EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised EudraVigilance Access Policy: Impact on stakeholders

Training Module PhV-M4

Overview of the key principles set out in revision 2 of the EudraVigilance Access Policy with an outline on how stakeholders obtain access to EudraVigilance

Sabine Brosch, Monitoring and Incident Management, Pharmacovigilance Department

An agency of the European Union

Version 1.0

Overview Module PhV-M4

- Introduction to this training module
- Scope, legal background, principles, objectives
- Access to EudraVigilance by stakeholder group
- How to get supporting information

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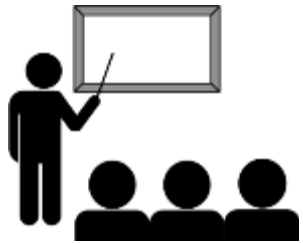
Introduction – PhV-M4 Context

- Target audience for this training module:
  - National Competent Authorities (NCAs) in the European Economic Area (EEA) *(=>Stakeholder Group I)*
  - Healthcare Professionals and the Public *(=>Stakeholder Group II)*
  - Marketing authorisation holders (MAHs) *(=>Stakeholder Group III)*
  - Academia *(=>Stakeholder Group IV)*
  - WHO Uppsala Monitoring Centre *(=>Stakeholder Group V)*
  - Medicines regulatory authorities in third countries *(=>Stakeholder Group VI)*



Introduction: Learning Objectives

- At the end of module PhV-M4 you should be able to:
  - Understand the legal background, scope and the key principles outlined in revision 2 of the EudraVigilance Access Policy
  - Describe the levels of access provided to stakeholders based on six stakeholder groups
  - Recognise how access will be granted to EudraVigilance data
  - Describe the impact of obtaining access to EudraVigilance data
  - Understand where to obtain supporting information

Overview Module PhV-M4

- Introduction to this training module
- **Scope, legal background, principles, objectives**
- Access to EudraVigilance by stakeholder group
- How to get supporting information

Session overview

In this session you will obtain an understanding of the:

- Scope of the Access Policy
- Legal basis for providing access to data held in EudraVigilance
- Key principles and objectives

Scope

- Provision of access to ICSR data held in EudraVigilance in line with the EU legal framework and requirements to protect personal data

Access to reports of suspected unexpected serious adverse reactions (SUSARs) based on the provisions set out in Regulation (EU) 536/2014 will be subject to a later review (where applicable)

Ad interim, the provisions of access to the EudraVigilance Clinical Trial Module (EVCTM) as outlined in revision 1 of the EudraVigilance Access Policy (December 2010) remain unchanged

Legal background

"2010 Pharmacovigilance legislation"
requires extended access to
EudraVigilance
based on the obligations and interests
of different stakeholders

Legal background

- Article 24(2) of Regulation (EC) 726/2004 defines access to EudraVigilance as follows:
  - Full access to the competent authorities of the Member States, the Agency and the European Commission
  - Access to marketing authorisation holders to the extent necessary for them to comply with their pharmacovigilance obligations
  - Appropriate levels of access for healthcare professionals and the public, while guaranteeing personal data protection

Legal background

Article 28(c) of Regulation (EC) No 726/2004 states that

- The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the WHO

Legal background

- The EudraVigilance Access Policy was revised as a result of the 2010 pharmacovigilance legislation and released for public consultation from 4 August 2014 until 15 September 2014
- 392 interested organisations and individuals provided feedback on the draft Access Policy (consolidated comments EMA/649218/2014)
- Revision 2 of the EudraVigilance Access Policy was adopted by the EMA Management Board at their meeting in December 2015

Legal background

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Access to EudraVigilance data

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The EudraVigilance access policy is designed to provide as much information as possible, while meeting all data protection obligations.

Stakeholders such as marketing-authorisation holders, regulatory authorities, academia, healthcare profesionals and patients all have access to data held in the EudraVigilance database. The policy defines the level of information and mechanisms by which the different parties can access the data, based on their likely interests, needs or legal and data protection obligations.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2015
EMA/759287/2009 Revision 2
Inspections and Human Medicines Pharmacovigilance Division

European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use
(EudraVigilance Access Policy)

