EuMAR by ESHRE

European monitoring of Medically Assisted Reproduction (EuMAR)

D5.1 Instructions on the use of the IRCC

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VERSION	PREPARED BY (name and organisation)	REVIEWED BY (name and organisation)	DATE
1.0	Veerle Goossens (ESHRE)	Project Support Team (ESHRE), Project Steering Committee.	17/09/2024

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Acronyms and abbreviations

API	Application Programming Interface
D	Deliverable
EMR	Electronic Medical Record
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
EuMAR	European monitoring of Medically Assisted Reproduction
GDPR	General Data Protection Regulation
ICSI	Intracytoplasmic Sperm Injection
IRCC	Individual Reproductive Care Code
IT	Information Technology
IUI	Intrauterine Insemination
IVF	In Vitro Fertilisation
MAR	Medically Assisted Reproduction
SO	Specific Objective
WP/s	Work Package/s

Executive Summary

This document with instructions on the use of the Individual Reproductive Care Code (IRCC) provides an overview of what the added value of the IRCC is, how it can be of use within the data collection and analysis and how it can serve as a quality control marker for the patients enrolled in the program.

The "Instructions on the use of the IRCC" is a WP5 deliverable that documents the different steps in requesting, using and changing the IRCC for clinics and national competent authorities.

Introduction

The European monitoring of Medically Assisted Reproduction (EuMAR) is set to develop a European registry of cycle-by-cycle data on Medically Assisted Reproduction (MAR) treatments. The EuMAR registry has the potential to improve research in the field by standardising data collection and making treatment outcomes transparent and accessible. It is also expected that, with the collection of cumulative cycle data (=addition of outcomes of a fresh embryo transfer and successive frozen transfers of embryos issued form a same/single egg retrieval), it can better inform patients and clinicians of the time to pregnancy per oocyte-pick up. It is also aimed at providing a comprehensive overview of cross-border care trends.

The ultimate goal of EuMAR is to provide the different stakeholders i.e., medical professionals, patients and patient organisations, policymakers and authorities, researchers and the general public, with high quality data to quantify the effectiveness and safety of current and new technologies in MAR, including IVF, ICSI, IUI and fertility preservation. To achieve this goal, EuMAR sets out to:

i) Develop a tailored data flow model that meets the national requirements of all EU Member States and avoids duplication of efforts.
ii) Prepare a glossary of standardised parameters on which data is to be collected with corresponding definitions.
iii) 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 will be tested in a pilot study in several different EU Member States that reflect the variation in current national data collection systems.

The EuMAR project involves more than 40 participants from 18 countries who are ESHRE members with extensive experience in MAR data collection. They work across eight Work Packages (WPs), each of which focuses on a specific area. WP5 addresses project Specific Objective 2 (SO2), being the development of the IRCC and a web-based transnational IT-solution able to ensure the prospective collection of cycle-by-cycle and case-based harmonised data sets. An IT solution for the IRCC was developed and supplemented with a manual for MAR services offering centres on how to use it, together with educational information for patients/donors and professionals.

The system must be able to link different steps of the sequential MAR treatment, potentially performed in different clinics European-wide, that may span long time intervals, so that a cumulative outcome report (per patient) can be generated.

Concept

The theoretical concept of the EuMAR registry was previously detailed in a scientific article published in a high-ranking peer-reviewed journal (De Geyter *et al.*, 2016). This concept includes a unique patient/donor identifier code named the IRCC. In practice, care providers will be able to obtain the IRCC via an easily accessible transnational web-based platform at the start of the treatment cycle for prospective registration. The IRCC will facilitate the ongoing monitoring of individual patients throughout their reproductive treatment process and outcomes and if applicable, across multiple care providers in Europe.

Health care institutions will enter the IRCC and treatment cycle parameters directly into the EuMAR data registry or through a national registry, where available. The IRCC will also enhance personal data security, as the IRCC will be encrypted when shared with the EuMAR registry and stored as a different code (Annex 1). Thus, analyses within the EuMAR registry can be conducted without accessing identifiable data, ensuring patient anonymity and full compliance with data protection. The functionality of the IRCC and data collection system will be evaluated during the pilot study.

Definitions and functional specifications

Individual Reproductive Care Code (IRCC) is a unique patient code (made up of a long code of letters and numbers) assigned to each patient, including each partner involved in the treatment cycle, to link all their treatments and to facilitate the calculation of cumulative live birth rates. Each IRCC will only be visible to the treating clinic and the national registry (when there is one). When shared with the EuMAR registry, the IRCC will be encrypted into the EuMAR code. These two codes are always different to ensure patients' privacy is protected. This means that the IRCC will never be stored in the EuMAR registry and it is essential that IRCCs are saved in the clinics' own medical record system as soon as they are created. That will be the only way to retrieve an IRCC.

ClinicSwitch Code is a QR code (made up of a long code of letters and numbers) that patients should use if they change clinics. It ensures the cumulative registration of data, while respecting patients' privacy. The ClinicSwitch Code does not contain any information whatsoever, it does not allow to see a patient's information. It is used by a clinic treating a patient that comes from another clinic to create a new IRCC. Each member of the couple will have a different ClinicSwitch Code.

Users are the clinic staff or registry members that will be authorized to log into the EuMAR registry and be responsible for requesting IRCCs and ClinicSwitch codes for patients.

System administrator is the ESHRE staff member responsible for assigning user roles to pilot study participants in the EuMAR registry.

