



European monitoring of Medically Assisted Reproduction (EuMAR)

D7.1 EuMAR plan for incorporation of innovation



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Acronyms and abbreviations

API	Application Programming Interface
ART	Assisted Reproductive Technology
CPRD	Clinical Practice Research Datalink
D	Deliverable
DPIA	Data Protection Impact Assessment
DPO	Data protection officer
EBMT	European Society for Blood and Marrow Transplantation
EHDS	European Health Data Space
EHDS2	European Health Data Space for secondary use of data
EIM	European IVF Monitoring
ESHRE	European Society of Human Reproduction and Embryology
ESOT	European Society for Organ Transplantation
EU	European Union
GDPR	General Data Protection Regulation
HaDEA	European Health and Digital Executive Agency
HSCT	Hematopoietic stem cell transplantation
IBD	Inflammatory bowel disease
IRCC	Individual Reproductive Care Code
IT	Information Technology
IVF	In Vitro Fertilisation
KPI	Key Performance Indicators
MAR	Medically Assisted Reproduction
NCA	National Competent Authority
PCOS	Polycystic ovary syndrome
PGT	Preimplantation Genetic Testing
PSC	Project Steering Committee
SoHO	Substances of Human Origin
SPE	Secure Processing Environment
TEHDAS2	Towards European Health Data Space 2 Joint Action

Authors

This report was written by the members of Work Package 7 (Table 1), under supervision of the EuMAR Project Steering Committee (PSC).

Table 1 Work Package 7 members

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Executive Summary

EuMAR aims to develop a pan-European registry of prospective cycle-by-cycle data on the use and outcomes of Medically Assisted Reproduction (MAR) treatments, with the overarching goal of improving monitoring transparency and trustworthiness in reported clinical outcomes across Europe.

Work Package 7 (WP7) addresses the need to ensure the terminology and the data registry can be updated according to future technical developments, new treatment strategies and innovations as well as other novelties. This is vital to keep the registry accurate, relevant, and responsive to regulatory and clinical developments.

To support this goal, this WP7 deliverable defines a structured change management procedure composed of six key subprocesses: (i) proposal submission, (ii) assessment, (iii) decision-making, (iv) technical implementation, (v) documentation and communication, and (vi) validation. This process ensures any changes to the registry preserve its scientific validity and integrity.

WP7 also explores the future interoperability of the EuMAR registry. Although connections to external registries will depend on the availability of relevant systems and the further development of implementation pathways under the European Health Data Space (EHDS), theoretical frameworks are being explored. Important tools in this are the Individual Reproductive Care Code (IRCC) and the Clinic Switch Code, both incorporated in the EuMAR Registry. These codes could be a key component in enabling future cross-registry data linkage, laying the foundation for broader connections between reproductive and general health registries in the EU.

The EuMAR registry has been deliberately designed with flexibility and openness to enable such future integration. This deliverable defines specific pathways through which this flexibility can be realized—without compromising the registry’s functionality or data integrity.

Introduction

EuMAR project Summary

EuMAR aims to develop a pan-European registry of prospective cycle-by-cycle data on the use and outcomes of Medically Assisted Reproduction (MAR) treatments. EuMAR aims to address the need for more transparency, surveillance, and biovigilance in MAR across country borders, including trusted data on the safety of MAR for patients, donors, recipients, and consequently for offspring, in line with the revision of the EU Directives on blood, tissues and cells [1].

Aims of the EuMAR project

The goal of EuMAR is to provide the different stakeholders, including EU and national health authorities as well as the public, with high quality data to quantify the effectiveness and safety of current and new MAR treatments, including fertility preservation. To achieve this goal, EuMAR sets out to

Objective 1) develop a tailored data flow model that endeavours to meet the national requirements of EU Member States and avoid duplication of reporting efforts.

Objective 2) prepare a glossary of standardised parameters on which data is to be collected with corresponding definitions.

Objective 3) develop an IT solution for data collection, including an "Individual Reproductive Care Code" (IRCC) that allows prospective data collection and cumulative follow-up across different centres/countries. The IT solution was tested in a pilot study in four different EU Member States reflecting the variations in current national data collection systems and data flows.

In these activities, EuMAR can build on the existing network of MAR professionals and the representatives of the health authorities of most EU Member States, as managed by the European IVF-Monitoring (EIM) consortium of the European Society of Human Reproduction and Embryology (ESHRE) and EuMAR's WP3.

To maximise the value of the data collection for all stakeholders and to allow keeping up with future innovation and extended digitalisation, the EuMAR Registry must be developed with flexibility towards innovation and towards a future connection with existing national and international databases (interoperability).

Work packages and outcomes of the EuMAR project

The EuMAR project includes seven work packages (WPs), including three horizontal work packages. In the first two years of the project and under the scope of WP3, 4, 5, and 6, the EuMAR team has developed a data registry to collect cycle-by-cycle data on MAR treatments and has tested this registry in four pilot countries.

By the start of 2025 (i.e. the initiation of WP7), the EuMAR project and particularly WP3, 4, 5, and 6, had resulted in a number of deliverables and project outcomes [2]. The deliverables and

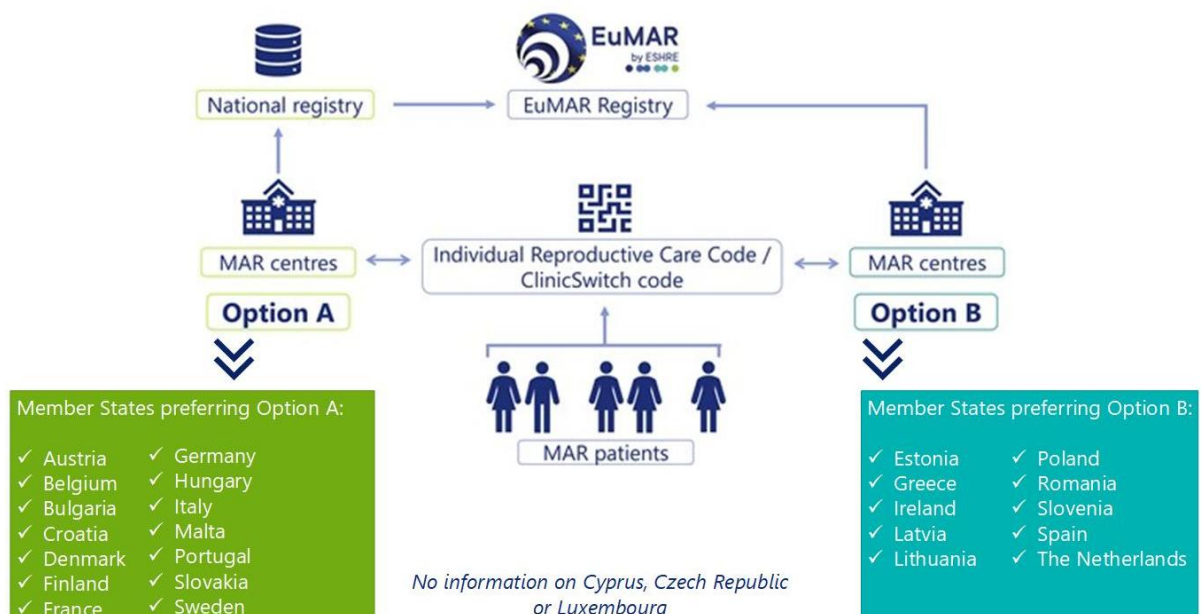
project outcomes relevant to be considered in the future, and hence in the development of deliverable D7.1, are brief summarized below.

Map of current data flows and information requirements at the EU Member states

As part of WP3 and in connection with objective 1, task 3.2 focused on mapping current data flows and information requirements. This effort resulted in a scientific publication “EuMAR stakeholder engagement: an analysis of medically assisted reproduction (MAR) data collection practices in EU countries” [3]. The analysis mapped the Data Flow Theoretical Model to current practice across EU countries.

A survey among representatives from national competent authorities (NCA) and professional associations involved in MAR data collection in all of the EU Member States provided information on the presence of national MAR data collection, as well as the modalities and the possibilities for a future connection to the EuMAR Registry. Regarding the data flow to EuMAR, 14 Member States confirmed a preference for establishing the connection through their national registry—either because they already collect data on a cycle-by-cycle basis or are in the process of developing such a registry. In contrast, ten Member States expressed a preference for sending data directly from the centres, primarily due to the absence of a national cycle-by-cycle registry, although in some of these Member States such a registry is currently under development. There was no information on Cyprus, Czech Republic or Luxembourg (Figure 1).

