Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium

Project Charter

# BBMRI-ERIC EOSC Node

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## 1. PROJECT SUMMARY

BBMRI-ERIC, one of the oldest and largest ERICs, is the only European infrastructure for biobanking and biomolecular resources. BBMRI-ERIC is specifically operating in the sensitive health data domain across 24 member and observer countries and WHO/IARC. It connects over 450 biobanks at universities and university clinics. Through its directory, which served over 10.000 users in 2024, BBMRI-ERIC operates the world's largest biobank directory. BBMRI-ERIC ensures full GDPR compliance, quality management (QM), and operates on TLR9 standards. As an independent legal entity with mature and scalable IT operations, BBMRI is poised for straightforward technical connection with the EU EOSC Node.

As Life Science Research Infrastructure, longstanding member of EOSC and its unique proposition in the sensitive health data domain, BBMRI-ERIC bridges the challenges of managing sensitive health data with the EOSC Federation's goals including fostering collaboration, enabling seamless access to FAIR data, and ensuring science is as open as possible but as closed as necessary. BBMRI-ERIC is also able to serve as a bridge between the developments in the European Health Data Space (EHDS) and the development in the EOSC Federation.

By joining the EOSC Build-Up phase, BBMRI-ERIC aims to integrate its services into the EOSC Federation and EOSC EU node services and other EOSC Nodes' services into BBMRI-ERIC's computational infrastructure, offering new functionality to biobanks, and the plentitude of its users. Key services to be integrated include monitoring, helpdesk, authentication, and HPC compute and storage. It will enable the computation of sensitive data in an EHDS2-compliant manner.

BBMRI-ERIC's will leverage its expertise in processing sensitive health data to demonstrate the integration of these services within the EOSC framework. Moreover, BBMRI-ERIC will contribute to the EOSC Health Data Task Force, co-chairing and aligning EOSC with the EHDS and other relevant data spaces and infrastructures, supporting the development of the EOSC Federation.

## 2. VALUE PROPOSITION

BBMRI-ERIC views joining EOSC Federation as a strategic step to address critical challenges not only within its own community but also across the broader European research landscape. With the One Health Approach as the cornerstone of its 10-year strategy for 2025-2035, BBMRI-ERIC is committed to strengthening interconnectivity across sectors and communities. The EOSC Federation offers a unique opportunity to propel cross-sector collaboration, drive innovation, and unlock the full potential of the long tail of science by expanding incentive schemes for data generation, sharing, reuse, and return in its aim to become a Federation of FAIR data. This will be pivotal in advancing the datafication of biobanks and biomolecular resources, transforming biobanks into vital data centres, not just within the Life Science and Health community but beyond.

Furthermore, in the face of complex funding landscapes, research fragmentation, and a rapidly evolving political climate, the EOSC Federation stands to enhance the sustainability of European research while optimising resource allocation—ultimately contributing to a more resilient, efficient, and innovative European research ecosystem.

BBMRI-ERIC seeks to address several opportunities by joining the EOSC Federation in the build-up phase, which are further described in the Use Cases. Primarily, BBMRI-ERIC aims to strengthen and expand its infrastructure through this collaboration. By leveraging the EOSC EU Node services and integrating its helpdesks, BBMRI-ERIC intends to enhance the robustness and availability of resources for users, ensuring improved access and support.

In addition to infrastructure development, BBMRI-ERIC emphasises the importance of including medical research communities in the EOSC Federation, particularly in the context of enabling One Health, through EOSC. To achieve this, BBMRI-ERIC is focused on integrating the LifeScience AAI (LSAAI), which will broaden access beyond the EduGAIN identity vetting system by incorporating government-backed eID.

Finally, the EOSC EU Node and potential future High-Performance Computing (HPC) offerings present flexible processing capacities that are of significant interest to BBMRI-ERIC. These capabilities could enable scalable and cost-efficient computation for biobanks, biomolecular resources, and their users, further enhancing the data processing capabilities required for cutting-edge research and discovery in the Life Sciences.

