nodes, including EOSC Node | Italy, EOSC Node | Czechia through SensitiveCloud operated by CERIT-SC at Masaryk University, and potentially EOSC Node | SURF. Additional scientifically suitable data sources may be connected through EOSC Node | Poland, EOSC Node | Slovakia and other Nodes. The selected combination depends on the legal, ethical, scientific, security and capacity requirements of each research project.

2.2 Value for providers and wider research communities

For biobanks and biomolecular-resource providers, the Node offers a route to make collections discoverable, manage access requests, prepare authorised data and use secure analysis capacity that may not be available locally. BBMRI-ERIC's work on MIABIS, the Data Use Conditions and Common Conditions of Use communities, and international standardisation supports interoperability and data quality across the Federation.

Life Science research communities benefit when studies must bridge experimental, animal or molecular resources with sensitive human health data. In the medium term, the OneHealth approach implemented via the BBMRI-ERIC Roadmap can extend the same discovery and access patterns to animal, plant, environmental, agricultural and biomonitoring resources, supporting cross-science research communities.

2.3 Value for the EOSC Federation

BBMRI-ERIC contributes a mature European legal entity, scalable IT operations, domain governance and a large community of data holders and users. As coordinator of ERIC Forum 2 and a long-standing member of the Life

Science Strategy Board, it can share operational and governance experience with other Research Infrastructures and future EOSC Nodes. Its Health Data Task Force role links EOSC developments with EHDS, the EU Cancer Mission, UNCAN.eu and related health-data initiatives.

BBMRI-ERIC is preparing for potential formal participation in EHDS secondary use through two complementary routes. It will assess its eligibility and develop the legal, organisational and technical evidence required for a future application to become an authorised participant in HealthData@EU. A formal application can be submitted only after the procedure established under EHDS Article 75(12) becomes operational. In parallel, BBMRI-ERIC will investigate whether it can qualify as a health data holder in Austria and, if appropriate, prepare for possible trusted health data holder designation once the Austrian procedure and requirements are available.

3. FEDERATING CAPABILITIES & INTEGRATION ACTIVITIES

The following capabilities underpin the scientific use cases. They describe the operational baseline and the intended development direction; they are not contractual deliverables of this Partner Charter.

Capability	Current baseline	2026 onward direction
Node enrolment and catalogues	Initial registration of EOSC Node BBMRI-ERIC in July 2026. Established BBMRI-ERIC services and data resources remain available through their existing access points.	Deploy the BBMRI-ERIC EOSC Node Service Catalogue and Research Product Catalogue in August 2026; connect AAI and catalogues to the Federation and Node Registry; expand the service portfolio through EOSC Mesh.
Data and resource discovery	Catalogue-based discovery through the Directory and privacy-preserving querying at source through the Federated Platform, including Locator and Finder.	Federate discovery across Nodes; extend the Directory and MIABIS model towards OneHealth; connect dataset discovery with catalogues of suitable analysis environments.
Access facilitation	Negotiator provides a workflow and communication channel for researchers and sample/data holders. The responsible data holder or access body makes the access decision.	Integrate Negotiator with authorised handover to datasets and compute resources after approval. Automation must not replace the legal, ethical or scientific access decision.
Federated identity and eID user experience	Life Science AAI/Login integration with the EOSC EU Node reached an initial eID integration capability in November 2025 and was demonstrated with MCVAL at EOSC Symposium 2025.	Refine identity handover and eID support during 2026, and optimise the user experience for biomedical researchers who are not infrastructure specialists.
Sensitive-data processing and secure analysis environments	The 2025 MCVAL implementation used secure storage and compute from EOSC Node Italy (ICSC/INFN). BBMRI-ERIC defines the domain-specific legal, ethical, security and workflow requirements.	Develop a reusable EOSC Mesh capability for project-specific secure environments, secure uploads and transfers, multi-source pooling, fine-grained access control, audit logging and controlled deletion; integrate cloud/container compute, FTS and REANA.
Cross-Node reproducible workflows	MCVAL established a first workflow combining external secure compute, data transfer and analytical pipeline deployment.	Continue development and validation of the BBMRI Data Exploitation Platform (DEP) through RI-SCALE (March 2025-February 2028), combining authorised data with preconfigured AI frameworks and models on scalable cloud/HPC resources, supported by data orchestration and federated access control. Through EOSC Mesh, participate in the CERN-led use case for reproducible workflows: send computation to the data, execute on closed or sensitive data, integrate REANA and storage/execution endpoints, and develop reusable cross-domain examples.
Node governance, service management and support	BBMRI-ERIC operates mature services with in-Node monitoring, accounting and helpdesk support. Direct cross-Node monitoring and helpdesk integration with the EOSC EU Node was not pursued in the 2025 build-up phase.	Define Node roles, Rules of Participation, agreements and onboarding procedures; establish an ITSM/FinSM-aligned Service Management System, security coordination, incident/problem management, continual improvement and a sustainability/financial plan. Add further Core capabilities where justified.

