# EuMAR - Mapping the national contexts of Medically Assisted Reproduction registries in the EU

## Introduction

The European Society of Human Reproduction and Embryology (ESHRE) is working on the Monitoring of Medically Assisted Reproduction (EuMAR), an EU co-funded project that aims to develop a pan-European registry of prospective cycle-by-cycle data on the use and outcomes of Medically Assisted Reproduction (MAR), in line with the new EU Regulation proposal on Substances of Human Origin (SoHO).

EuMAR will be a first step to increase biovigilance and surveillance in MAR, allow cross-border data collection and work with harmonised parameters to facilitate international cooperation. We believe this will be of benefit to patients seeking care, professionals pursuing medical excellence and health authorities.

We invite you to take part in this survey to help us understand the current MAR data collection processes of all 27 EU Member States. The results of this survey will assist us in developing the EuMAR platform, tailored to the needs of all relevant stakeholders. They will also serve us as a basis to formulate EU and national policy recommendations that will be published at the end of the project.

The survey has a total of 35 questions and it will take you approximately 15 minutes complete it.

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## Privacy notice

ESHRE collects and processes your data based on your explicit consent and in accordance with ESHRE's Privacy Declaration, which you can read here. ESHRE is in charge of the survey data collection as a data controller. The results may be published but your personal data will be accessed only by authorised ESHRE staff and other members of the project, including our project partners, uniquely for the purposes of its completion. We will retain your answers to the survey for the duration of the project to be able to contact you for follow-up and updates on EuMAR.

Should you have any queries or comments related to EuMAR or to the survey, please email

Elena Achotegui Sebastian, EuMAR's Research Assistant, at elena@eshre.eu. If you want to exercise your data subject rights under data protection law as described in our Privacy Declaration, you may contact us by sending an email to privacy@eshre.eu. If you feel that we are not fully respecting your data subject rights, you can also lodge a complaint with the data protection authority in your own country (the contact details for all the European Data Protection Authorities can be found here).

We only collect and use your data on the basis of your consent. If you prefer not to participate or want to withdraw your consent at some point in the future, please let us know by sending an email to eumar@eshre.eu and we will respect your wishes.

* 1. Before you start filling in the survey, please check the box below if you agree to your data collection as described above:

◯ I agree with the data collection through this survey and I agree with the Privacy Declaration of ESHRE.

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## General information

In the following section, please fill in the name of the country, institution or organisation that you are representing and your contact details. Your personal details will only be used for follow-up and will not be included in the survey results.

* 2. Country

* 3. Type of institution/organisation

- ◯ National competent authority
- ◯ Ministry of Health
- ◯ Another governmental body
- ◯ National professional association
- ◯ Other (Please specify)

* 4. Name of institution/organisation

* 5. Name and surname

6. Job title

* 7. Email address

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## Information on MAR data collection

The following section consists of questions about the current data collection system in the field of Medically Assisted Reproduction (MAR) in your country. Please answer the following questions in regards to a single national registry of Medically Assisted Reproduction activity data, even if there is more than one MAR registry in your country.

For the purposes of our research project, the EuMAR data collection will cover gametes and embryos preparation and handling (IVF, ICSI, IUI), as well as fertility preservation through

gamete/embryo/gonadal tissue cryopreservation. Whereas the definition of MAR genuinely includes also gynaecological surgery and ovulation induction, those activities will not be covered in the EuMAR registry as they do not involve the ex-vivo handling of gametes or gonadal tissues.

### 8. Is there a national registry collecting MAR activity data in your country?

- ◯ Yes, it is compulsory
- ◯ Yes, it is voluntary
- ◯ No

If applicable, please specify the name of the registry as well as the law that sets its legal basis. Please add the links to access them.