Figure 1 Data Flow Theoretical Model versus current practice in EU Member States



Characteristics and parameters with accepted terminology

WP4 is a crucial element of the EuMAR project, aligning with project objective 2 to identify and define key parameters in MAR.

The overarching goal of WP4 is to develop a comprehensive understanding of relevant MAR parameters, encompassing patient and lab characteristics, as well as treatment and outcome parameters. This understanding is crucial for prospective cycle-by-cycle data collection, especially in the context of the longitudinal EuMAR data collection, which incorporates cumulative outcome data¹ analysis. Through this approach, WP4 aims to surpass the limitations of the current data collections.

WP4 is structured around three tasks:

1. *Characteristics and Parameters with Accepted Terminology (Task 4.1)*: Develops a list for comprehensive cycle-by-cycle data collection, considering MAR treatment cycles. Standard definitions are created with stakeholder input and endorsement is sought.
2. *Characteristics and Parameters: Definition of Type, Format and Validation Conditions (Task 4.2)*: Complements identified characteristics and parameters with data type, format and validation conditions for integration into the registry roadmap.
3. *Characteristics and Parameters: Translation to Other Languages (Task 4.3)*: Translates characteristics and parameters into national languages of EU Member States, ensuring accuracy through professional translation and verification.

Ultimately, the successful completion of WP4 will contribute to the establishment of a standardised glossary and framework for MAR parameters, facilitating proper data harmonisation and enabling seamless integration with existing registries.

The work of WP4 was concluded 31/12/2023 with the finalisation of Deliverable 4.1 (Characteristics and parameters with accepted terminology) [4].

In addition to the parameters included in the EuMAR Registry for the collection of data from the treatments performed, outcome parameters will be defined to allow assessment of performance, including benchmarking.

The technical solution of the EuMAR registry (WP5) was built using the parameter list as the backbone. Upon finalisation of the first version of the EuMAR registry it was subject to input and feedback from stakeholders (professionals, national competent authorities, EU), as well as to testing in four countries (pilot study, WP6). The pilot study and the evaluation of the submitted data will provide information on the true potential for harmonization across countries and proper understanding of parameters, and the feasibility for completing them. The pilot study further included seeking structured feedback from the professionals submitting data in the MAR centres, NCAs and IT providers. At the same time, patients were surveyed, and their feedback was discussed in focus group meetings. At the end of the pilot study and considering the lessons learned from it, the parameter list will be updated. The parameter

¹ Cumulative outcome data (for example cumulative pregnancy rate) refers to the outcome of treatment (for example, the chance of achieving a pregnancy) over a defined number of treatment cycles (embryo transfers), rather than per individual attempt.

adaptations will be transferred to the EuMAR registry, thereby ensuring the registry, as completed at the end of the EuMAR project (December 2025), is ready for further dissemination in different EU countries.

A Data Protection Impact Assessment (DPIA) was conducted, which included a detailed list of all parameters collected in the registry. Each parameter was individually assessed to determine its potential impact on privacy, specifically whether the inclusion of that parameter could compromise the anonymity of the data.

This parameter-by-parameter evaluation is essential to establish the legal basis for data processing and to ensure compliance with applicable data protection regulations, including the General Data Protection Regulation (GDPR). It also serves to determine whether the registry can be classified and legally defended as an anonymous registry or as a pseudonymised registry, and whether written informed consent from patients is required.

EuMAR registry and outcomes

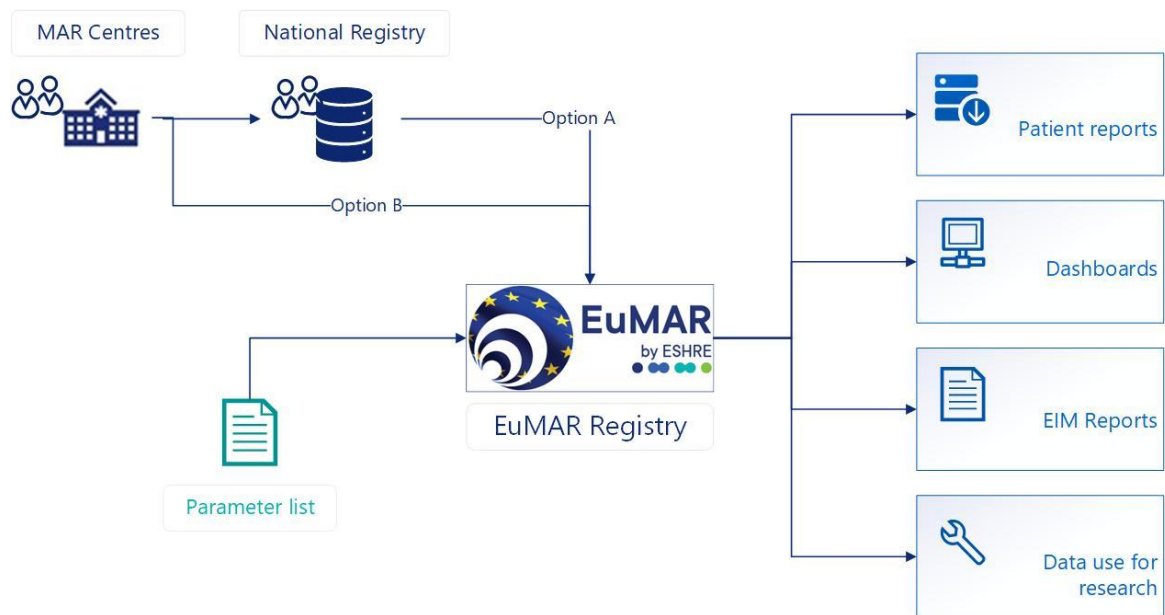
The EuMAR registry technical solution is focussed on capturing the data and having them available for data analysis. In its development the EuMAR registry will be complemented by dashboards and patient reports, as well as the possibility to export data for inclusion in the EIM reports (as the sole current collection of EU-wide MAR data) or to be used for research within the scope of the European Health Data Space (EHDS) (

Figure 2).

One outcome is the data dashboards, which provide a visualisation of the outcome parameters for the general public and for the MAR centres. For the public, including policy makers, these data dashboards offer insight into current practices in the participating MAR centres.

MAR centres will have access to the general dashboards, but also restricted access to dashboards showing their own data and mapping them against the national data. Filters will enable centres to visualise the data for specific criteria, such as a particular calendar year, a specific treatment modality or for population subgroups. These data should enable the MAR centres to evaluate/benchmark their data against the national standards, as well as published standards and support them to improve the quality and safety of care at their centre. Furthermore, some laboratory and clinical Key Performance Indicators (KPIs) are designed to detect occasional issues and errors and thereby help centres to improve their clinical and safety outcomes. It is nevertheless to be acknowledged that not all defined and recommended KPIs will be calculated and available in the EuMAR dashboards as this requires prospective monitoring and an alarm system, which will not be possible through the current EuMAR set up, particularly when the data are transmitted to the national registry and subsequently transmitted to the EUMAR registry, creating a delay.

Figure 2 EuMAR registry and output



WP5 will also develop personal treatment reports, that can be requested through the clinic and made available to patients, particularly when changing from one MAR centre to another. The patient reports include the data on the treatment cycle as included in and reported to the EuMAR registry. These reports aim to create transparency to the patients on which data is collected on their treatment and also to allow them to facilitate the transition to another MAR centre. It may reduce the duplication of failed treatments and overtreatment.

The ESHRE European IVF Monitoring Programme (EIM) has been reporting annually on ART practices in Europe, and these reports will be continued, as they provide a historical overview, provide the possibility to visualise trends and incorporate data from all European countries [5].

Work Package 7: Plan for incorporation of innovation

While the developments continue based on the results of the pilot study, WP7 aims to facilitate the flexibility of the data registry with regards to the inclusion of additional parameters, amendments based on emerging insights and innovations and possible future connections to other data registries (e.g. obstetric data, birth registries, paediatric disease registries, cancer registries, transplantation registries, or cardiovascular disease registries).

WP7 addresses a substantial part of project objectives 1 and 2, which both specify the need to ensure the terminology, and the data registry are able to be updated according to technical developments, new treatment strategies and innovations as well as other novelties. The work package aims to develop a plan for adaptation of the data collection, including IT solutions, which should ensure the data registry is adjustable, making it future proof.

Methodology

This deliverable was developed through combining information from several deliverables and project documents that outline the route of development and current status of the registry. This information was used to brainstorm on possible future adaptations based on technical developments, new treatment strategies and innovations and other novelties, and how these would impact on the registry. From this brainstorming, major topics and necessary steps in a plan for incorporation of innovation were derived, which were further developed and discussed by the working group in an in-person meeting (May 2025). The draft deliverable was afterwards circulated for review, as defined in the Evaluation plan (Deliverable 8.1).

