EuMAR Stakeholder Event – Agenda

10:00 - 10:05	Welcome	*Carlos Calhaz-Jorge*
10:05 – 10:15	The EuMAR Project, rationale, main aims and work packages	*Christine Wyns*
Session 1	The EuMAR project – Laying the basis	*Chairs: Carlos Calhaz-Jorge, Christian De Geyter*
10:15 – 10:30	Work package 3 - NCA survey results and data flow analysis	*Cristina Magli*
10:30 – 10:45	Work package 4 - Defining MAR parameters and ensuring harmonization	*Jesper Smeenk*
10:45 – 11:00	EuMAR's potential to create value for patients	*Bojana Santic*
11:00 - 11:30	Discussion	
11:30 – 12:00	Coffee Break	
Session 2	The EuMAR project – Facing data protection	*Chairs: Jesper Smeenk, Veerle Goossens*
12:00 – 12:15	GDPR considerations for EuMAR (health data registries)	*Jolien Clemens & Ruben Roex (Timelex)*
12:15 – 12:30	Work package 5 - IRCC Concept & EuMAR registry prototype	*Christine Wyns*
12:30 - 13:00	Discussion	
13:00 – 14:00	Networking Lunch	
Session 3	The EuMAR project – The next steps	*Chairs: Christine Wyns, Cristina Magli*
14:00 – 14:15	Work package 6 - Embarking on the next steps with the Pilot Study	*Christian De Geyter*
14:15 – 14:35	EuMAR and the EU SoHO Platform	*DG SANTE*
14:35 – 14:50	Work package 7 - Perspectives of interoperability and innovation	*Jesper Smeenk*
14:50 - 15:20	Discussion	
15:20 – 15:30	Work package 2 - Spreading knowledge: Leveraging project dissemination resources	*Laura Rossignoli*
15:30 – 15:40	Closing remarks	*Carlos Calhaz-Jorge*

Please note changes may occur.

Co-funded by the European Union.

Project: 101079865 — EuMAR — EU4H-2021-PJ2

EuMAR

European monitoring of Medically Assisted Reproduction

www.eshre.eu/eumar

Stakeholder event 5 December 2023

EuMAR by ESHRE

Co-funded by the European Union.

Project: 101079865 — EuMAR — EU4H-2021-PJ2

The EuMAR project, rationale, main aims and word packages

Christine Wyns

EuMAR
by ESHRE

Introduction

- Increased number of individuals and couples seeking medical care for infertility and fertility preservation ≈25 million people in the EU
- Significant impact of MAR on the number of pregnancies and births in EU countries (≈3.1% ranging from 0.9% to 6.3% for ART in 2018)
- Increasing variation/innovation in MAR treatment modalities/technologies

→ Need for surveillance and vigilance to assess MAR treatment efficacy and the safety of procedures

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Introduction

Data collections in MAR across Europe

Eurocet	2005:	→ unknowns on MAR treatment details and consequences for individuals involved
SARE	2008:	→ unknown denominators (= activity data)
EIM	1997:	→ retrospective, aggregated data from a fragmented legislative and socio-economical landscape → contains activity data and SARE (underreported)

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Introduction

EIM data collection: overview on systems/flows

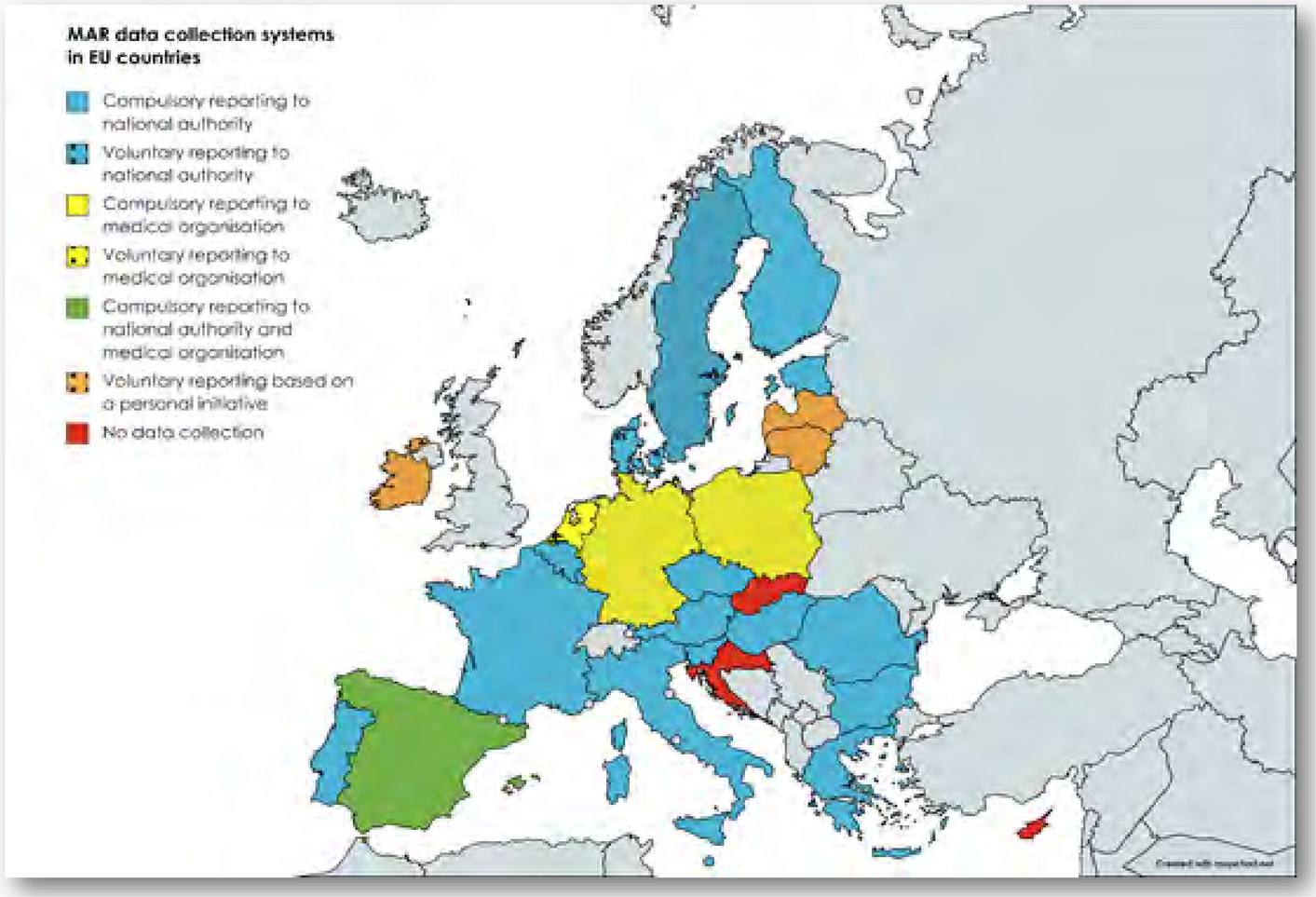

Figure 1: Current MAR data collection systems in EU countries.
Note: "Personal initiative" means that, in countries without a registry, an individual voluntarily takes up the task to collect all the data and report them to the EIM.
Source: EIM data from 2018.

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Introduction

EIM data collection: overview on types of data

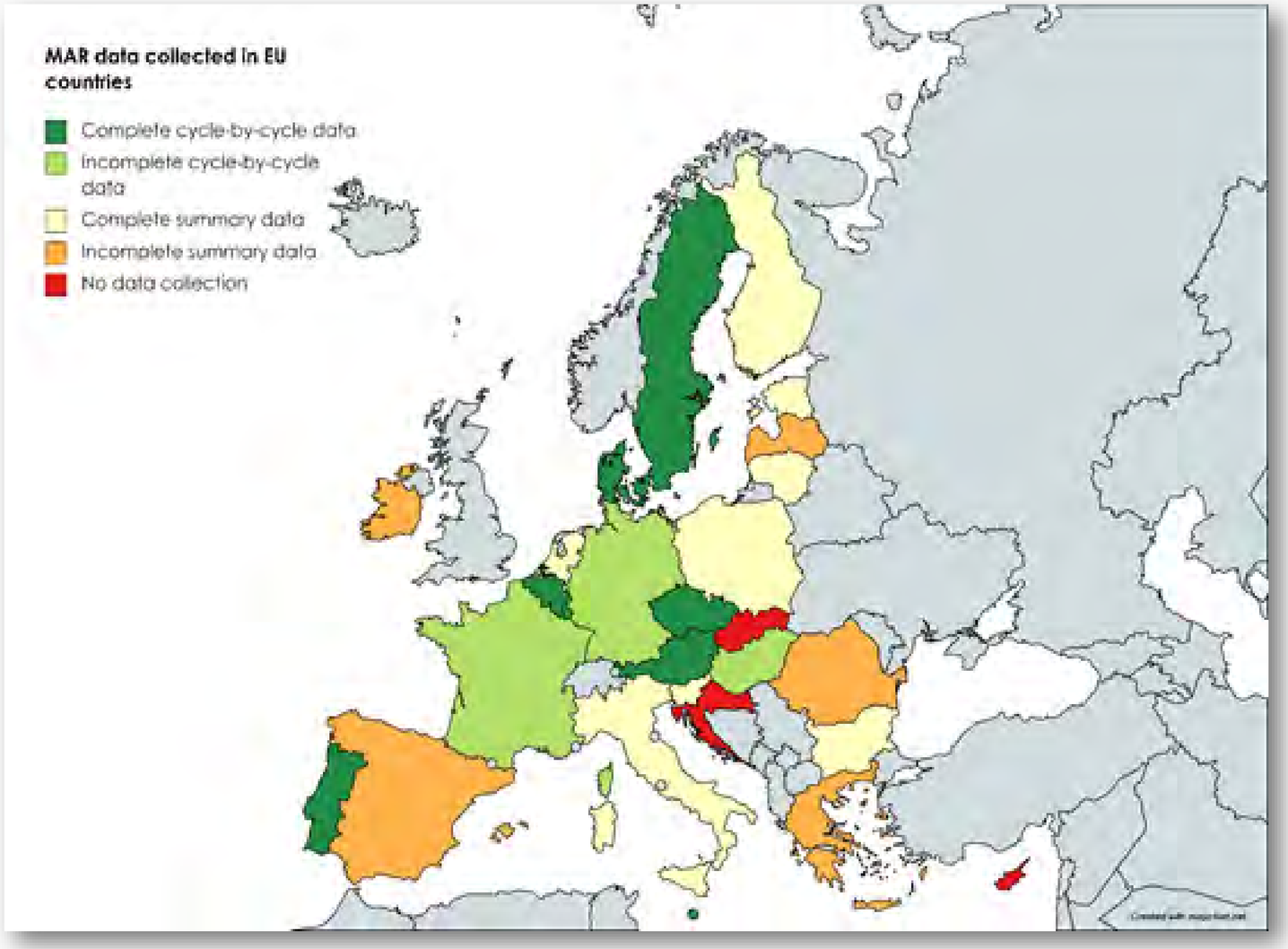

Figure 2: MAR data currently collected in EU countries

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Introduction

International registries in MAR: challenges

Different **data collection systems** and **organisations** that manage data	• Unified approach • Unique European platform
Different **measurement properties**	• Harmonised data
Different **regulations** (e.g. mandatory reporting, socio-economical issues)	• Legal basis (SoHO Regulation)
Different **technological evolutions/innovations**	• Timely uptake
Sequential treatment → **cross-border care/exchange** of biological material	• Identification of procedures linked to the same patient/treatment cycle covering all countries in Europe • Longitudinal follow-up over long periods

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Towards a unified approach of MAR data collection over Europe

The EuMAR project

Aim of the project

To establish the first 'overarching' European, standardised, web-based data registry, containing high-quality cycle-by-cycle data entries from medical professionals across the EU, facilitating data sharing for open science across institutes and allowing the longitudinal and cross-border follow up of medically-assisted reproduction (MAR) data.

- **Type of action:** EU4H-PJG
- **Project coordinator:** European Society of Human Reproduction and Embryology (ESHRE)
- **Timeframe:** start 1 January 2023, running for 3 years
- **Funding programme:** EU4Health

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The EuMAR project: general objectives

- Moving the data collection from retrospective aggregated to prospective cycle-by-cycle
- Making data FAIR for all stakeholders (patients, public, competent authorities at country and EU levels)
- Covering cross-border care
- Achieving full traceability of MAR treatments
- Interoperating with other EU initiatives (SoHO plaform, EHDS) to avoid duplication of work

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The EuMAR project: specific objectives

SO1: Data flow

Develop a **flexible data flow model** that can be implemented in the local contexts of all Member States

SO2: Core parameters

Develop a **list of core, standardised parameters** with corresponding definitions on which data is to be collected

SO3: Technical solution

Establish a transnational web-based data registry to collect and store cycle-by-cycle and case-based harmonised MAR data, including a unique **Individual Reproductive Care Code (IRCC)** for MAR patients

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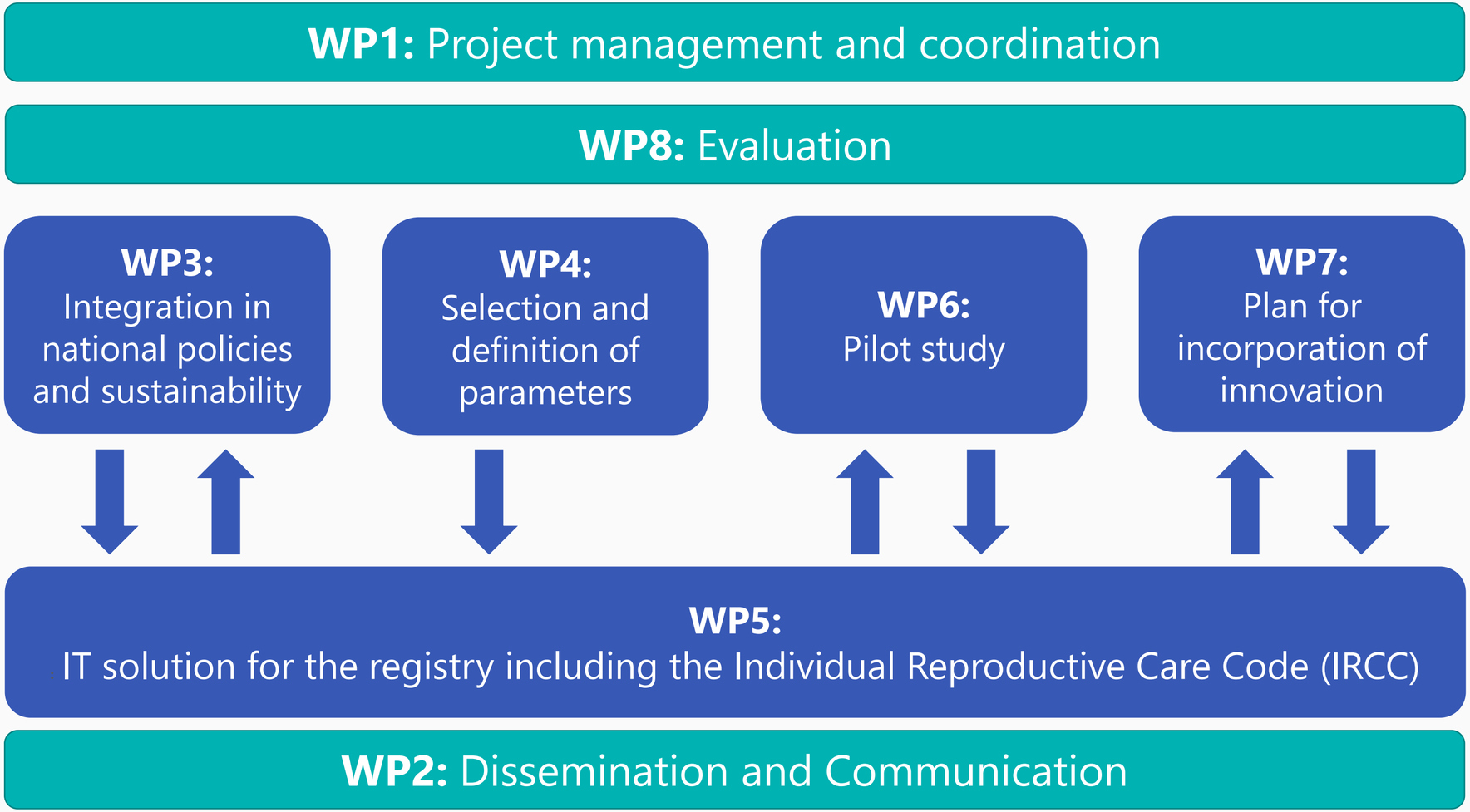
The EuMAR project: 8 work packages



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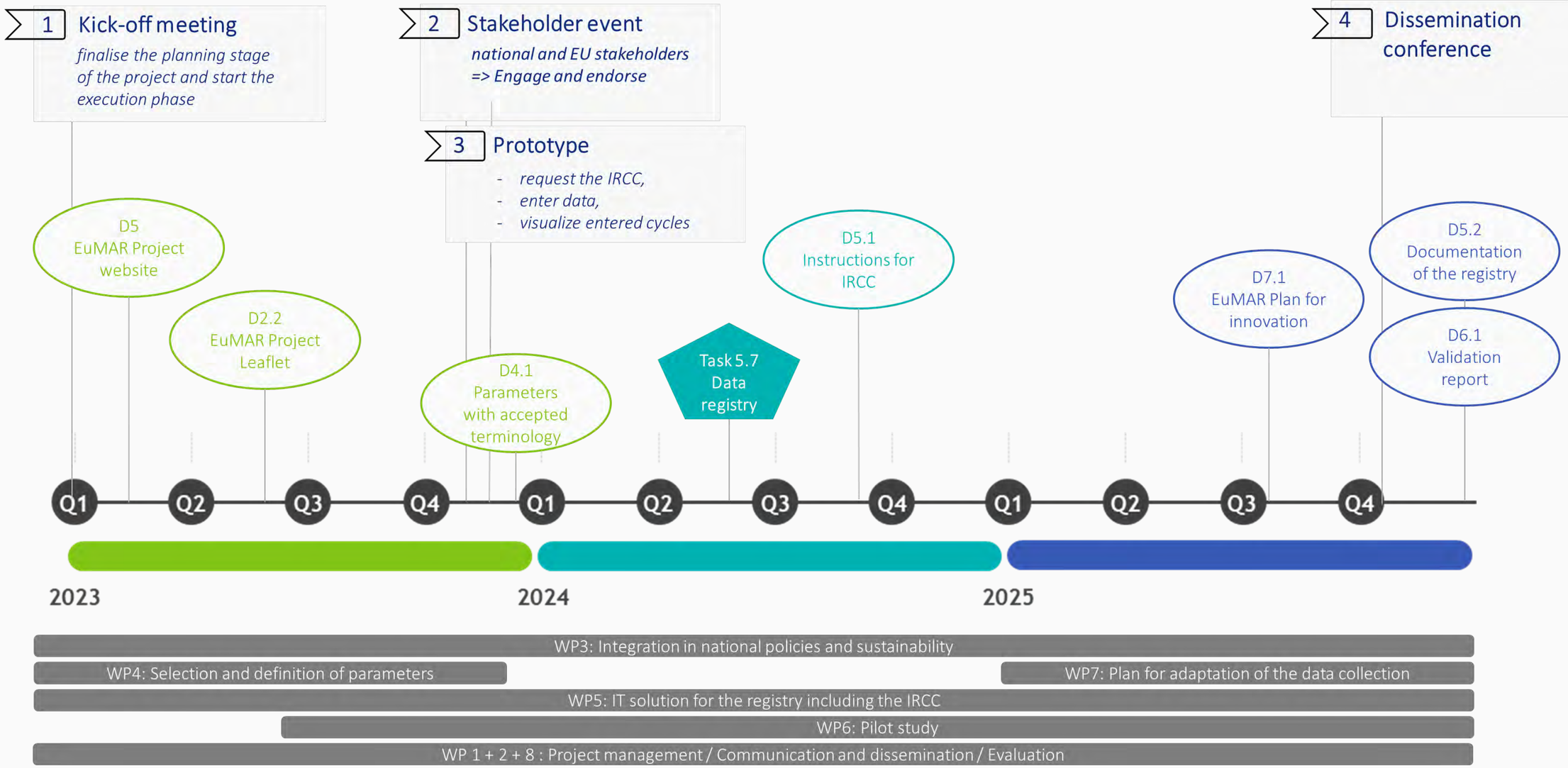
The EuMAR project timeline



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Benefits of EuMAR per stakeholder

Benefit	Stakeholder
Quality assurance Improving performance based on benchmarking (including safety)	Centres
Compliance towards efficient reporting	NCAs
Outcomes (cumulative including cross-border)	Patients Centres NCAs EU
Transparency of data Open science	Patients Centres NCAs Researchers

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Conclusion

EuMAR is designed for MAR data

- acquisition (standardised-centralised)
- use
- sharing

For all stakeholders

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Thank you!

www.eshre.eu/Data-collection-and-research/EuMAR

European Society of Human Reproduction and Embryology

WP3 - NCA survey results and data flow analysis

M. Cristina Magli

Co-funded by the European Union.
Project: 101079865 — EuMAR — EU4H-2021-PJ2

WP3 - Integration in national policies and sustainability

T3.1

Extend existing stakeholder community with national competent authorities and policy makers

T3.2

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

T3.3

Prepare and facilitate national endorsement

T3.4

Write policy recommendations

Main objective

Connect with National Competent Authorities and policymakers to prepare the implementation of the EuMAR data registry, gathering their feedback and examining their needs.

EuMAR by ESHRE

WP3 members

Cristina Magli
WP Leader

Elena Achótegui Sebastián
Project Support

Susanne Hultsch
Project Support

Johanna Tassot
Project Support

Thomas Ebner
WP3 Member

Edgar Mocanu
WP3 Member

Anja Pinborg
WP3 Member

Carlos Plancha
WP3 Member

Nikolaos Polyzos
WP3 Member

Ioana Rugescu
WP3 Member

Thomas Strowitzki
WP3 Member

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Data flow methodology

EuMAR survey

Understand the current MAR data collection processes of all EU Member States to develop a platform tailored to the needs of all relevant stakeholders.

May 2023

Follow-up calls

Semi-structured interviews to define how EuMAR, as an EU-wide, centralised MAR registry, could be integrated into the national context by establishing data flows per country.

October 2023

Target group: institutions managing national registries (National Competent Authorities and national professional associations).