Capability	Current baseline	2026 onward direction
Federation alignment, engagement and EHDS	BBMRI-ERIC co-chairs the Health Data Task Force, chairs the sensitive-data subgroup and contributes to Federation coordination and the Handbook.	Align with the EOSC Federation Handbook, Interoperability Framework and Rules of Participation; organise pilots and interoperability activities; train and engage users; gather feedback; and continue EOSC/EHDS alignment. Prepare BBMRI-ERIC for potential formal EHDS participation by completing the legal and operational readiness work for a future authorised-participant application and by assessing an Austrian health data holder and possible trusted health data holder pathway. Submit applications or designation requests only after the relevant European or Austrian procedures become operational.

EOSC Mesh starts on 1 September 2026 (M1) and runs for 36 months. BBMRI-ERIC contributes to Node governance and enrolment, Node operations, sensitive-data processing, the Directory and Negotiator, user engagement, and the cross-Node scientific use cases.

4. SCIENTIFIC USE CASES

4.1 MCVAL - multicentric validation of an AI model for prostate cancer screening

MCVAL validates an existing prostate cancer screening model developed by the Masaryk Memorial Cancer Institute (MMCI) and the RationAI Laboratory at Masaryk University using BBMRI.cz/MMCI data. Medical University Graz (MUG) contributes an independent validation dataset and expertise. MUG does not hold rights to the original model; it collaborates on validation and may participate in subsequent development or retraining. The work processes pseudonymised whole-slide images and associated clinical information and therefore requires controlled legal, ethical and technical arrangements.

The use case tests model generalisability across institutions and creates a reusable pattern for multicentric AI validation. It connects data holders, access workflows and secure compute environments while preserving data protection, institutional control and the principle that only authorised outputs leave the analysis environment.

4.1.1 Achievements in 2025

Date	Achievement
2025	Work started entirely in kind through the participating institutions.
June 2025	The contractual framework with EOSC Node Italy (ICSC/INFN) was established.
September 2025	The secure data-analysis environment was established, MUG validation data were transferred, and deployment of the analytical pipelines started.
September-November 2025	The environment was further optimised and the analytical pipelines were adjusted.
October-November 2025	Preliminary validation results were obtained.
November 2025	MCVAL and the initial eID-enabled access pathway were presented and demonstrated at EOSC Symposium 2025.

4.1.2 Continuation from September 2026

Further work slowed during Q1-Q2 2026 because of the lack of dedicated EU funding. From September 2026, EOSC Mesh is expected to resume and expand the work. The project use case combines AAI, helpdesk and catalogues; sensitive-data processing, cloud and container compute, REANA and FTS data transfer; and the BBMRI-ERIC Directory and Negotiator. The target is secure, multi-institutional access through project-specific environments on trusted compute providers.

Within EOSC Mesh, the MCVAL use case brings BBMRI-ERIC together with CERN, EGI and the Scholarly Communications partners; EOSC Node | Italy is an optional external collaborator. In parallel, BBMRI-ERIC anticipates collaboration with EOSC Node | Czechia through SensitiveCloud and is exploring other secure compute options, including EOSC Node | SURF. Work with EOSC Node | Poland and EOSC Node | Slovakia aims to add validation data sources where these are scientifically, legally and technically suitable.

Further information: [EOSC Federation scientific use case - MCVAL](#).