Plan for adaptation of parameters

The parameters in the EuMAR data registry form its core structure. To maintain accuracy, relevance, and usability, any data registry must periodically update its parameters. This is particularly crucial in a field like reproductive medicine, where rapid advancements—such as innovations in MAR treatments, lab technologies, genetic screening, and fertility preservation—continuously reshape best practices and standards. Outdated parameters can lead to irrelevant or misleading data collection while regular updates ensure that the registry reflects current realities, improving data quality and usability for research, decision-making, and policy development.

While updating parameters is a necessity, any changes to the parameters must be carefully considered and prioritisation rules should be used to limit the unnecessary burden of too frequent changes to the EuMAR registry, and to the national registries in countries where they exist. Moreover, the EuMAR registry aims to serve as a reference point for clinics and establishments across Europe - as well as for national competent authorities, EU policymakers, professionals, and patients - and hence its content and parameters should be carefully managed and kept to a minimum to maintain continuity, reduce complexity, and avoid potential errors. In addition, the registry must also provide access to historical data after

updates have been introduced. The registry can serve not only to produce annual statistics and to calculate cumulative outcomes, but also as a multiannual database for research.

This chapter outlines the adaptation of the parameters in the EuMAR registry, as well as a pathway to possible future parameter adaptations.

Considerations related to parameter changes

There are foreseeable scenarios in which adding or adapting parameters will be justified—such as expanding undeveloped modules from the EuMAR project, aligning with evolving legal requirements, and reflecting advances in MAR treatment and clinical practice.

- **Expanding undeveloped modules from the EuMAR project.** Some areas, such as neonatal outcomes and the health of children born through MAR treatments, were not comprehensively covered in the original EuMAR project and were not fully assessed during the pilot phase, due to the limited duration of the project and the time needed for such data to become available. Another example is the collection of data on cross-border MAR treatments, which could not be tested due to the limited time frame to allow sufficient patients or biological material to move across countries. Further follow-up data collection in these areas may warrant the introduction of new parameters in the future, or adaptation of the current parameters following further testing, as well as linkage to other registries (see also “connection to other registries”).
- **Aligning with evolving legal requirements.** To support data collection for the SoHO Platform, relevant parameters may need to be integrated into the EuMAR registry. These parameters could then be transferred—either automatically or manually by participating centres—from the EuMAR registry to the SoHO Platform. Automatic data transmission can be achieved after a connection is established between the EuMAR registry and the SoHO Platform (see also Connection to other registries). As the SoHO Platform is not expected to be completed before the planned parameter review period (April–September 2025), any alignment will need to be implemented post-finalisation of the registry. In addition, parameters required for SARE (Serious Adverse Reactions and Events) annual reporting could be included, which could structure data collection processes for the centres, and data flows for national competent authorities (NCAs) to reduce workload and support them in meeting their reporting obligations without duplicating efforts.
- **Reflecting advances in MAR treatment and practice.** The field of MAR has evolved significantly since the first treatments were carried out in the eighties. Developments such as improved cryopreservation techniques have led to the expansion of frozen-thawed embryo transfer cycles, and optimisation of lab procedures for embryo culture created a shift towards elective single embryo transfer. Such advances and developments can be expected in the future as well, for example in fertility preservation with planned evolutions in the use of cryopreserved gonadal tissues, and they will necessitate periodic updates to parameters and their definitions to accurately capture current practices. While advancements in technologies and interventions are likely to be incorporated, changes may also be needed to record information on newly

identified complications or the exploration of new associations that may lead to improvements in quality and safety of care.

Despite the need for flexibility, several important risks must be taken into account when considering changes to parameters:

- **Impact on data interoperability.** The EuMAR registry is the endpoint in a complex data chain, often collecting information via automated application programming interfaces (APIs) from centres or national registries. Uncoordinated parameter changes could result in missing or incorrect data due to mismatches in data mapping.
- **Technical and Resource Burden.** Any change in parameters requires corresponding updates to APIs and system integrations. This involves coordination among IT providers, NCAs, and local centres, incurring financial costs and potentially reducing engagement if updates are frequent or burdensome.
- **Impact on other parameters and outcomes.** Parameters are interconnected through validation rules and influence various outputs, including dashboards, checklists, and patient reports. A change in one parameter may necessitate updates to multiple dependent systems and calculations to prevent validation failures or reporting errors.
- **Disruption in reporting of trends.** The integrity of long-term trend analysis depends on consistent data. Altering or retiring parameters can compromise the continuity of historical comparisons, such as those presented in the EIM reports, thereby limiting the ability to assess developments over time.

Given these risks and the inevitability of change, maintaining a high-quality registry requires a structured approach to parameter updates. A dedicated change management procedure — outlined below—will guide the process, ensuring updates are implemented with minimal disruption and maximum coordination across stakeholders.

Technical provisions to allow adaptations

The EuMAR registry is built in three environments in order to maintain the system. A test environment to roll-out new versions of the system, an integration environment to enrol new clinics and a production environment with the actual data.

- **Test environment:** Used to deploy new functionality, hotfixes and changes to the system. It is needed to validate changes by the EuMAR team after the IT developer made the technical changes.
- **Enrolment environment:** This environment will be an exact copy of the production environment. It is used to allow new centres to test the upload of data in a system without performing the actual data collection.
- **Production environment:** This is the system clinics and NCAs will use on a regular basis. It will contain the actual database and is used to extract the data as well as collecting it.

Change management procedure

A procedure for parameter adaptation was drafted in 6 subprocesses, aimed to ensure the integrity and validity of the registry: i) Proposal submission, ii) Assessment of the proposed change, iii) Consideration and decision-making, iv) Technical implementation, v)

Documentation and communication, and iv) Validation (Figure 3). As part of the change management procedure, specific roles and responsibilities (throughout the different stages of the process) were assigned to key individuals and groups (Table 2).

Table 2 Key individuals and groups involved in the Change Management Procedure. Their specific role in the different steps of the procedure is outlined in the Protocol Annex 1. Change Management Protocol

Role	Function (in general)	Composition/explanation
EuMAR Staff	Execution of specific tasks, drafting documents	Members of ESHRE staff assigned to the EuMAR project team.
EuMAR Project Steering Committee (PSC)	Oversight and decision-making	Multidisciplinary group of people with clinical expertise as well as in depth knowledge of the registry and data collection. In the longer term, this task may be assigned to a specific Committee tasked with the management and strategic development of the registry. The composition, roles, and tasks of such a committee would need to be included in ESHRE Internal Regulations.
IT Developer	Advisory and task execution	The IT Developer managing the technical development and maintenance of the registry. Where needed, database specialists could be consulted.
Legal Advisor/ Data protection officer (DPO)	Advisory	Legal advisor as appointed for the EuMAR project and/or the DPO appointed by ESHRE.
Data submitters	Advisory role, to be informed towards implementation	This includes MAR centres (healthcare professionals), national registries and NCAs, but possibly also the IT developers that linked the centres/national registries to the EuMAR registry.

I. Proposal submission

Objective: Initiate and formally document the intent to add, remove, or modify a parameter.

- Any stakeholder (e.g., researchers, registry staff, data controllers) may submit a formal proposal to add, remove, or modify a parameter (see *Annex 2. Proposal Form – Parameter Change Request* for further details). Modifying a parameter could include modifying the parameter itself, the variables to a parameter, the definition, or the validation criteria linked to the parameter.
- The proposal must include:
 - a. A detailed description of the parameter adaptation (new parameter, modification of the parameter).
 - b. Justification for the change.
 - c. Expected impact to other parameters or outcome calculations.

II. Assessment of the proposed change

Objective: Conduct a thorough assessment of scientific validity, feasibility, legal implications (e.g. GDPR), and relevance for EuMAR.

- Each proposal for a change in the Registries' parameters will be subject to a formal assessment, documented in a report.
- The assessment of a proposed parameter change will include:
 - Scientific validity and necessity.
 - Acceptability to stakeholders.
 - Feasibility of data collection (i.e. the degree at which the parameter data can be provided by the data submitters, or is already recorded in some countries)
 - Relevance for EuMAR (i.e. does the parameter fall within the scope of the EuMAR registry).
 - Overlap/consistency with other parameters.
 - Need to define/adapt validation criteria, definition, connection to and impact on other parameters.
 - Privacy impact (risk of identification) and compliance with data protection laws, through an evaluation of the changes (as done during the DPIA).
 - Impact on other parameters/patient reports/dashboards, and risk of disruptions.
 - Feasibility of technical implementation.
- Where needed, the assessment will be done in collaboration with a dedicated legal advisor and/or Data Protection Officer (DPO), healthcare professionals, centres or national registries connected to the EuMAR registry, the IT provider for the registry and/or database specialists.
- The report detailing the proposed parameter change, the justification as well as the details on the assessment will be developed by the EuMAR staff, under the supervision of the EuMAR PSC.