IT-scheme of the Individual Reproductive Care Code (IRCC)

Different data collection scenarios require tailored approaches for setting up the IRCC. These scenarios include countries without a registry, countries with a registry but without patient identification and countries with a registry that includes patient identification. Detailed schemes for each scenario are provided in the annexes to this report.

Request and use of the Individual Reproductive Care Code (IRCC)

There are two options for requesting an IRCC:

1. Clinics can manually request an IRCC through the portal and then either manually input the data or add the IRCC to their own Electronic Medical Record (EMR) system which then allows clinics or national registries to upload all data via an API.
2. The EMR system provider integrates an IRCC request function directly within the EMR system, utilising an API.

Option 1. Manual request through portal

For each new patient, a new IRCC must be requested. The following instructions, illustrated with screenshots of the data registry, explain the process:

1. Log in to the data collection portal.
2. Click on the "+New registration" button (Figure 1).
3. This will open the "New patient" window.
4. Enter the patient's sex, month and year of birth and registration date (Figure 2).
5. The EuMAR portal will automatically generate an IRCC for each new patient, as indicated by the green arrow in Figure 2. Copy this code and then paste it into the patient's record.

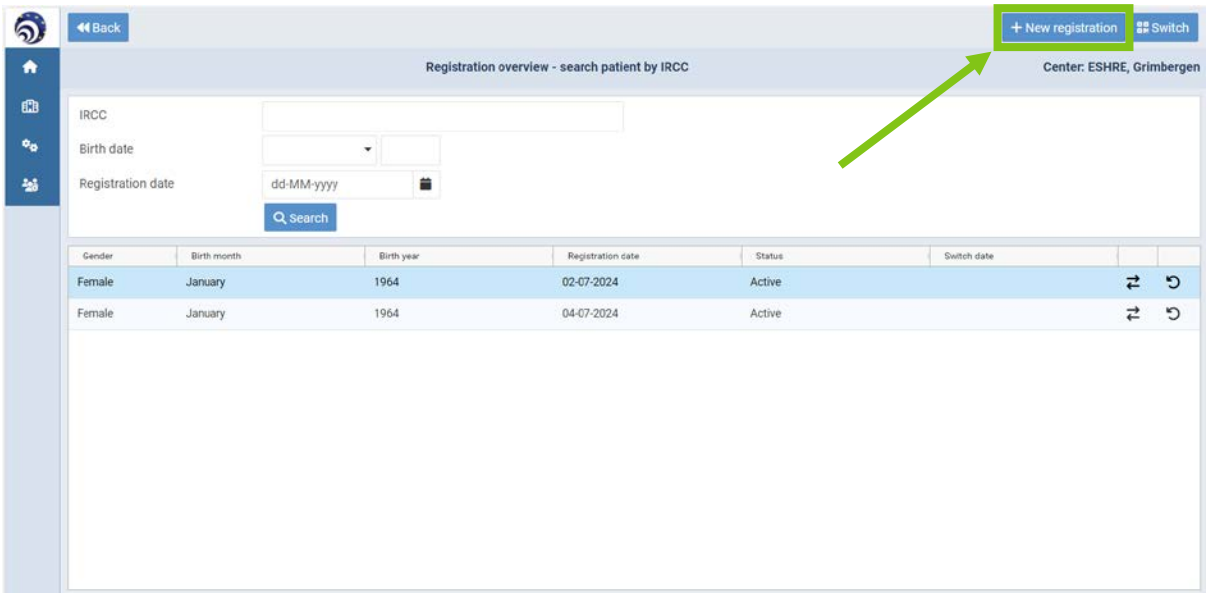


Figure 1: Registering a new patient.

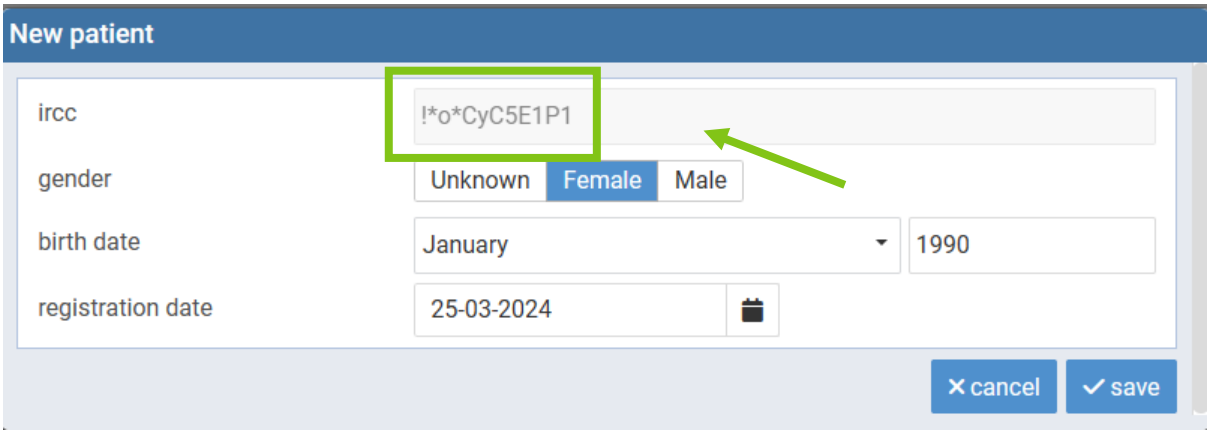


Figure 2: New patient registration window.