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Data flow methodology

EuMAR survey

35 questions in **5** thematic blocks

- General information
- Information on MAR data collection
- Type of data collected
- Legal requirements and data access
- Perception towards EuMAR

26/27

Member States **completed** the survey

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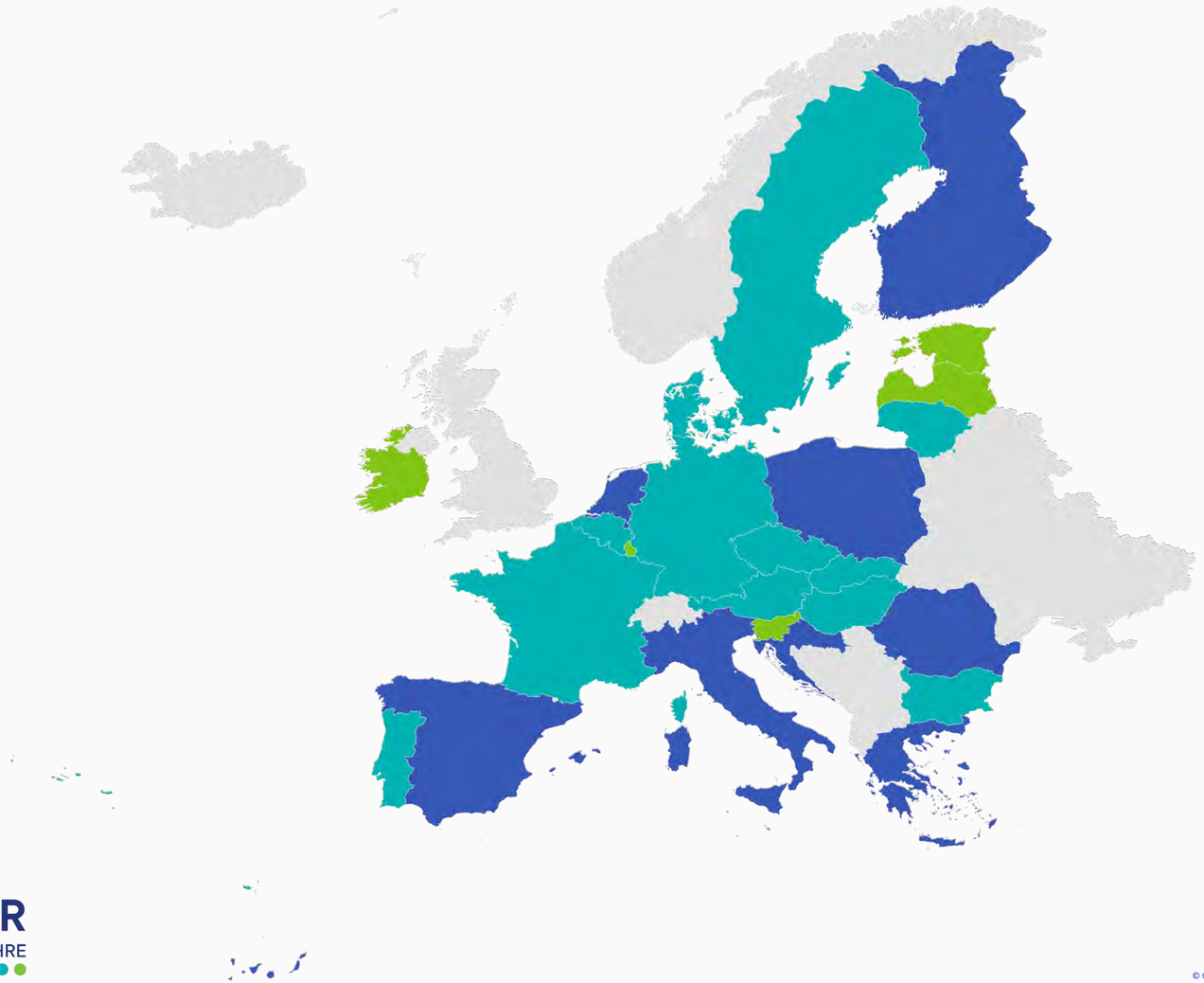
Type of data collected per country



- Cycle by cycle **13**
- Aggregated **8**
- No national registry **5**

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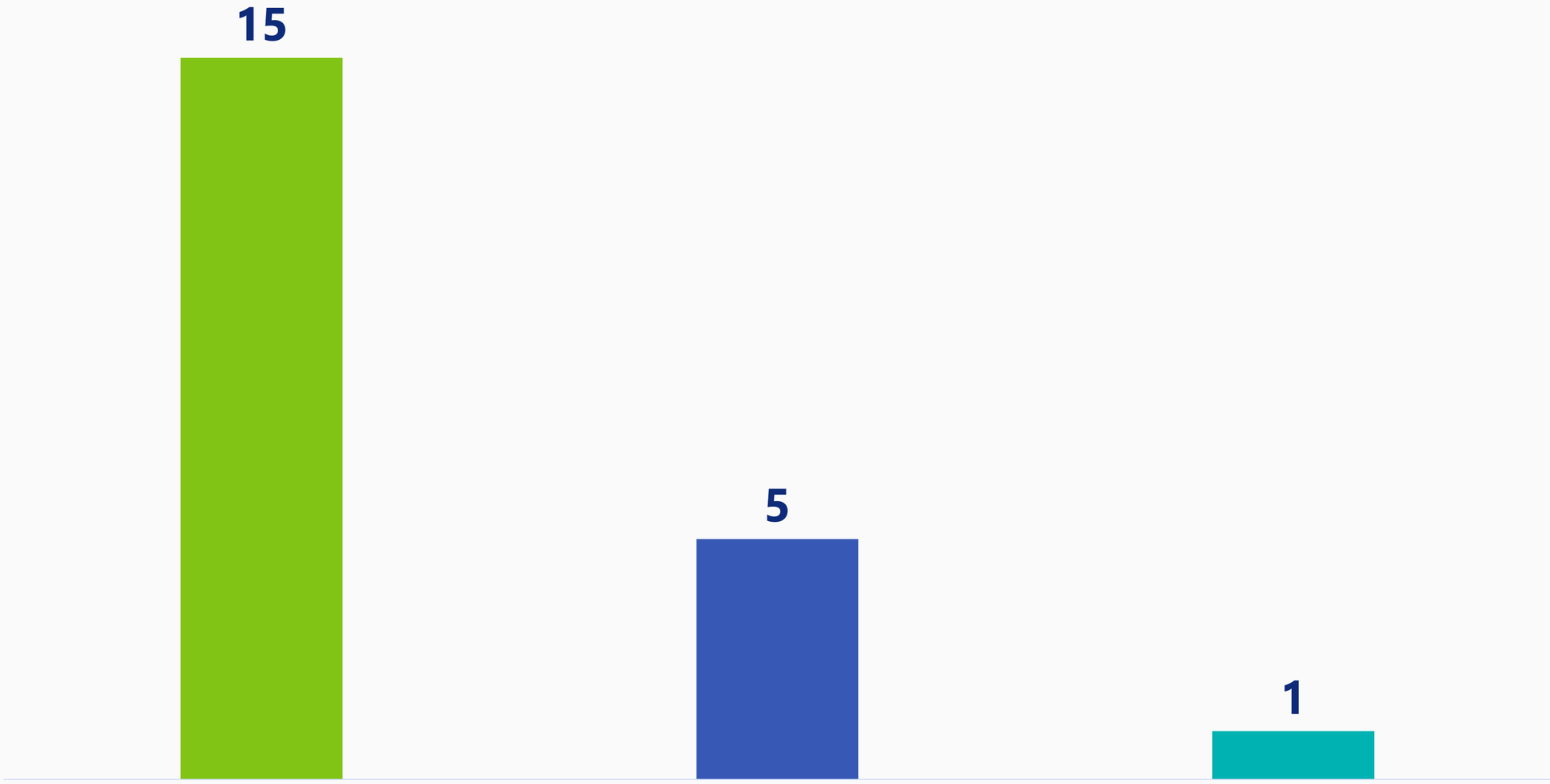
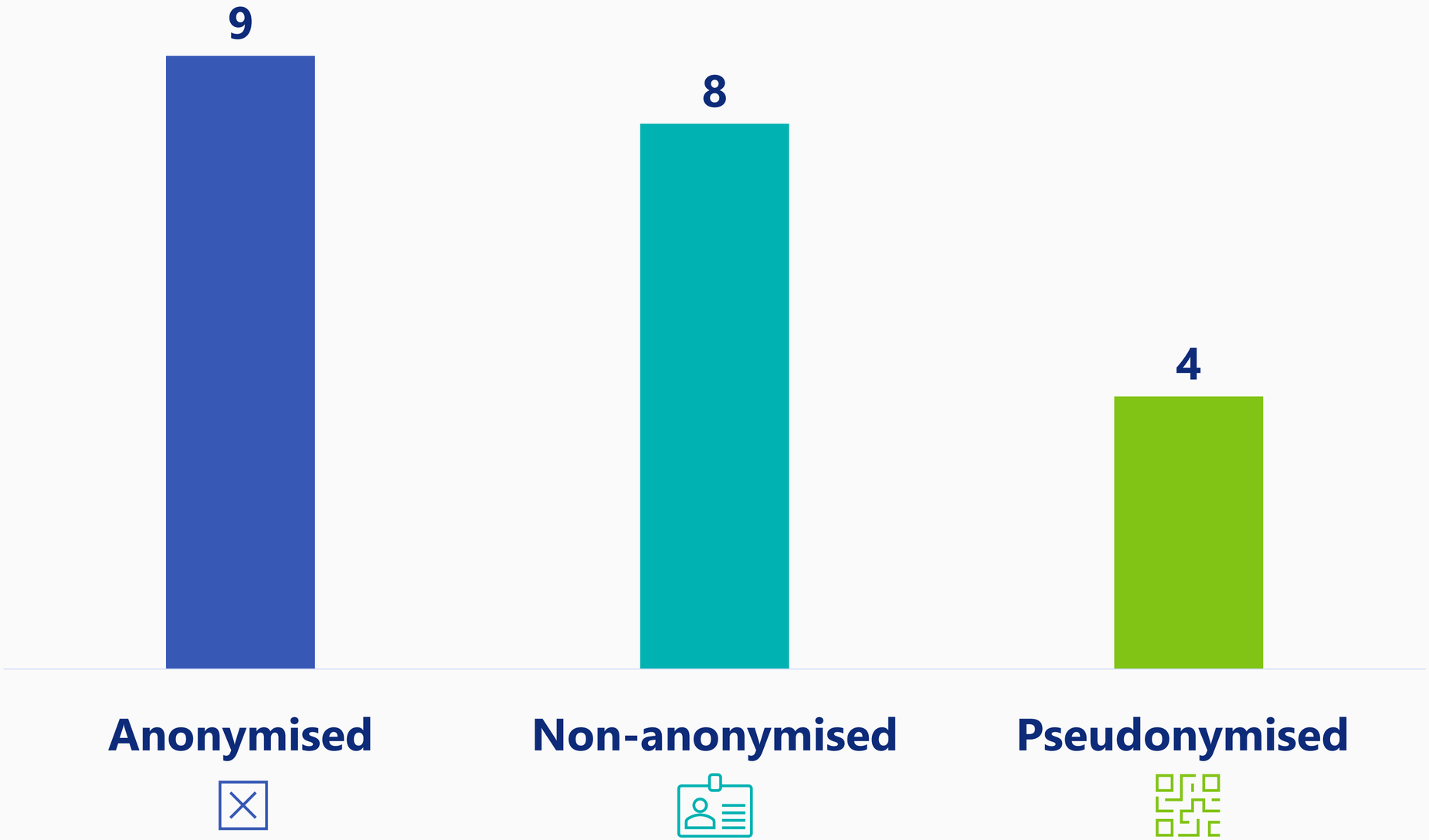
Institutions managing voluntary and mandatory national registries

Tools used to collect MAR activity data



Level of data protection in national registries



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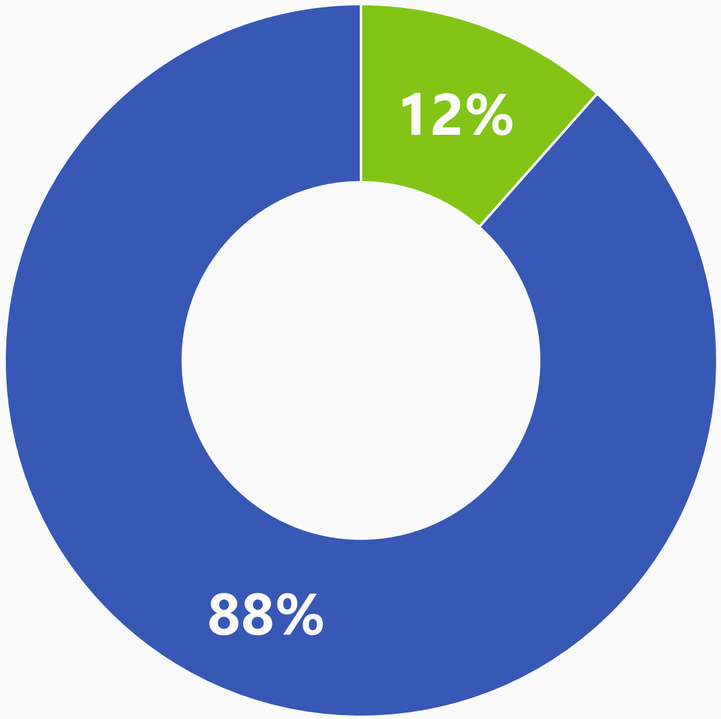
Countries with a national registry that do not collect but would find cross-border data valuable

Perceptions towards EuMAR

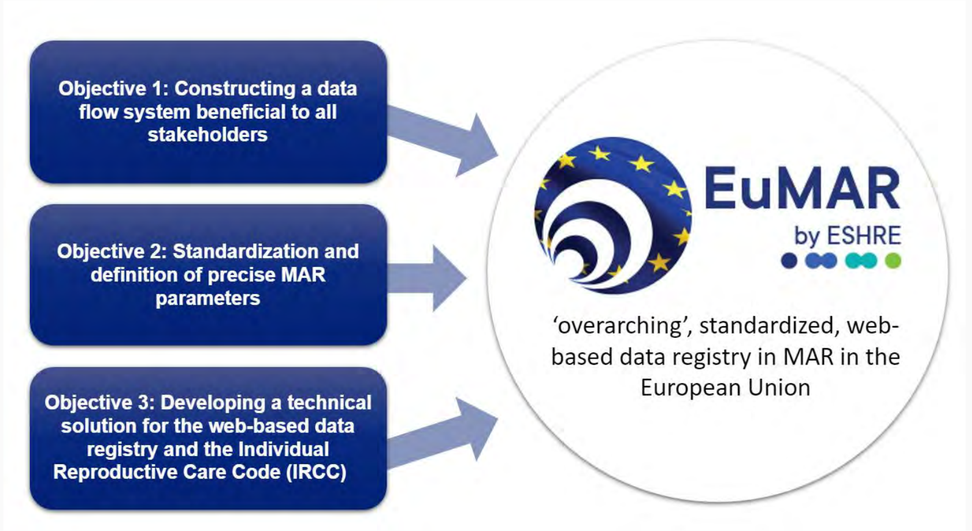


Data Flow

Building a data flow system is EuMAR's Objective 1

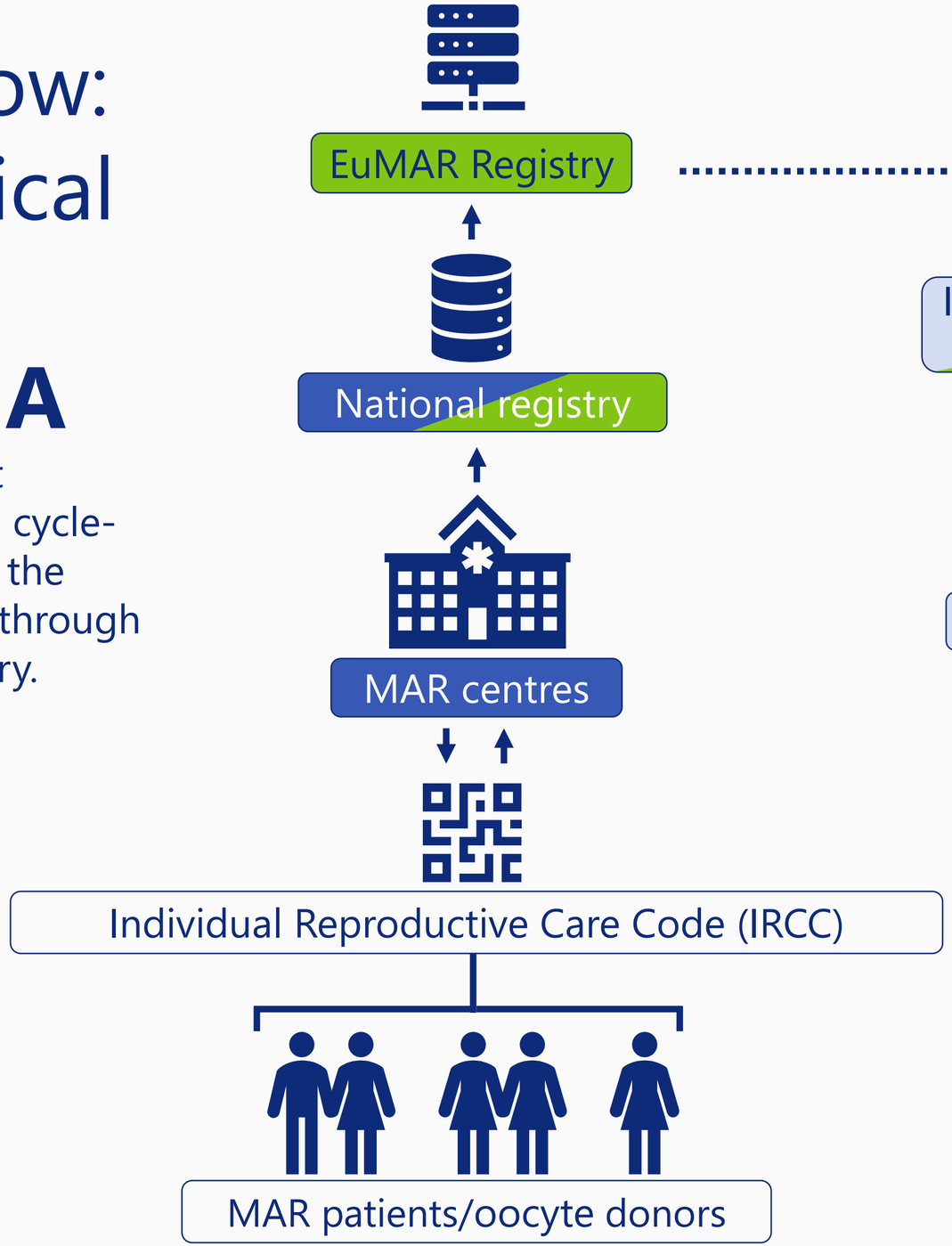
Establishing a model that is compatible with specific country regulations.

Consultations with National Competent Authorities and national professional associations to define the appropriate data flow in each country once the EuMAR registry is adopted.



Data Flow: theoretical model **option A**

Countries report pseudonymised, cycle-by-cycle data to the EuMAR registry through a national registry.



Legend	
	Access to identifiable personal data
	Access to pseudonymised personal data (with IRCC)
	Access to aggregated data only or completely anonymised data only

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Data Flow: theoretical model **option A**

Countries report pseudonymised, cycle-by-cycle data to the EuMAR registry through a national registry.


Austria


Belgium

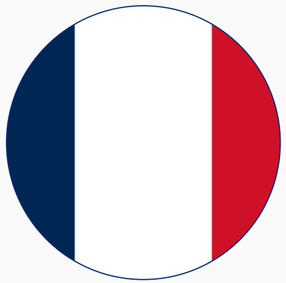

Bulgaria


Croatia


Czech Republic


Denmark

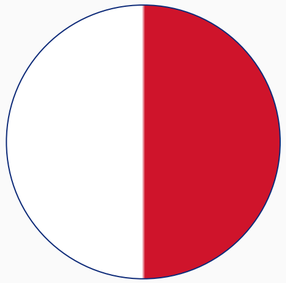

Finland


France


Germany


Hungary


Italy


Malta


Portugal

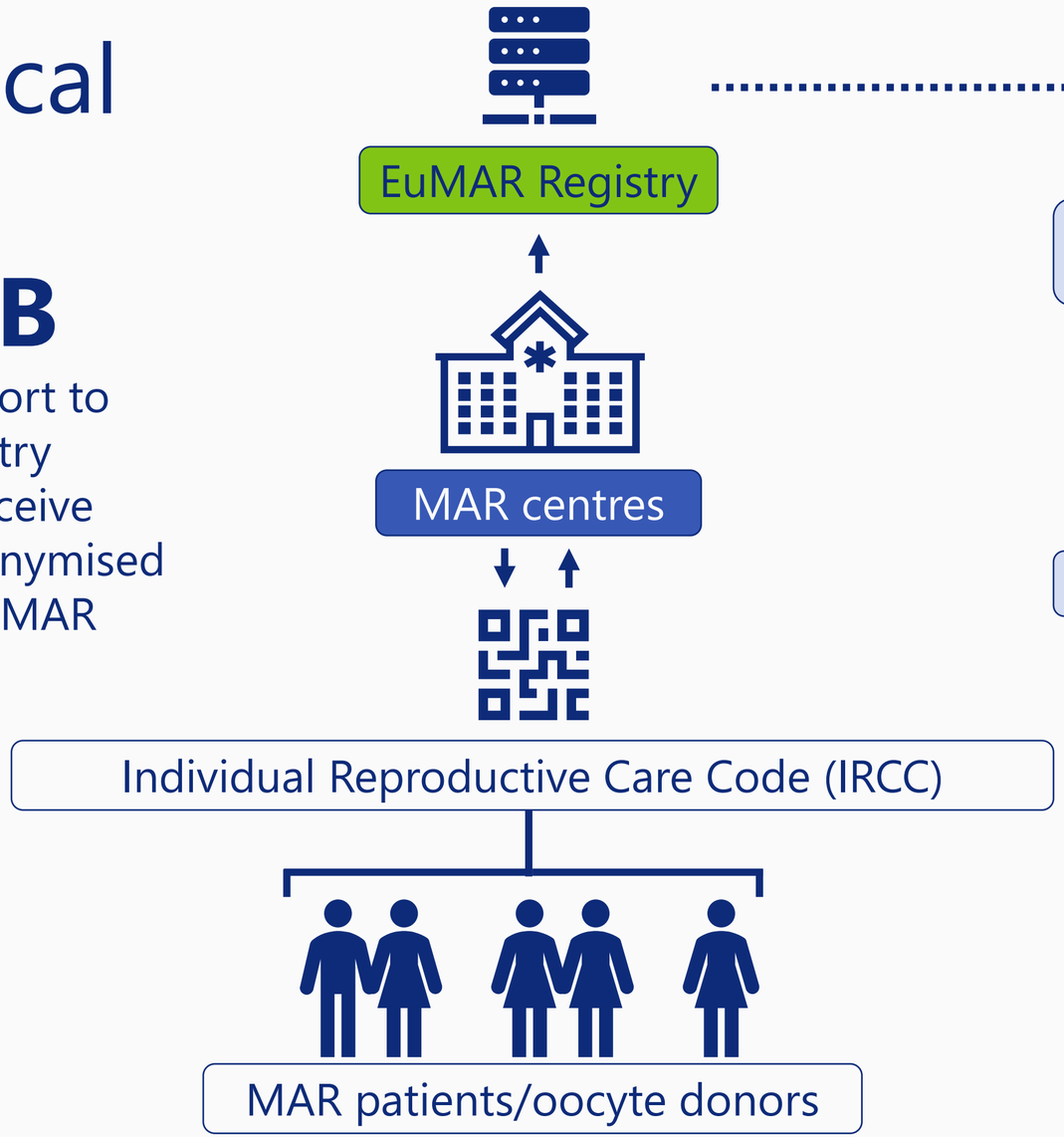

Slovakia

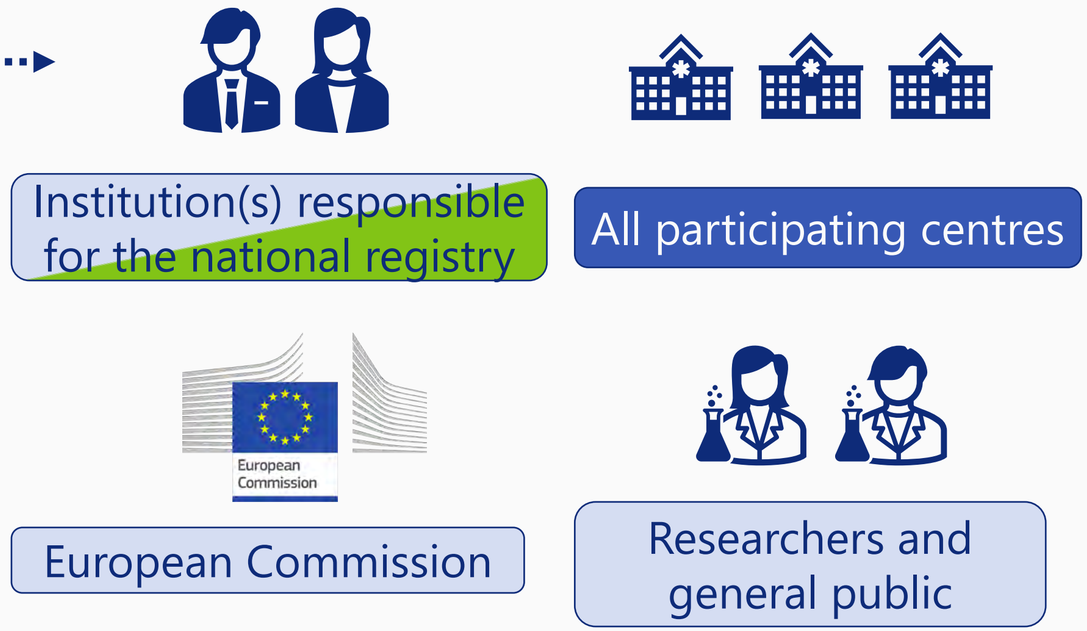

Sweden

EuMAR by ESHRE

Data Flow: theoretical model **option B**

MAR centres report to the EuMAR registry directly. NCAs receive national, pseudonymised data from the EuMAR registry.





Legend	
	Access to identifiable personal data
	Access to pseudonymised personal data (with IRCC)
	Access to aggregated data only or completely anonymised data only

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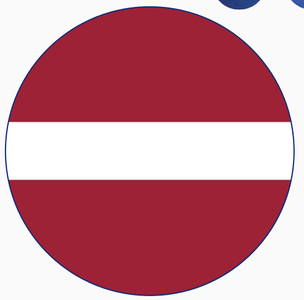
Data Flow: theoretical model **option B**

MAR centres report to the EuMAR registry directly. NCAs receive national, pseudonymised data from the EuMAR registry.