III. Consideration and decision-making

Objective: To apply a structured and transparent decision-making process for proposed parameter changes, based on the assessment report. This process ensures that decisions are well-informed, clearly documented, and provide sufficient guidance for accurate technical implementation.

- The report detailing the proposed parameter change, the justification as well as the details on the assessment will be submitted to the EuMAR PSC or designated working group for final decision. Where needed, an online meeting will be organised for in depth discussion of the report and decision-making.
- Decisions may include:
 - Approval of the change as proposed.
 - Conditional approval (with modifications).

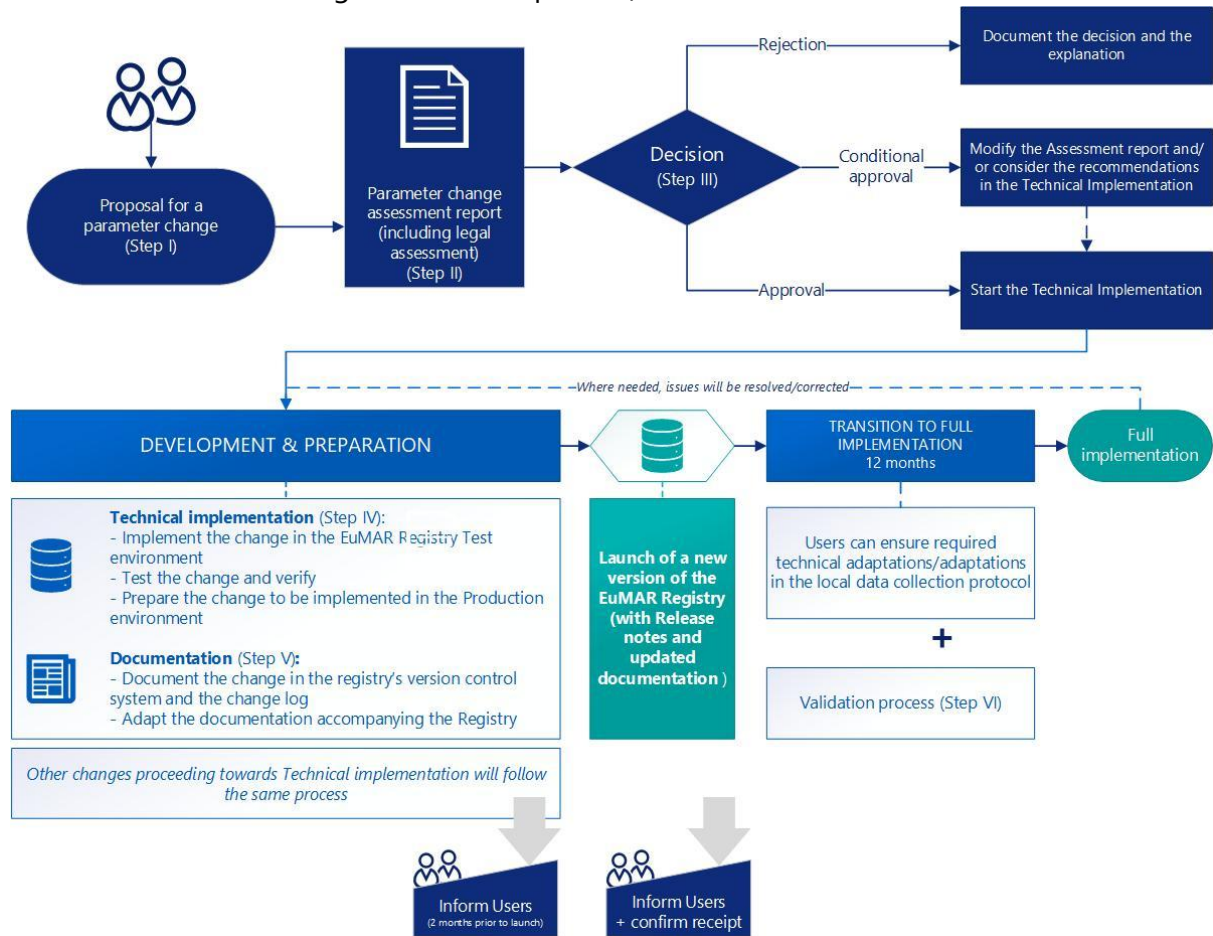
- Rejection (with explanation).
- The final decision must be documented and archived.
- If the change is approved, the EuMAR PSC will assess the technical complexity and impact of the change, and the urgency, and document it.
 - Complexity and impact: Changes will be assessed for technical complexity and impact of the modification. Possible changes (from minimal and simple to integrate to more complex) include:
 - clarifications in the terminology/definition, or correction of the validation criteria.
 - Adding new variables to an existing parameter.
 - Removing old variables in an existing parameter.
 - Adding a new parameter.
 - Removing an old parameter.
 - Adding a new module/group of parameters.
 - Removing a module/group of parameters.
 - Urgency: It is planned to release a new version of the EuMAR registry biennially or less frequently. This means that proposals for parameter adaptations will be individually assessed but simultaneously implemented. Immediate adaptations will only be made for changes that are deemed to be urgent or of high importance.

IV. Technical Implementation

Objective: Execute the approved changes/adaptation

- Approved changes are scheduled for development and deployment by the IT developer, in collaboration with the EuMAR staff.
- Implementation includes:
 - Defining the parameter, where and how it needs to be inserted in the registry and which validation criteria to apply. This information should be already detailed in the assessment report, but it will need to be adapted to ensure the required change is clear to the IT developer.
 - Adapting/adding the parameter will be done in the test environment of the system.

A verification of the changes will be completed (see



)

- After this during-development verification, the changes will be implemented in the production environment, to which the data submitters will be able to link to submit the data. Where needed, the verification will be repeated after the changes are implemented in the production environment.
- The new version will be complemented with modified user interfaces and online API documentation.
- Where needed, the parameter and its definition need to be translated before integration.
- If the change is significant and includes the removal of a variable, parameter or module, the new version of the parameter will be included and the old version of the parameter hidden. This approach aims to avoid the loss of historical information and trends.
- New parameters will initially be included as optional parameters (transition period of 12 months), allowing the gradual inclusion of data on the parameter, in line with local data collection and IT development.
- The possibility of manual data entry of missing data on new parameters – when data are transmitted through an API - will be examined as an option to increase the amount of data collected for newly added/adapted parameters.

Table 3 Verification and validation activities linked to a change to the EuMAR registry

	Verification	Validation
Purpose	Ensures the change was made correctly according to the specifications and design documents.	Ensures the final change actually meets user needs and fulfils its intended purpose.
When	During development and during implementation.	After verification, during or after implementation.
Methods	Review, testing with dummy data, checking documents, code	Dynamic validation report (standard, irrespective of changes of parameters)
Steps/tasks	<ul style="list-style-type: none"> • Verification of technical accuracy and functionality. • Verification that the changes have been correctly transmitted in the outcome and calculated parameters, dashboards and patient reports. 	<ul style="list-style-type: none"> • Validation that the data are/can be completed for the newly added/adapted parameters, • Considering the validation report to check for any impact on the other parameters. <p>More details on the validation process are available in the Data Management Plan.</p>