After clicking the "save" button, a warning screen will appear (Figure 3). In this screen the IRCC code should be pasted to verify that it was copied correctly. This step is solely for validation. The IRCC must then be saved in the clinic's own records.

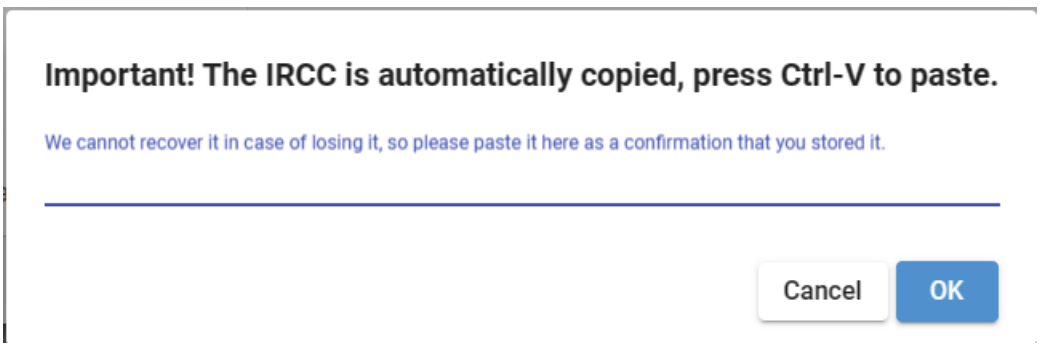


Figure 3: Verification copying the IRCC code.

Once saved, the patient is added to the list and can be searched by using the IRCC (Figure 4).

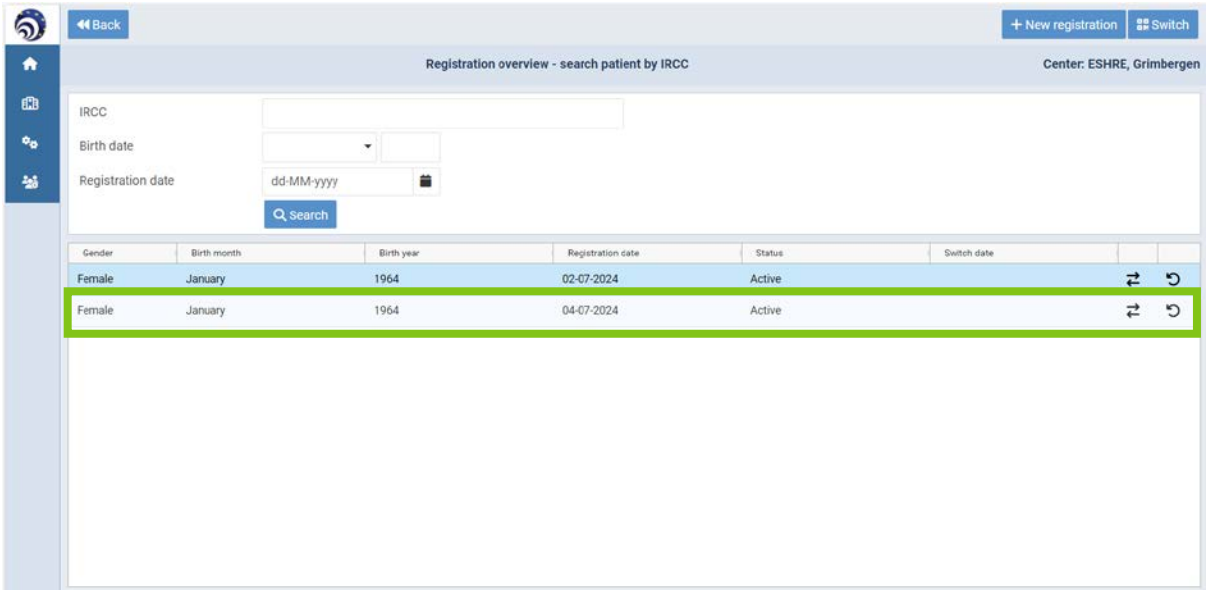


Figure 4: Patient overview.

If the treatment concerns a couple, the same process needs to be repeated for the partner. Each member of a couple needs their own IRCC.

Option 2. Request through EMR system

In this option, the EMR provider incorporates a function within the EMR system that enables automatic IRCC requests and additions. The use of an API is mandatory for this functionality. However, the specific implementation details will vary by provider and are not covered in this project.

Once an IRCC is assigned to a patient (and the partner if applicable), all data collected and transmitted to EuMAR will be linked to this IRCC. This ensures that system administrators can analyse cumulative data, as all treatment cycles will be recorded anonymously under the same code.

Deviations from the proposal

1. Need of a ClinicSwitch Code

In the initial proposal for this project, a single IRCC code was planned. However, as we prepared for the pilot study, it became clear that this would be insufficient for patients transitioning between centres, especially considering the strict data protection regulations and the need to ensure patients' anonymity in the EuMAR registry. To address this, the ClinicSwitch Code was introduced. This QR code, which contains no personal information, allows patients to move from one clinic to another while maintaining the same code in the EuMAR registry.

When a patient decides to pursue their treatment in another clinic, they can request a ClinicSwitch Code (QR) from their current clinic. The new clinic will not have access to any information about previous treatments and similarly, the previous clinic will not see any new data. Each clinic will only be able to view the treatments it has administered.

In the patient list on the portal, patients can be categorised as either "Active" or "Switched" to reflect their status. Users can generate a QR code for clinic switching, facilitating smooth transitions between clinics.