Estonia

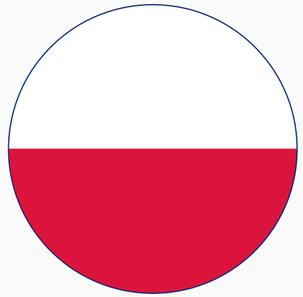

Greece


Ireland


Latvia


Lithuania


Luxembourg


Poland


Netherlands

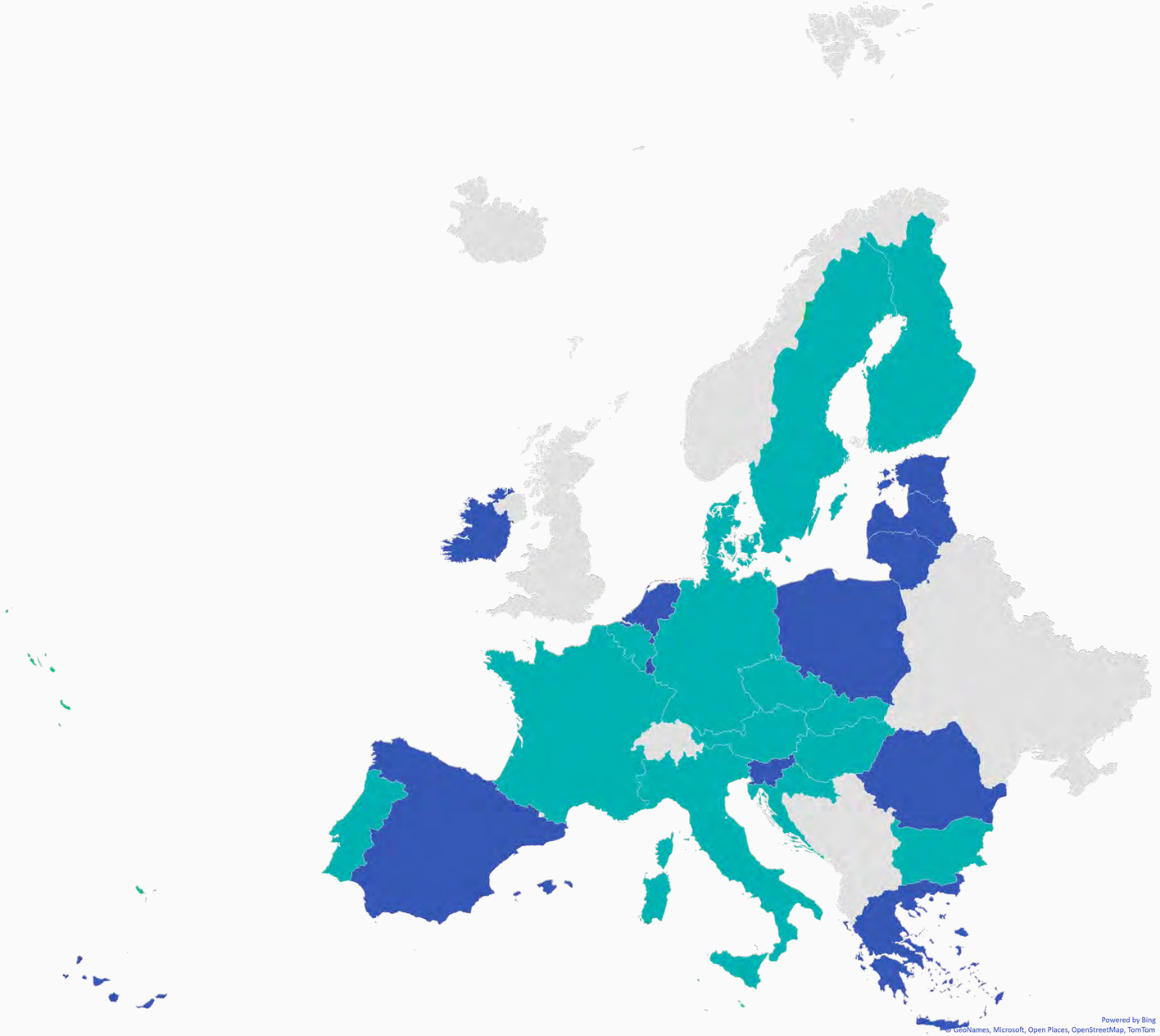

Romania


Slovenia


Spain

EuMAR by ESHRE

Data Flow: theoretical model **Option A and option B countries**



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Thank you!

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Work package 4 – Parameters and definitions

Jesper Smeenk

EuMAR
by ESHRE

WP4 members

Veerle Goossens
Project Support
Belgium

Jesper smeenk
WP Leader
The Netherlands

Susanne Hultsch
Project Support
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Nathalie Vermeulen
WP4 Member
Belgium

Christina Bergh
WP4 Member
Sweden

Janos Urbancsek
WP4 Member
Hungary

Mary Wingfield
WP4 Member
Ireland

Mika Gissler
WP4 Member
Finland

Borut Kovacic
WP4 Member
Slovenia

Roberto De Luca
WP4 Member
Italy

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WP4 : Selection and definition of parameters

Aims

- Identify and define relevant MAR parameters, including fertility preservation (Objective 1)

Specific aims

- To identify relevant items to be registered taking into account the different stakeholders (tissue establishments, country, and EU competent authorities ensuring surveillance and biovigilance, patients/donors).
- To create a glossary of standardised definitions in order to ensure proper data harmonisation.

Tasks

T4.1
- **Characteristics and parameters with accepted terminology**
- By 30 September 2023

T4.2
- **Characteristics and parameters: definition of type, format, and validation conditions**
- By 30 September 2023

T4.3
- **Characteristics and parameters: translation to other languages**
- By 30 December 2023

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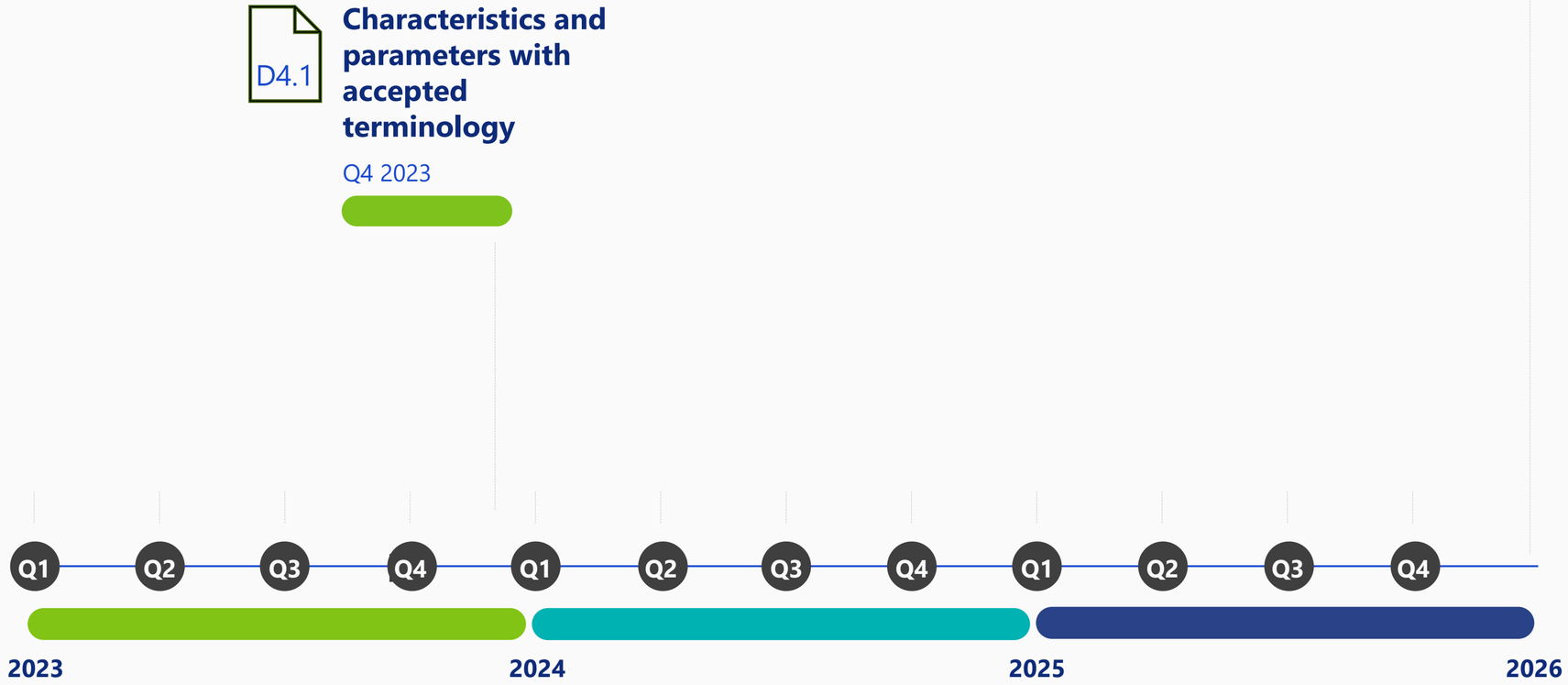
WP4 : Selection and definition of parameters

M1-M12



Milestones

Deliverables

D4.1 - Characteristics and parameters with accepted terminology

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Decision making - timeline

BELRAP

- Starting point dataset

WP4 - meeting

- Decide which registers can further serve as base =>Ex. Portugal, EDQM, ICMART,…
- Add parameters to be collected from other datasets
- Discussion on the relevance of the parameters within the different countries

1st revision

- Parameters discussed during the first meeting were assembled
- All WP4 members revised the document

2nd revision

- Feedback first revision was taken into account
- Parameters to be derived from the register were added
- Document was revised by the chair of the WG and two ESHRE Central Office collaborators

3rd revision

- Definitions and validations were added to the parameter set
- Document was revised by all WP4 members and the Project Steering Committee

Consolidation validations and definitions

- Feedback was taken into account
- Final definitions and validations were added

Final revision

- Document was revised by all WP4 members and the Project Steering Committee
- Final document was sent to eFertility and Timelex

Final documents

- Ready for further endorsement

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Parameters – set-up

Part 1: Parameters to be included in the register

Module 1 – Identification

Module 2 – Patient variables

Module 3 – Cycles with ovarian stimulation

Module 4 – Laboratory data

Module 5 – Embryo transfer

Module 6 – Complications during pregnancy

Module 7 – Pregnancy and outcome

Module 8 – IUI

Module 9 – Fertility preservation

Part 2: Parameters to be derived from the register

9 Modules
64 Parameters

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9 Different modules: 1-2-3

Module 1 - Identification

1. EuMAR IRCC
2. Cycle identification

Module 2 – Patient variables

3. Country of current residence
4. Female Date of Birth
5. Female Body Mass Index (BMI)
6. Female current smoking status
7. Male Date of Birth
8. Male Body Mass Index (BMI)
9. Male current smoking status
10. Indication for treatment

Module 3 – Cycles with ovarian stimulation

11. Ovarian stimulation
12. Date of start cycle
13. Treatment Protocol
14. Cancellation prior to Ovum Pick Up (OPU)
15. OPU Cancellation cause
16. Date of ovum pick-up
17. N of cumulus oocytes retrieved
18. In-vitro maturation (IVM)
19. Number of oocytes cryopreserved
20. Reasons for oocyte cryopreservation
21. Number of oocytes donated

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9 Different modules: 4-5

Module 4 – Laboratory data

22. Source of sperm
23. Source of oocytes
24. Date of insemination
25. Insemination technique
26. N of oocytes inseminated (IVF)
27. N of oocytes injected (ICSI)
28. N of 2 pronuclei (2pn) – IVF
29. N of 2pn – ICSI
30. N of embryos developed (IVF and ICSI)
31. Total N of embryos cryopreserved
32. Optional: N of cleavage stage embryos cryopreserved
33. Optional: N of blastocysts cryopreserved
34. Reasons for embryo cryopreservation
35. Pre-implantation Genetic Testing

Module 5 – Embryo transfer

36. Embryo transfer
37. Embryo transfer with:

Use of fresh embryos

38. Date of embryo transfer
39. Number of cleavage stage embryos transferred
40. Number of blastocysts transferred.
41. Embryo Transfer Outcome

Use of frozen embryos

42. Date of thawing
43. Frozen embryo transfer protocol (FET)
44. Embryo Transfer
45. Date of embryo transfer (link to OPU if available)
46. Number of cleavage stage embryos transferred
47. Number of blastocysts transferred
48. Embryo Transfer Outcome
49. Cause of no embryo transfer

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9 Different modules: 6-7-8-9

Module 6 – Complications during pregnancy

50. Complications
51. Causes

Module 7 – Pregnancy and outcome

52. Highest number of intra-uterine gestational sacs on ultrasound scan
53. Details of twin pregnancy
54. Fetal reductions
55. Pregnancy outcome
56. Date of delivery
57. N of children born
58. of stillbirths

Liveborn Child 1

59. Sex
60. Birth weight
61. Neonatal outcome
62. Neonatal malformations

Questions for every liveborn child
Child 2/3

Module 8 - IUI

Parameters 4/5/6/7/9/18/19/20/21/

- Indications
- Age male/female
- BMI/smoking
- Stimulation
- Own/donor sperm

Link to complications and pregnancy

Module 9 – Fertility preservation

63. Method of fertility preservation
64. Reason for fertility preservation

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Details parameters

Module 2 – Patient variables

1. **Country of current residence**

   Validation cell: drop down list
   Validation crosslink: /
   Definition:
   Residence: The place where one actually lives, which may be different from one's domicile.
   (https://www.law.cornell.edu/wex/residence#:~:text=1.,to%20residents%20of%20the%20state.)

2. **Indication for treatment**

   a. Female

      a. Unexplained infertility
      b. Tubal pathology
      c. Ovulatory disorder
      d. Endometriosis
      e. Psychosexual (can be an indication for IUI and occasionally IVF)
      f. Premature Ovarian Insufficiency (POI)/oocyte issue (these are women who need donor eggs)
      g. Uterine absence or dysfunction (female who needs surrogacy)
      h. Medical contraindication to pregnancy (surrogacy for medical disorders)
      i. Other

   a. Male

      a. Unexplained
      b. Sperm factor
      c. Psychosexual (can be an indication for IUI and occasionally IVF)
      d. Other

   a. Relationship status

      a. No male partner (same-sex and single women)
      b. No female partner (same-sex and single males)

   a. Genetic reasons

      a. Genetic disorder (Need Preimplantation Genetic Testing - PGT)

Module 2 – Patient variables

Validation cell: tick boxes, multiple options possible on the different levels
Validation crosslink: Depending on whether you tick Female/male/… different list of options appears
Combinations possible (eg female + male or male + genetic reason,…)

Definitions:
Unexplained infertility: Infertility in couples with apparently normal ovarian function, Fallopian tubes, uterus, cervix and pelvis and with adequate coital frequency; and apparently normal testicular function, genito-urinary anatomy and a normal ejaculate. The potential for this diagnosis is dependent upon the methodologies used and/ or those methodologies available (IG)

Tubal pathology: Tubal abnormality resulting in dysfunction of the Fallopian tube, including partial or total obstruction of one or both tubes (proximally, distally or combined), hydrosalpinx and/or peri-tubal and/or peri-ovarian adhesions affecting the normal ovum pick-up function. It usually occurs after pelvic inflammatory disease or pelvic surgery. Tubal disease due to endometric adhesions is classed as endometriosis. (IG)

Ovulatory disorder: a group of disorders in which ovulation fails to occur or occurs on an infrequent or irregular basis. Ovulatory disorders are one of the leading causes of infertility.
Shadygrovefertility.com/infertility-causes/ovulatory-disorder
PCOS guideline ?

Endometriosis: A disease characterized by the presence of endometrium-like epithelium and stroma outside the endometrium and myometrium. Intrapelvic endometriosis can be located superficially on the peritoneum (peritoneal endometriosis), can extend 5 mm or more beneath the peritoneum (deep endometriosis) or can be present as an ovarian endometriotic cyst (endometrioma) (IG)
Guidelines

Premature Ovarian Insufficiency (POI): A condition characterized by hypergonadotropic hypogonadism in women younger than age 40 years (also known as premature or primary ovarian failure). It includes women with premature menopause.

Uterine absence or dysfunction (female who needs surrogacy - males needing surrogacy): congenital anomalies, adenomyosis

Medical contraindication to pregnancy (surrogacy for medical disorders eg severe renal disease, heart disease, Turner syndrome, …):

Genetic disorder (Need PGT): An inherited medical condition caused by a DNA abnormality.

Surrogacy: gestational carrier

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Parameters – set-up

Part 2: Parameters to be derived from the register

Totals

Timeframes

Rates

Cumulative rates

Part 2: Number of Parameters

25 parameters

# of treated individuals	# of individual persons that had at least one treatment cycle intervention (IUI, IVF/ICSI and/or FET) completed
Age of the individual	Date of start cycle minus date of birth
# of couples that had at least one treatment cycle intervention (IUI, IVF/ICSI and/or FET) completed	# of couples that had at least one treatment cycle intervention (IUI, IVF/ICSI and/or FET) completed
# of treatment cycles without stimulation	# of cycles without ovarian stimulation (includes hormone substituted cycles) that ended up with one of the interventions
Cumulative pregnancy rate	The number of oocyte retrievals resulting in at least 1 clinical pregnancy within 1 year of the oocyte retrieval cycle divided by the total number of oocyte retrieval cycles that had at least 1 fresh or frozen embryo transfer.

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by ESHRE

Thank you!

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European Society of Human Reproduction and Embryology

ESHRE EuMAR Stakeholder Event

Brussels, 5 December 2023

On Perspectives: Revealing EuMAR

EuMAR's Potential to Create Value for Patients

Bojana Santic, Croatia

On Perspectives: Revealing EuMAR

More than 25 million citizens

1 in 6

Up to 10% of children

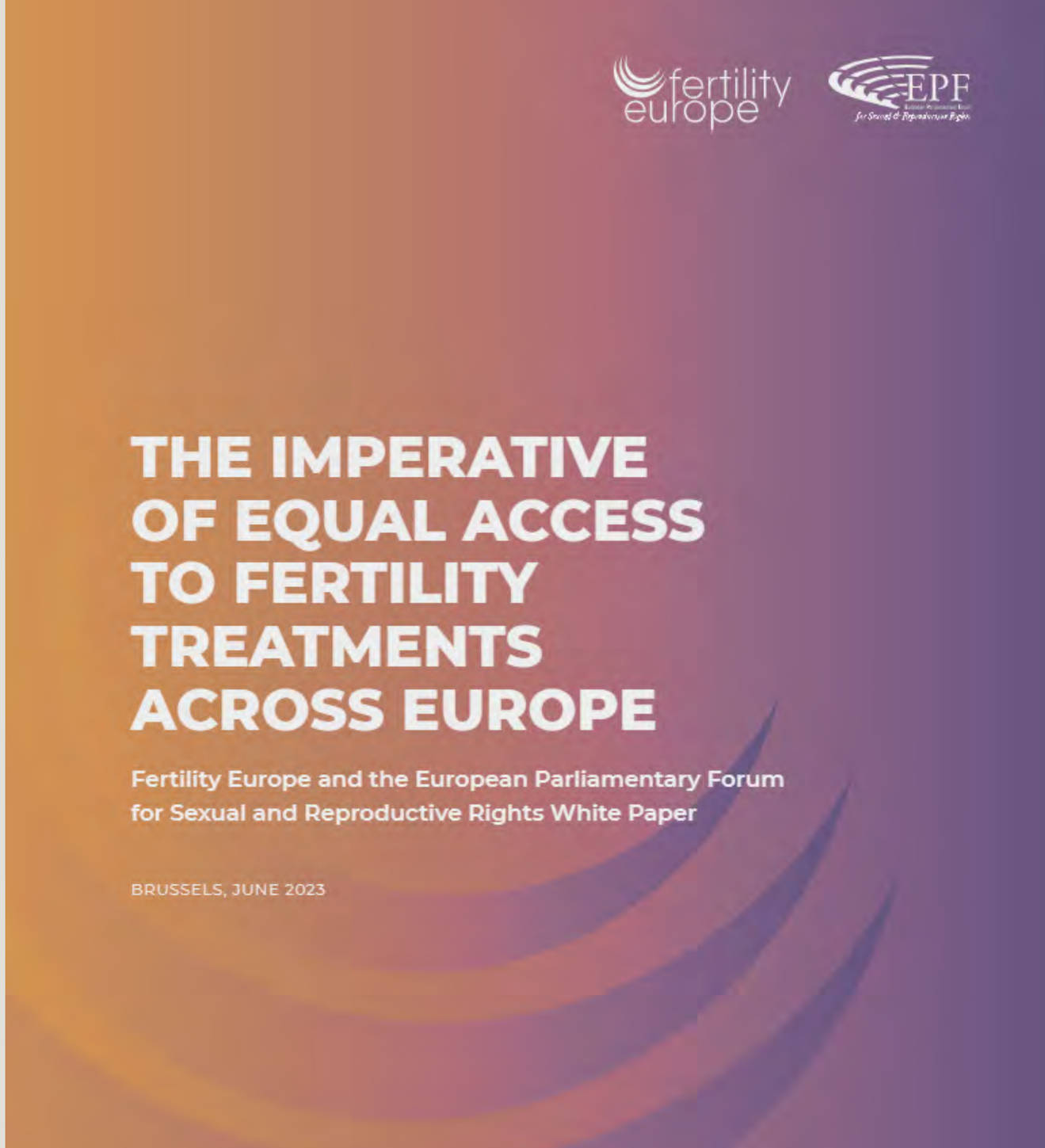
Your story

My story

Access to treatment vs. practice

Anonymous donation
vs. child rights

“The needs and life goals of potential and intended parents should be acknowledged and accommodated in a broad interdisciplinary aspect of medical and socio-economic care.”



12 recommendations for European policymakers

1. Creating safe and inclusive regulations considering the rights of all parties

3. Establishing and maintaining a legal obligation for EBM treatments

12. Creating a central and mandatory European register

Disclosing success rates, costs, and potential risks fosters a culture of transparency

EuMAR

Transparency

Standardisation

Patient-center approach

Recommendation 1

Creating Safe and Inclusive Regulations

Cumulative & Cross-Border Follow-Up

Transparency of Data

Recommendation 3
Establishing and maintaining a legal obligation for EBM treatments

Standardization

Transparency of Data

Quality Assurance (Benchmarking)

Cumulative & Cross-Border Follow-Up

Patient-Centered Approach

Recommendation 12

Creating a Central and Mandatory European Register

“A view from outside”

EuMAR aims to bring transparency, standardisation, and a patient-centered approach to the European landscape of medically assisted reproduction

On Perspectives: Revealing EuMAR

EuMAR's Potential to Create Value for Patients

Brussels, 5 December 2023

Thank you

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Photo courtesy of: Pexels, Pixabay, private album

TIMELEX

GDPR CONSIDERATIONS FOR EUMAR (HEALTH DATA REGISTRIES)

EuMAR Stakeholder event

5 December 2023

Ruben Roex & Jolien Clemens

LEADING BELGIAN NICHE LAW FIRM

- Information technology
- Privacy & data protection
- Intellectual property
- Media & entertainment
- Policy & legislation
- Research & innovation

Sources say:

“High marks for expertise and prompt, well-executed work.”

“In data protection, I doubt that there are other firms more aware of the key compliance and regulatory issues than this firm.”

“This TMT boutique is highly praised for its IT and data protection expertise.”

RANKED IN Chambers EUROPE 2021

The LEGAL 500 EMEA TOP TIER 2021

TIMELEX

PERSONAL DATA IN EUMAR?

Question: can the IRCC be considered personal data?

IRCC IN EUMAR

- Data collected in EuMAR is registered using **an Individual Reproductive Care Code (IRCC)**
  - Patient is not identifiable in EuMAR
  - The code used in EuMAR differs from the IRCC that the national registry and/or MAR centre uses to register cycle data
  - The EuMAR registry does not save any data that would make it possible to identify the patient

THE CONCEPT OF PERSONAL DATA IN THE GDPR

- **Personal data (article 3 GDPR):** information relating to an identified or identifiable person
  - So, also data that relates *indirectly* to a person
- **Possibility of identification (recital 26 GDPR)**: you must take into account all means that can be reasonably used by the controller or by another person to identify the person directly or indirectly
  - The question is whether any party may be able to identify the person
- **Extremely broad definition**

DEFINITION OF PERSONAL DATA IN CASE LAW OF COURT OF JUSTICE

- Previous case law

Nowak case

personal data is ‘personal’ if by means of their content, purpose or effect it can be linked to an identifiable natural person

Breyer case

IP-address is considered personal data for a website owner if it has legal means to access identifying data from the internet service provider (ISP) → the identifiable information was held by a third party

NEW APPROACH IN CASE LAW OF THE COURT OF JUSTICE (2)

EDPS v. SRB case

- Facts
  - **The Single Resolution Board (SRB)** adopted a resolution scheme for Banco Popular Espanol
  - The affected shareholder could provide comments on this resolution scheme
  - **Phase 1 of feedback**: registration via online registration form (including proof of identity and ownership of capital instruments)
  - **Phase 2 of feedback**: unique link to an online form containing questions
  - Submitted forms linked to an alphanumeric code
  - **Deloitte** was used as external valuer → did not receive the information to link the comments to the individual
- Question: does the information that was provided to Deloitte constitute personal data?