V. Documentation and Communication

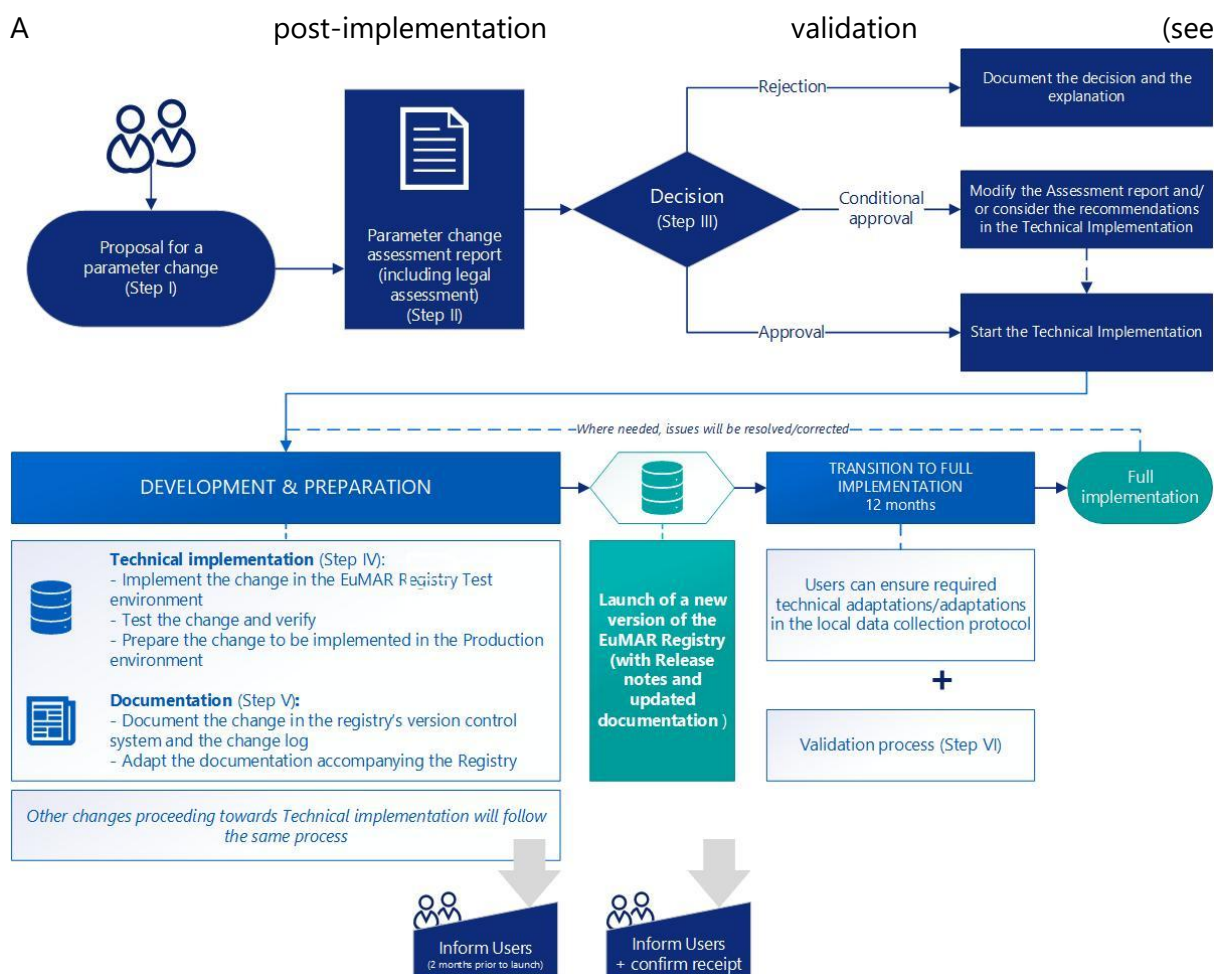
Objective: Ensure transparency, alignment, and operational readiness.

- The adaptations must be recorded in the following documentations:
 - a. the registry’s version control system
 - b. change log
 - c. the documentation on the technical aspects of the registry

- d. the documentation of the definition of fields and validations
- Upon release of a new version of the registry, an updated version of all accompanying documentation to the registry should also be available, including user information, parameter lists, the Data Management Plan, which includes a change log, and the Data Quality Plan.
- Relevant stakeholders (e.g., data submitters, NCAs, centres, national registries, ...) must be informed of the changes through appropriate communication channels.
 - a. A first communication will need to be sent 4 months prior to the launch of the new version, to allow the stakeholders to include the parameter in the data collection at the centre and adapt API connections.
 - b. A second communication will be sent upon releasing a new version of the registry, accompanied with all relevant documentation.
 - c. The relevant stakeholders (e.g., data submitters, NCAs, centres, ...) will be asked for confirmation/verification that the information was received

VI. Validation

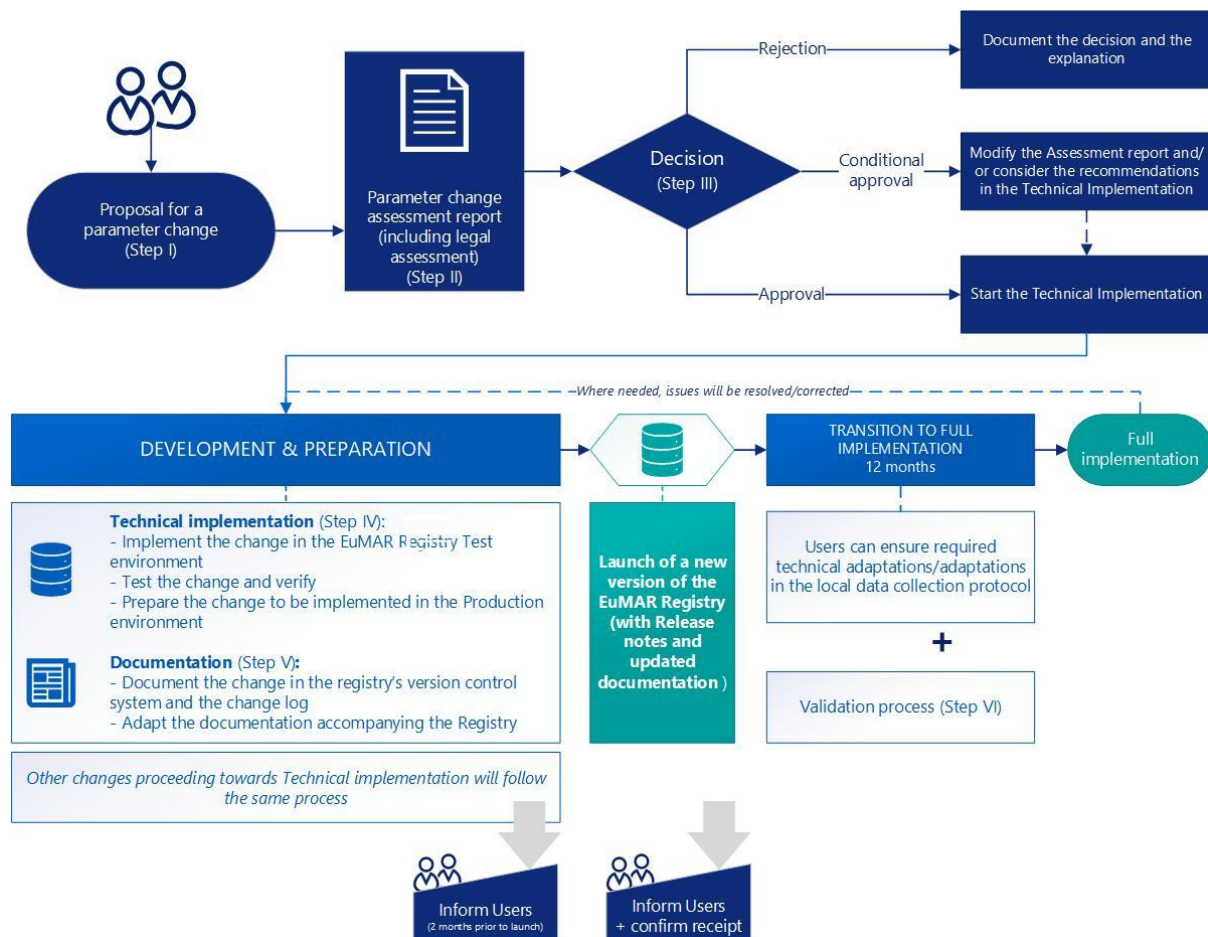
Objective: Ensure that any newly implemented or modified parameters within the system function correctly, are accurately represented across all outputs, and maintain data integrity, while also remaining compliant with data protection standards.



) will need to be performed, including an evaluation of the degree at which the parameter data can be provided by the data submitters. This will need to be considered in calculating and reporting, and where needed actions would need to be taken to increase the data submission for the respective parameter.

- Updating of the DPIA for the combination of the parameter changes.

Figure 3 Overview of the procedure for introducing a parameter adaptation



Introducing a new module

Rather than adapting/adding a new parameter, it may also be necessary to add a group of parameters on the same topic, and to combine the integration through the introduction of a new module. Examples could be a module to collect specific parameters related to in vitro gamete/tissue maturation or stem-cell derived gametes. The procedure for introducing a new module is similar to the procedure for parameter adaptation, outlined above in six subprocesses, aimed to ensure the integrity and validity of the registry: i) Proposal submission, ii) Assessment of the proposed change, iii) Consideration and decision-making, iv) Technical implementation, v) Documentation and communication, and vi) Validation.