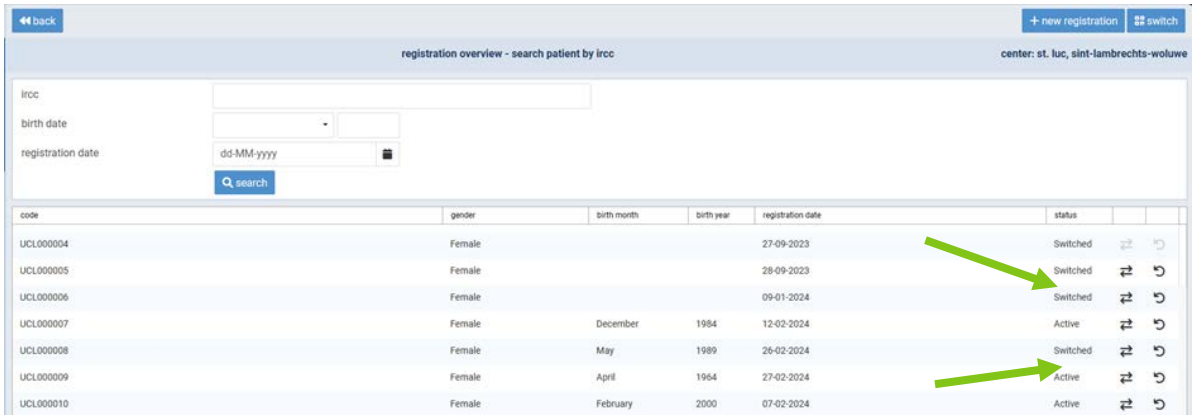


Figure 5: Patient list.

Clicking on the ⇄ allows users to generate a switch letter that includes a QR code, which patients can present at their next clinic. An example of this letter is provided in Annex 2. If the patient has a partner linked to their record, the system will prompt whether you also want to switch the partner to the new clinic.

The new clinic can scan the QR code with a mobile device to complete the clinic switch. This process provides the new clinic with a new IRCC associated with the original IRCC, enabling the EuMAR registry to receive data in a cumulative manner while maintaining strict anonymisation. With this process, each clinic will have a different IRCC, but the EuMAR code will remain the same, encrypted from all the different IRCCs. If the ⇄ is accidentally selected or if the patient decides not to proceed with the clinic switch, users can click the reverse button next to it ↺) to invalidate the ClinicSwitch code scans.

Once the ClinicSwitch code has been scanned by the new clinic, the switch and reverse buttons will no longer be functional. Additionally, after scanning, all previous cycle information for the patient becomes uneditable to safeguard data integrity and ensure the accuracy of the patient's medical history.

2. Translations of the IRCC scheme and manual

The participating centres received more extensive manuals which were shared in English, including the instructions on the IRCC, as well as other instructions needed for the pilot study.

During the pilot study, it was not considered necessary to translate the different documents as the main language, comfortable for all was English.

Conclusions

This deliverable provides an overview of how the IRCC can be requested and utilised by various stakeholders. It also explains the necessity of using a ClinicSwitch code to create a comprehensive register that tracks all stages of a patient's fertility journey while remaining fully GDPR compliant.

In the coming months, the use of these codes will be validated through the pilot study.

References

De Geyter Ch, Wyns C, Mocanu E, de Mouzon J, Calhaz-Jorge C. Data collection systems in ART must follow the pace of change in clinical practice. Hum Reprod. 2016 Oct;31(10):2160-3.

