EMA
EUROPEAN MEDICINES AGENCY

Session 5: Looking at the future

Updates on EudraVigilance

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1st EMA/HMA Multi-Stakeholder Forum
on EudraVigilance and Signal Detection

Agenda

- EV data masking guideline
- ICSR download APIs
- Additional values for *C.5.4 Study type* and *D.5 Patient sex*

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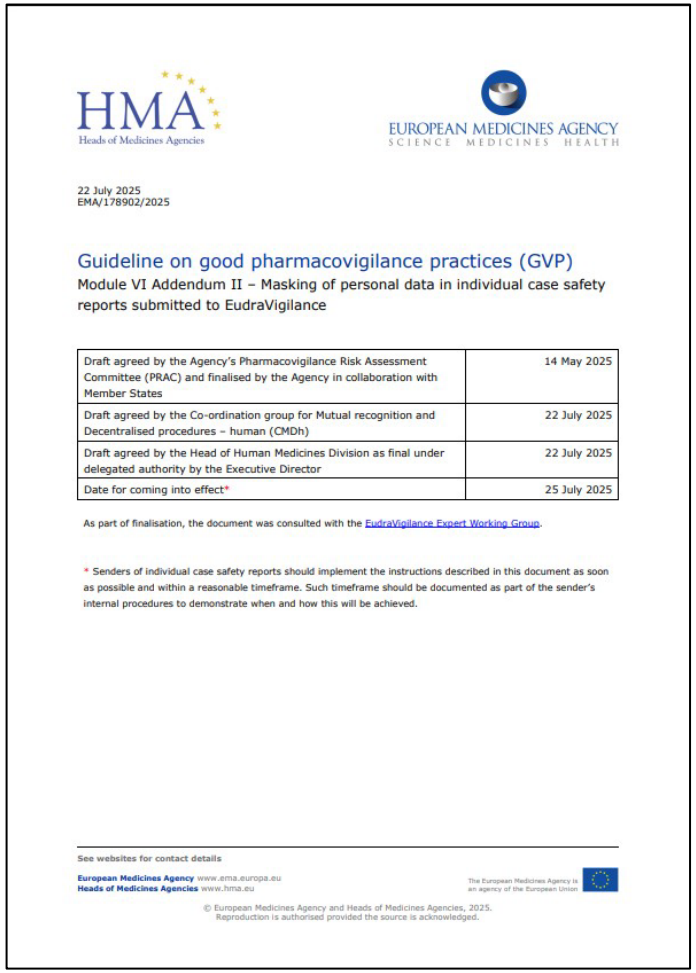
EV data masking guideline

EV Data masking guideline

- As outcome of an EV audit performed by the EDPS in the context of pseudonymisation procedures and personal data masking, the EDPS recommended to the Agency to adopt, together with the joint controllers (EC and NCAs), a common masking policy that should be complied with by all entities reporting to EudraVigilance.
- EMA together with NCAs and in consultation with the MAHs developed a masking guideline to be implemented by all senders of individual case safety report (ICSRs) and suspected unexpected serious adverse reactions (SUSARs) to EV.
- This masking guideline was published in July 2025 as **GVP Module VI - Addendum II: Masking of personal data in individual case safety reports submitted to EudraVigilance**[1] and provides instructions that complement Section *VI.C.6.2.2.10. Data protection laws*, forming an integral part of the guidance in **GVP Module VI**[2].



HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2025
EMA/178902/2025

Guideline on good pharmacovigilance practices (GVP)
Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance

Draft agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	14 May 2025
Draft agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)	22 July 2025
Draft agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	22 July 2025
Date for coming into effect*	25 July 2025

As part of finalisation, the document was consulted with the EudraVigilance Expert Working Group.

* Senders of individual case safety reports should implement the instructions described in this document as soon as possible and within a reasonable timeframe. Such timeframe should be documented as part of the sender's internal procedures to demonstrate when and how this will be achieved.

See websites for contact details
European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

The European Medicines Agency is an agency of the European Union

1 - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-addendum-ii-masking-personal-data-individual-case-safety-reports-submitted-eudravigilance_en.pdf
2 - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports-suspected-adverse-reactions-medicinal-products-rev-2_en.pdf

GVP Module VI – Addendum II

- All ICH-E2B(R3) data elements were assessed to determine if their data was required in support of the pharmacovigilance (PV) and safety monitoring obligations set out in the EU pharmaceutical legislation.
- The relevant obligations placed on the Agency, NCAs and the Pharmacovigilance Risk Assessment Committee (PRAC) were also taken into consideration.
- The GVP VI Add. II instructions do not change the current **EV Business Rules**[3] (there is no impact to the electronic submission process of ICSRs and safety messages).
- The **EU Individual Case Safety Report Implementation Guide**[4] does not require any changes and remains fully applicable.