Connection to other registries

The field of (in)fertility and assisted reproduction is intricately connected to numerous other areas of medicine. First and foremost, there is a clear link with the field of maternal-fetal medicine and neonatology, which focuses on monitoring pregnancy outcomes and the health of newborns, including those conceived through medically assisted reproduction (MAR).

Other examples include, cancer patients facing gonadotoxic treatments that may require fertility preservation interventions prior to therapy, while others may experience infertility as a long-term consequence and later rely on MAR to fulfil their wish for children. Similarly, metabolic disorders—such as polycystic ovary syndrome (PCOS), diabetes, and obesity —, but also medical interventions — such as organ, or bone marrow transplantation — can significantly impact both natural fertility and the outcomes of fertility treatments. Moreover, fertility treatments themselves may influence the health of the women through her risk of developing certain conditions, as well as the health of the resulting offspring, highlighting the importance of long-term follow-up. Finally, the impact of pathogenic agents on ART outcomes, including the offspring, can be evaluated through linking ECDC data with ART registries.

In this context, research based on registry data is gaining increasing relevance. Registries offer a wealth of structured longitudinal information that allows for the study of outcomes across extended timeframes—something that is often not feasible in traditional clinical trials or short-term studies.

National and EU-wide registries

A first step towards addressing the connection to other registries in a realistic manner, is to map the available and established registries in Europe.

In terms of European registries of relevance to EuMAR, only two registries are established.

- The EBMT Registry [6]: This registry is maintained by the European Society for Blood and Marrow Transplantation (EBMT). It is one of the largest databases in the field, collecting data on hematopoietic stem cell transplantation (HSCT) and cellular therapies.
- The Organ Transplant Registry [7]: This registry is under development by the European Society for Organ Transplantation. It aims to be a platform to host pan-European registries on transplant recipients and living donors, building on existing single-organ registries.

Also of interest to EuMAR are registries including data on cancer diagnoses and treatments (data.europa.eu), data on obstetric outcomes, and paediatric or perinatal data. To the best of our knowledge, no European registries are available with these data.

ESHRE's own registry on Preimplantation Genetic Testing, managed by the ESHRE PGT Consortium, has recently been transformed from a cycle-by-cycle registry to an aggregated data registry, mainly due to low data submissions based on workload. In time, a connection to the EuMAR registry could automate data collection, reduce the workload for the centres, and allow the relaunch of the cycle-by-cycle data collection on Preimplantation Genetic Testing, through an additional module linking the current parameter on PGT.

While linkage can be done at a European level, between European registries, an alternative approach could involve linking MAR Registries with other registries at the national level and subsequently transferring the combined dataset to EuMAR. From this perspective, documenting the existence of national registries becomes relevant, as it informs the feasibility and potential scope of such data integration efforts. ESHRE has and will be able to rely on its network of national representatives for such information (See Table 4).

On a national level, cancer registries exist in numerous European countries. According to the European Network of Cancer Registries (ENCR), which promotes collaboration between registries and defines data collection standards, national cancer registries are present in many European countries [8]. In some countries, a single national registry is maintained, while in others, multiple registries operate—either regionally or with a focus on specific cancer types, or on childhood or all-age cancers. In terms of registries in the field of Perinatal & Maternal–Fetal Health, the EURO-PERISTAT project provides a list of registries on Perinatal health, or registries from which these data can be deduced in several European countries [9].

There are fewer national initiatives to collect neonatal data. A International Neonatal Research Database (eNewborn) includes data from Belgium, Czech Republic, Finland, France, Germany, Greece, Italy, Luxembourg, Poland, Portugal, Spain, Switzerland, United Kingdom, and Armenia [10]. The database is managed in the UK, in conjunction with the UK National Neonatal Research Database [11].

Specialized paediatric registries exist in some countries for cancer [8], and less often also for other conditions. For example, Switzerland has several paediatric registries for paediatric renal disease, cerebral palsy, or inflammatory brain disease [12]. In the German-speaking countries, CEDATA GPGE collects clinical data of children and adolescents with Inflammatory bowel disease (IBD) from paediatric gastroenterology centres [13].

Table 4 Overview of available national registries (information sources from [8,9,10 and 11])

Country	National Perinatal health registry (and data providers) [9]	National Cancer registry [8]	National Neonatal registry [10,11]
Austria	* Birth statistics * Cause of death statistics (<i>Statistics Austria</i>)	Yes	
Belgium	* Vital Statistics, Statistics Belgium (<i>Statbel</i>)	Yes	Contributes to eNewborn
Bosnia and Herzegovina		Yes	
Bulgaria		Yes	
Croatia	* Croatian Medical Birth Database * Croatian Mortality Database (<i>Croatian Central Bureau of Statistics</i>)	Yes	
Cyprus	* Medical Birth register * Causes of Death register (<i>Cyprus Ministry of Health</i>)	Yes	
Czech Republic	* Institute of Health Statistics and Information of the Czech Republic national birth register	Yes	Contributes to eNewborn
Denmark	* Medical birth register * Danish causes of death register (<i>Danish Ministry of Health</i>) * The Centralized Civil Register	Yes	

Country	National Perinatal health registry (and data providers) [9]	National Cancer registry [8]	National Neonatal registry [10,11]
Estonia	* Estonian Medical Birth Register * Estonian Cause of Death Register (National Institute for Public Health)	Yes	
Finland	* Medical Birth Register linked with Central Population Register and Cause of Death Register * Register on Induced Abortions for late terminations 22–24 weeks (Finnish Institute for Health Welfare, Digital and Population Data Services Agency, and Statistics Finland)	Yes	Contributes to eNewborn
France	* Hospital discharge data in the French National System of Health Data	Yes	Contributes to eNewborn
Germany	* IQTIG * Destatis (Federal Institute for the Quality of Medical Care, Federal Statistical Office)	Yes	Contributes to eNewborn
Gibraltar		Yes	
Greece		Yes	Contributes to eNewborn
Hungary		Yes	
Iceland	* The Icelandic Birth Registration * Hospital register (National University Hospital)	Yes	
Ireland	* National Perinatal Reporting System (the Healthcare Pricing Office)	Yes	
Italy	* Birth certificates * Causes of deaths * Terminations of pregnancies * Miscarriages (Ministry of Health, Istat)	Yes	Contributes to eNewborn
Latvia	* Newborn Register of Latvia * Register of Causes of Death (Centre for Disease Prevention and Control of Latvia)	Yes	
Lithuania	* Medical Date of Births * Database of the Demographic Statistics * Causes of Death register (Institute of Hygiene Health Information Centre, Central Statistical Office)	Yes	
Luxembourg	* Perinatal Health Monitoring System * National Causes of Death Registry (Luxembourg Institute of Health, Directorate of Health of Luxembourg)	Yes	Contributes to eNewborn
Malta	* National Obstetrics Information System * National Mortality Register (Directorate for Health Information and Research)	Yes	
Moldova		Yes	
Montenegro		Yes	
Netherlands	* Perined (The Netherlands Perinatal Registry)	Yes	
Norway	* Medical Birth Register of Norway (The Norwegian Institute of Public Health)	Yes	
Poland	* Central Statistical Office * Ministry of Health	Yes	Contributes to eNewborn
Portugal	* Instituto Nacional de Estatística – Portugal * Central Administration of the Health System (Statistics Portugal)	Yes	Contributes to eNewborn
Romania	* National Institute for Public Health Romania	Yes	
Serbia		Yes	

Country	National Perinatal health registry (and data providers) [9]	National Cancer registry [8]	National Neonatal registry [10,11]
Slovakia	*National Health Information Center	Yes	
Slovenia	*Perinatal information system (<i>National institute of public health</i>)	Yes	
Spain	* Vital Statistics * Specialized Care Registry – Minimum Basic Data Set (<i>National Statistics Office, Ministry of Health</i>)	Yes	Contributes to eNewborn
Sweden	* Medical Birth Register (<i>The National Board of Health and Welfare</i>)	Yes	
Switzerland	* Vital Statistics (<i>BEVNAT</i>)	Yes	Contributes to eNewborn
Türkiye		Yes	
United Kingdom	* MBRRACE UK (<i>University of Oxford and University of Leicester</i>) and additional regional registries	Yes	National Neonatal Research Database
Ukraine		Yes	

The promise of linking registries

Looking ahead, linking such diverse registries holds great promise. By integrating data from oncology, endocrinology, reproductive medicine, and paediatrics, researchers could gain deeper insights into how pre-existing conditions, treatments, and patient characteristics influence fertility, treatment success, and child health.