BBMRI-ERIC offers a unique position and capabilities that highlight the value of BBMRI-ERIC in the EOSC Federation. BBMRI-ERIC's own services, operating in the sensitive health data domain, are fully GDPR-compliant, quality-managed, are built on TLR9 standards. As a European legal entity with matured and scalable IT operations, BBMRI-ERIC is well-positioned to connect with the EU EOSC-Node and other thematic and national EOSC nodes, facilitating straightforward legal and technical integration, as well as being the linking pin to other relevant European developments, such as the EHDS and the EU Cancer Mission.

Additionally, BBMRI-ERIC holds an important strategic position as an ERIC and as a central member of the ERIC Forum as coordinator of the ERIC Forum 2 project. Due to its legal status and role in the ERIC Forum 2 project, BBMRI maintains an important connection to other ERICs and future ERICs across scientific domains/clusters. Through its experiences as a node in the Build-Up phase of the EOSC Federation, BBMRI is determined to share experience in the broader ERIC community, in particular in view of future EOSC Node recruitments. Through this position, BBMRI-ERIC can act as a role-model and a discussion partner for other ERICs.

Moreover, BBMRI-ERIC is also a long-standing member or the Life Science Strategy Board and is also committed to share its experience also within this platform, with other RIs, ERICs or not.

BBRMI-ERIC brings together service providers on one side and service consumers/users on the other side. As regards service providers, which are represented by the network of the biobanks and biomolecular resources, BBMRI-ERIC can provide a set of services and resources, which include complex data discovery and access support pipeline, including catalogue-based discovery (Directory), federated privacy-preserving querying and analysis of data at source (Locator/Finder), and access facilitation services (Negotiator). BBMRI hosts grassroot standardization (MIABIS and DUC/CCE communities) as well as active involvement in international standardisation organizations (ISO), thus advancing `I' of FAIR principles and data quality related aspects across broad research communities. BBMRI-ERIC aims to further strengthen its technical support, helpdesks, and service infrastructure, ensuring more efficient and reliable access to data and computational resources to support research and data analysis.

In the mid-term and aligned with its 10-year Roadmap and its 2025-2027 Work Programme, BBMRI-ERIC will interconnect also biobanks and other resources storing animal, plant, and

environmental or agricultural data. The Directory and Federated Platform offer services that could be extended to biobanks of other domains, enabling the exchange of data and samples through the BBMRI pipeline. This will further enrich the EOSC Federation for its potential users.

With this service offer BBMRI-ERIC EOSC Node will be able to reach a number of different users in the wider EOSC ecosystem:

- **Medical Research User Communities**: BBMRI-ERIC facilitates health data discovery on two levels: (1) catalog-based discovery via the BBMRI-ERIC Directory (representing 7 Mio. patients/probands across 32 countries), and (2) real-time, privacy-preserving querying of personal data at source via BBMRI-ERIC Federated Platform (460,000 donors across 10 countries today; tools: Locator and Finder). All systems are operated on TLR9. Additionally, with the planned integration of the LifeScience AAI (LSAAI) that supports eIDAS-backed identities, medical researchers will have enhanced access to EOSC, enabling smoother and broader participation.
- **Life Science Research User Communities**: Access to sensitive health data is becoming ever more important also for the broader life science research community, as research projects nowadays often need to bridge between their own and sensitive health data community (eg intersections between animal and human models in life science research).
- **Cross-science Research User Communities:** In the mid-term, due to its "One Health" approach, BBMRI-ERIC will be able to offer access to data even to users in other scientific domains, such as biomonitoring, plant, agriculture, environment and others.