4.2 Colorectal cancer prediction with explainable AI

Through RI-SCALE, BBMRI-ERIC is implementing a scientific use case to identify a novel digital biomarker for colorectal cancer (CRC) risk stratification from abnormalities in lymph-node tissue. Using a weakly supervised approach guided by disease-free survival data, the work will improve an existing foundation model for lymph-node analysis, use its embeddings to train a risk-stratification predictor, apply explainable AI methods to identify tissue patterns most relevant to prediction, and prepare a validation study. The use case involves BBMRI-ERIC, MMCI, MUG and Masaryk University and draws on histopathology data from MUG and EUCAIM. Its intended value is an additional diagnostic parameter and new insights that may support biomarker discovery, therapeutic targets and more effective treatments.

4.3 Synthetic data for computational pathology

RI-SCALE's second BBMRI-ERIC scientific use case addresses barriers to sharing histopathological whole-slide images, including privacy restrictions and missing consent to share original data. It will train a diffusion-based model on colorectal cancer data from the MUG data holding to generate synthetic whole-slide images, condition image generation on diagnostic parameters, evaluate the images with medical experts, compare AI models trained on real and synthetic data, and investigate whether generated images could leak sensitive patient information. The use case aims to produce an open-access research dataset and a reusable pathway for synthetic-data generation in digital pathology; the resulting model may also support future foundation-model development.

5. STATUS & TIMELINE

5.1 EOSC Node and Federation development

Period	Status or planned activity	State
March 2025	Initial Partner Charter published and the in-kind Federation build-up work started.	Completed
November 2025	EOSC Federation launch and MoU phase; initial Life Science AAI/eID integration demonstrated with MCVAL at EOSC Symposium 2025.	Completed
27 March 2026	EOSC Health Data Task Force Deliverable 1 published: analysis of researcher journeys, gaps, redundancies and synergies between EOSC and EHDS.	Completed
July 2026	EOSC Health Data Task Force Deliverable 2 submitted as an initial draft for internal and external review.	In review
July 2026	Initial registration of EOSC Node BBMRI-ERIC.	Completed
August 2026	Deployment of the BBMRI-ERIC EOSC Node Service Catalogue and Research Product Catalogue.	Planned
During 2026	Further refinement of eID integration and optimisation of the user experience for non-technical biomedical research communities.	Ongoing
August–December 2026	Assess BBMRI-ERIC's potential EHDS roles. For the authorised-participant route, confirm the eligibility of BBMRI-ERIC as the applying legal entity, assess whether its Statutes and mandate permit the relevant data-sharing and access functions, identify the datasets and services that could be made available, and document the expected time and cost advantage over an equivalent health data access body route. In Austria, begin the legal assessment of whether BBMRI-ERIC qualifies as a health data holder for any relevant data and whether future trusted health data holder designation would be appropriate.	Preparatory assessment; no application possible
Sep 2026–Aug 2027 EOSC Mesh PY1	Define Node roles and Rules of Participation; establish Node-level service management and security coordination; connect AAI, catalogues and the Node Registry; prepare detailed cross-Node use-case integration.	Planned
January–June 2027	Complete an authorised-participant readiness assessment and supporting evidence pack. Cover legal authority, governance, data-protection roles, access-decision responsibilities, catalogues, AAI, secure processing environments, security and incident handling, service management, cost model and sustainability. Complete the initial Austrian health data holder and trusted health data holder feasibility assessment and take an internal decision on whether to continue preparing either route.	Readiness and internal decision
July 2027–December 2028	Update the readiness evidence against the adopted EHDS implementing acts and technical specifications. Engage with the relevant European and Austrian implementation bodies; prepare the technical and contractual interfaces for authorised-participant-to-SPE access; and, where feasible, pilot the Austrian data holder or trusted health data holder model using a suitable contracted secure processing environment. Prepare application or designation documentation, but do not describe BBMRI-ERIC as already holding either status.	Pre-application preparation and piloting
Sep 2027–Aug 2028 EOSC Mesh PY2	Deploy additional Core capabilities where needed; offer Generic and Thematic capabilities for cross-Node use; target an MCVAL proof of concept around M18 (February 2028).	Planned
Sep 2028–Aug 2029 EOSC Mesh PY3	Integrate Node service management into the cross-Node model; refine capabilities from user feedback; complete targeted use cases; adopt a financial and sustainability plan.	Planned
From 26 March 2029, subject to the procedure being operational	Submit BBMRI-ERIC's application to become an authorised participant in HealthData@EU, with a target of submission within three months after the application and connection procedure opens. Complete the required compliance and technical connection checks. Separately, seek trusted health data holder designation in Austria only if BBMRI-ERIC qualifies as a health data holder, the Austrian designation procedure is available, and the preceding legal and operational assessment is positive.	Conditional application and designation phase