Record linkage is a powerful and well-established method for enhancing the completeness and accuracy of health data in public health research. National-level initiatives, such as the UK's Clinical Practice Research Datalink (CPRD), have demonstrated the value of connected health records for large-scale epidemiological studies [14]. At the international level, however, challenges arise—such as navigating data privacy regulations (like the GDPR), harmonising data standards, and enabling secure cross-border data exchange.

There are three well-established methods for record linkage across databases:

- **Deterministic matching:** Links records only when they exactly match on one or more identifiers (e.g., patient ID, date of birth, treatment code, patient code).
- **Probabilistic matching:** Links records based on a combination of variables (e.g., demographic, clinical, and treatment-related data). It does not require exact agreement between variables in the 2 databases but is based on a generated match core reflecting the likelihood that two records refer to the same case.
- **Unique identifier approach:** Links records through a consistent identifier across all databases at the point of data collection. This avoids the need for “matching”, making linkage direct and unambiguous.

Linking the EuMAR registry – technical provisions

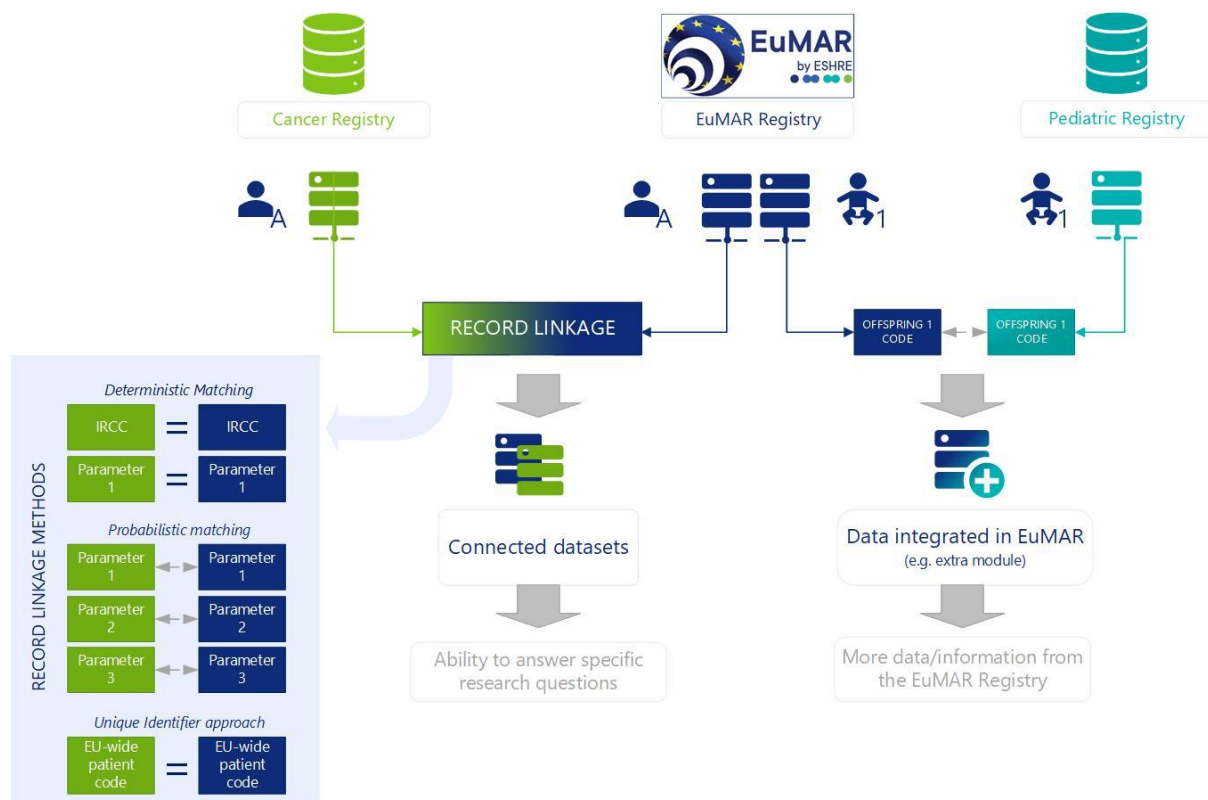
With the development of the IRCC (Individual Reproductive Care Code) and the CSC (Clinic Switch Code), the EuMAR project has proactively incorporated tools for secure and privacy-respecting record linkage across clinics and countries.

Theoretically, the IRCC could function as a patient code when connecting same patient data from different sources (see Figure 4). Such connections could provide insight in specific clinical questions.

Another option for registry linking could be to allow the extraction of a dataset through integrating data from existing data registries. Again, there would need to be a patient code that would enable the connection. In the example outlined in the figure, the connection would be made for offspring data, and the Clinic Switch Code (if established) could be used/adapted, as one would “switch” between care at fertility centres and care at paediatric units (as compared to switching between two fertility centres for which the code was originally developed).

These innovative IRCC and the Clinic Switch Code therefore lay the groundwork for future linkage between reproductive and non-reproductive European registries using deterministic matching.

Figure 4 Theoretical possibilities of linking the EuMAR registry to other Registries



Irrespective of the IRCC and the Clinic Switch Code, probabilistic matching can be used, though it may be more difficult to establish technically. This approach can be applied to connecting the EuMAR Registry with a paediatric registry, where linkage can be done through a combination of the following parameters: month of birth, month of birth of the mother, birth weight range, APGAR score and gestational age at birth.

Finally, a unique EU wide patient identifier, if established, can be added as a parameter in the EuMAR Registry, for both the patients and the offspring. This overarching approach will allow the EuMAR Registry to establish direct and unambiguous links with other EU wide registries.

The European Health Data Space Regulation (EHDS)

The EHDS Regulation aims to establish a common framework for the use and exchange of electronic health data across the EU. It enhances individuals' access to and control over their personal electronic health data (primary use of data). The EHDS will also enable certain data to be reused for public interest, policy support, and scientific research purposes (secondary use of data) [15].

Linking registries of collected data will be one aspect of secondary use of data within the EHDS.

The EU notes the following benefits of the secondary use of health data:

- better healthcare outcomes – helps identify best practices, improve patient care, and develop new treatments
- advances in medical research – supports scientific discoveries and a deeper understanding of diseases
- stronger public health policies – helps track disease outbreaks, assess risk factors, and inform decision-making
- greater transparency and accountability – improves healthcare service evaluation and promotes responsible data use.

The EU-funded HealthData@EU Pilot project has been concluded. This project aimed to build a pilot version of the European Health Data Space (EHDS) infrastructure for the secondary use of health data which will serve research, innovation, policy making and regulatory proposes. The project aimed to connect data platforms in a network infrastructure and develop services supporting the user journey for research projects using health data from various EU Member States. It will also provide guidelines for data standards, data quality, data security and data transfer to support this cross-border infrastructure. Priority services include a metadata discovery service and a common health data access request [16].

The HealthData@EU Pilot project included 5 use cases:

- Foster a better understanding of the risk of thrombosis in COVID-19 patients
- Mobilise and chain clinical and genomic data to enhance our understanding of colorectal cancer
- Compare care pathways for cardiometabolic diseases in European countries and build prediction models, using artificial intelligence
- Compare COVID-19 testing, vaccination and hospitalisation between the general population and vulnerable subpopulations
- Demonstrate the feasibility of using the EHDS to carry out infectious disease surveillance, focusing on antimicrobial resistance

The current project focused on the secondary use of health data under the EHDS is the TEHDAS2 (Towards European Health Data Space 2) Joint Action. The TEHDAS2 Joint Action is

developing a total of 20 guidelines and technical specifications covering the key digital capabilities of the EHDS framework for secondary use (e.g. national dataset catalogues, Secure Processing Environments, etc.) which will inform any steps taken by EuMAR in terms of linking registries or linking collected data [17].