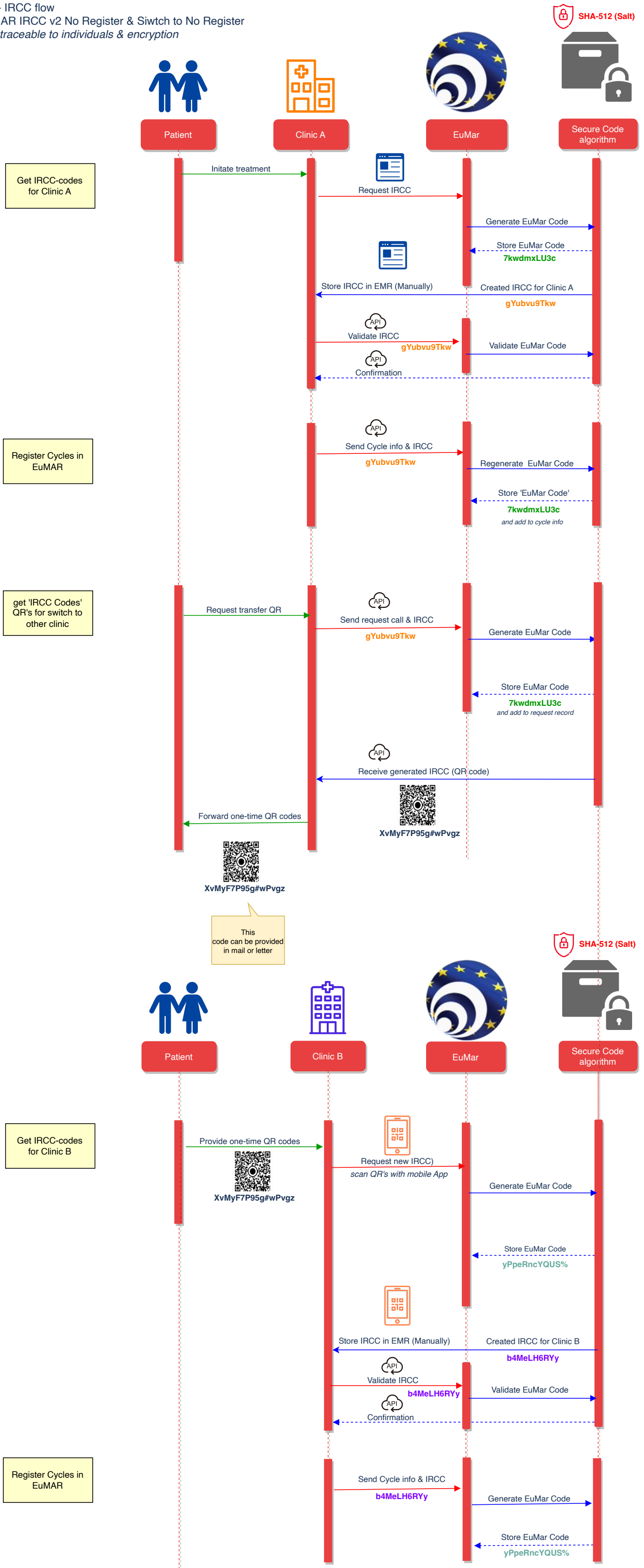
Annex 1. EuMAR IRCC IT- schemes

Annex 2. Example ClinicSwitch code letter

EuMAR - IRCC flow

1.a. EuMAR IRCC v2 No Register & Siwtch to No Register

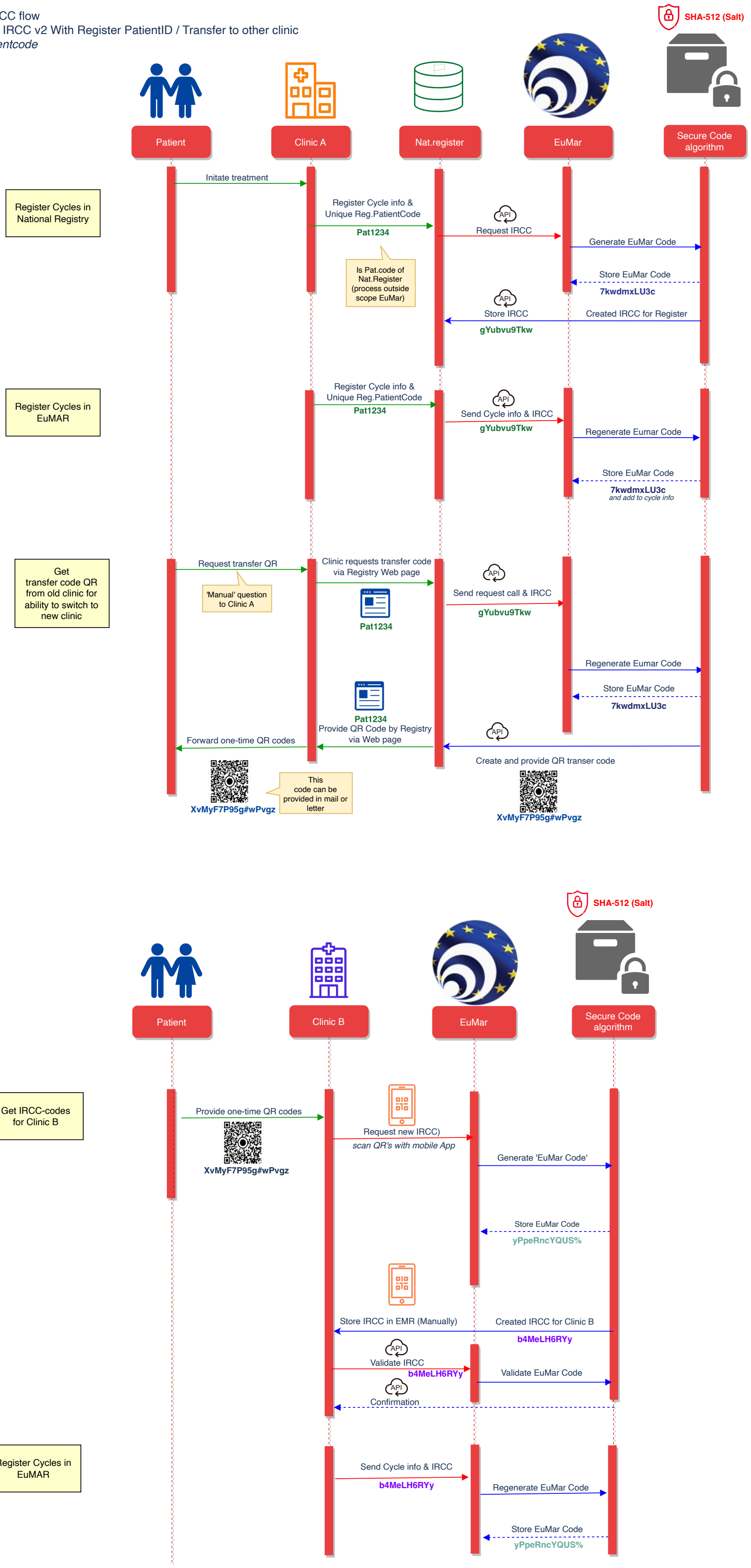
data not traceable to individuals & encryption