Start of public consultation	4 August 2014
End of public consultation	15 September 2014
Final draft agreed by Project Team 1 "Collection of key information on medicines" of the EMA/Member States governance structure for the implementation of the pharmacovigilance legislation	September 2015
Final draft submitted to the EudraVigilance Expert Working Group for information	23 September 2015
Final draft agreed by Pharmacovigilance Risk Assessment Committee (PRAC)	5-8 October 2015
Final draft agreed by Project Co-ordination Group of the EMA/Member States governance structure for the implementation of the pharmacovigilance legislation	12 October 2015
Final draft agreed by the European Risk Management Facilitation Group (ERMS-FG)	12 October 2015
Final draft agreed by the Committee for Human Medicinal Products (CHMP) and the Co-ordination group for Mutual recognition and Decentralised procedures – human(CMD-h)	19-21 October 2015
Final draft submitted to IT Directors for information	22 October 2015
Final draft submitted to Heads of Medicines Agencies Human (HMA-h) for information	21-23 October 2015
Final draft adopted by the EMA Management Board	16-17 December 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Legal background

Entry into force of the EudraVigilance Access Policy

- Revision 2 of the Access Policy will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report the EudraVigilance database has achieved full functionality

Principles

- The policy takes into account the legal requirement of broadening stakeholder access to EudraVigilance data
- The policy drives to enable pharmacovigilance monitoring for public health
- The policy is fully in line with EU data protection law
- The policy recognises the applicable ISO ICSR standard/ICH E2B(R3) guideline

Principles

All stakeholders have the responsibility to:

- Protect personal data and ensure confidentiality of ICSR data in accordance with the applicable law on personal data protection
- Apply appropriate technical and organisational measures to protect information and personal data processed against:

–Unauthorised or unlawful access
–Disclosure
–Dissemination
–Alteration
–Destruction
–Accidental loss

Objectives

A proactive approach to disclosing information brings several benefits, most notably:

- More effective safety monitoring of authorised medicines
- Better support for signal detection and evaluation of potential safety issues
- More data made available for research
- Better information on suspected adverse reactions for healthcare professionals and patients

Session summary

In this session you obtained an understanding of:

- Scope of the Access Policy
- Legal basis for providing access to data held in EudraVigilance
- Key principles and objectives

Overview Module PhV-M4

- Introduction to this training module
- Scope, legal background, principles, objectives
- **Access to EudraVigilance by stakeholder group**
- How to get supporting information

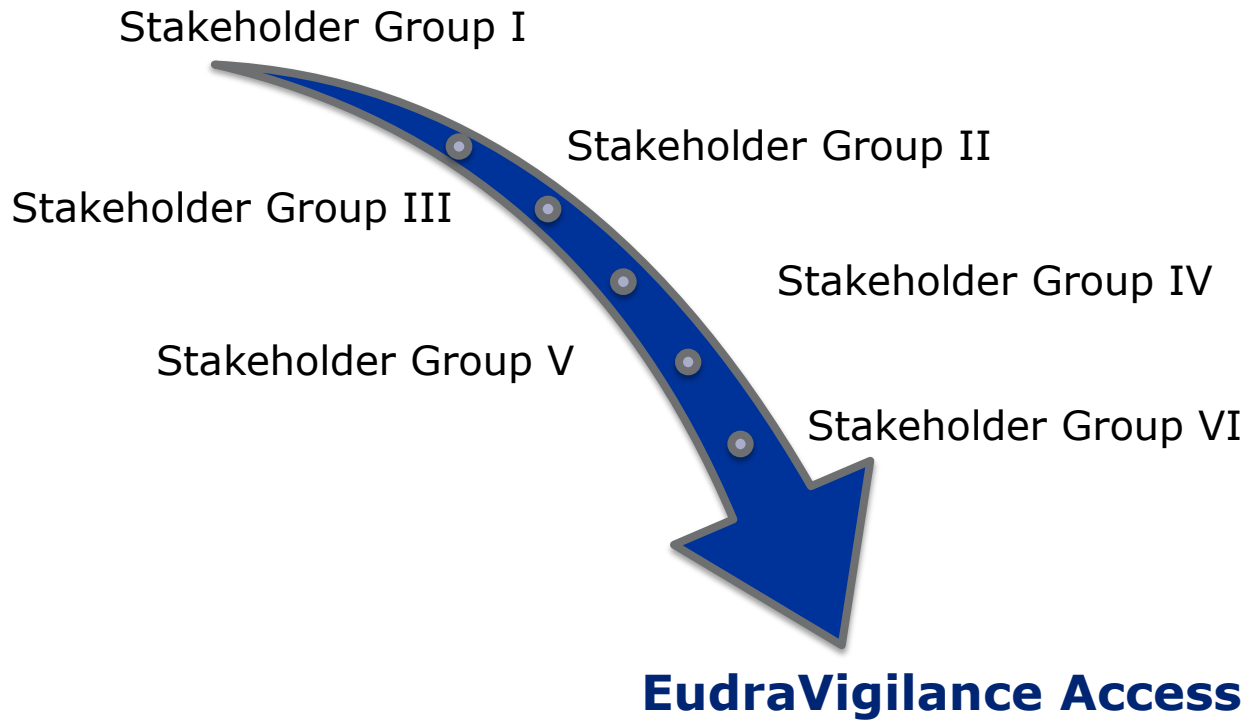
Access to EudraVigilance by stakeholder group