## 3. USE CASES

Based on the insights of the EOSC node kick-off workshop, BBMRI proposes the following use cases for implementation*:*

| *Use Case ID* | *Use Case Description* | *Federation Contributions & Value to Users* |
|---|---|---|
| **Priority Use Case (short-term): Timeline April – November 2025 (EOSC Symposium)** | | |
| 1 | **Multi-centric validation of AI model for prostate-cancer screening (MCVAL)**<br><br>*Objective of the use case:* The aim of this use case is to validate an existing prostate cancer screening model that was initially developed through a collaboration between the Czech (BBMRI.cz) and Austrian National Nodes of BBMRI (BBMRI.at). The model uses data from research groups at the Masaryk Memorial Cancer Institute (MMCI), Medical University Graz (MUG), and RationAI at Masaryk University. The validation process will leverage the computing resources of the EOSC Italian node (ICSC), with the aim of supporting | • Enable multi-centric validation of AI models for medical researchers and for AI companies<br><br>• Improved early detection of prostate cancer through validated AI models that have been trained and tested on diverse, multi-centric datasets.<br><br>• Greater generalizability and reliability of AI-based screening tools across different populations and healthcare systems (Czech, Austrian, and potentially others).<br><br>• Potential expansion among other EOSC nodes for the provision of data for the validation of the AI model or for computing capacities. Other nodes who have |

| *Use Case ID* | *Use Case Description* | *Federation Contributions & Value to Users* |
|---|---|---|
| | the Secure Processing Environment (SPE) specification under the European Health Data Space (EHDS) Regulation. Given the sensitivity of the validation data, the project will focus on ensuring secure data storage, transfer, and processing.<br><br>Elements of the use case:<br>• collaboration between Czech and Austrian National Nodes of BBMRI (BBMRI.cz and BBMRI.at) and the research groups at Masaryk Memorial Cancer Institute, at Medical University Graz and RationAI at Masaryk University<br>• use compute capacities from ICSC and other HPCs in an EHDS2 SPE compliant manner<br>• existing prostate screening model is developed using data only from BBMRI.cz/MMCI and is validated with data from BBMRI.at/MUG | expressed potential interest in contributing data are: EOSC-PL, EOSC Finland node, EUDAT and EOSC SK-CVTI SR. Nodes that potentially could contribute computing capacities are: SURF. |
| **Second Use Case (long-term): After EOSC Build-Up phase (Nov 2025 - ...)** | | |
| 2 | AI-Guided Biomarker Discovery for CRC Risk Stratification (MCBIO)<br><br>Objective: The aim of this use case is to develop an AI-Guided Biomarker Discovery that improve risk stratification for colorectal cancer (CRC) stage 2, based on the existing collaboration between BBMRI.at/MUG, BBMRI.cz/RationAI+MMCI, BBMRI-ERIC, and ICSC. The project will also demonstrate compliance with the CEN/CENELEC AI standards in the life science and HPC domains to ensure governance, regulatory adherence, and ethical application of AI in biomedical research.<br><br>Elements of the use case: | • Enable computation compliant with the CEN/CENELEC AI standards for medical researchers<br>• Improved risk stratification for stage 2 colorectal cancer, enabling earlier and more personalized treatment planning.<br>• Identification of digital biomarkers that could lead to better prediction of disease progression and therapy response.<br>• Potential expansion among other EOSC nodes for the provision of data for the validation of the AI model or for computing capacities. |

| *Use Case ID* | *Use Case Description* | *Federation Contributions & Value to Users* |
|---|---|---|
| | • collaboration between BBMRI-ERIC and ICSC on training and inference<br>• develop digital biomarker for colorectal cancer stage 2 stratification<br>• demonstrate entire governance for compliance with the CEN/CENELEC AI standards in the life science and HPC domain | |

***In-Scope***

**Use cases**

*Short-term (within EOSC Federation Build-up Phase, until November 2025):*

**Multi-centric validation of AI model for prostate-cancer screening (MCVAL)**

The initial focus of the BBMRI node will be on its use case for the multi-centric validation of an AI model for prostate cancer screening (MCVAL), which will be conducted within the short-term build-up phase, running until November 2025. BBMRI-ERIC will lead the initiative in collaboration with identified key partners, Medical University of Graz (MUG), Masaryk Memorial Cancer Institute (MMCI), and the Italian EOSC node (ICSC). As part of this effort, BBMRI-ERIC aims to expand the project's reach by engaging additional EOSC nodes. This will involve defining clear criteria and requirements for participation, either as a data-providing node for the AI model or as a node contributing computing resources.