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## Information on MAR data collection

### 9. What are some of the reasons for currently not having a national MAR registry in your country? [Tick all that apply]

- ☐ It is not legally required
- ☐ Lack of funding
- ☐ Lack of human resources
- ☐ Other (please specify)

## 10. Is there an intention to establish a national MAR registry in the future?

- ◯ Yes, it is in the process
- ◯ Yes, but there are no concrete actions at this point
- ◯ No

## 11. Are MAR data collected in a way other than a national MAR registry?

- ◯ Yes, some MAR data are collected through other registries (e.g., medical birth registry; local registry)
- ◯ Yes, other
- ◯ No

Please specify your answer

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## Information on MAR data collection

## 12. What organisation(s) or institution(s) are responsible for analysing and reporting data to the national registry? [Tick all that apply]

- [ ] National competent authority
- [ ] Ministry of Health
- [ ] National professional association
- [ ] Another governmental body
- [ ] Other

Please specify the name of the organisation(s)/institution(s) and their responsibilities towards the registry

## 13. What is the method currently used to collect MAR data in your country [Tick all that apply]

- [ ] National platform
- [ ] Excel sheets
- [ ] Other (please specify)

## 14. How is the MAR data collection organised in your country?

- ◯ Data is gathered and reported to the registry in real time
- ◯ Data is gathered and reported to the registry several times a year
- ◯ Data is gathered and reported to the registry once a year
- ◯ Other

Please specify your answer (frequency and timeline)

## 15. Are the MAR data collected in the national registry reported? [Tick all that apply]

- ☐ Yes, national authorities have an internal live feed of real-time data
- ☐ Yes, periodic reports are published and open to everyone
- ☐ Yes, data is reported to specific third parties (other national or international registries and/or organisations)
- ☐ Yes, in a different way
- ☐ No

Please specify your answer

## 16. Is there a legal obligation to report the MAR data collected in your country? [Tick all that apply]

- ☐ Yes, national reports are mandatory
- ☐ Yes, regional reports are mandatory
- ☐ No

## 17. In addition to the national registry, are there other MAR activity data registries in your country?

- ◯ Yes
- ◯ No

If applicable, please specify what other MAR activity data registries there are in your country

## 18. Is there a national registry for donors in your country?

- ◯ Yes, it is compulsory
- ◯ Yes, it is voluntary
- ◯ No

If applicable, please specify if the donor registry is specific for MAR donors or if it is a general donor registry

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## Type of data collected

The following section is dedicated to gathering your insights on the type and quality of data collected in your country's MAR registry. We are also interested in understanding any potential shortcomings or challenges of the current data collection process in your country.

## 19. What type of MAR data are collected in your country?

- ◯ Aggregated
- ◯ Cycle-by-cycle

## 20. Is there a list of mandatory core parameters that must be collected in the national MAR registry?

- ◯ Yes
- ◯ No

If available, please share the link to the core dataset

## 21. What are the data collected in the national MAR registry used for in your country? [Tick all that apply]

- ☐ Monitoring (efficiency, efficacy, safety, traceability)
- ☐ Policy planning
- ☐ Research and innovation
- ☐ Health services evaluation
- ☐ Other (please specify)

## 22. How would you rate the quality of the data collection in your country?

| | Very good | Good | Acceptable | Weak | Very weak |
|---|---|---|---|---|---|
| Accuracy (The data in the registry are correct, they pass validation checks and can be trusted) | ◯ | ◯ | ◯ | ◯ | ◯ |
| Timeliness (The data in the registry are up to date, there are no major data entry delays affecting the reporting process) | ◯ | ◯ | ◯ | ◯ | ◯ |
| Clarity (The data stored in the registry are presented in a logical order and it is easily accessible for its intended users) | ◯ | ◯ | ◯ | ◯ | ◯ |

## 23. Is there any quality control in data reporting, such as plausibility testing of reported data or external audits?

◯ Yes

◯ No

If applicable, please specify what type of quality control methods there are

## 24. Are there any additional data currently not recorded in the registry that would represent an added value? [Tick all that apply]