In this session you will obtain an understanding:

- Which factors are essential in organising the provision of access
- How each stakeholder group obtains access to EudraVigilance
- Which data can be accessed by each stakeholder group

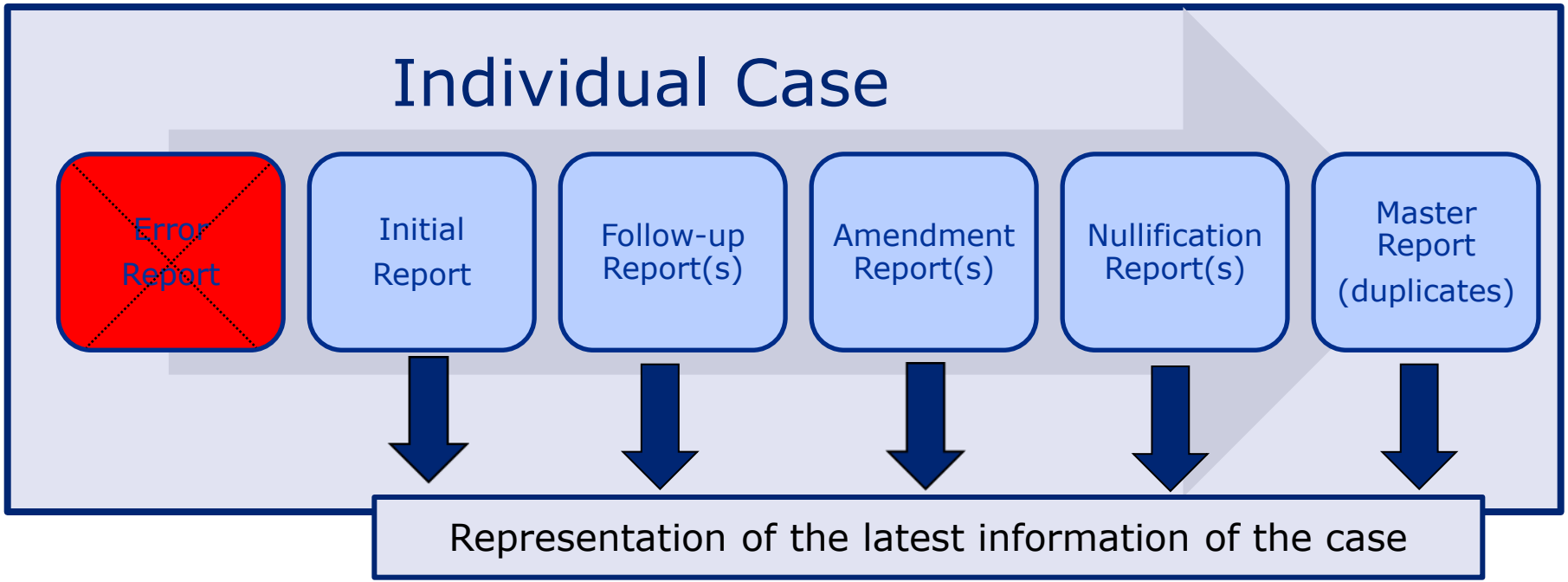
Access to EudraVigilance – factors

Access by stakeholder group



Access to EudraVigilance - factors

Access by report status



Access to EudraVigilance - factors

Access by report type

Spontaneous report	An unsolicited communication by a healthcare professional, or consumer to a competent authority, marketing authorisation holder or other organisation
Report from study	Reports of suspected adverse reactions derived from organised data collection systems; differentiation by study type: –Clinical trials (interventional studies) –Individual patient use (e.g. ‘compassionate use’ or ‘named patient basis’) –Other studies (e.g. pharmacoepidemiology, pharmacoeconomics, intensive monitoring)

Access to EudraVigilance - factors

Access by report type

Other	Where it is unclear from a literature report whether or not the case(s) cited are spontaneous observations or whether they arise from a study
Not available to sender	Report by a secondary sender (e.g. regulatory authority) where the initial sender did not specify the type of report