NEW APPROACH IN CASE LAW OF THE COURT OF JUSTICE (3)

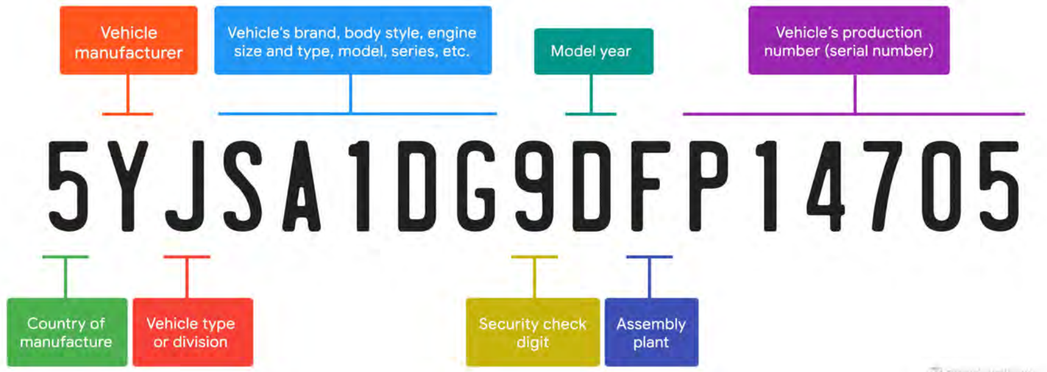
EDPS v. SRB case

- Findings of the ECJ:
  - The assessment of the identifiability should be done from *the perspective of the data recipient* (in this case = Deloitte)
  - It should be assessed whether Deloitte had any legal means to get the additional information held by SRB to re-identify the data subjects

NEW APPROACH IN CASE LAW OF THE COURT OF JUSTICE (4)

Gesamtverband Autoteile-Handel V. Scania

- Facts:
  - Vehicle manufactures must provide certain vehicle data to other market players based on a legal obligation in EU law
  - **Vehicle Identification Number (VIN):** related to anyone who owns or drives the respective vehicle
- Question: does the VIN qualify as personal data?



NEW APPROACH IN CASE LAW OF THE COURT OF JUSTICE (5)

Gesamtverband Autoteile-Handel V. Scania

- Findings
  - The VIN can be considered personal data when someone who has access to it has the means to identify the owner of the vehicle
  - Owner is indicated in the registration certificate

WHAT DOES THIS MEAN FOR EUMAR? (1)

Arguments to conclude that the IRCC is not personal data:

1. MAR patients cannot be identified by ESHRE in EuMAR
2. ESHRE does not have the legal means to identify the MAR patient because the information to identify the MAR patient is held by the clinics
3. The data that is entered in EuMAR is pre-defined (no free text fields)

WHAT DOES THIS MEAN FOR EUMAR? (2)

- No legal basis needed for maintaining EuMAR for ESHRE
- Data subject rights will not apply for ESHRE
- No storage limitation periods will be applicable

ANY QUESTIONS?

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Work package 5 – IT solution for the registry including the IRCC

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EuMAR by ESHRE

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EuMAR
by ESHRE

WP5: IT solution for the registry including the IRCC

Aim:

- Develop the IRCC and a web-based transnational IT solution able to ensure the prospective collection of cycle-by-cycle and case-based harmonized data sets (Objective 2)

Specific aims:

- To develop an **IT solution for the IRCC** and supplement it with a **manual** for MAR services offering centres on how to use it, together with **educational information for patients/donors and professionals.**
- To enable **the web-based transnational IT solution** which ensures the prospective collection of cycle-by-cycle and case-based harmonized data sets. Starting with **documentation** and a **prototype**, followed by the data registry and, finally, the **output tools** (data visualization tool and patient portal).
- To ensure that the system can **link together different steps of the sequential MAR treatment** that may span long time intervals so that a **cumulative outcome** report (per patient) can be generated.

Tasks:

- ❑ Data protection Impact Assessment→ Timelex
- ❑ Roadmap for the registry
- ❑ Prototype of software for the data registry
- ❑ Prototype – proof of concept
- ❑ EuMAR patient/donor portal set-up
- ❑ Set up of output options for stakeholders
- ❑ Data registry
- ❑ Documents and agreements for implementation of the data registry
- ❑ Documentation of the registry
- ❑ Training and support for users

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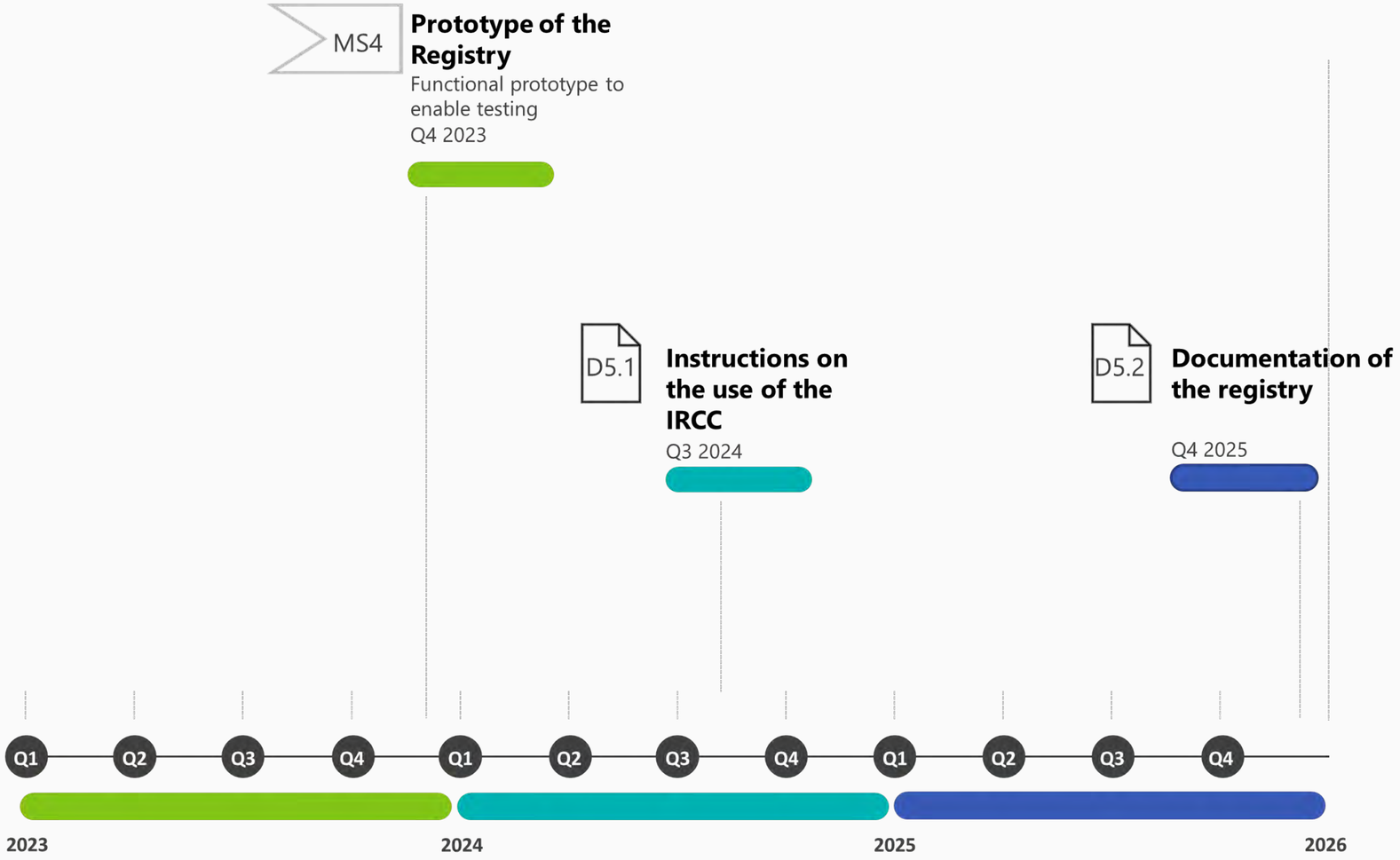
WP5: IT solution for the registry including the IRCC

M1-M36



Milestones

MS4 - Prototype of the Registry

Deliverables

D5.1 - Instructions on the use of the IRCC

D5.2 - Documentation of the registry

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Individual reproductive care code (IRCC)

Why do we need it ?

Unique patient indentifier to follow the patients (and all their reproductive material) through their treatment process across care providers in Europe

→ Enables a prospective follow-up of segmented treatment steps and their outcomes in different institutions across Europe

→ Allows calculation of cumulative data (linking consecutive treatment cycles)

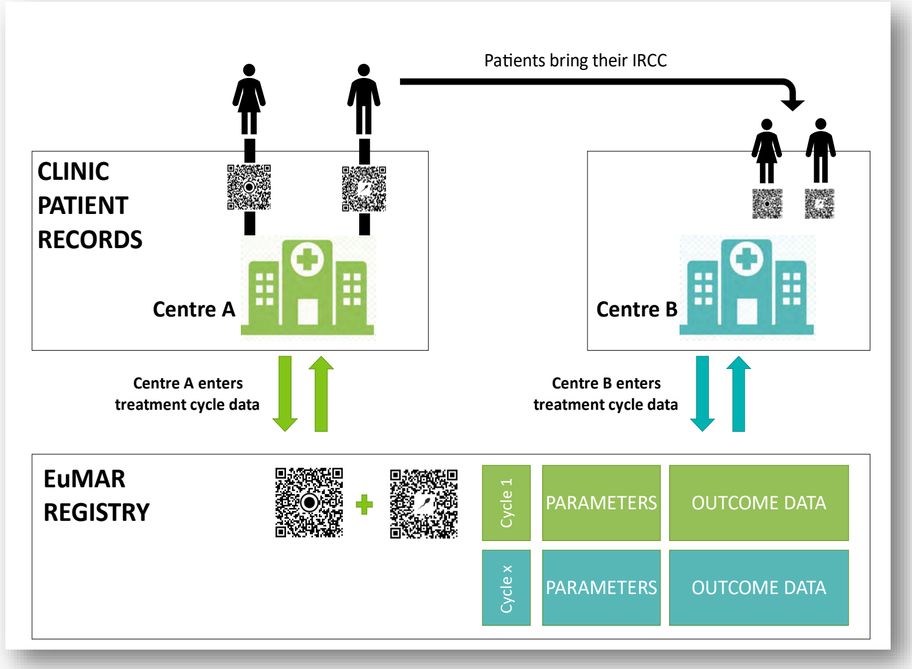

Figure 5 Integration of the Individual Reproductive Care Code (IRCC) in clinical practice; Patients can bring their IRCC from clinic A to clinic B which allows for collection of data in the EuMAR registry of data on cross-border or interinstitutional migration of infertile patients.

EuMAR
by ESHRE

IRCC generation and use: why is it safe?

Requirement

• Analyses can be performed without the risk that data is identifiable to individuals.

•The solution should be GDPR proof:

- Data can not be **(in)directly** traced back to personal information.
- No personal data such as name, address, security number, etc. is stored in the EuMAR registry.

IT solution

Creation of a Secure coding algorithm (‘black box’*).

- **IRCC** obtained by the clinic is not stored in EuMAR database.
  → IRCC codes in EuMAR can not trace back individual patients.
- Clinics store a **EuMAR code** in the patient’s medical record.
- IRCC codes are linked to the login of the clinic and are not the same in different EMR systems/clinics.
- The IRCC will automatically renew per clinic change: request for **transfer code.**
  → No link between patients’ treatments in different clinics.

Use of a state-of-the-art encryption technology/algorithm → even in a theoretical situation of decryption data is not traceable to a real person because codes in the EMR system and EuMAR system will be different.

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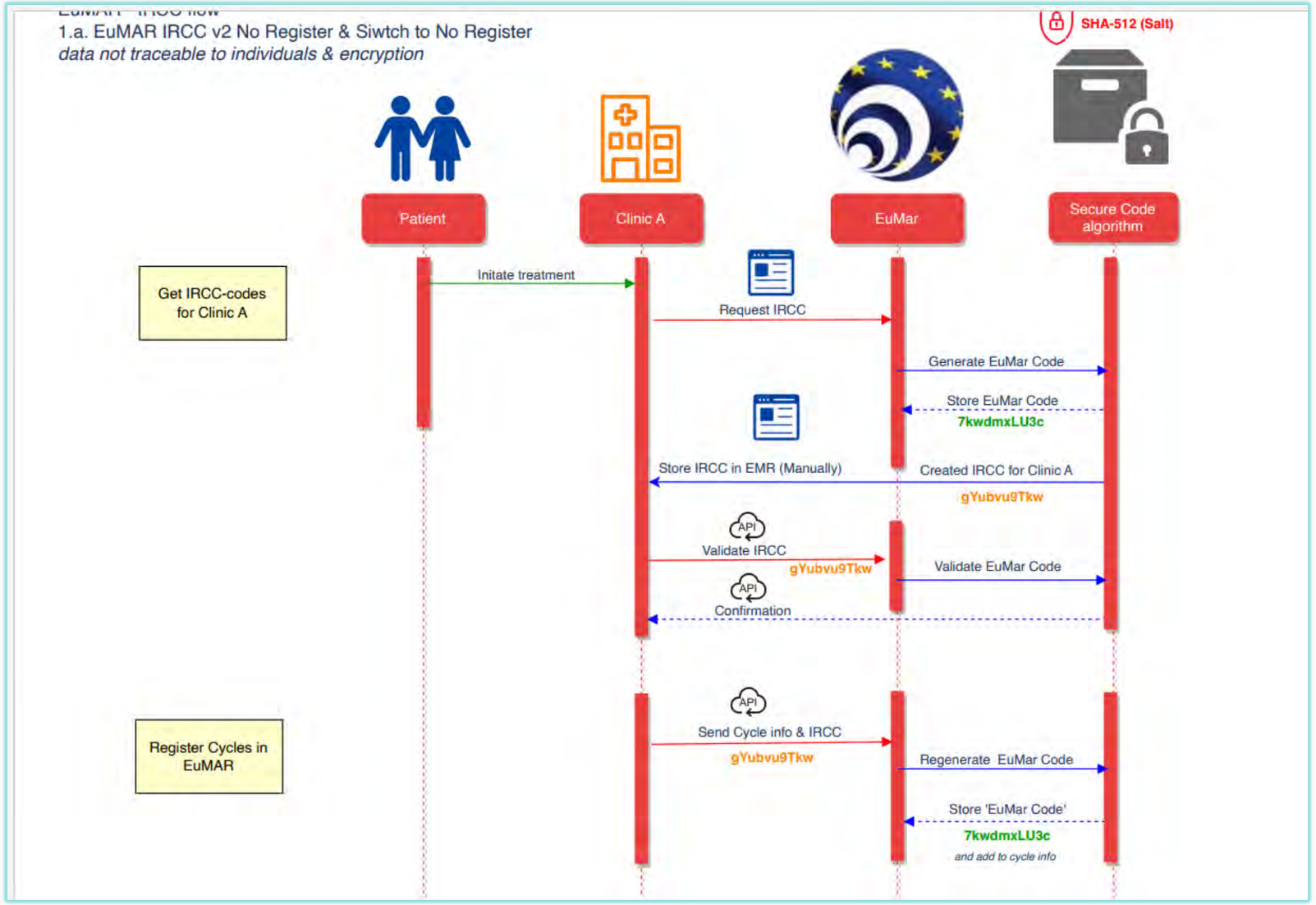
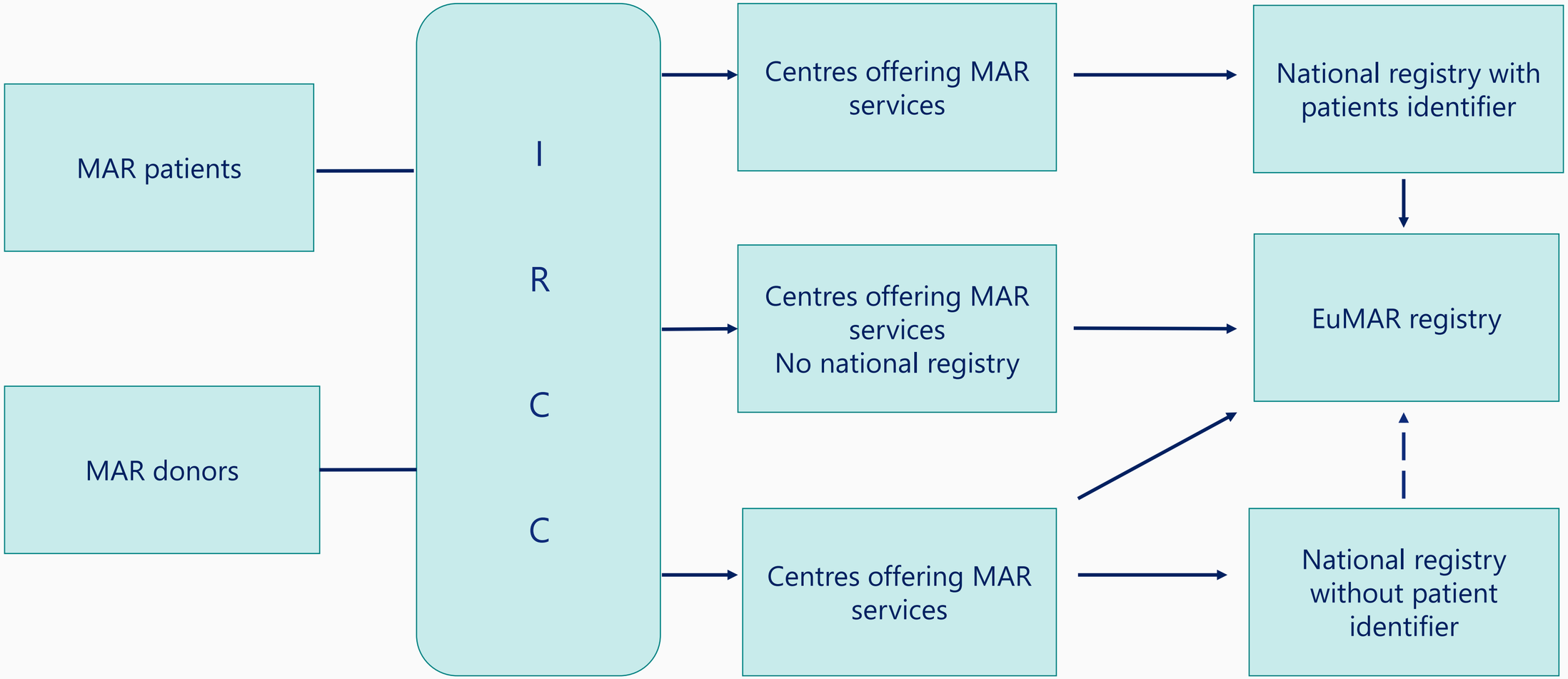
IRCC flow between clinic and EuMAR



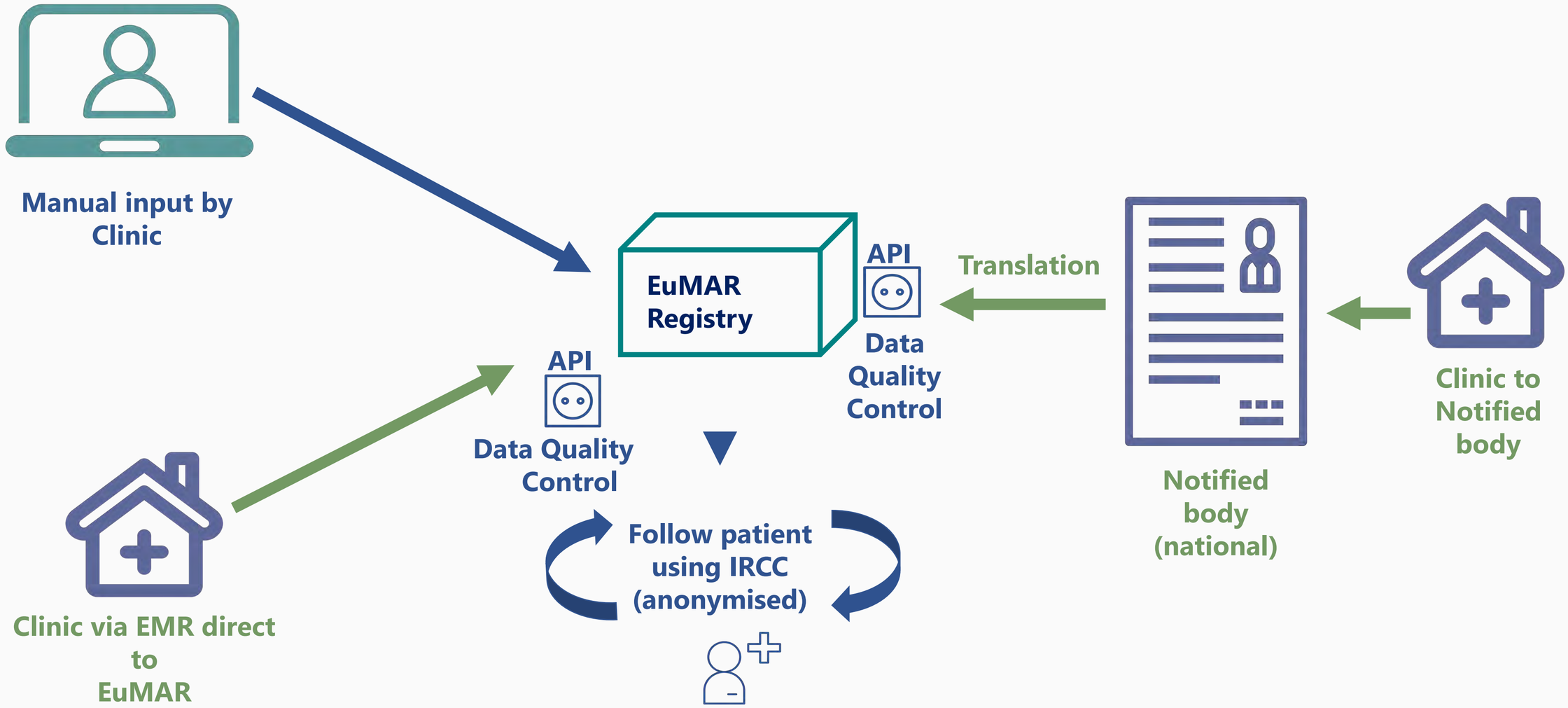
EuMAR by ESHRE

Reporting options using IRCC



EuMAR by ESHRE

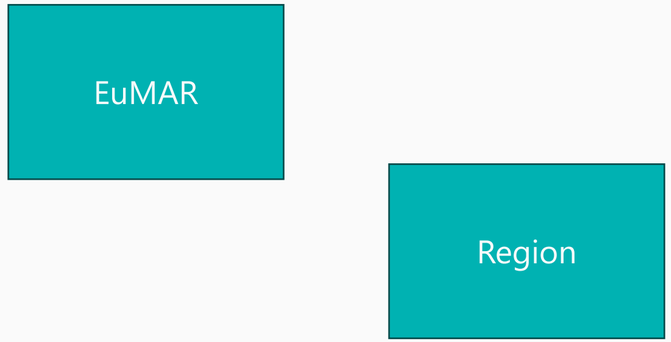
IT tools for data flows



EuMAR by ESHRE

Data base structure

4 Levels of viewing the data



Data not directly linked between systems to avoid data breaches.

EuMAR

- Will see all clinics.
- Can define regions with attached clinics.
- Can define National Authorities with attached clinics.
- Will define and authorise new clinics.

Clinic

- Can see its own patients/treatments.
- Can not see the treatments of previous clinics, while EuMAR will see the whole history of a patient.