Note # 1:

The instructions should be implemented **as soon as possible** and within a **reasonable** timeframe

Note # 2:

The timeframe should be **documented** to demonstrate **when** and **how** this will be achieved.

Note # 3:

They apply to **all** cases: **ICSRs** (including Literature & non-EEA cases) and **SUSARs**.

3 – https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eu-individual-case-safety-report-icsr-implementation-guide-business-rules-spreadsheets_en.zip
4 – https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-union-individual-case-safety-report-icsr-implementation-guide_en.pdf

GVP Module VI – Addendum II

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Data elements to be left blank

- The 11 data elements provided in **Table VI.Add.II.2.** are **not** necessary for signal management, duplicate detection or ICSR processing.
- Since the use of nullFlavors is not supported by the ICH E2B(R3) guideline (see Annex IV ICH-E2B(R3)), the sender of the ICSRs should leave these 11 data elements **blank** when submitting ICSRs to EudraVigilance.

Table VI.Add.II.2.: 11 ICSR data elements to ALWAYS be left blank by the sender of ICSRs to EudraVigilance (provided that the data are available to the sender)

Field Identification ICH or EU E2B(R3) Data Elements in line with EU ICSR Implementation Guide		
Field ICH or EU	**ICH E2B(R3) data element reference**	**Data field name**
ICH	C.3.3.2	Sender's Title
ICH	C.3.3.3	Sender's Given Name
ICH	C.3.3.4	Sender's Middle Name
ICH	C.3.3.5	Sender's Family Name
ICH	C.3.4.1	Sender's Street Address
ICH	C.3.4.2	Sender's City
ICH	C.3.4.3	Sender's State or Province
ICH	C.3.4.4	Sender's Postcode
ICH	C.3.4.5	Sender's Country Code
ICH	C.3.4.6	Sender's Telephone
ICH	C.3.4.7	Sender's Fax

Data elements to be masked

- The 13 data elements provided in **Table VI.Add.II.1.** are **not** required for signal management, duplicate detection or ICSR processing.
- Whenever directly reported to organisation by the reporter, the data element(s) should be populated with the ***MSK*** nullFlavour.

Table VI.Add.II.1.: 13 ICSR data elements to ALWAYS be masked by the sender of ICSRs to EudraVigilance (provided that the data are available to the sender)

Field Identification ICH or EU E2B(R3) Data Elements in line with EU ICSR Implementation Guide		
Field ICH or EU	**ICH E2B(R3) data element reference**	**Data field name**
ICH	C.2.r.1.1	Reporter's Title
ICH	C.2.r.1.2	Reporter's Given Name
ICH	C.2.r.1.3	Reporter's Middle Name
ICH	C.2.r.1.4	Reporter's Family Name
ICH	C.2.r.2.1	Reporter's Organisation
ICH	C.2.r.2.2	Reporter's Department
ICH	C.2.r.2.3	Reporter's Street
ICH	C.2.r.2.6	Reporter's Postcode
ICH	C.2.r.2.7	Reporter's Telephone
ICH	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)
ICH	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)
ICH	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)
ICH	D.10.1	Parent Identification

Data elements that may contain (or not) personal data and are required for PV processes

- The data elements provided in **Table VI.Add.II.3.** and **Table VI.Add.II.4.** may contain (or not) personal identifiers or quasi-identifiers. In any case, they are required for signal management, duplicate detection and ICSR processing.
- When available, these elements should **not be masked nor left blank** by the sender of the ICSR to EudraVigilance.