The EuMAR registry and registry linking in the EHDS context

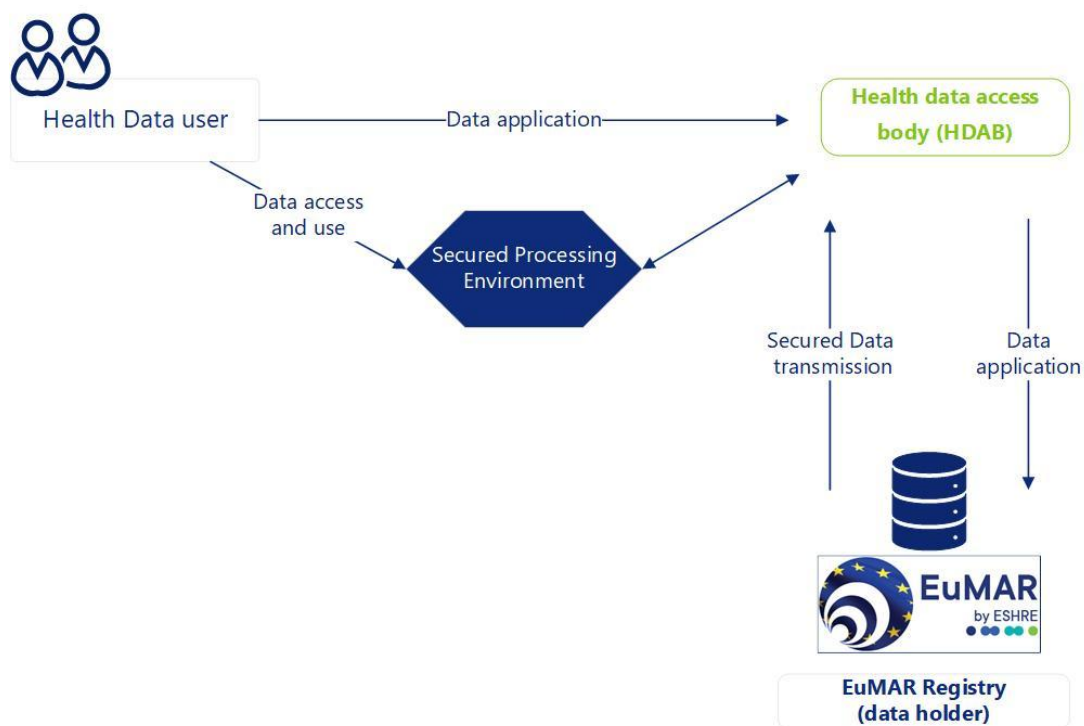
The EuMAR registry aims to be a valuable tool in the context of the EHDS, supporting broader EU goals around digital health, cross-border care, and better use of health data.

Because the EHDS framework and data-sharing pathways were not yet available when EuMAR was developed, the registry was built with openness in mind—from both a technical and governance perspective. This means it has been designed to be flexible and adaptable, with features that make it easier to connect to other registries or data sources in the future [18].

In practical terms, EuMAR can add new connectors or adapt existing ones to support data sharing and integration (see also Plan for adaptation of parameters). Depending on how the EHDS defines the technical and legal requirements for such connectors, components like the IRCC and the Clinic Switch Code could be adapted to function as EHDS-compatible connectors (see also Linking the EuMAR registry).

The details of how to link registries and share data across borders within the EHDS framework are still being worked out. Much will depend on the outcomes of the EU-funded HealthData@EU Pilot project. Until that work is complete, many questions remain—about standards, governance, and how different systems will talk to each other. The EuMAR registry could have a role as a data holder (Figure 5).

Figure 5 Possible role for the EuMAR registry in the EHDS framework



The EuMAR PSC will closely monitor the developments of the HealthData@EU Pilot project and ensure the EuMAR registry aligns with recommendations and guidance provided by the EHDS and the Pilot project.

While a specific procedure for linking registries and connecting data collections could be developed in theory, doing so now would be premature. Without clear guidance from the ongoing development of the EHDS, any such procedure risks becoming outdated or incompatible once formal requirements and technical standards are defined. For this reason, the focus remains on building flexibility into the system, so that it can adapt once the outcomes of the HealthData@EU Pilot project and the full EHDS framework are available.

Conclusion

Work Package 7 plays a central role in ensuring that the EuMAR registry will remain a resilient, future-ready platform for the collection and analysis of MAR data across Europe. By establishing a rigorous and transparent change management procedure, WP7 ensures that the registry can evolve in step with scientific, clinical, and regulatory advancements—without compromising data integrity or usability.

In addition, WP7 lays important groundwork for future interoperability by incorporating the Individual Reproductive Care Code (IRCC) and the Clinic Switch Code into the registry design. These innovations position EuMAR to be a valuable contributor to the broader European health data ecosystem, particularly as the European Health Data Space (EHDS) framework continues to develop.

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Annexes

Annex 1. Change Management Protocol

Steps	Responsible ²	Accountable	Consulted	Informed
I Proposal submission				
Draft a proposal, including: <ul style="list-style-type: none"> A detailed description of the parameter adaptation (new parameter, change of the parameter or its definition). Justification for the change. Expected impact to other parameters or outcome calculations. 	PSC / any stakeholder	/	/	
II Assessment of the proposed change				
Assessment should include: <ul style="list-style-type: none"> Scientific validity and necessity. Acceptability to stakeholders. Feasibility of data collection (whether the parameter can be collected by the MAR centres, or is already recorded in some countries). Relevance for EuMAR (i.e. does the parameter fall within the scope of the EuMAR registry). Overlap/consistence with other parameters. Need to define/adapt validation criteria, definition, connection to and impact on other parameters. Privacy impact (risk of re-identification) and compliance with data protection laws, through an evaluation of the changes (as done during the DPIA). Impact on other parameters/patient reports/dashboards, and risk of disruptions. Feasibility of technical implementation. 	EuMAR staff	PSC	Legal advisor and/ or DPO, healthcare professionals, centres or NCAs, IT developer	
Drafting the report detailing the proposed parameter change, the justification as well as the details on the assessment	EuMAR staff	PSC		
III Consideration and decision-making				

² The roles and responsibilities are defined as in the RACI matrix. RACI stands for:

- Responsible – the person(s) who do the work to complete the task.
- Accountable – the person who is ultimately answerable for the outcome and must sign off on the work.
- Consulted – people who provide input or expertise before the task is completed.
- Informed – those who are kept updated on progress or decisions but are not actively involved.

Evaluation of the report + decision-making with the following outcome:			
<ul style="list-style-type: none"> Approval of the change as proposed. Conditional approval (with modifications). Rejection (with explanation). 	PSC		EuMAR staff
If approved, assess the significance of the change, and the urgency, and document it.	PSC		EuMAR staff
IV Technical Implementation, including verification			
Defining the parameter, where and how it needs to be inserted in the registry and which validation criteria to apply. The information in the assessment report will need to be adapted to ensure the required change is clear to the IT developer.	EuMAR staff	PSC	
Adapting/adding the parameter in the test environment of the system.	IT	EuMAR staff	PSC
Verification:			
<ul style="list-style-type: none"> Verification of technical accuracy and functionality. Verification that the changes have been correctly transmitted in the outcome and calculated parameters, dashboards and patient reports. 	EuMAR staff	PSC	
Implementation of the changes in the production environment, to which the data submitters will be able to link to submit the data. This includes adapting the user interfaces and online API documentation.	IT	EuMAR staff	PSC
V Documentation and Communication			
Adapt the relevant documentations:			
<ul style="list-style-type: none"> The registry's version control system. Change log. The documentation on the technical aspects of the registry. The documentation of the definition of fields and validations. 	EuMAR staff	PSC	
Inform stakeholders:			
<ul style="list-style-type: none"> First communication will need to be sent 2 months prior to the launch. Second communication will be sent upon releasing a new version + verification that the information was received. Third communication at the end of the transition period to assess status, and follow up on issues with local implementation. 	EuMAR staff	PSC	
VI Validation			
<ul style="list-style-type: none"> Validation that the data are/can be completed for the newly added/adapted parameters. Considering the validation report to check for any impact on the other parameters. 	EuMAR staff	PSC	

Annex 2. Proposal Form – Parameter Change Request

For submission to: eumar@eshre.eu

Please complete all sections below. This form is required for any proposal to add, remove, or modify a parameter within the EUMAR dataset.

Section 1: Requester Information

- **Full Name:**
- **Organisation / Affiliation:**
- **Position / Role:**
- **Email Address:**

- **Stakeholder Type:**
 Researcher Registry Staff Data Controller Other: _____

Section 2: Proposal Details

- **Date of Proposal Submission:**

- **Type of Proposal:**
 Add new parameter
 Remove existing parameter
 Modify existing parameter

- **Name of Parameter (if applicable):**

- **Detailed Description of the Proposed Change:**
(Please describe the new parameter or the proposed change to the existing parameter, including any revised definitions or values)
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.....

- **Justification for the Proposed Change:**

(Why is this change necessary? Please explain the rationale or background)

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- **Expected Impact:**

(Describe any expected impact on other parameters, data collection, or outcome calculations)

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Section 3: Additional Comments (Optional)

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