EuMAR by ESHRE

Data base validation

Three levels:

- Per field
- Fields in relation to each other
- Phasing eg. cycle, pregnancy, child

EuMAR by ESHRE

Data base validation

Three levels:

- Per field
- Fields in relation to each other
- Phasing eg. cycle, pregnancy, child

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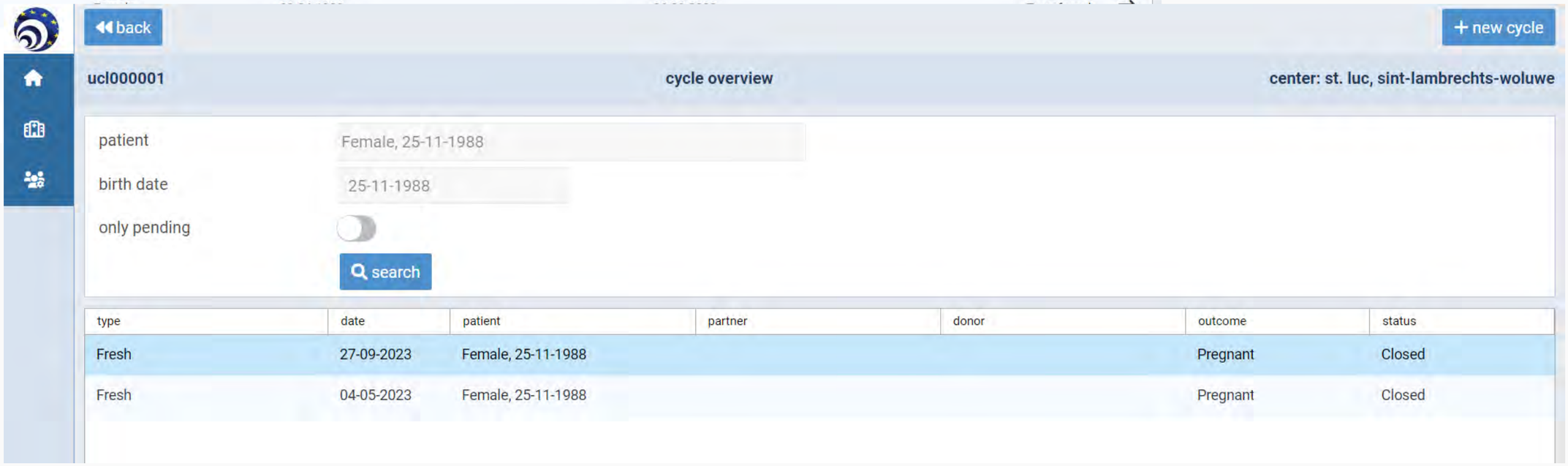
Prototype of software for the data registry

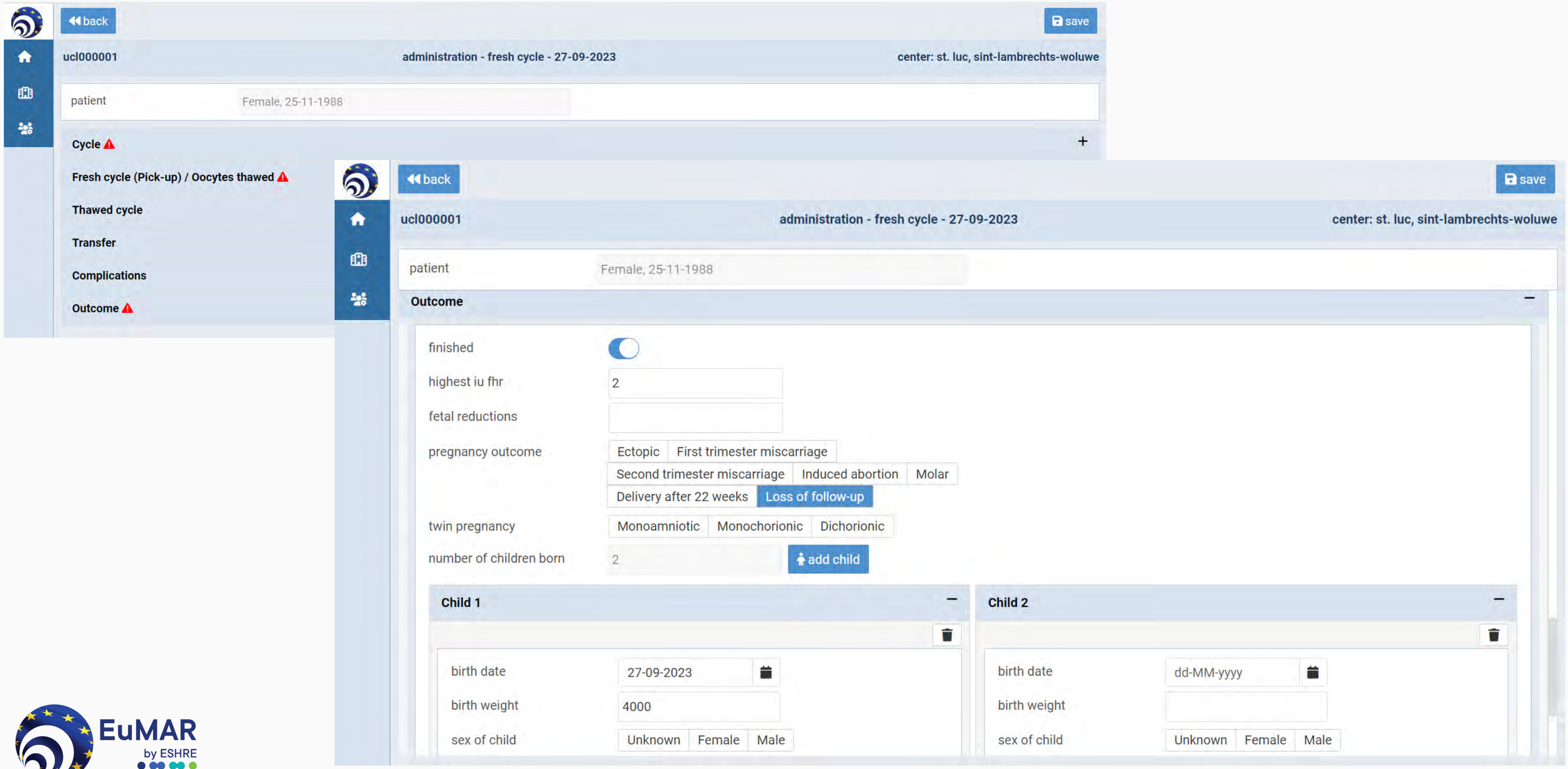
EuMAR
by ESHRE

Manually providing data to EuMAR



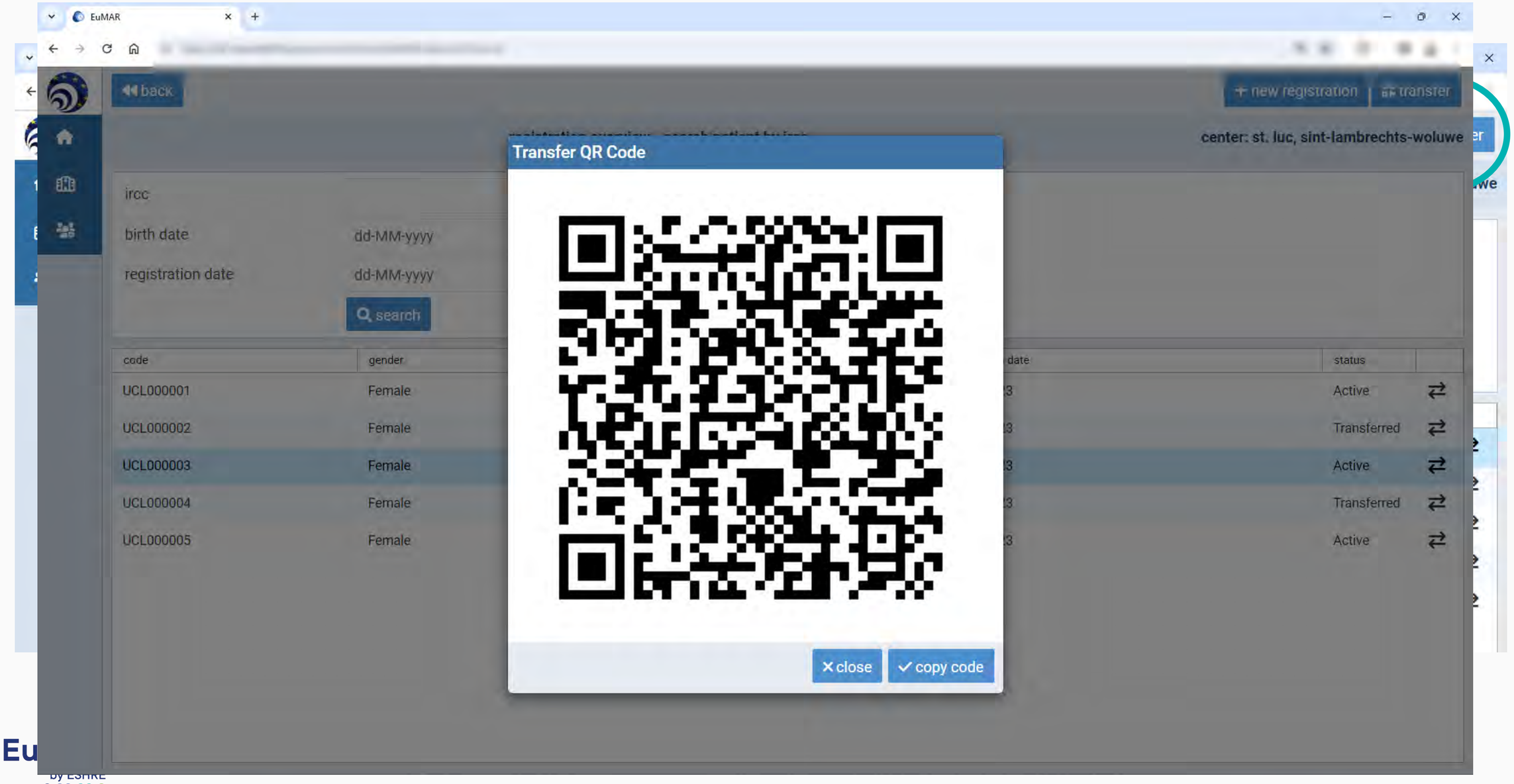
EuMAR by ESHRE

EuMAR points to data discrepancies



EuMAR by ESHRE

Request the transfer code



EuMAR
by ESHRE

Thank you!

www.eshre.eu/Data-collection-and-research/EuMAR

European Society of Human Reproduction and Embryology

WP6 - Embarking on the next steps with the Pilot Study

Prof. Dr. Christian De Geyter

Co-funded by the European Union.
Project: 101079865 — EuMAR — EU4H-2021-PJ2

WP6 Timeline

M1-M36

Tasks
T6.1 Identify collaborators
T6.2 Pilot Study
T6.3 Validation

Deliverable
D6.1 - Validation report

EuMAR by ESHRE

WP6 Timeline – Identifying collaborators

T6.1 Identify collaborators

1. Select pilot countries
2. Select stakeholders within pilot countries
3. Send formal proposals
4. Prepare consent forms

T6.2 Pilot study

Implementation and support phase

1. Monitor implementation process
2. Link EuMAR system with pilot countries' systems
3. Implement IT solution
4. Provide training & support

Q1 Q2 Q3 Q4

2023

Q1 Q2 Q3 Q4

2024

2025

EuMAR by ESHRE

Pilot countries selection criteria

The availability of a national data collection (yes/no)

The type of data collection (aggregated or cycle-by-cycle)

Geographic diversity

Possibility to communicate in English

NCAs interest in the project and the pilot study

EuMAR by ESHRE

WP6 Timeline – Implementation and support

T6.1 **Identify collaborators**

1. Select pilot countries
2. Select stakeholders within pilot countries
3. Send formal proposals
4. Prepare consent forms

T6.2 **Pilot study**

Implementation and support phase

1. Monitor implementation process
2. Link EuMAR system with pilot countries' systems
3. Implement IT solution
4. Provide training & support

Q1 Q2 Q3 Q4 — 2023

Q1 Q2 Q3 Q4 — **2024**

2025

EuMAR by ESHRE

WP6 Timeline – Pilot study

T6.2 **Pilot study**

Collection of data of newly started fresh cycles → *September 2024*

Collection of cumulative data of subsequent thawing cycle → *December 2024*

Collection of pregnancy outcome and neonatal data from all recorded cycles → *September 2025*

Monitoring and Validation → *December 2025*

EuMAR by ESHRE

Pilot study objectives

FEASIBILITY	FUNCTIONALITY	USABILITY	ENGAGEMENT
Test the feasibility of collecting prospective, cycle-by-cycle data on MAR in countries with and in countries without an existing registry.	Test the functionality of obtaining an IRCC in new individuals embarking on MAR.	Test the performance of the data collection software provided by eFertility.	Test the compliance of national health authorities and of MAR centres in transferring the data to a voluntary cycle-by-cycle registry of MAR in the EU.

EuMAR by ESHRE

Validation of results

Validation report D6.1

1. **Quantitative assessment of the collected data sets** (e.g.: the numbers of initiated fresh cycles and the numbers of subsequent linked thawing cycles); calculation of cumulative outcome data.
2. **Partial comparisons with the EIM data collection** may be made by extrapolating with historical data of each participating country.
3. **Comparison of the numbers of retrieved IRCC-codes** in participating countries with expected numbers of cycles.
4. **Comparison of** actual **number of MAR centres** with the number of institutions that provided data in each country.
5. **Narrative assessment of data flow** by representatives of the national competent authorities via a survey, including the use of the consent form.

EuMAR by ESHRE

WP6 members

Christian De Geyter
WP Leader

Carlos Calhaz-Jorge
Project member

Johanna Tassot
Project support

Susanne Hultsch
Project support

Elena Achótegui Sebastián
Project support

EuMAR
by ESHRE

EuMAR
by ESHRE

Thank you!

www.eshre.eu/Data-collection-and-research/EuMAR

European Society of Human Reproduction and Embryology

Status of the development of the EU SoHO platform

Presentation to EuMAR project meeting

5 December 2023

Health

Proposal for a Regulation published in July 2022

https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin_en

European Commission

Digital Functionalities to support implementation of the SoHO regulation

European Commission

Important to tailor to variety of organisational models

SoHO Actors

- > 5,000 (often small) authorised establishments (today)
- Adding entities across many healthcare providers
- Different SoHO sectors, different organisational models
- Many public services, academic hospitals, non-profit sector (e.g., Red Cross)
- Professional and scientific societies can be facilitators

SoHO authorities

- Large vs small countries: different possibilities to have/use own data-solutions
- Central vs regional authorities
- Consolidated vs sector-specific authorities
- Standalone vs integrated with pharma/devices

- Flexible and scalable solutions needed to address variety
- Public actors and authorities, with limited resources
- Potential to add/support admin efficiency

Overview of process

European Commission

Key concerns to consider

Recycle common work (EuroCET, EDQM)

1. **Data Harmonisation and Reporting:** Need to harmonize data, classifications, vocabulary, definitions.
2. **Data governance**: ownership, access, role publication…
3. **GDPR, Privacy:** How will the EU SoHO Pl privacy and security? Ensure access to
4. **IT Systems:** How to connect existing IT sy SoHO Platform (connectivity) + possibilities for direct entry
5. **Common users and rules:** e.g., when to
6. **Cultural acceptance and transition:** How can we ensure that SoHO entities can adapt to the new requirements in a fast and correct way?
7. **Communication** – how to (architecture, database
8. **Automation –** leverage potential of IT systems to lighten admin workload for entities and authorities

Verification by CA's before publication

No personal data at EU-level needed, but for some alerts (as-in RAB/TC), and possibly on responsible persons in entities

direct entry by entities/establishments into SoHO-X, and/or upload of data collected in existing (e.g., national) databases

Build on existing practices

Map national IT-systems + clarify EU-specs, so EU and national IT-plans can align

EU4Health supported actions for entities (professional societies), for CA's

Let platform take over some work (draft vérifications, draft consolidation data reports, …)

European Commission

AGENDA

1. Welcome, introductory remarks and agenda
2. Relevant functionalities of the EU SoHO platform
3. Supporting contracts
4. Existing national platforms
5. Next steps
6. Q&A
7. Final remarks

5. Supply (monitoring and) alerts

Activity data overview

- **Supports MS policies for supply sufficiency**
- **Provides denominators for SAO reports**
- **Gives visibility to citizens**

SoHO Entities

May delegate

Existing professional registries

(that collect data on the relevant activities)

Conditional on CA verification of data quality

Submit annual summary of data collected to the EU SOHO Platform

Publish annual SoHO activity report

Competent Authorities

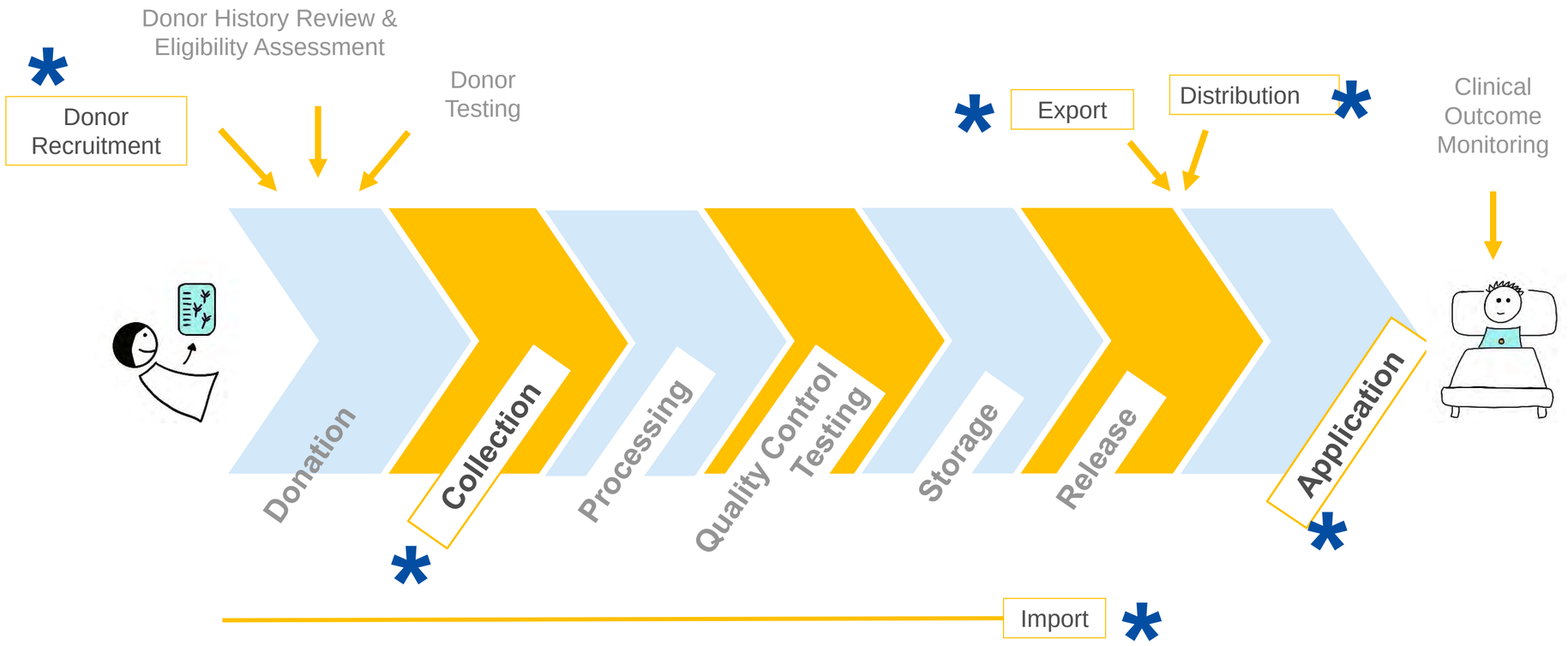
- **Verify** that their entities have submitted complete & accurate summaries

- **Publish** aggregated annual report for their SoHO entities

European Commission

a. Legal: Which data?

* SoHO activities for which data shall be collected



b. What we have so far…

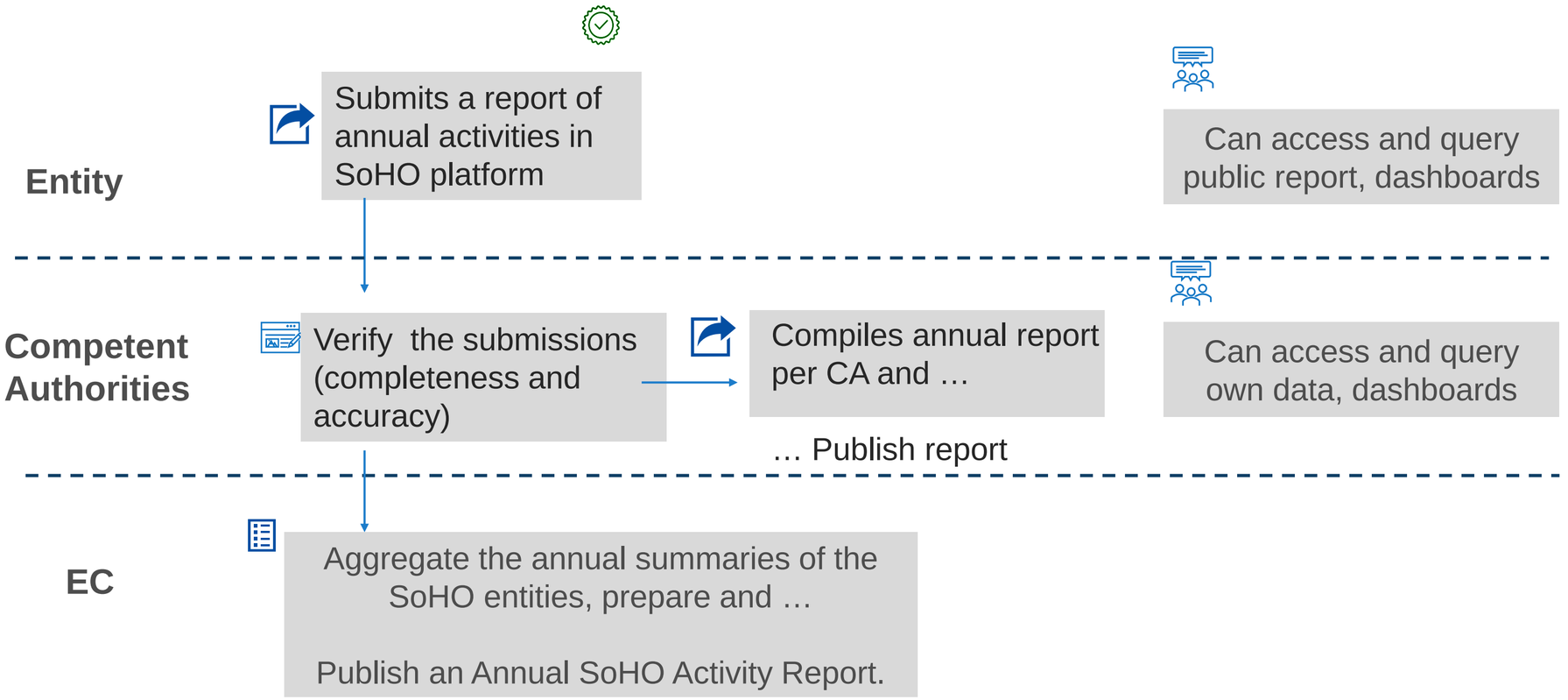
- Exercises to harmonise activity data collection exercises in the field of tissues and cells in Europe (EuroCET, EDQM)
- Preparedness planning blood sector (B-SCEP, EDQM)
- Guidance Vigilance Expert Subgroup (VES) for annual data reporting reporting (common approach) and
- Extenal contractors' work: use cases specifications, business process and mock-ups
- External contractors' workshop with EDQM and relevant stakeholders

DRAFT

c. (standard) digital flow

In SoHO digital platform (COM SoHO proposal)