EuMAR - IRCC flow

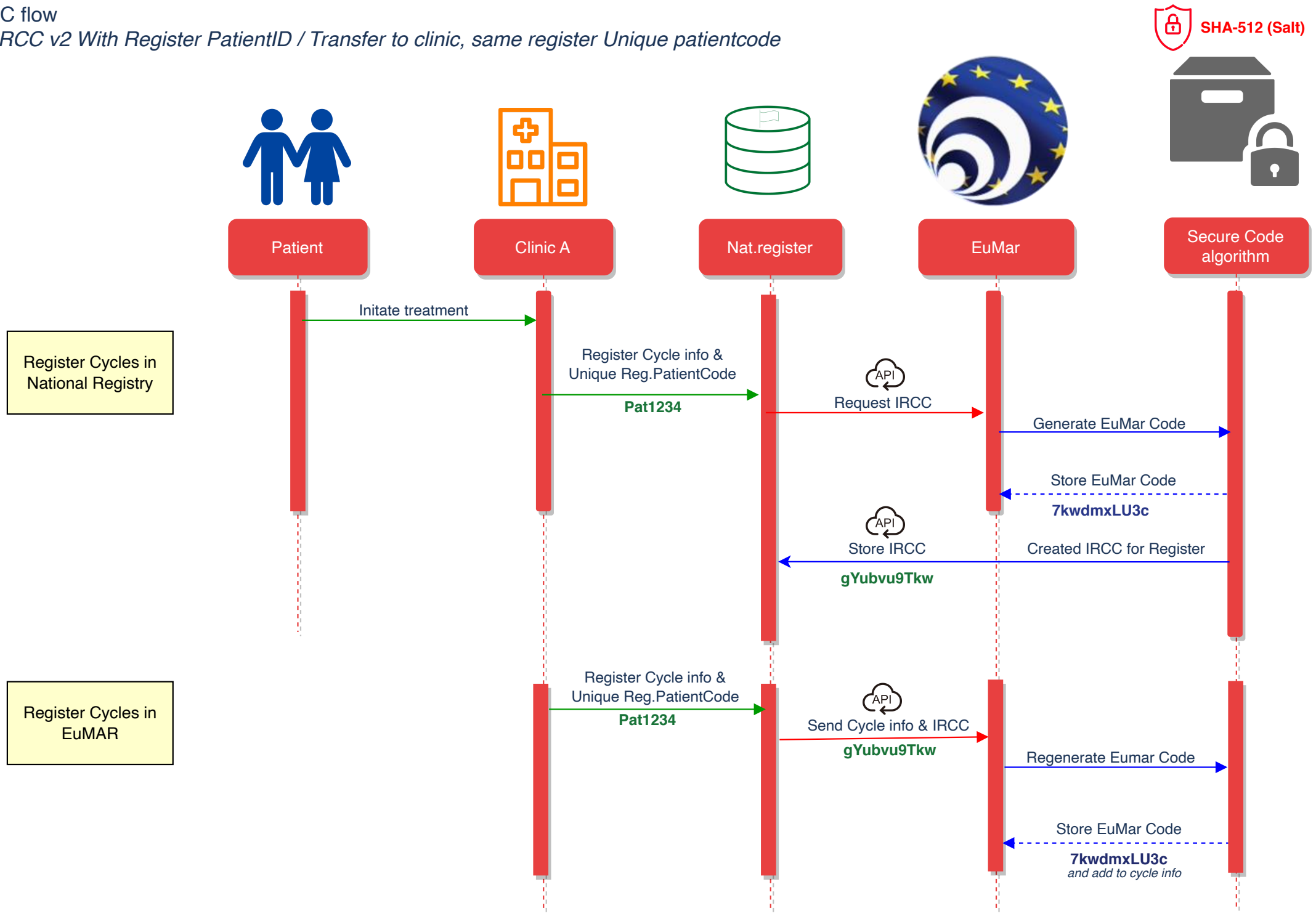
2.a. EuMAR IRCC v2 With Register PatientID / Transfer to other clinic