ICH	C.2.r.2.4	Reporter's City
ICH	C.2.r.2.5	Reporter's State or Province
ICH	C.2.r.3	Reporter's Country Code
ICH	C.3.2	Sender's Organisation
ICH	C.3.3.1	Sender's Department
ICH	C.3.4.8	Sender's E-mail Address
ICH	C.4.r.1	Literature Reference(s)
ICH	D.1	Patient (name or initials)
ICH	D.1.1.4	Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)
ICH	D.2.1	Date of Birth
ICH	D.2.2a	Age at Time of Onset of Reaction / Event (number)
ICH	D.2.2b	Age at Time of Onset of Reaction / Event (unit)
ICH	D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (number)
ICH	D.2.2.1b	Gestation Period When Reaction/Event Was Observed in the Foetus (unit)
ICH	D.2.3	Patient Age Group (as per reporter)
ICH	D.3	Body Weight (kg)
ICH	D.4	Height (cm)
ICH	D.5	Sex
ICH	D.6	Last Menstrual Period Date
ICH	D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)
ICH	D.10.2.1	Date of Birth of Parent
ICH	D.10.2.2a	Age of Parent (number)
ICH	D.10.2.2b	Age of Parent (unit)
ICH	D.10.3	Last Menstrual Period Date of Parent
ICH	D.10.4	Body Weight (kg) of Parent
ICH	D.10.5	Height (cm) of Parent
ICH	D.10.6	Sex of Parent

Clarification & EVWEB implementation

Does the masking guideline contradict the current GVP VI and EU ICSR Imp. Guide?

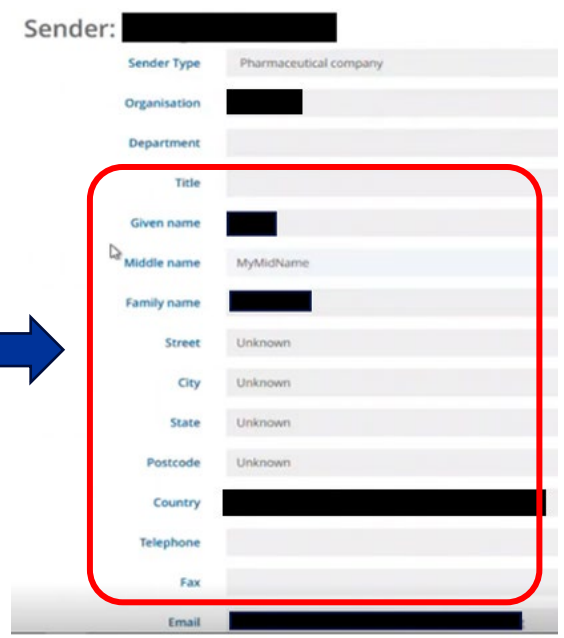
- The ICSR implementation guide acknowledges that for certain data elements that can identify an individual (such as the *D.1 Patient (name or initials)* or the *D.2.1 Date of Birth)*, the use of the ***MSK*** flag *can* be appropriate.
- In any case, the EMA would like to highlight that GVP Module VI was last revised in 2017 and the latest version of the EU ICSRs implementation guide dates to March 2021.
- Despite the GDPR being published in 2016 and becoming effective in May 2018, there was no agreed common masking policy among EU Member States.
- **The masking policy published in 2025 supersedes the older guidance** (provided in GVP Module VI and the EU ICSRs implementation guide).

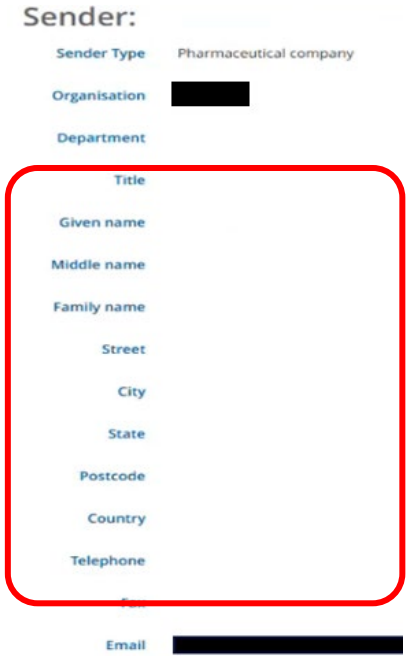
EVWEB implementation:

- Changes to the EVWEB tool are being made by EMA and will be implemented before the end of the year.
- Legacy ICSR data in EV will also be updated accordingly.