Period	Status or planned activity	State
After approval and connection	Operate an authorised-participant access route for cases in which BBMRI-ERIC's mandate and the applicable legal basis already permit the requested reuse, aiming to provide secure access faster and at lower cost than an equivalent health data access body route. Where no effective direct route covers the requested reuse, support eligible cases through the Austrian EHDS route if BBMRI-ERIC has obtained the necessary health data holder or trusted health data holder status.	Future operational phase

5.2 Scientific use cases

Period	Scientific use-case status
2025	MCVAL completed its contractual, technical and analytical set-up, transferred the MUG validation data, deployed and adjusted the pipelines, produced preliminary results and was demonstrated at EOSC Symposium 2025.
Q1-Q2 2026	Further MCVAL work slowed while a suitable continuation route for sensitive-health-data processing was being established.
From September 2026	EOSC Mesh work starts to expand MCVAL towards additional data sources, trusted compute providers, secure data transfer, reproducible workflows and project-specific secure environments.
1 March 2025–29 February 2028	RI-SCALE develops, deploys and validates the BBMRI Data Exploitation Platform (DEP), including the scientific use cases on colorectal cancer prediction with explainable AI and synthetic data for computational pathology.

Related public information: [EOSC Node | BBMRI-ERIC](#); [EOSC Health Data Task Force Deliverable 1](#); [EOSC Mesh project record](#).

6. EXTERNAL DEPENDENCIES & KEY RISKS

Current dependency or risk	Mitigation and management approach
Legal, ethical and consent conditions differ between data sources.	Apply source-specific onboarding criteria; verify approvals and permitted uses; establish data-use, transfer and processing agreements; retain controls with the responsible data holder.
Available secure environments may not satisfy the legal, security, capacity or workflow requirements of a health-data project.	Maintain explicit participation requirements; assess providers before use; support both authorised data transfer and compute-to-data patterns; develop alternatives across eligible EOSC Nodes.
Cross-Node AAI, catalogues, secure transfer, helpdesk and workflow integration are not yet mature production capabilities.	Implement in stages through RI-SCALE and EOSC Mesh; test handovers and failure modes; use scientific use cases for validation; retain functioning in-Node support while Federation integration matures.
Sustainable financing and allocation of secure compute and storage are not yet established.	Develop cost-sharing, usage-accounting and financial-planning approaches; diversify providers; match resource allocation to approved projects and available funding.
Identity, access and environment provisioning may be difficult for non-technical biomedical users.	Refine eID and Life Science AAI handover; provide a guided discovery-to-analysis workflow; integrate user support and training; collect and act on user feedback.
EOSC Federation governance, Requirements evolve in a way that imposes disproportionate adaptation burden on participants, leading to compliance gaps and delayed onboarding.	Participate in Federation coordination, Handbook and interoperability work; review Node policies and service-management procedures regularly; update agreements and onboarding practices when required.

7. ACCESS POLICIES

BBMRI-ERIC will adhere to its established Acceptable Use Policy and Policy for Access to and Sharing of Biological Samples and Data when offering resources through the EOSC Federation. Access to samples and data remains governed by the responsible data holder and the applicable legal, ethical, consent and scientific conditions. Negotiator facilitates the process but does not grant access.

Provisioning of an analysis environment or transfer of authorised data will occur only after the relevant access decision and under the applicable agreements and provider policies. Any adaptations to BBMRI-ERIC policies will be discussed and agreed with the BBMRI-ERIC Assembly of Members to maintain alignment with the organisation's governance and the EOSC Federation framework.

Policies: [BBMRI-ERIC Acceptable Use Policy for IT Services](#); [BBMRI-ERIC Policy for Access to and Sharing of Biological Samples and Data](#).

8. CONTACTS

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