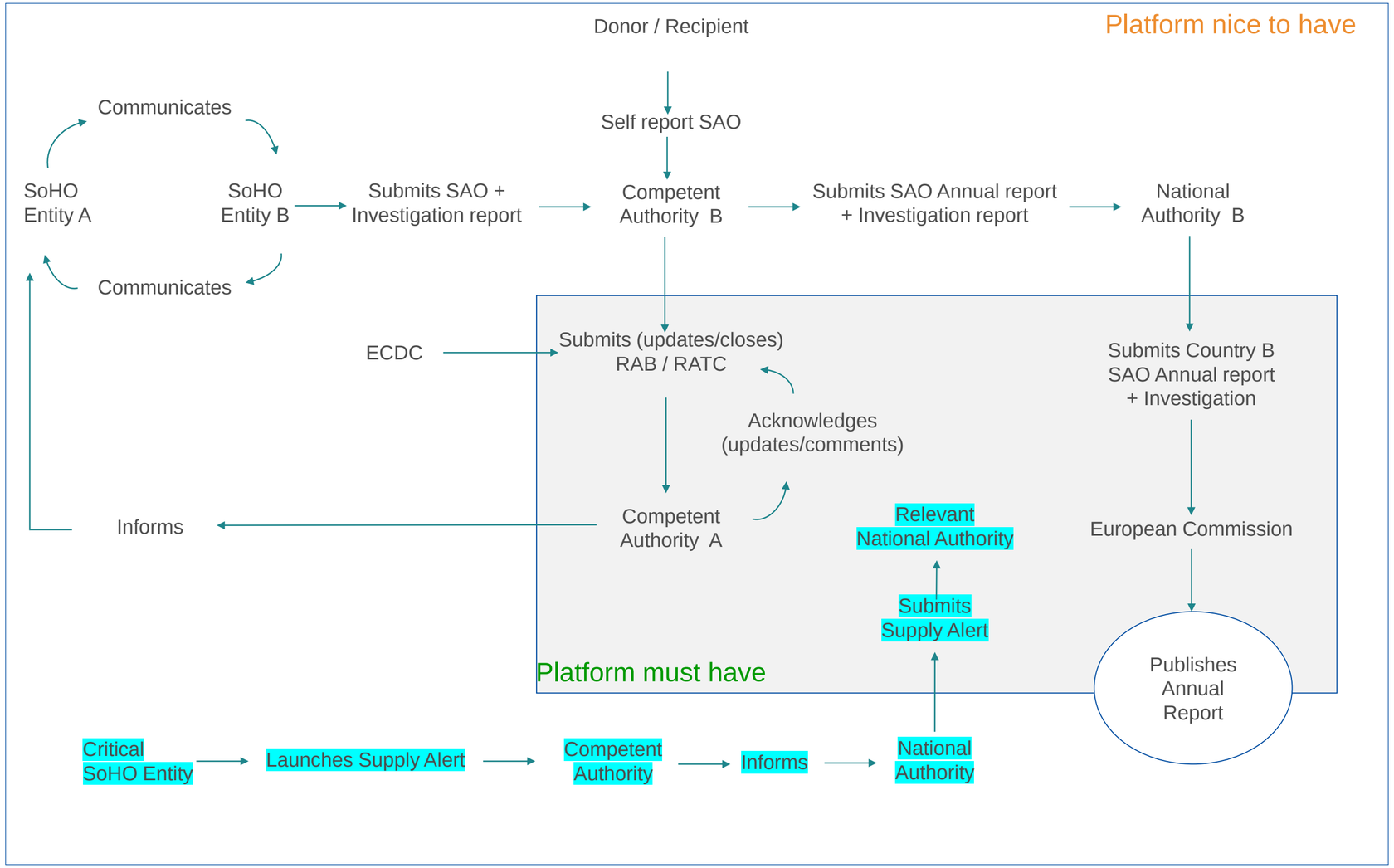
Article 33, 44



c. Digital flow

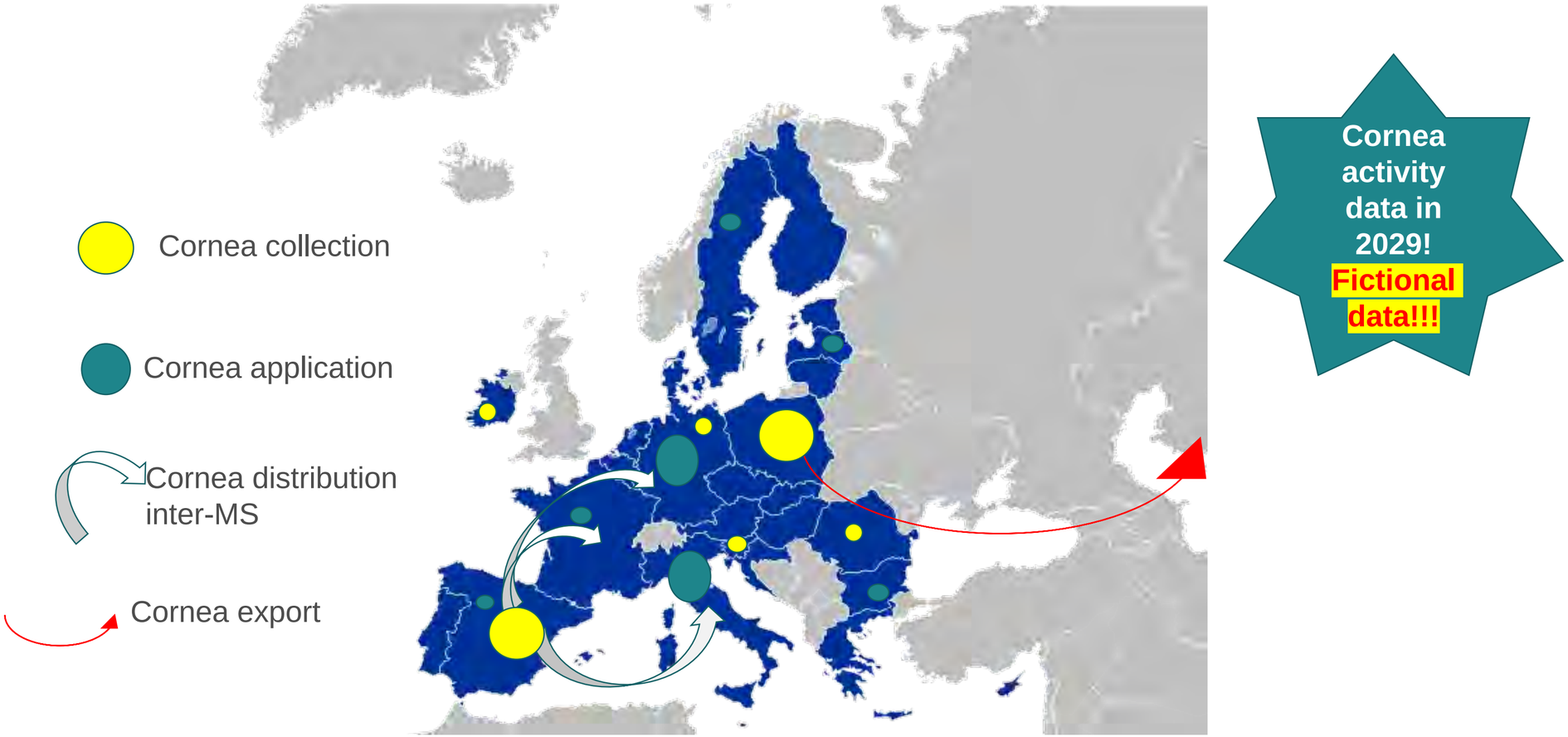
DRAFT

In SoHO digital platform (COM SoHO proposal)



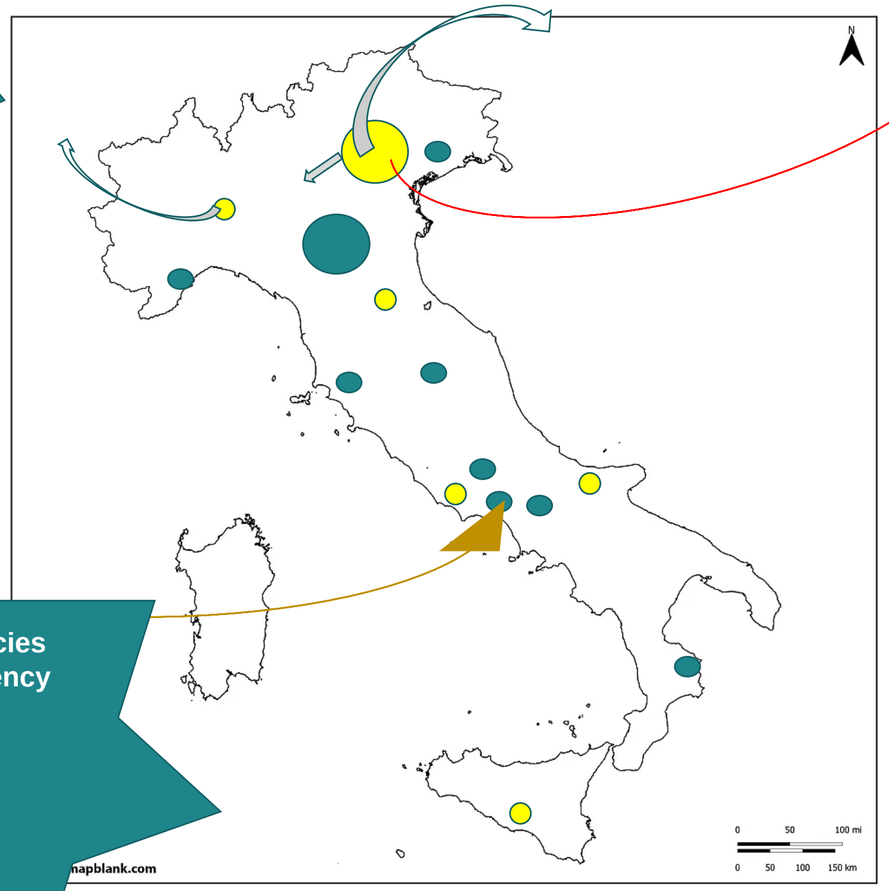
European Commission

e. How it might look - EU



e. How it might look – zooming in to one MS

Cornea activity data in 2029 - one Member State!
Fictional data!!!



Cornea collection

Cornea application

Cornea distribution inter-MS

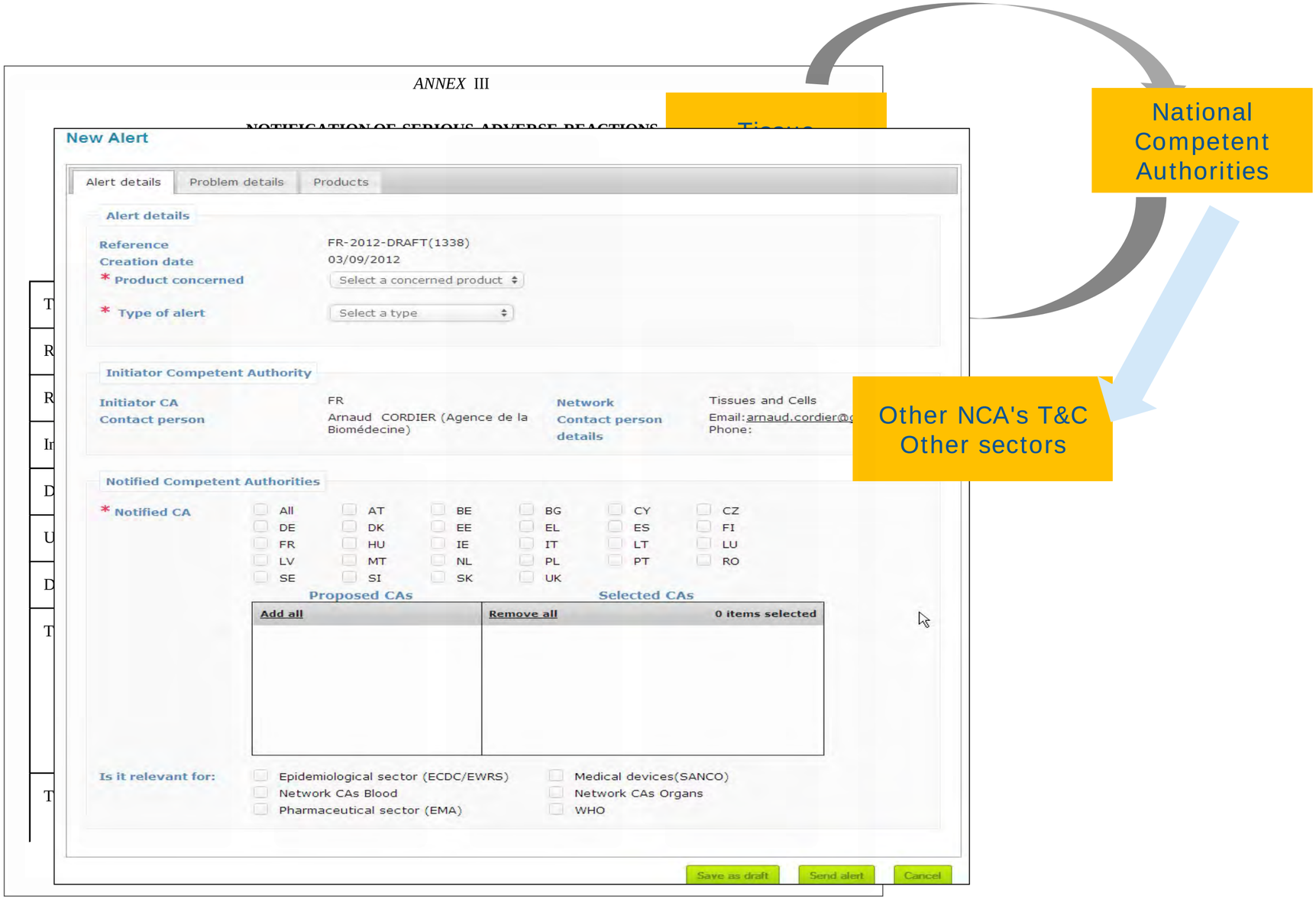
Cornea import

Cornea export

- Supports MS policies for supply sufficiency
- Provides denominators for SAO reports
- Gives visibility to citizens

European Commission

e. How it could look like – supply alerts



[RAB/RATC platform (europa.eu)]

e. Open questions and user engagement

- **(Main) open questions**
  - Integrate a local/national channel entity/authority to report supply situation/issues ?
  - Alternative pathway to use/recycle data reports to existing registries – upload, interoperability ?
  - Reuse (RAB/TC) tools for reporting vigilance alerts adapted for the management of supply alerts ?
  - Allow SoHO-X to prepare (draft) annual consolidated reports (per MS, for EU) ?
  - Coordinate with/recycle non-SoHO supply monitoring efforts post-COVID (EMA, HERA, …)?

- **User Engagement**
  - User group: continue with NCA's members of VES
  - Engage EuroCET, engage members EDQM work BSCEP
  - …

2. Authorizing SoHO preparations

European Commission

a. Legal 1/2: Processing SoHO leads to SoHO preparations

What is a ‘SoHO Preparation’?

A particular SoHO that has been **subjected to one or more SoHO activities, including processing,** with **pre-defined specification** and **specific clinical indication**

→ Must be **authorised**

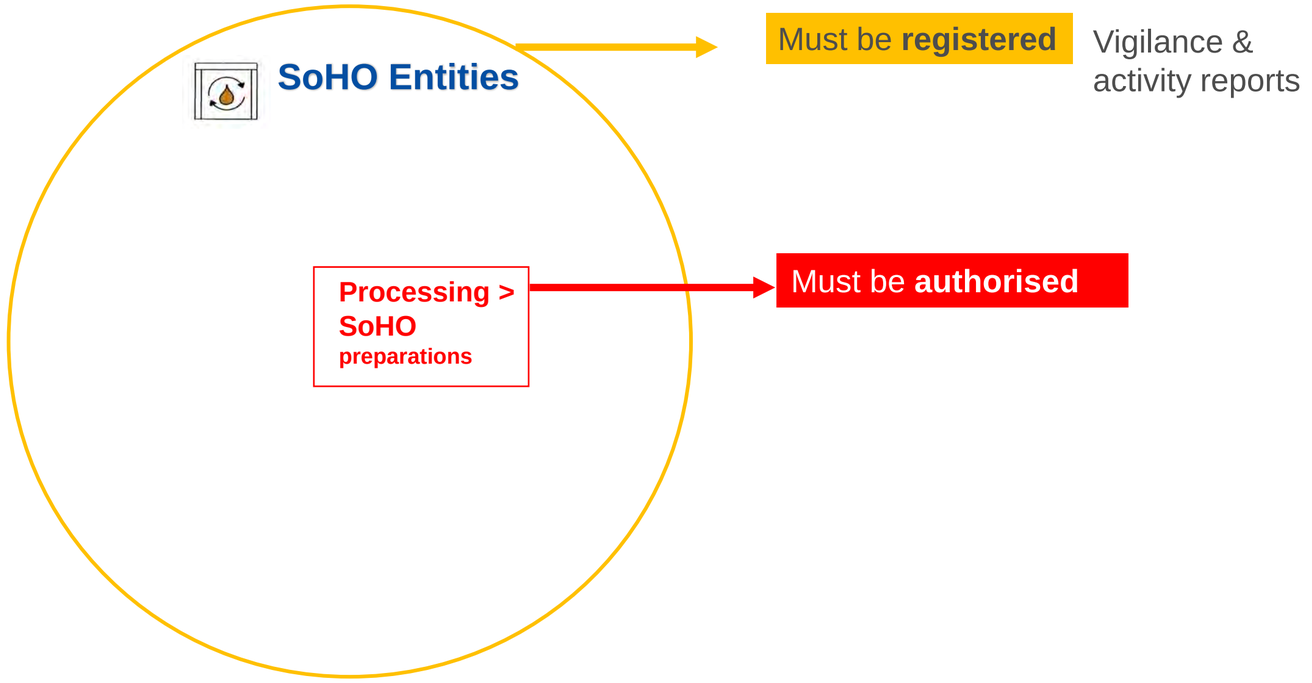
SoHO ⇨ **SoHO Preparation**

Example:

Blood →
- Plasma
- Red blood cells
- Platelets

a. Legal 2/2: SoHO preparation(s) require an authorisation

Article 21



b. What we have so far…

- **Joint Action GAPP: Facilitating the Authorisation of Preparation Process for blood, tissues and cells (**gapp-ja.eu)**)**
  - Developed authorization process
  - Tested risk assessment tool (EuroGTP-2)
  - Made a first map of existing preparations
  - IT blueprint
- **Meeting with NCAs involved in GAPP II (Joint Action) 10 November 2022**
- **External contractors' work: use cases specifications, business process**

b. Development SoHO Preparation Authorisation process (GAPP-JA)

- **Use EuroGTP2 tool or similar**
- **Taking into account any relevant EDQM monograph**

1 Systematic Risk Assessment to determine the requirements for aut

2 Submission of an application dossier, including laboratory validation and, where relevant, a clinical outcome monitoring plan proportionate to risk

3 Assessment of the application by the competent authority

Grant authorisation **OR** Grant of a **conditional** authorisation to allow evidence gathering **OR** Refuse authorisation

4 Assessment by the competent authority of evidence gathered

Grant authorisation **OR** Refuse authorisation

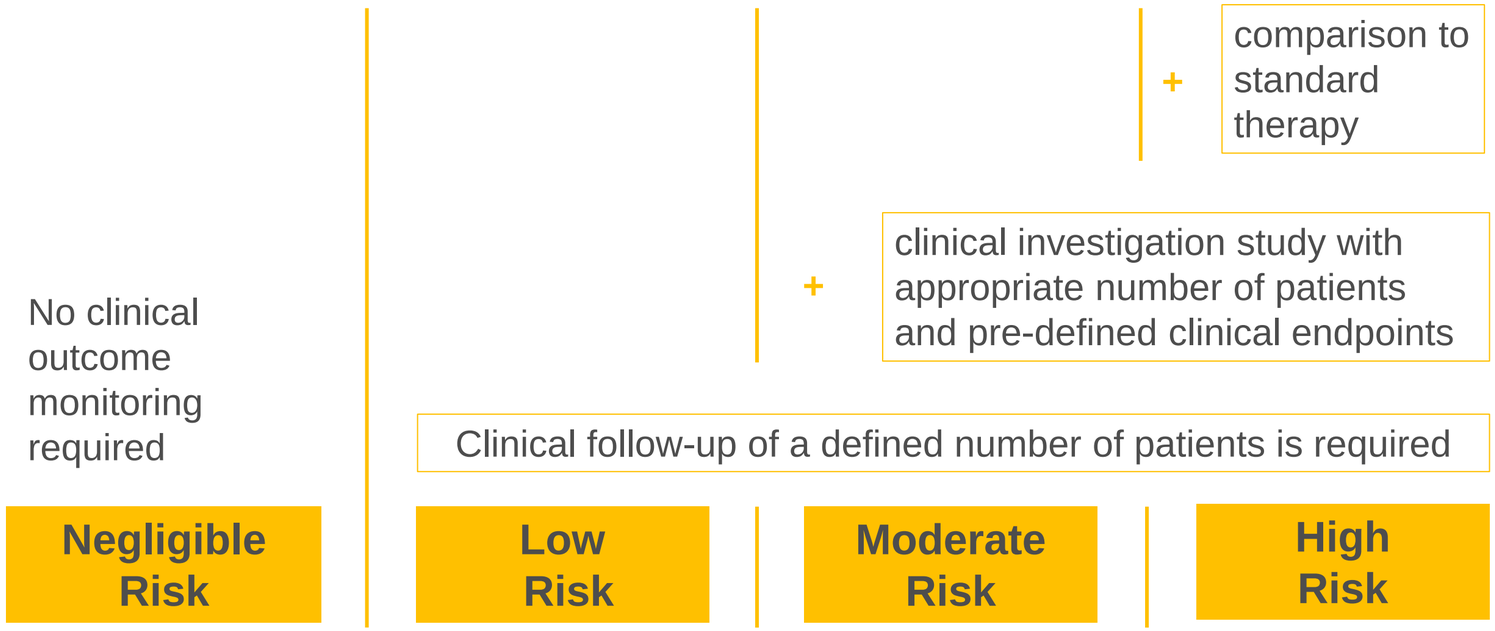
+ blueprint for the auhorisation submission/ assessment (WP8 GAPP)

Based on preparatory work done by GAPP Joint Action
(incl. stakeholders from 17 countries: 15 CAs & professional associations)

GAPP

European Commission

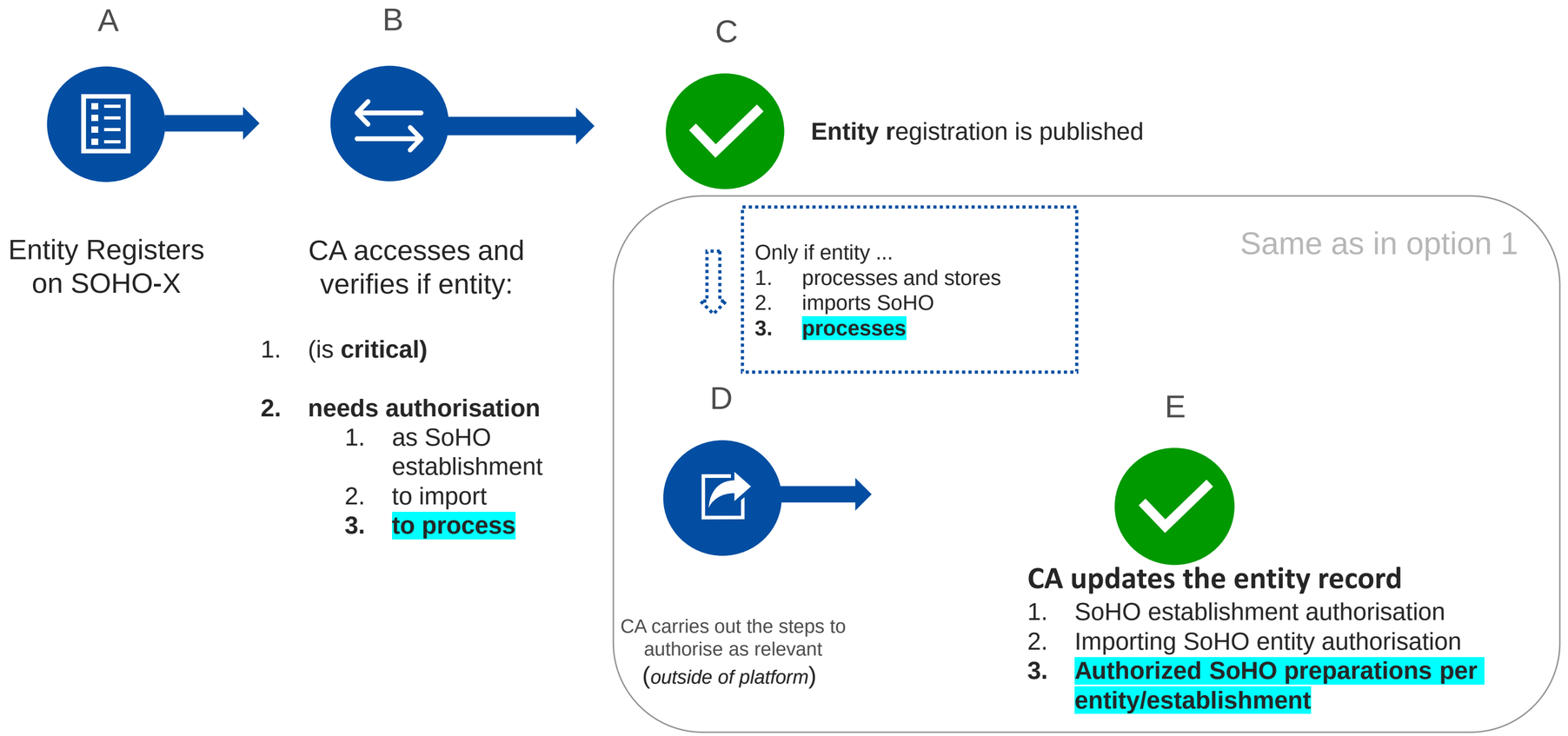
b. Developments clinical Outcome Monitoring Plans for Conditional authorisation (GAPP-JA)