Data elements to be left **blank** (Sender section)

ICH	C.3.3.2	Sender's Title
ICH	C.3.3.3	Sender's Given Name
ICH	C.3.3.4	Sender's Middle Name
ICH	C.3.3.5	Sender's Family Name
ICH	C.3.4.1	Sender's Street Address
ICH	C.3.4.2	Sender's City
ICH	C.3.4.3	Sender's State or Province
ICH	C.3.4.4	Sender's Postcode
ICH	C.3.4.5	Sender's Country Code
ICH	C.3.4.6	Sender's Telephone
ICH	C.3.4.7	Sender's Fax

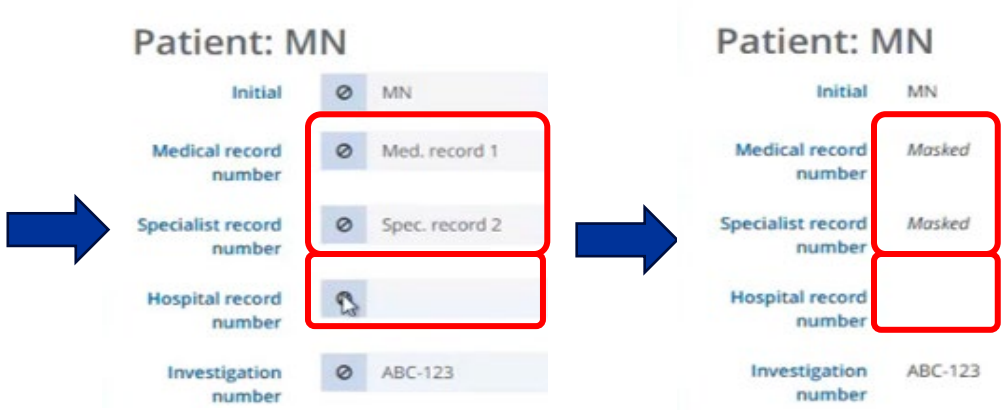




Note:
Where the user/Sender failed to erase the data, the EV system will delete it.
This also applies to cases sent with the EVWEB tool.

Data elements to be ***Masked*** (patient, parent & reporter sections)

ICH	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)
ICH	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)
ICH	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)



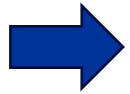
ICH	D.10.1	Parent Identification

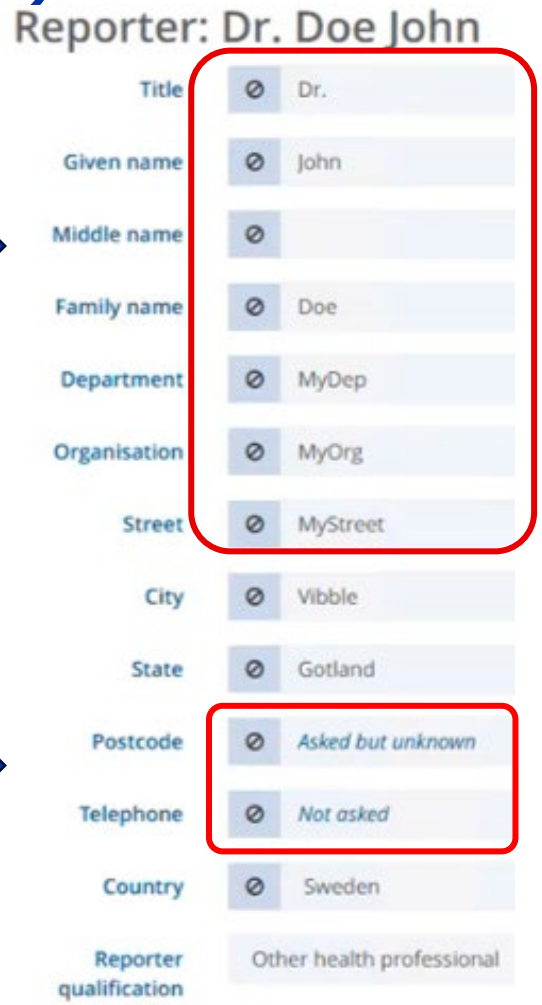
Note # 1:

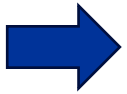
If the User/Sender failed to mask the data, the system will automatically apply the ***MSK*** nullFlavor to any field that contains a value other than a nullFlavor.

Data elements to be ***Masked*** (patient, parent & reporter sections)

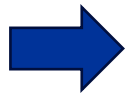
ICH	C.2.r.1.1	Reporter's Title
ICH	C.2.r.1.2	Reporter's Given Name
ICH	C.2.r.1.3	Reporter's Middle Name
ICH	C.2.r.1.4	Reporter's Family Name
ICH	C.2.r.2.1	Reporter's Organisation
ICH	C.2.r.2.2	Reporter's Department
ICH	C.2.r.2.3	Reporter's Street







ICH	C.2.r.2.6	Reporter's Postcode
ICH	C.2.r.2.7	Reporter's Telephone



Note # 2:

For the fields with no data or populated with a *nullFlavor*, the system will not make any changes.