The deliverables and milestones that will be achieved within the timeframe of the EOSC Federation Build-Up phase, are collected in the designated tables, and are indicated as the activities under WP1 and WP2.

*Mid-term to Long-term (delivery after November 2025):*

**AI-Guided Biomarker Discovery for CRC Risk Stratification (MCBIO)**

A second use case that will be explored for the BBMRI EOSC node is the AI-Guided Biomarker Discovery for CRC Risk Stratification. This initiative will be a collaboration between BBMRI.at/MUG, BBMRI.cz/RationAI+MMCI, and ICSC, leveraging ICSC's computing resources for both training and inference. Beyond biomarker discovery, this project aims to establish governance frameworks ensuring compliance with CEN/CENELEC AI standards in life sciences and HPC. Also, for this use case, BBMRI-ERIC will aim to enable cross-node collaboration by defining clear criteria and requirements for participation, either as a data-providing node for the AI model or as a node contributing computing resources.

The timeline for this use-case will extend over the EOSC Build-Up phase and will move into 2026. Due to its longer timeline, no deliverables and milestones have been included as the primary focus will be on the MCVAL use case. The project charter will be updated over time to include the timeline of this use case. Given the alignment of collaboration partners for the MCVAL use case, it is anticipated that the insights gained from MCVAL will provide valuable support for the MCBIO use case. Additionally, lessons learned in the development of legal frameworks for

MCVAL are expected to be transferable and can be leveraged in the MCBIO use case, ensuring greater efficiency and consistency across both initiatives.

**Technical onboarding to EOSC Federation**

**Infrastructure Hardening and Expansion for External Monitoring and Authentication Integration (INT)**

The integration of services from the EU Node for external monitoring, along with the alignment of helpdesk systems across the EU Node and BBMRI-ERIC Node, will improve service support and operational efficiency. Furthermore, integrating authentication systems with LifeScience AAI (LSAAI) and EOSC AAI will enable LifeScience AAI to utilise eID as a source of identity, ensuring secure and streamlined access to services.

*The project aims to provide the following in the short term (until November 20*25):

- Integration with EOSC EU node monitoring for detailed resource/usage monitoring of BBMRI node services (CNT-MONITOR)
- Integration with EOSC EU helpdesk to provide helpdesk functionality to users of BBMRI node services accessing the BBMRI node from other EOSC nodes (CNT-HELP)
- Integrate compute capacities from ICSC and possibly other HPCs capable of hosting and processing sensitive data as part of the MCVAL and MCBIO use cases
- Be a cornerstone link with the Health Data TF in practically exploring integration options between EOSC and EHDS (e.g., via provisioning EHDS SPE-compatible compute and storage resources)

*The project aims to provide the following on the mid-term and long-term (after November 2025, with initial progress made in initial period)*:

- Integration with EOSC EU AAI with the purpose to
  - hand-over authenticated EOSC users to LS AAI for BBMRI node services
  - use eID for authentication with BBMRI node services
- Cross-domain research fostering One Health starting thanks to the multi-disciplinary nature of EOSC

BBMRI-ERIC aims to federate its services as much as possible via the EOSC Federation, following a realistic and step-by-step approach, leveraging the flexibility of the EOSC Federation Build-Up phase. We therefore have no activities that we will exclude beforehand and BBMRI will discuss any challenges that will appear with the EOSC Federation partners.