☐ Cumulative data (the link of consecutive treatments of the same patient to estimate pregnancy and live birth rate derived from the same oocyte retrieval and the resulting fresh/frozen embryo transfers)

☐ Cross-border data (treatments of patients in countries other than their country of residence)

☐ Demographic data (e.g., educational level, income group, ethnicity, geographic location)

☐ Other (please specify)

## 25. What proportion of MAR treatments performed in your country are included in the national registry?

- ◯ 0-20%
- ◯ 21-40%
- ◯ 41-60%
- ◯ 61-80%
- ◯ 81-99%
- ◯ 100%
- ◯ There are no records of the number of treatments performed

## 26. Are there any difficulties associated with the collection of MAR data? [Tick all that apply]

- ☐ Delays in receiving information
- ☐ Lack of funding
- ☐ Not all clinics and laboratories in the country are reporting to the national registry
- ☐ Insufficient follow up of deliveries and live births
- ☐ Only publicly funded cycles are recorded
- ☐ Not all patients consent to their data being collected
- ☐ Other difficulties
- ☐ No significant difficulties encountered in collecting MAR data

Please describe in your own words what difficulties, if any, are encountered

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## Legal requirements and data access

The following section relates to legal requirements concerning data collection, access to data in the national registry, and any specific measures in place to safeguard the confidentiality and integrity of the collected MAR data in your country.

### 27. What is the level of confidentiality and protection of personal information in the national registry?

- ◯ Data in the registry is anonymised (removing personal identifiers, aggregating data, or processing this data in a way that it can no longer be related to an identified or identifiable individual)
- ◯ Data in the registry is pseudonymised (processing of personal data in such a way that this data can no longer be attributed to a specific individual, without the use of additional information)
- ◯ Data in the registry is non-anonymised

### 28. Who can have full access to the data in the registry? [Tick all that apply]

- ☐ National competent authorities
- ☐ National professional association
- ☐ Other (please specify)

_____

## 29. Are there any restrictions regarding data sharing with third parties?

- ◯ Third parties can be granted full access to the data in the registry when requested
- ◯ Third parties can be granted partial access to the data in the registry when requested
- ◯ Third parties cannot access the data in the registry
- ◯ Other

Please specify which third parties can be granted access to the registry

## 30. Can the patients and donors access their own data in the registry?

- ◯ Both patients and donors can access their own data as collected in the registry
- ◯ Only patients can access their own data as collected in the registry
- ◯ Only donors can access their own data as collected in the registry
- ◯ No, they cannot access their data

## 31. Are there any specific (informed) consent requirements for patients and/or donors in your country regarding data collection and data sharing in registries?

- ◯ Yes
- ◯ No

Please specify if applicable

32. Are there any specific infrastructure/security requirements for health data registries in your country?

- ◯ Yes
- ◯ No

Please specify if applicable

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### EuMAR, European Monitoring of Medically Assisted Reproduction

In this final part of the survey, we would like to know more about your thoughts on the EuMAR project.

33. Do you think that your country would be **willing** to contribute to a cycle-by-cycle European registry?

- ◯ Yes
- ◯ No

If you would like to provide any details to your answer please add them here

34. Do you think it would be **possible** for your country to contribute to a cycle-by-cycle European registry?

- ◯ Yes
- ◯ No

If you would like to provide any details to your answer please add them here

35. Is there anything that you would like to add or comment on that was not covered in the survey?

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## End of the survey

Thank you very much for taking the time to complete this survey.

We highly value your participation and your insights will play a crucial role in our efforts to improve the quality of data collection in the field of Medically Assisted Reproduction. The survey results may be presented in our Stakeholder Event at the end of the year and we will follow up with more information about them and the advancements of the project in the coming months.

We welcome any additional questions and feedback you may have. Please contact us at elena@eshre.eu or eumar@eshre.eu.

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