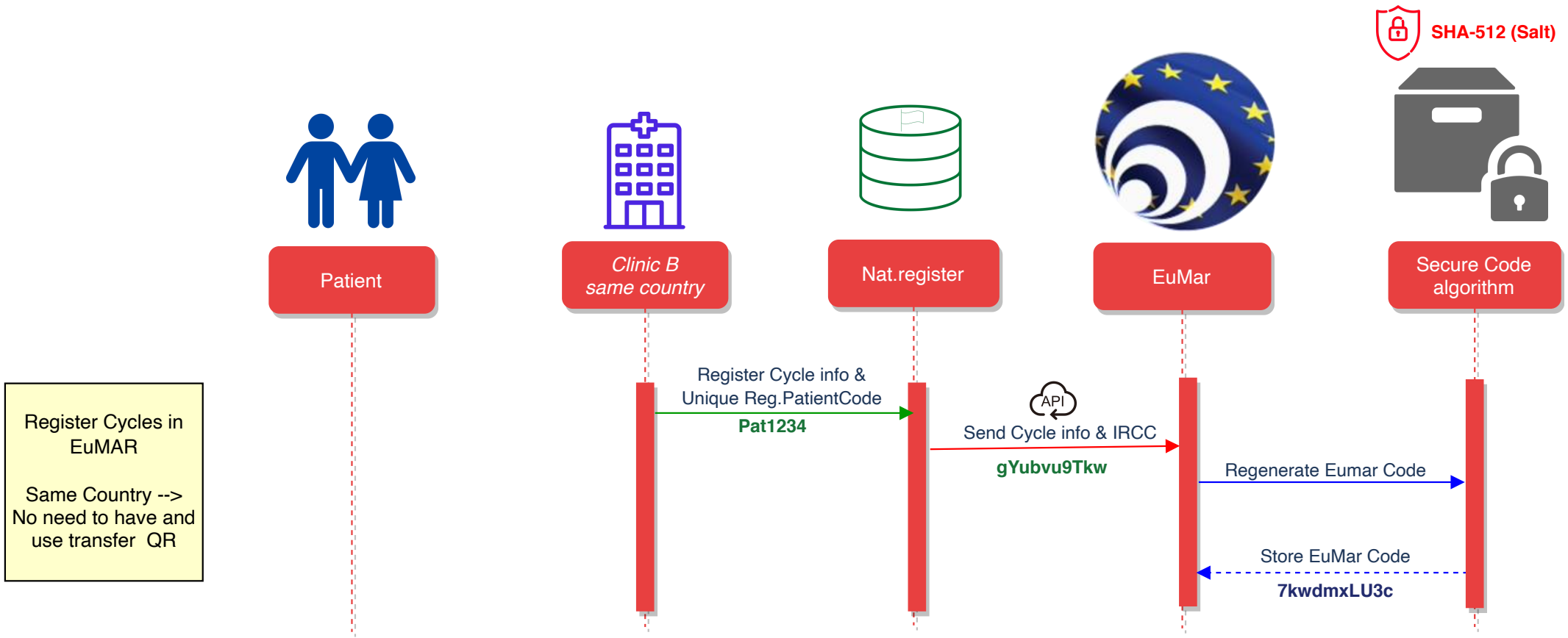
Unique patientcode



EuMAR - IRCC flow

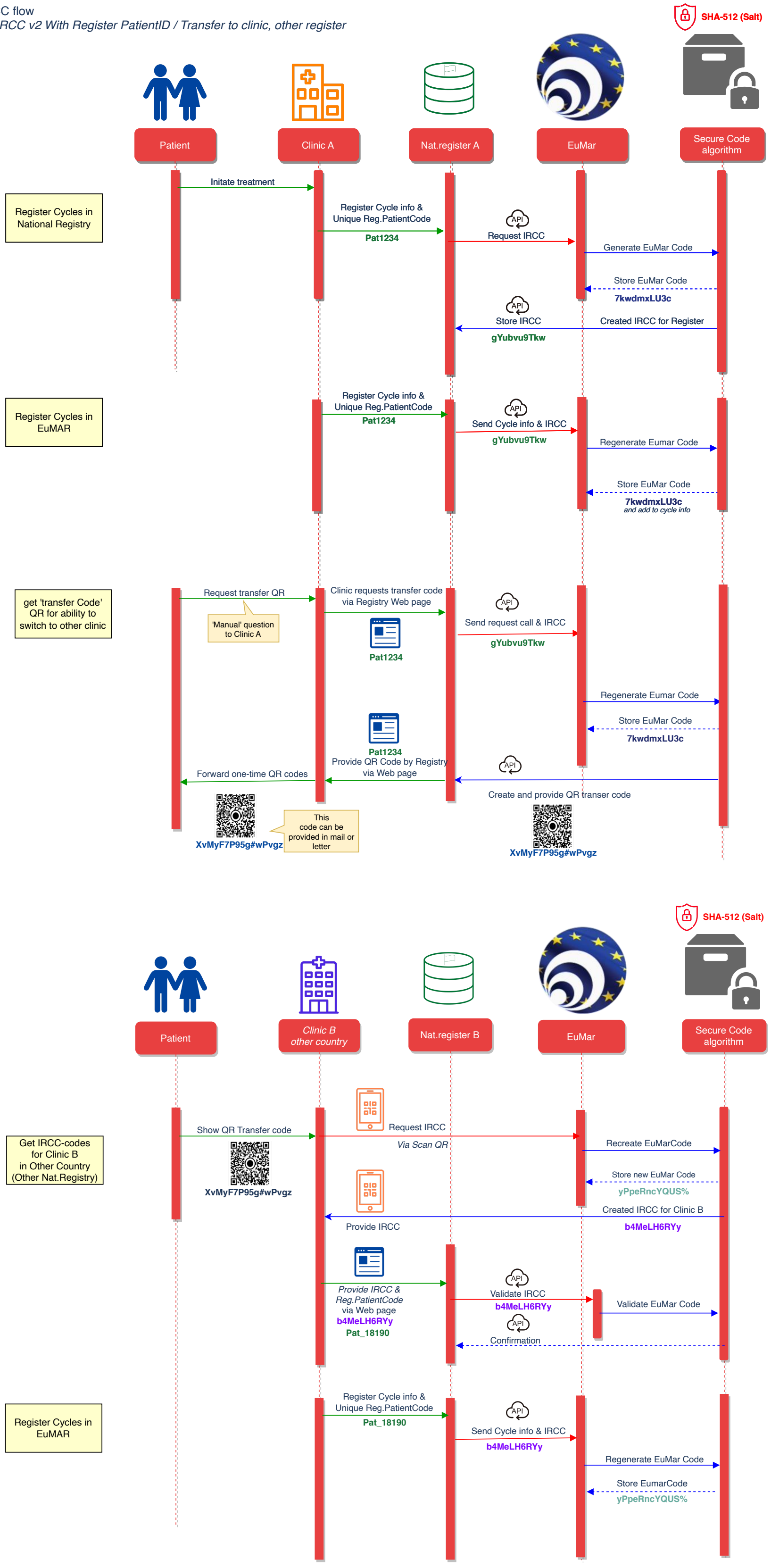
2.b. EuMAR IRCC v2 With Register PatientID / Transfer to clinic, same register Unique patientcode in Register