## 4. EXTERNAL DEPENDENCIES & KEY RISKS

| External Dependencies & Risks | Actions | Deadline |
|---|---|---|
| Risk: HPC infrastructure is not compatible with requirements for sensitive data | BBMRI will provide clear criteria and requirements to other EOSC nodes to ensure cross-collaboration and to enlarge the change of finding a suitable infrastructure. | May 2025 |
| Risk: Data transfer does not comply with requirements for sensitive data | BBMRI will provide clear criteria and requirements to other EOSC nodes to ensure cross-collaboration and to | May 2025 |

| | | |
|---|---|---|
| | enlarge the change of finding a suitable infrastructure. | |
| Risk: Legal framework<br>The legal framework with the external partners is essential for the continuation of the use cases. Delays in finalising these agreements may result in delays to the progress of the use case. | To mitigate this risk, the identification and establishment of necessary legal frameworks with external partners has been prioritised and set into motion by dedicated BBMRI team members. | June 2025 |
| Risk: Data processing requirements beyond HPC capacities (hardware and financial restrictions) | BBMRI and ICSC will develop a viable business model for the continuation of the use case. In case that resources are insufficient, the effort will be spread among other nodes. | November 2025 |
| Risk: no capacities available for hosting and processing sensitive data in capacity-providing EOSC Nodes | Search for other capacities, using capacities of other possible future EOSC nodes | As applicable |
| Risk: lack of capacities in LifeScience AAI and EU Node AAI teams to integrate eID | Ongoing discussions to mitigate any obstacles or delays with key partners | As applicable |
| Risk: overload of BBMRI-ERIC Node capacity due to the overload by the volume of users coming through EOSC | BBMRI will build on its National Node capacities to upscale the operations | As applicable |

## 5. CONTRIBUTIONS [DELIVERABLES (INCLUDING DOCUMENTATION)]

| ID | Deliverable Name | Deliverable Description | Deliverable Owner (the partner within the organisation responsible for producing the deliverable, if applicable) |
|---|---|---|---|
| WP1 | ***MCVAL-SINGLE-HPC: Multi-centric AI model validation using single HPC provider – Build-Up Phase EOSC Federation (March 2025 – November 2025)*** | | |
| D1.1 | ***MCVAL-SINGLE-HPC: Short report on run of RationAI model on MUG data*** | This deliverable contains a short description of the technical requirements for processing sensitive data | BBMRI-ERIC<br>Delivery Date: June 2025 |

| ID | Deliverable Name | Deliverable Description | Deliverable Owner (the partner within the organisation responsible for producing the deliverable, if applicable) |
|---|---|---|---|
| | | and their implementation in MCVAL-SINGLE-HPC. | |
| D1.2 | *MCVAL-SINGLE-HPC:* ***Report on multi-centric validation of RationAI prostate model and on utilization of capacities of other EOSC Nodes*** | This deliverable contains the documentation of the workflow for validating AI models from MMCI using sensitive data from MUG and HPC capacities from ICSC. | BBMRI-ERIC<br>Delivery Date: October 2025 |
| WP2 | ***MCVAL-MULTI-HPC: Multi-centric AI model validation using multiple HPC providers - Second Phase EOSC Federation (November 2025 – December 2026)*** | | |
| D2.1 | ***MCVAL-MULTI-HPC: Short report on run of RationAI model on MUG data*** | This deliverable contains a short description of the technical requirements for processing sensitive data and their implementation in MCVAL-MULTI-HPC. | BBMRI-ERIC<br>TBC |
| D2.2 | *MCVAL-MULTI-HPC:* ***Report on multi-centric validation of RationAI prostate model and on utilization of capacities of multiple EOSC Nodes*** | This deliverable contains the documentation of the workflow for validating AI models from MMCI using sensitive data from MUG and HPC capacities from TBD HPC provider(s) | BBMRI-ERIC<br>TBC |
| WP3 | ***CNT: Connecting BBMRI EOSC node with EOSC EU node services*** | | |
| D3.1 | *CNT-MONITOR:* | Documentation on integration of services publicly available in EOSC Federation | BBMRI-ERIC & EOSC EU Node<br>Delivery date: October 2025 |
| D3.2 | *CNT-HELP* | Documentation on integration of services publicly available in EOSC Federation | BBMRI-ERIC & EOSC EU Node<br>Delivery date: October 2025 |
| D3.3 | *CNT-AAI-HANDOVER* | Documentation on integration of services publicly available in EOSC Federation | BBMRI-ERIC & EOSC EU Node<br>Delivery date: March 2026 |
| D3.4 | *CNT-AAI-EID* | Documentation on integration of services | BBMRI-ERIC & EOSC EU Node |