Based on preparatory work done by GAPP Joint Action
(incl. stakeholders from 17 countries: 15 CAs & professional associations)

European Commission

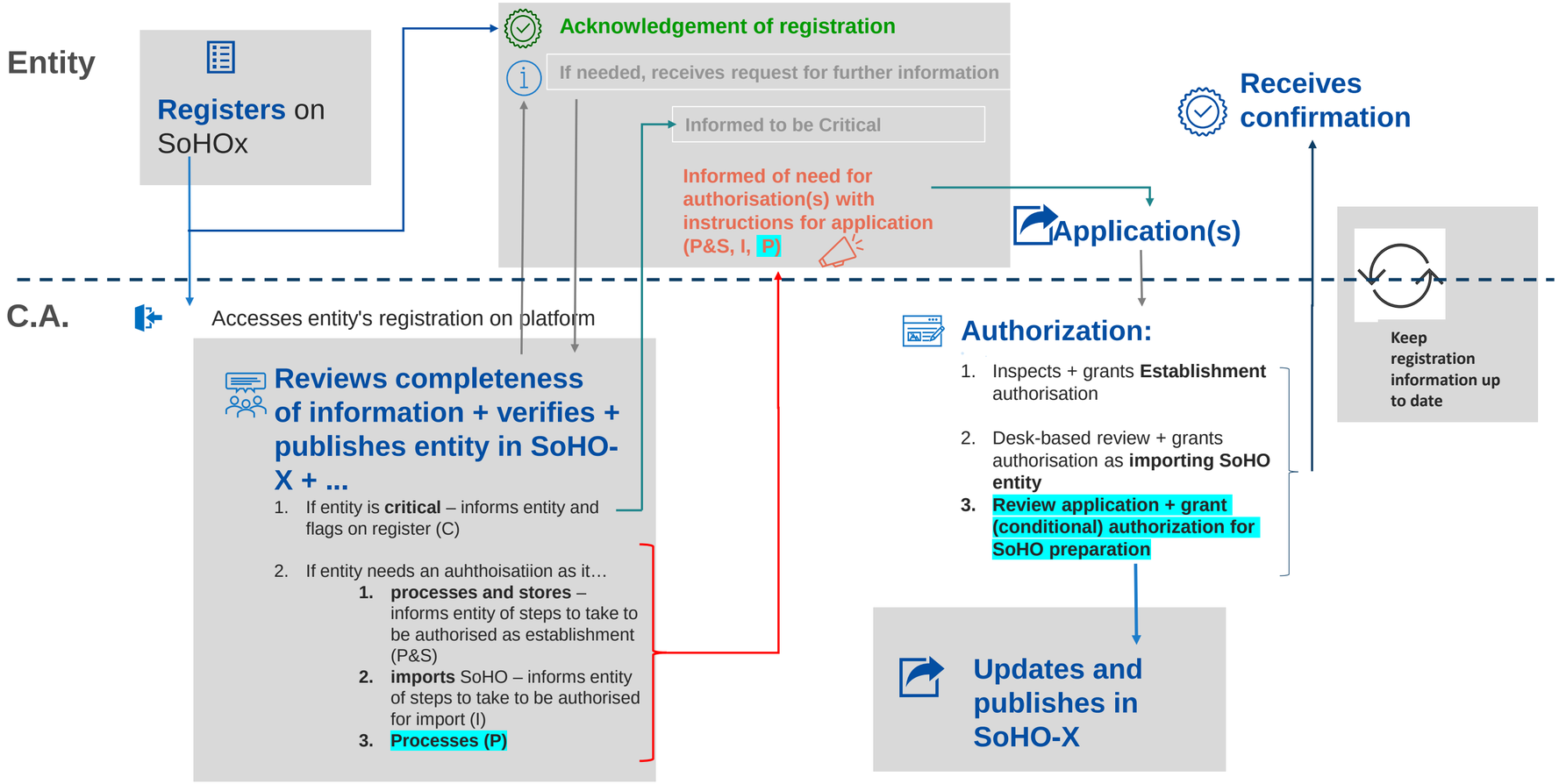
c. (Standard) Flow: SoHO entities can apply for a SoHO preparation authorisation



DRAFT

c. Digital flow as from first registration as entity…

In SoHO digital platform (COM SoHO proposal)



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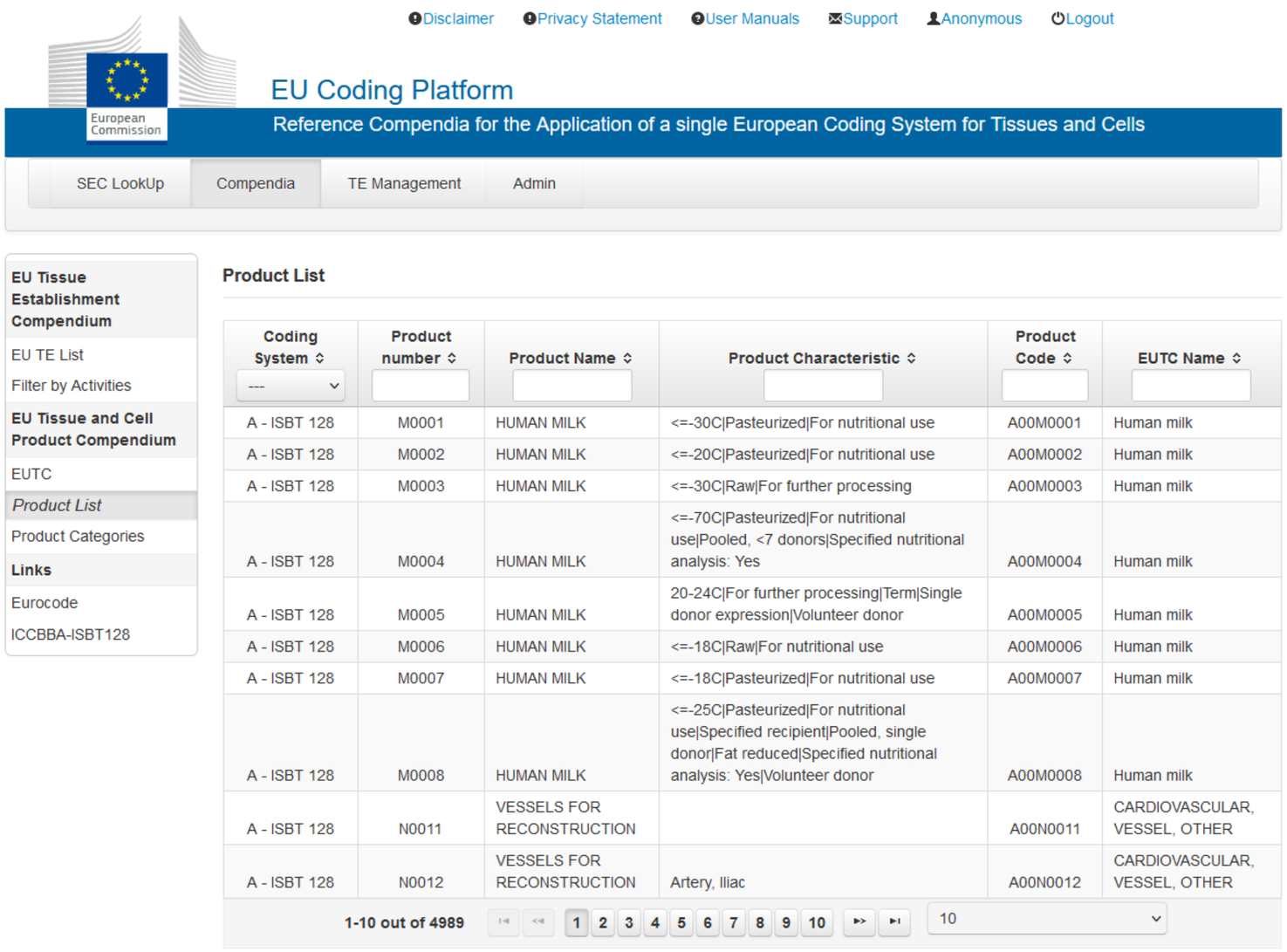
d. Look & feel – compendium of SoHO preparations authorised in the EU

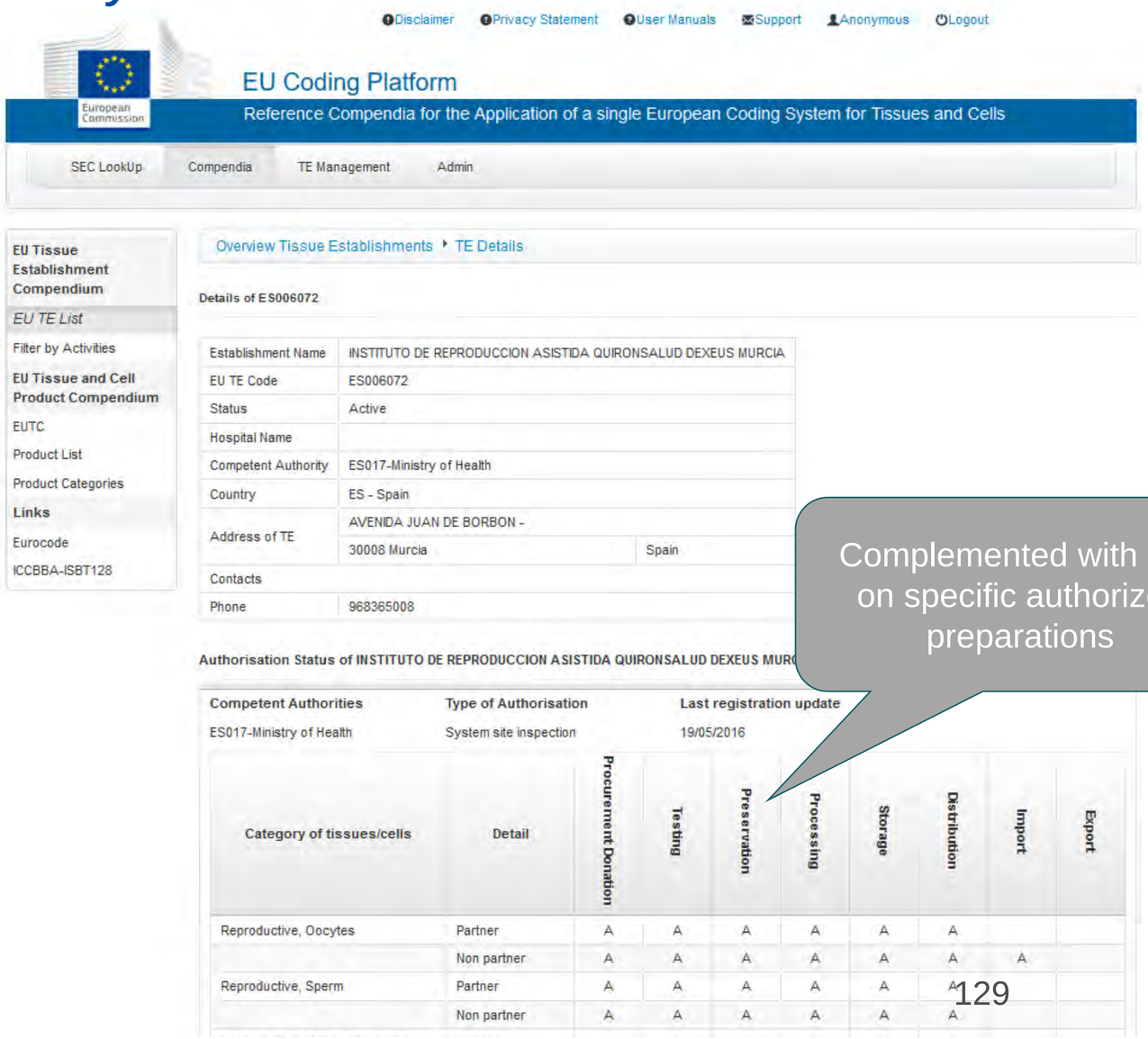


Coding System	Product number	Product Name	Product Characteristic	Product Code	EUTC Name
A - ISBT 128	M0001	HUMAN MILK	<=-30C|Pasteurized|For nutritional use	A00M0001	Human milk
A - ISBT 128	M0002	HUMAN MILK	<=-20C|Pasteurized|For nutritional use	A00M0002	Human milk
A - ISBT 128	M0003	HUMAN MILK	<=-30C|Raw|For further processing	A00M0003	Human milk
A - ISBT 128	M0004	HUMAN MILK	<=-70C|Pasteurized|For nutritional use|Pooled, <7 donors|Specified nutritional analysis: Yes	A00M0004	Human milk
A - ISBT 128	M0005	HUMAN MILK	20-24C|For further processing|Term|Single donor expression|Volunteer donor	A00M0005	Human milk
A - ISBT 128	M0006	HUMAN MILK	<=-18C|Raw|For nutritional use	A00M0006	Human milk
A - ISBT 128	M0007	HUMAN MILK	<=-18C|Pasteurized|For nutritional use	A00M0007	Human milk
A - ISBT 128	M0008	HUMAN MILK	<=-25C|Pasteurized|For nutritional use|Specified recipient|Pooled, single donor|Fat reduced|Specified nutritional analysis: Yes|Volunteer donor	A00M0008	Human milk
A - ISBT 128	N0011	VESSELS FOR RECONSTRUCTION		A00N0011	CARDIOVASCULAR, VESSEL, OTHER
A - ISBT 128	N0012	VESSELS FOR RECONSTRUCTION	Artery, Iliac	A00N0012	CARDIOVASCULAR, VESSEL, OTHER

[EU Coding Platform (europa.eu)](), following COM Directive 2015/566

European Commission

d. Look & feel – authorised (processing) activities per entity



[EU Coding Platform (europa.eu)](), following COM Directive 2015/566

e. Open questions and user engagement

- **(Main) open questions**
  - Module for local/national process to apply and authorize SoHO preparations ?
  - Integrate tools to make risk-assessments (EuroGTP-2) ?
  - Integration in EU Coding platform (possible reuse) or development of new compendia ?
  - …
- **User Engagement**
  - Map out existing national initiatives/registries (see agenda 4.)
  - Map out authorized preparatons (GAPP/GAPP-pro)
  - Call for interested authorities to co-develop (GAPP-pro?)
  - Training for eventual users (e.g., SIGHT-SoHO, …)

4. Vigilance reporting and alerts

a. Legal: Vigilance overview

SoHO Entities

Send SAO notification & SAO investigation report to their CA

Competent Authorities

- Verify info of SAO notifications & investigation reports, assess the results of the investigation, informs the entity
- Launch SoHO rapid alerts
- Send annual summary of SAO notifications & investigation reports received to their **SoHO National Authority**

- Submits annual summary to the **EU SoHO Platform**
- Publishes aggregated summary for their MS

- Aggregate the summaries from the **SoHO National Authorities**
- publish annual SoHO vigilance report

Communication with CAs from other frameworks

European Commission

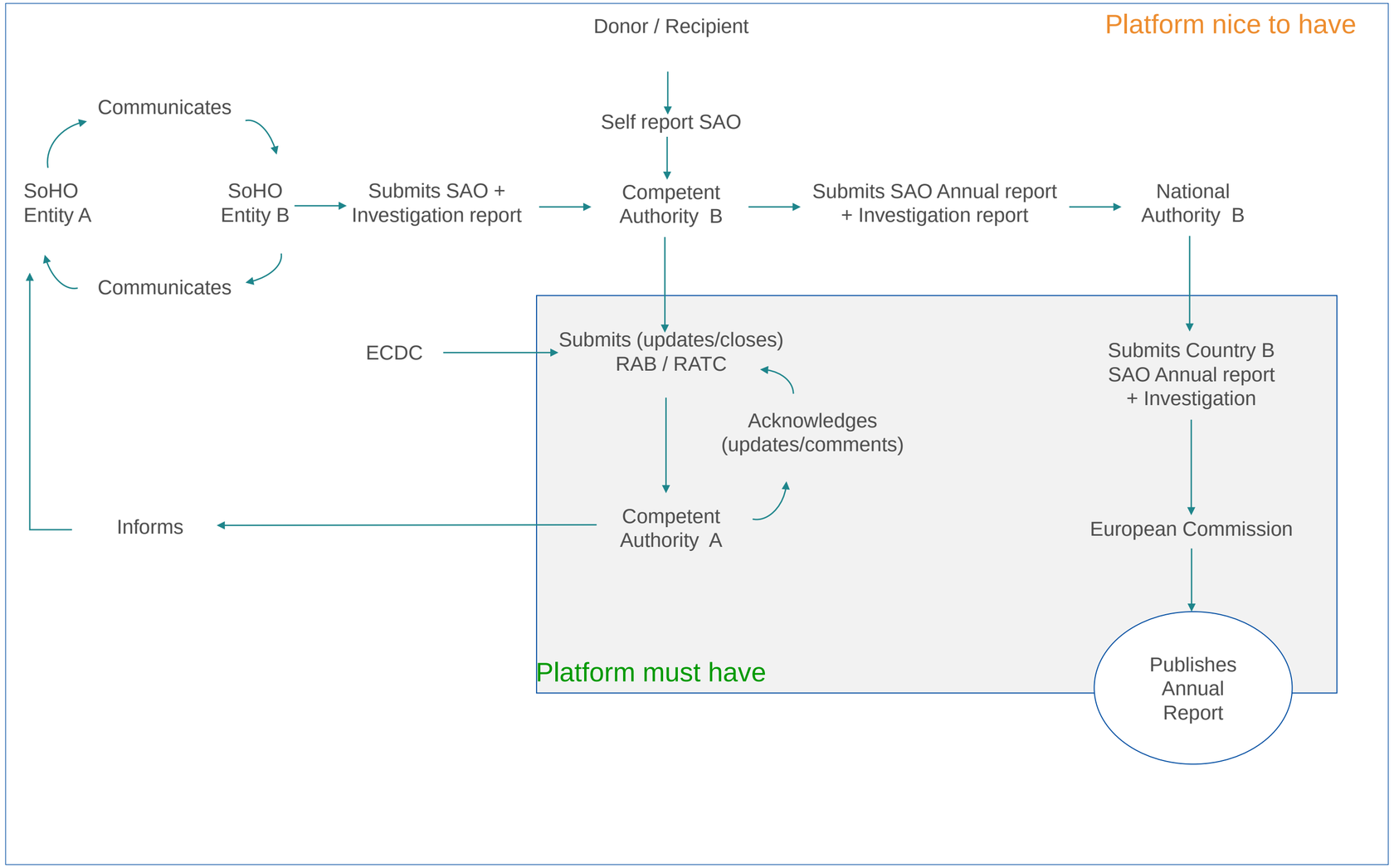
b. What we have so far…

- Well-established vigilance systems under Directives 2002/98/EC and 2004/23/EC, including …
  - reporting templates/forms (establishment to authority)
  - rapid alert systems (RAB/TC)
  - annual data collection and consolidation SARE (per MS, EU-wide)
- Guidance Vigilance Expert Subgroup (VES) for annual data reporting reporting (common approach)
- External contractors' work: use cases specifications, business process and mock-ups

c. Draft Digital flow

DRAFT

In SoHO digital platform (COM SoHO proposal)



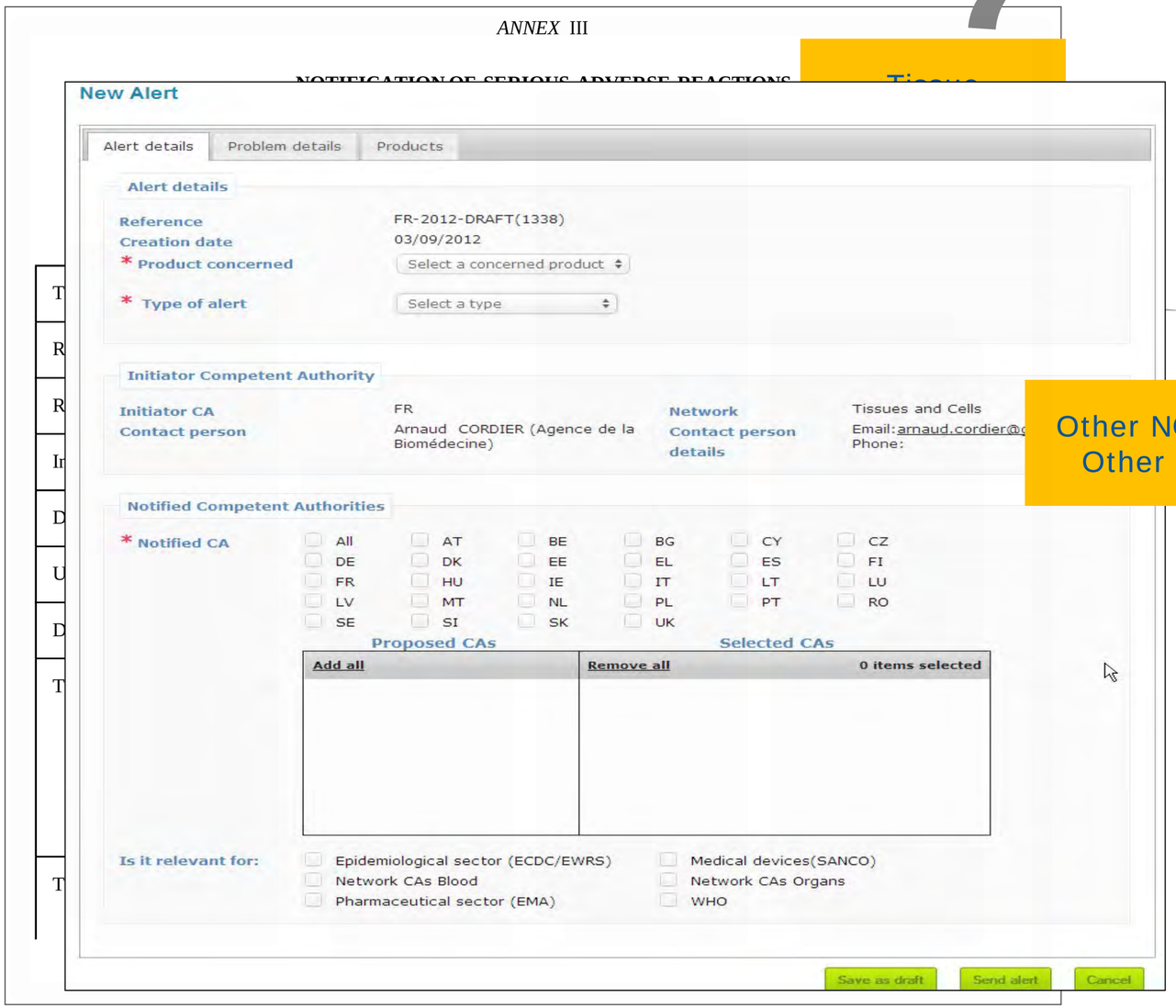
European Commission

d. How it could look – rapid alerts

DRAFT

National Competent Authorities

Other NCA's T&C
Other sectors

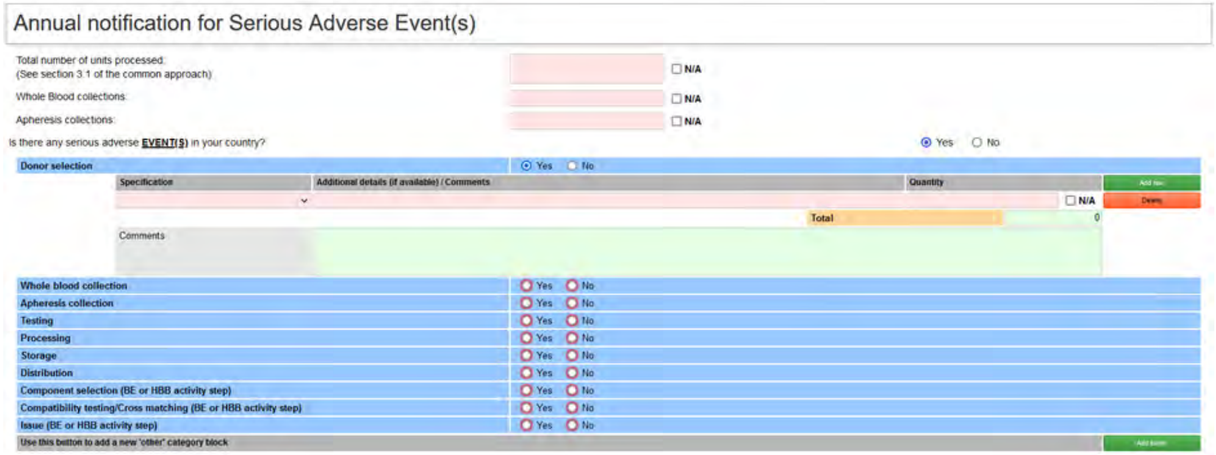


RAB/RATC platform (europa.eu)

European Commission

DRAFT

d. How it could look – annual reports



Annual notification for Serious Adverse Event(s)

Total number of units processed:
(See section 3.1 of the common approach)
N/A
Whole Blood collections:
N/A
Apheresis collections:
N/A
Is there any serious adverse **EVENT(S)** in your country?
Yes No

Donor selection	Yes No
Specification / Additional details (if available) / Comments / Quantity	N/A
Total	0
Comments	
Whole blood collection	Yes No
Apheresis collection	Yes No
Testing	Yes No
Processing	Yes No
Storage	Yes No
Distribution	Yes No
Component selection (BE or HBB activity step)	Yes No
Compatibility testing/Cross matching (BE or HBB activity step)	Yes No
Issue (BE or HBB activity step)	Yes No
Use this button to add a new 'other' category block	

National Competent Authorities

European Commission (EDQM)

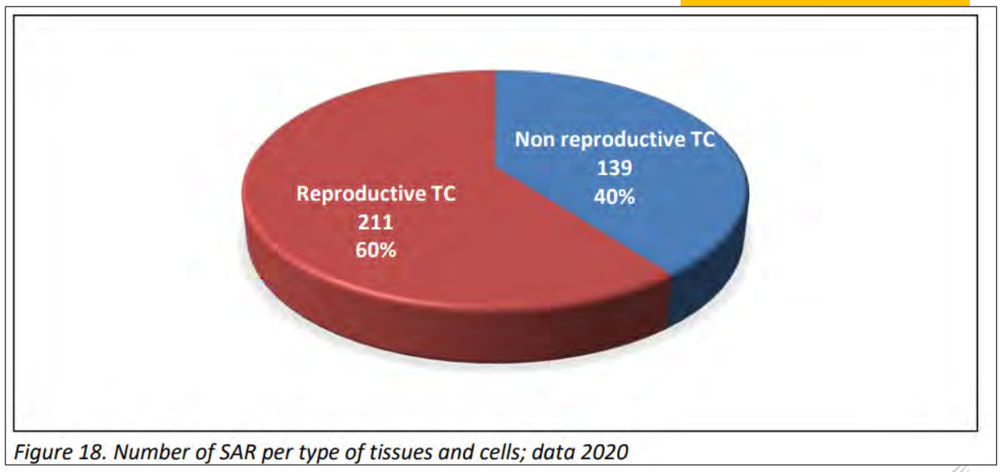


Figure 18. Number of SAR per type of tissues and cells; data 2020

[Summary of annual reporting of serious adverse reactions and (europa.eu)]

European Commission

e. Open questions and user engagement

- **(Main) open questions**
  - Secure communication channel entity/authority to integrate model for national process/forms to submit and follow-up on SAO ?
  - Allow SoHO-digital platform to auto-prepare (draft) annual consolidated reports (per MS, for EU) ?
  - Re-use existing RATC platform - ask VES proposal for RATC platform improvement and extension to non BTC ?
  - …
- **User Engagement**
  - User group: continue with NCA's members of VES
  - **...**

Thank you

European Commission

WP7 - Perspectives of interoperability and innovation

Jesper Smeenk

EuMAR by ESHRE

Co-funded by the European Union.