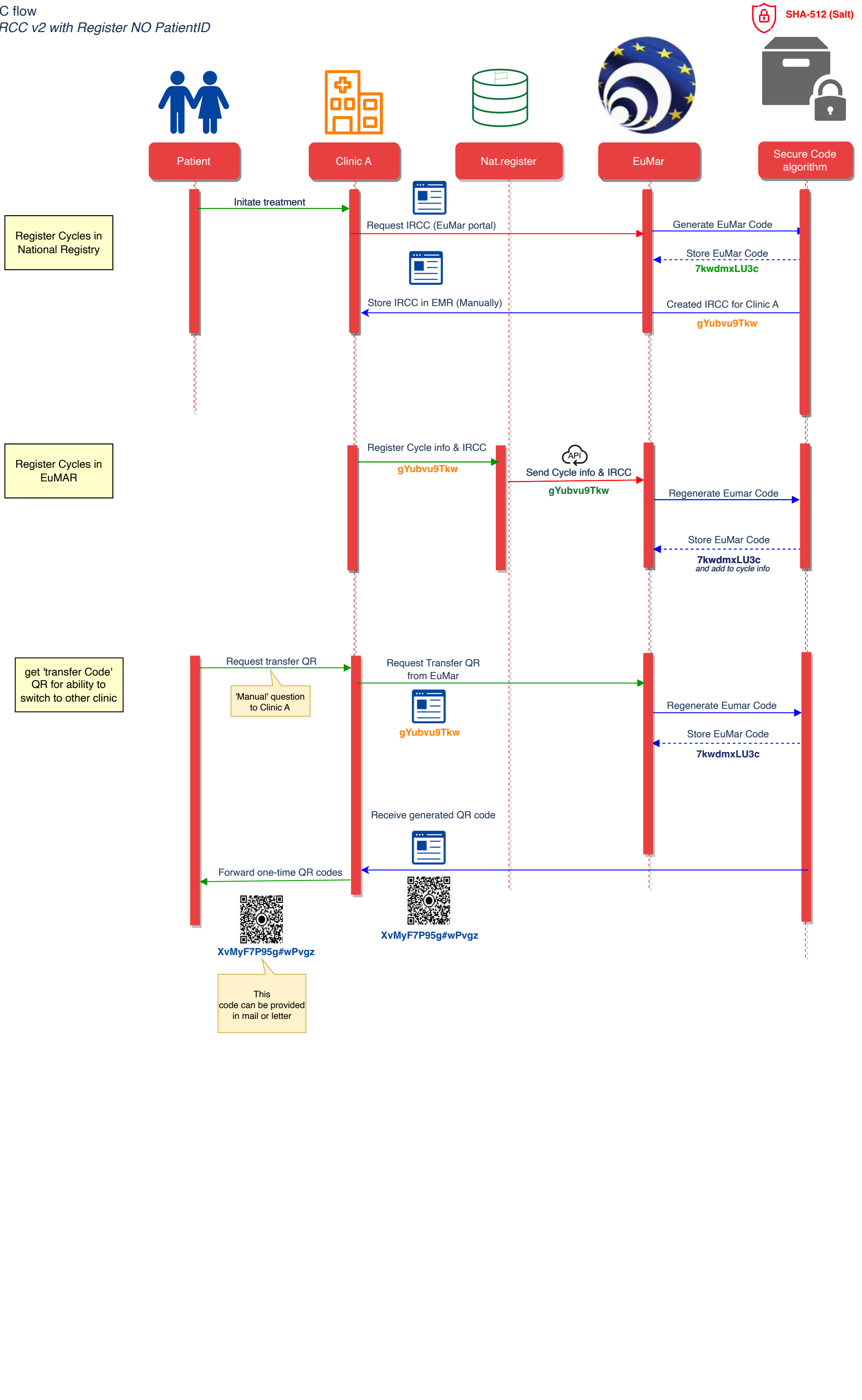
EuMAR - IRCC flow

2.c. EuMAR IRCC v2 With Register PatientID / Transfer to clinic, other register



EuMAR - IRCC flow

2.d. EuMAR IRCC v2 with Register NO PatientID



02-07-2024

IMPORTANT: Bring this letter with you on your first visit to a new clinic

Dear patient,

Enclosed you will find your EuMAR ClinicSwitch code. We kindly ask you to provide this letter to your new clinic if you decide to continue your infertility treatment elsewhere.

EuMAR is a European registry of medically assisted reproduction treatments. The data in the EuMAR registry will be used for statistical and scientific purposes. EuMAR maintains complete anonymity, ensuring that none of the data on your treatments can be traced back to you. **Your new clinic will not be able to access any data on your previous treatments with this code.**

The purpose of the ClinicSwitch code is to allow linking the anonymous data on your treatments at different clinics within the EuMAR registry. This is important for estimations of the real chances of achieving a live birth over an entire treatment course.

Thank you for your cooperation.

For more information on the EuMAR registry and the ClinicSwitch code, please visit www.eshre.eu/eumar or reach out to eumar@eshre.eu.

qaBz5FNJevqfOlEi$wHBU\hd@IF4cgzMkb8jlQgai6FtzfuFsGM2$U4Bxz%9cm3wbjG1lCI*6*'b03fi6XTIqQdohgIkm6m6eYBhz9S$xKiWDqzumiZUAy%s

Figure 23: Example of a ClinicSwitch code letter together with the QR code and the plain code.

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