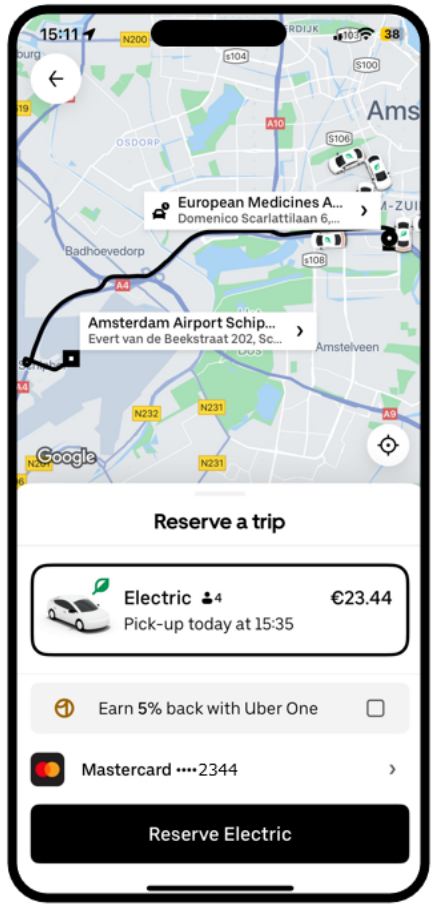
2

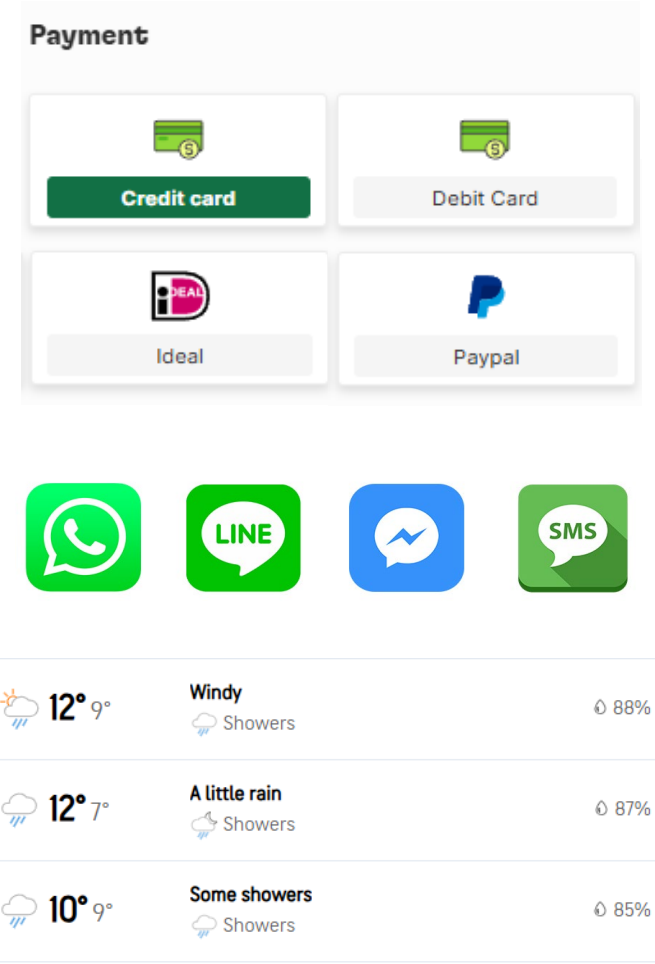
ICSR download API

What is an API and how does it work?

- API or application programming interface is a set of rules that enables software applications to communicate with each other to exchange data.

- They only share the required data and functions to execute specific tasks.
- This way, servers do not have to fully expose data; only small packets of information.
- Other internal system details are kept hidden, helping to preserve the integrity of the system security.