Project: 101079865 — EuMAR — EU4H-2021-PJ2

WP7: Plan for incorporation of innovation

Aims

- Facilitate the flexibility of the data registry with regards to the inclusion of additional parameters, amendments towards innovations and possible future connections to other data registries (e.g., obstetric data, birth registry, paediatric diseases' registries, cancer registries, cardiovascular disease registries)

- **Specific aim:**
  - To create a plan for adaptation of the data collection, including IT solutions, which should ensure the data registry is adjustable, making it future proof.

Tasks

- ❑ EuMAR plan for incorporation of innovation (T7.1)

EuMAR by ESHRE

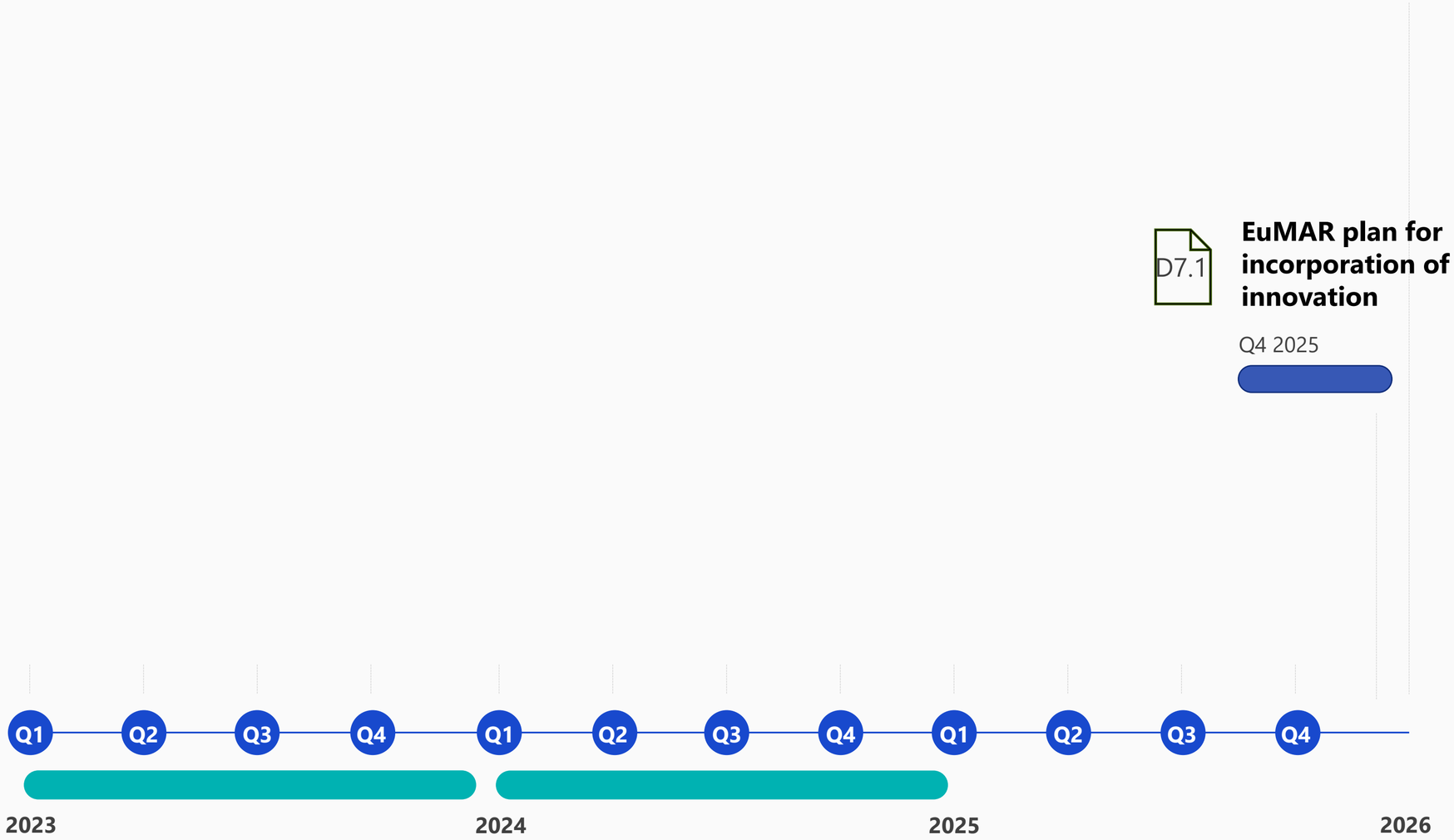
WP7: Plan for incorporation of innovation

M25-M33

Milestones

Deliverable

D7.1 - EuMAR plan for incorporation of innovation



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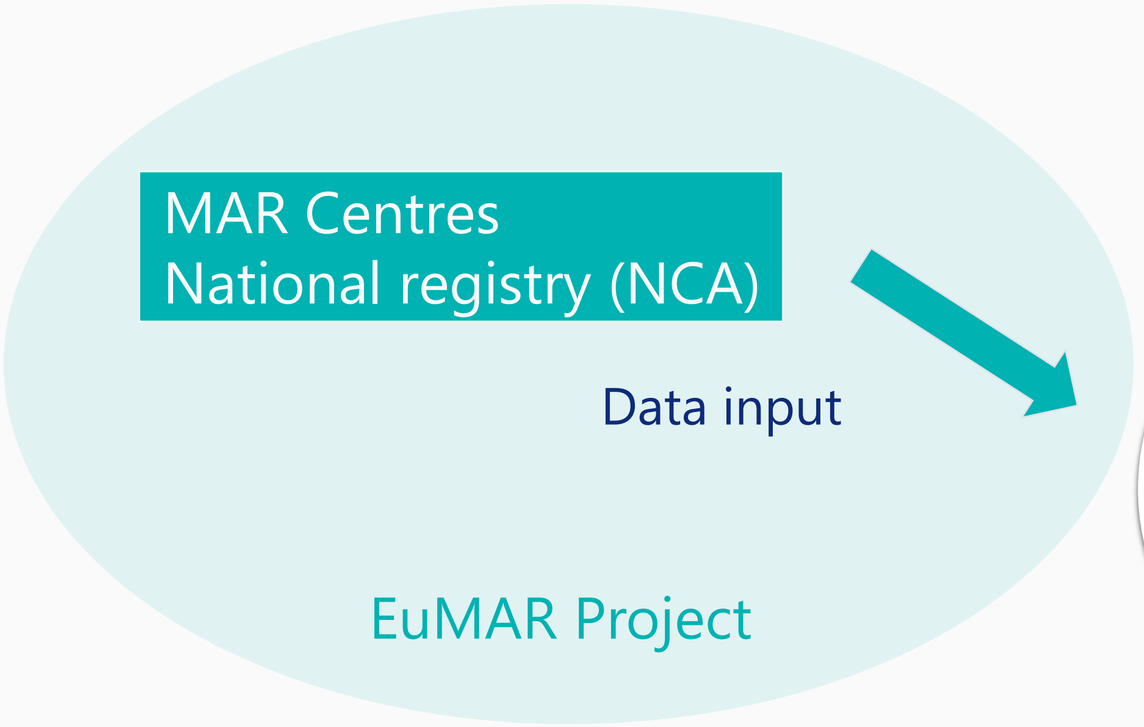
Interoperability



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Data export

SoHO-X platform

Data input
& export

Cancer registry

Birth registry

EuMAR by ESHRE

Interoperability

Connections with other registries

=> How can we adapt the EuMAR Registry to be able to link to other registries?

- Relevance :
    Which data are collected in the other registries?
    Does a link create any value?
        - Birth registry: link prenatal data to ART
        - Cancer registry: link the ART outcomes to cancer diagnosis

If relevant..

- Technical possibilities / limitations
- GDPR – legal restraints (data exchange, patient identification)

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Interoperability

SoHO-X platform

=> aggregated data per clinic, once a year

- Which data will be collected in the SoHO platform?

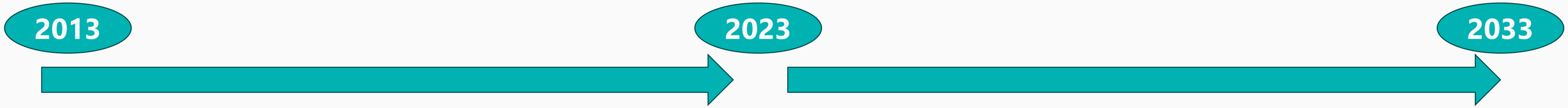
- Technical possibilities / limitations of direct transfer, or better download/upload

- GDPR – legal restraints

EuMAR by ESHRE

Innovation

ART is always developing / improving



IVM

Freeze-all

?

Ovarian tissue cryopreservation

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by ESHRE

Innovation

In the next years, there may be ..

- New treatments?
- Changes in treatment structures?
- Adapted legislation?
- ..

How can the EuMAR registry adapt to this?

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Innovation

Plan for incorporation of innovation

Identify

- Identify novelties in clinical practice
- Analyse whether the novelties would impact on the EuMAR registry

Decide

- Decide whether and when to adapt the EuMAR registry to include the novelties

Adapt & Test

- Execute the adaptation of the EuMAR registry
- Adapt parameters
- Cross check validations

Implement & Report

- Inform all data submitters to amend their API

EuMAR by ESHRE

Take-home message

WP 7 will evaluate the feasibility of

- connecting the EuMAR data registry with other registries
- adding parameters to reflect changes in ART

For both scenarios, if they are feasible, WP 7 will develop a checklist / SOP on how to execute these changes while safeguarding the integrity of the EuMAR data registry

EuMAR by ESHRE

WP2 – Spreading knowledge: Leveraging project dissemination resources

Laura Rossignoli

EuMAR by ESHRE

Co-funded by the European Union.
Project: 101079865 — EuMAR — EU4H-2021-PJ2

Communication & Dissemination

Good communication is the bridge between confusion and clarity!

To have effective communication we must understand the capacity of the audience!

EuMAR
by ESHRE

Target audience

- MAR Patients
- MAR Professionals & Clinics
- Policymakers
- Research Community / Academia
- General Public

EuMAR by ESHRE

Key deliverables

EuMAR by ESHRE

Event/Media	Specific Action	Date	Description of the action (promotion, general update, announcement, event)	Audience	Attendance number	Virtual or In-person	Link
Website	Created a dedicated section to EuMAR Grant	22/02/2023	A dedicated section on the ESHRE website has been created to share the information, updates and practical information regarding events			-	www.eshre.eu/EuMAR
Mailing	Mailing to announce the grant	14/11/2022	Mailing to announce the grant received from EU ("📢 News – ESHRE wins EU4Health Grant for monitoring of Medically Assisted Reproduction!)	ESHRE Members 8,722 receipients		-	📢 News ESHRE wins EU4Health Grant for monitoring of Medically Assisted Reproduction!
Presentation	Competent authority meeting - presented by DGSANTE	01/01/2023	Competent authority meeting (Jan 2023) – 2 slides presented by DGSANTE	National Competent Authorities	unknown	virtual	
Presentation	Project objectives presented	07/02/2023	Competent authority meeting: NV presented the projects objectives and plan	National Competent Authorities	1-2 CAs per EU MS	in-person	
Leaflet	Project overview	10/03/2023				-	
Event	Kick off Meeting	10/03/2023	Meeting to get the porject started, bringing the various stakeholders together Organised by the Project Support Team	Key stakeholders of project		in-person	https://www.eshre.eu/Data-collection-and-research/EuMAR/Events
Presentation	20230502_invitation_Presentation on EuMAR at the Working Group on Infertility and MAR	02/05/2023	Presentation on how to improve data infrastructure and measurements to study infertility and MAR. In a webinar hosted by the Working Group on "Infertility and MAR" in the European Association for Population Studies (EAPS). Presentation by Christine Wyns	Researchers with a focus on infertility and MAR	unknown	virtual	
Media	Social media to announce the Scientific Paper		Social media to announce the Scientific Paper in HROpen. Shared on ESHRE social media channels - Twitter, Facebook and LinkedIn	Instagram | Facebook | Twitter | Linkedin		-	
Media	Focus on Reproduction (FoR) article published online	26/05/2023	FoR Article. "ESHRE's ART monitoring collaboration with the European Commission moves towards cycle-by-cycle data collection"		-	-	https://www.focusonreproduction.eu/article/ESHRE-News-European-IVF-data-monitoring
Mailing	DGSANTE - competent authorities	05/05/2023	Mailing by DG SANTE to competent authorities with some general information and a reminder about the survey for WP3	National Competent Authorities	-	-	
Mailing	6 month mailing	29/09/2023	Transforming the future of MAR through data sharing - mailing with an overview of the project, whats happened in the last 6 months and what is coming in the next months	ESHRE Members: 8,722 receipients & Advocacy and Policy 849 receipients mailing lists	-	-	Transforming the future of MAR through data sharing
Presentation	10. DVR Kongress	22/09/2023	Jesper Smeenk Presente a few slides on EuMAR within his talk on Reproduktionsmedizin im europäischen Umfeld – eine Bestandsaufnahme	Mainly German Doctors/Researches form the field of reproductive healthcare			https://www.medical-communications.de/fileadmin/user_upload/DVR23_Programm_A5_WEB_230901_NEU.pdf
Presentation	Presentation at the annual meeting of the Polish Society of Repro. Medicine and Embryology (by Anna Janicka)	6-7/10/2023	Anna Janicka (EIM representative for Poland) presented the EuMAR project at the annual meeting of the Polish Society of Repro. Medicine and Embryology	Polish Society of Repro. Medicine and Embryology	unknown	in-person	https://eshre.sharepoint.com/:p:/r/sites/EU4Healthactionsgrantworkingroup/Gedeald6e%20documenten/WP2%20-%20Dissemination%20and%20communication/RESOURCES/TEMPLATES/SLIDES6?d=w83209eb696b46bb83e159e271a284866&csf=1&web=1&e=wFZwuf
Presentation	CD-P-TO meeting (Council of Europe)	10/08/2023	Kersti Lundin presented the EuMAR project at the annual meeting of the Steering Committee on Organ Transplantation (CD-P-TO) at the Council of Europe	Competent authorities of the member countries of the Council of Europe	Ca. 60	in-person (also online participants in the audience	https://eshre.sharepoint.com/:p:/r/sites/EU4Healthactionsgrantworkingroup/Gedeald6e%20documenten/WP2%20-%20Dissemination%20and%20communication/RESOURCES/TEMPLATES/SLIDES6?d=w9d16aa7be3e4ce13b1aef2&csf=1&web=1&e=qvvu1h
Mailing	Invitation to members to join the staeholder event	30/11/2023	Mailing to all ESHRE members letting them know about the stakeholder event and inviting them to join virtually	ESHRE Members 8,722 receipients		-	

www.eshre.eu/Data-collection-and-research/EuMAR

EuMAR by ESHRE

Key deliverables

Work packages

The work for the EuMAR project is divided into 8 Work Packages (WP), including 5 core WPs and 3 horizontal WPs, each executed by a dedicated working group.

→ WP3 Integration in national policies and sustainability

The project specifically aims to prepare the implementation of the central EuMAR data registry through developing connections with the national competent authorities and policymakers and gathering their feedback. To achieve this goal, ESHRE will map the different stakeholders across the EU member states, distribute information on the project and gather feedback on barriers to implementation and examine with Competent Authorities on what data they and the centres in their countries need/would like to receive.

→ WP4: Selection and definition of parameters

To prepare the data registry, this WP aims to identify relevant items to be registered and create a glossary of standardised definitions in order to ensure proper data harmonisation.

→ WP5: IT solution for the registry including the IRCC

Expected impact

ESHRE is convinced the EuMAR registry will be a first step towards increased uptake of surveillance and vigilance in MAR, which, in turn, could allow for a better understanding of the overall effectiveness and potential risks related to novel and established MAR treatments. These insights will be of benefit to patients seeking care, professionals pursuing medical excellence and health authorities.

Individual Reproductive Care Code (IRCC)

The IRCC will identify individuals (and their reproductive material) during case-by-case data reporting to the EuMAR registry. The code will be unique for each individual, even if individuals change the institution, including across country borders within the EU. The IRCC will also allow patients to visualize their own treatment data.

Background and Aims

The European IVF-monitoring (EIM) cons
European Society of Human Reproductio
Embryology (ESHRE) has been collecting
1997 with annual reports summarizing eff
treatments and trends. While valuable, th
data collection is limited in terms of the p
can be calculated from the collected sum
(such as cumulative pregnancy rates) an
collecting data on cross border activity.

European monitoring of Medically Assiste
(EuMAR) aims to develop a pan-Europea
prospective cycle-by-cycle data on the u
of Medically Assisted Reproduction (MAR

EuMAR addresses the need for more tran
surveillance and biovigilance in MAR acr
borders, including better data on the safe
offspring, donors and recipients.

Key steps of EuMAR

1. Develop a tailored data flow model that meets the national requirements of all EU Member States and avoids duplication of efforts;
2. Prepare a glossary of standardised parameters on which data is to be collected with corresponding definitions;
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.

Contact

eumar@eshre.eu | www.eshre.eu/EUMAR

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Nijverheidslaan 3, 1st floor
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EuMAR

EuMAR by ESHRE

EU Funding

The EuMAR project is co-funded by the European Union, Project: 101079865 — EuMAR — EU4H-2021-PJ2*

*Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

Kick-off meeting – 10 March 2023

The official EuMAR Kick-off Meeting was held at ESHREs headquarters in Strombeek-Bever (Belgium) on 10 March 2023.

It was the starting block where the project's background, objectives and organisation were presented by the EuMAR Team, along with input from the HaDEA project officer regarding the project's technical requirements. Each of the Work Package leaders presented their lines of actions for the different work packages aiming to meet the EuMAR projects objectives and timelines.

View agenda

EuMAR by ESHRE

Leaflet & Kick off meeting

Resources & Dissemination


PLEASE CLICK HERE IF YOU CAN'T READ THE CONTENT OF THIS EMAIL

ESHRE
Advocacy and policy engagement

European monitoring of Medically Assisted Reproduction

Dear ESHRE member,

We have some exciting news to share with you all. ESHRE was recently awarded an EU4HEALTH project grant of 1.2 million euro for the development of the EuMAR data registry. The project will run between January 2023 and December 2025.

The EuMAR data registry will be the first 'overarching' European, standardised, web-based data registry, containing high-quality cycle-by-cycle data entries from medical professionals across the EU. The EuMAR registry aims to facilitate data sharing for open science across institutes and to allow the longitudinal and cross-border follow up of medically assisted reproduction (MAR) data.

ESHRE is convinced the EuMAR registry will be a first step towards increased uptake of surveillance and vigilance in MAR, which, in turn, could allow for a better understanding of the overall effectiveness and potential risks related to novel and established MAR treatments. These insights will be of benefit to patients seeking care, professionals pursuing medical excellence and health authorities - a win for all.

We are excited about the prospects of this project and what it means and look forward to keeping you posted through mailings and social media. More details on the project will be available on the ESHRE website as of spring 2023.

Co-funded by the European Union

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We hope you find this information useful. For questions, comments, feedback or suggestions please reply to this e-mail and tell us exactly what you think.

Please add kristina@eshre.eu to your address book to ensure our e-mails reach your inbox!

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Article Contents

JOURNAL ARTICLE

EuMAR: a roadmap towards a prospective, cycle-by-cycle registry of medically assisted reproduction in Europe†

Christian De Geyter, Carlos Calhaz-Jorge, Veerle Goossens, Cristina M Magli, Jesper Smeenk, Kristina Vesela, Nathalie Vermeulen, Christine Wyns

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Published: 24 April 2023 **Article history** ▾

Interview 01 Christian De Gryter
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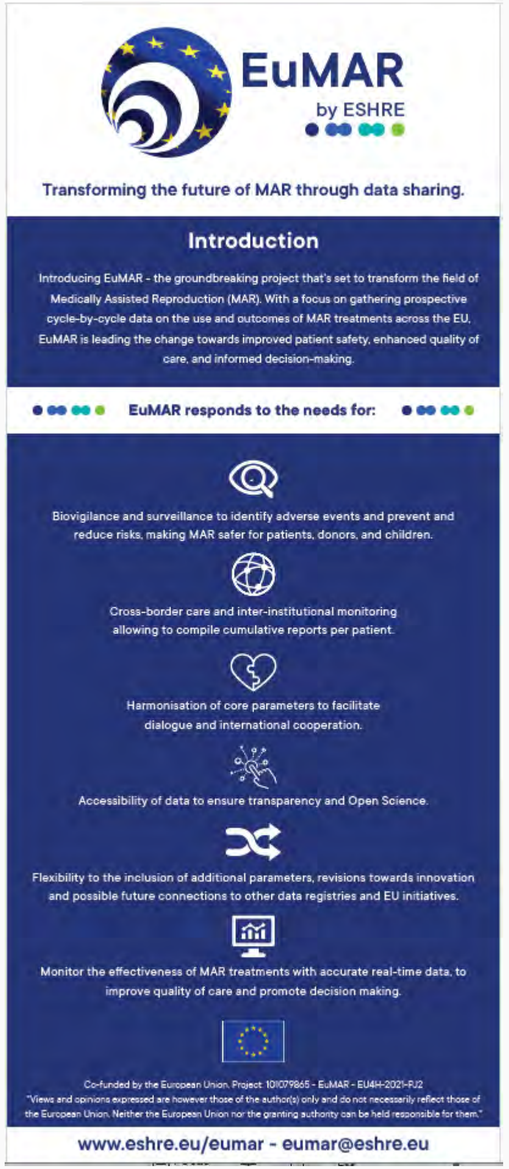
Interview 02 Carlos Carlos Calhaz-Jorge
Add description

Interview 03 Veerle Goossens
Add description



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Thank you!

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