Access to EudraVigilance - factors

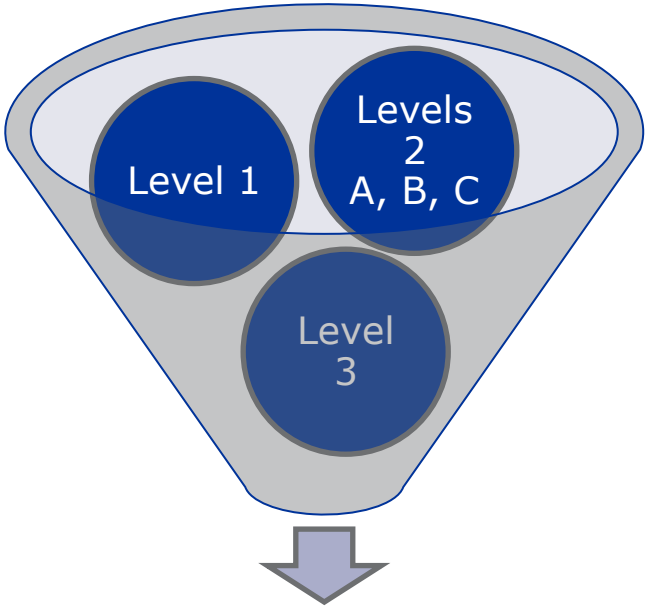
Access by data elements set out in the ICH E2B(R3) Individual Case Safety Report (ICSR) Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Stakeholder Group I	Stakeholder Group II-VI	Stakeholder Group III & IV	Stakeholder Group III	Stakeholder Group III	Stakeholder Group V & VI
		Level 3	Level 1	Level 2A	Level 2B	Level 3	Level 2C
C.1 Identification of the case safety report	20	20	3	18	18	20	16
C.2.r Primary source(s)[20] of information	15	15	4	4	4	15	4
C.3 Information on sender of case safety information	16	16	3	3	3	16	3
C.4.r Literature reference(s)	2	2	1	1	1	2	1
C.5 Study identification	6	6	4	5	5	6	5
D. Patient characteristics	96	96	4	87	87	96	16
E.i Reaction(s)/event(s)	21	21	11	21	21	21	18
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13	0	13	13	13	0
G.k Drug(s) information	76	76	23	72	72	76	71
H. Narrative case summary and further information	7	7	0	4	7	7	0
Grand Total	272	272	53	228	230	272	134

Access to EudraVigilance - factors

Access levels in line with:

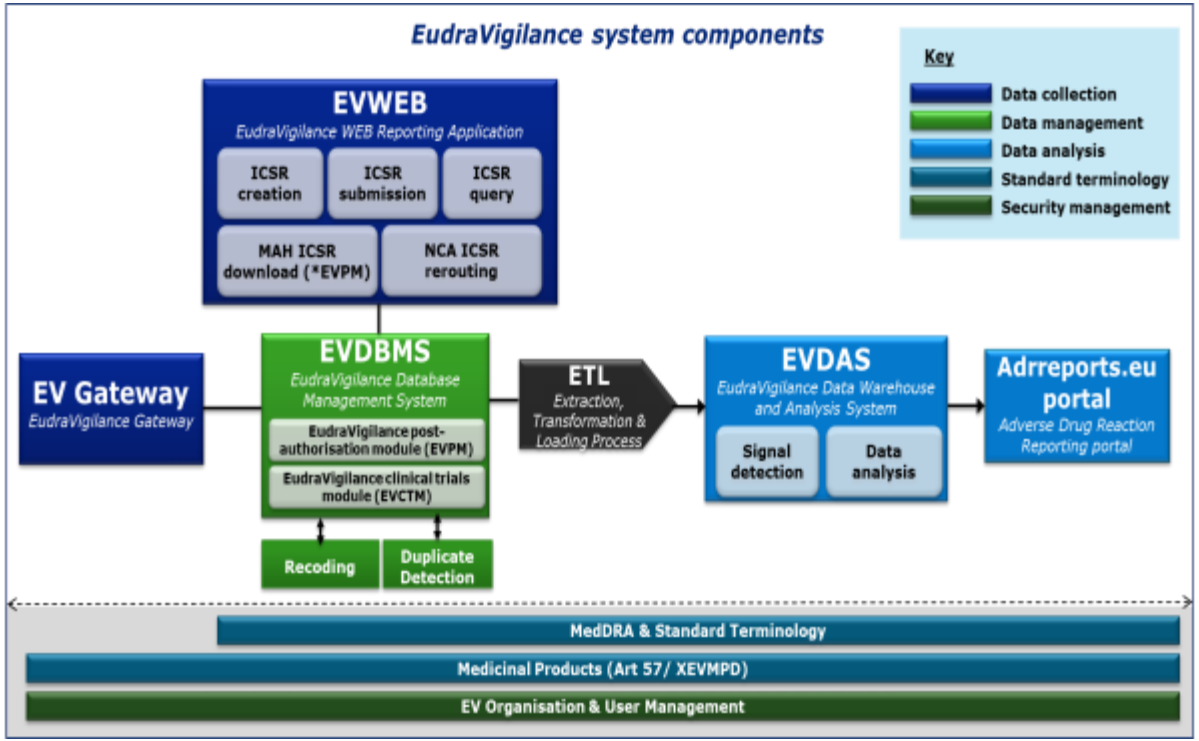
- **Stakeholder needs**
- **Personal data protection requirements**