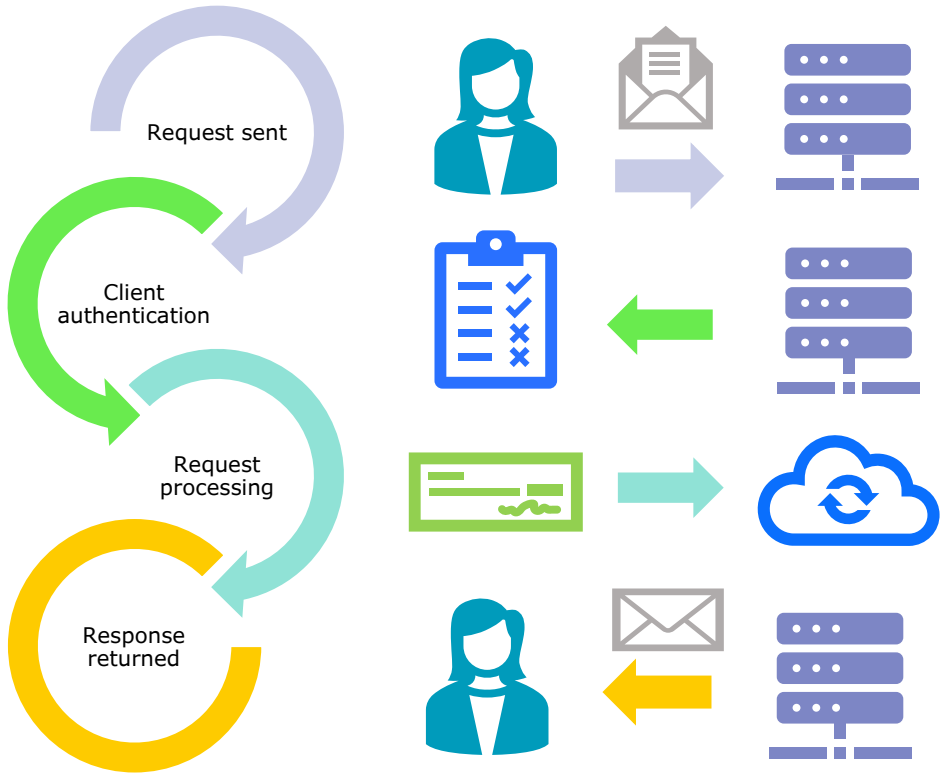




Why is there a need for an ICSR download API?

- MAHs are required to monitor the data available in EV and use the reports obtained to enrich and supplement their own databases and to fulfil their PV obligations.
- Access to the reports in EV is made via the *ICSR Download* section.
- The controlled access made in line with the provisions of the EMA's **EudraVigilance Access Policy**[5] protects the data.
- This entails the manual download of ICSRs.
- As such, the Agency started working on EV APIs.
- Different types of API exists. Of interest: REST (Representational State Transfer) APIs.

REST (or RESTful) APIs:



5 - https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-access-eudravigilance-data-medicinal-products-human-use_en.pdf

3

Additional values for *C.5.4 Study Type* and *D.5 Patient Sex*

C.5.4 Study Type - Confirmed new values for codelist

- To align with E2D(R1), E2B EWG approved the addition of 3 new values for the codelist of field *C.5.4 Study Type Where Reaction(s) / Event(s) Were Observed*
- The existing values are:

C.5.4 Study type where reaction(s) / event(s) were observed

User Guidance	This information should be provided if the 'Type of Report'(C.1.3) has been populated with 'Report from study'.
Conformance	Optional, but required if C.1.3=2 (Report from study).
Data Type	1N
OID	2.16.840.1.113883.3.989.2.1.1.8
Value Allowed	1=Clinical trials 2=Individual patient use(e.g. *'compassionate use' or 'named patient basis')* 3=Other studies *(e.g. pharmacoepidemiology, pharmacoeconomics, intensive monitoring)*
Business Rule(s)	

- The additional new values are:

4. **Patient Support Program**
5. **Market Research Program**
6. **Organised Data Collection System with source data from a digital platform**

Note:

BFC: When converting to R2, the values 4-6 should be mapped to the value "3".

D.5 Patient Sex - Proposed new value for codelist

- A number of EEA Member States have rules forbidding sex/gender discrimination.
- PhVBT and PRAC had already endorsed proposals for discussing extending the codelist of field D.5 “Patient sex” to include “Intersex”.
- Therefore, EMA is now seeking EEA Member State approval to add a value reflecting **Intersex** as a regional variation of the codelist for field ICH E2B(R3) D.5 “Patient Sex”.

D.5 Sex

User Guidance	This data element captures the sex of the patient.
Conformance	Optional
Data Type	1N
OID	1.0.5218
Value Allowed	1=Male 2=Female

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Thank you

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