| ID | Deliverable Name | Deliverable Description | Deliverable Owner (the partner within the organisation responsible for producing the deliverable, if applicable) |
|---|---|---|---|
| | | publicly available in EOSC Federation | Delivery date: March 2026 |

## 6. TIMING AND MILESTONES

| ID | Milestone Description | Target Delivery Date |
|---|---|---|
| **Milestones WP 1: MCVAL-SINGLE-HPC: Multi-centric AI model validation using single HPC provider – Build-Up Phase EOSC Federation (March 2025 – November 2025)** | | |
| MS 1.1 | *MCVAL: Criteria for Data or Computing Capacities in Sensitive Health Use Case provided to other EOSC nodes:* These criteria include ensuring compliance with data protection regulations (such as GDPR), securing appropriate ethical approvals, meeting technical standards for data security and privacy, as well as scientific criteria for data needed to make a valuable contribution. | May 2025 |
| MS1.2 | *MCVAL-SINGLE-HPC: Multi-centric legal framework using single HPC provider signed* | June 2025 |
| MS1.3 | *MCVAL-SINGLE-HPC: BBMRI as EOSC node represented at EOSC Symposium:*<br>- Poster in booth session<br>- Lightning talk on experience as EOSC node<br>- Presentation of Use Case MCVAL | November 2025 |
| MS1.4 | *MCVAL-SINGLE-HPC: Multi-centric workflow on sensitive data operational using single HPC provider published* | December 2025 |
| **Milestones WP 2: MCVAL-MULTI-HPC: Multi-centric AI model validation using multiple HPC providers - Second Phase EOSC Federation (November 2025 – December 2026)** | | |
| MS2.1 | *MCVAL-MULTI-HPC: Multi-centric legal framework in place using multiple HPC providers signed* | TBC |
| MS2.2 | *MCVAL-MULTI-HPC: Multi-centric workflow on sensitive data operational using multiple HPC providers published* | TBC |
| **Milestones WP 3: CNT: Integration of BBMRI EOSC node with EOSC EU node services** | | |

| ID | Milestone Description | Target Delivery Date |
|---|---|---|
| MS 3.1 | *CNT: Integration of EU node helpdesk into BBMRI-ERIC node complete* | June 2025 |
| MS3.2 | *CNT: Integration of EU node monitoring into BBMRI-ERIC node complete* | October 2025 |
| MS3.3 | *CNT: Integration of EU node AAI into BBMRI-ERIC node complete* | March 2026 |
| MS3.4 | *CNT: Integration of LSAAI in EOSC EU Node complete; use eID for authentication with BBMRI node services* | March 2026 |

## 7. ACCES POLICIES

BBMRI-ERIC will adhere to its established Acceptable Use Policy[1] and BBMRI-ERIC Policy for Access to and Sharing of Biological Samples and Data[2] when offering resources through the EOSC Federation, ensuring that all resource access and usage align with the organisation's standards and frameworks. Should adaptations to these policies be required, they will be discussed and agreed upon with the BBMRI-ERIC Assembly of Members (AoM) to ensure alignment with broader governance frameworks.

## 8. CONTACTS

| Role | Name | Email |
|---|---|---|
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[1] https://web.bbmri-eric.eu/Policies/BBMRI-ERIC-AUP-IT-Services-1_3.pdf

[2] https://www.bbmri-eric.eu/wp-content/uploads/AoM_10_8_Access-Policy_FINAL_EU.pdf