EudraVigilance Access

Access to EudraVigilance - factors

Access by EudraVigilance system component



Access to EudraVigilance - factors

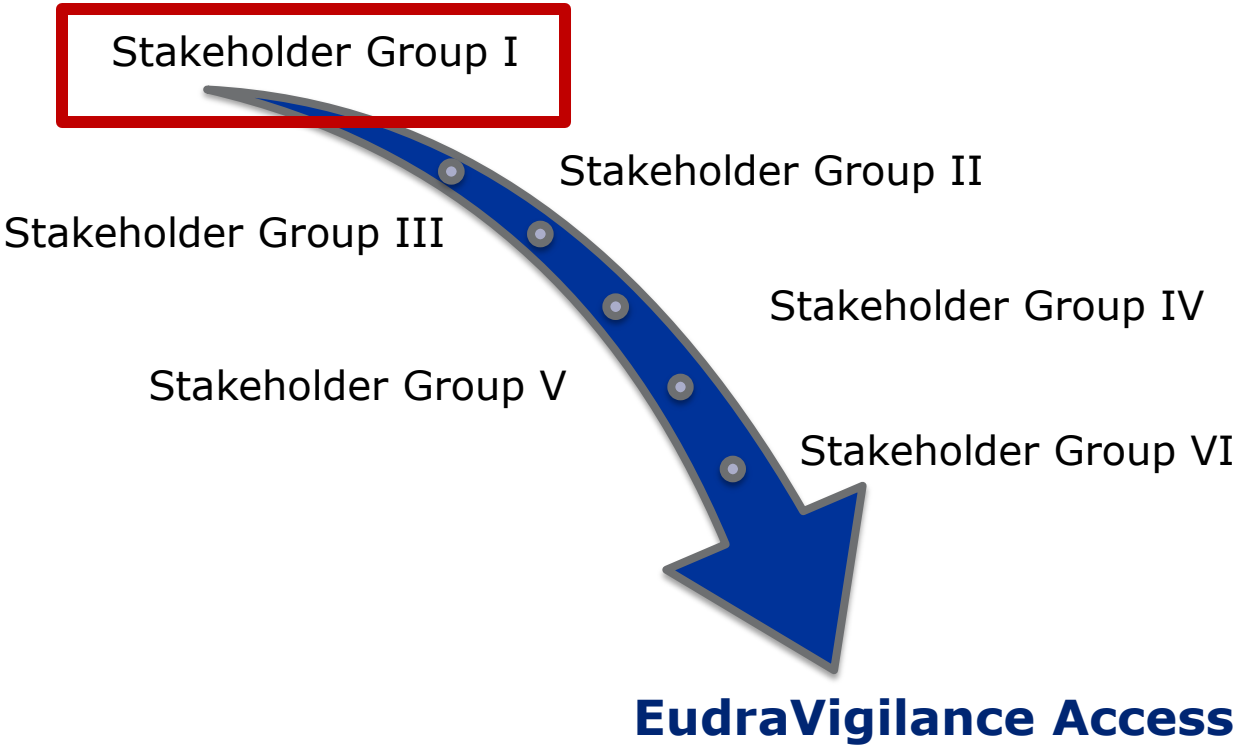
Access by authorisation

- **Authorisation based on EudraVigilance registration**
- **No authorisation (public access)**

Access to EudraVigilance - factors

Access by
medicinal product(s)/
active substance(s)
with a marketing
authorisation in the EEA

Access to EudraVigilance

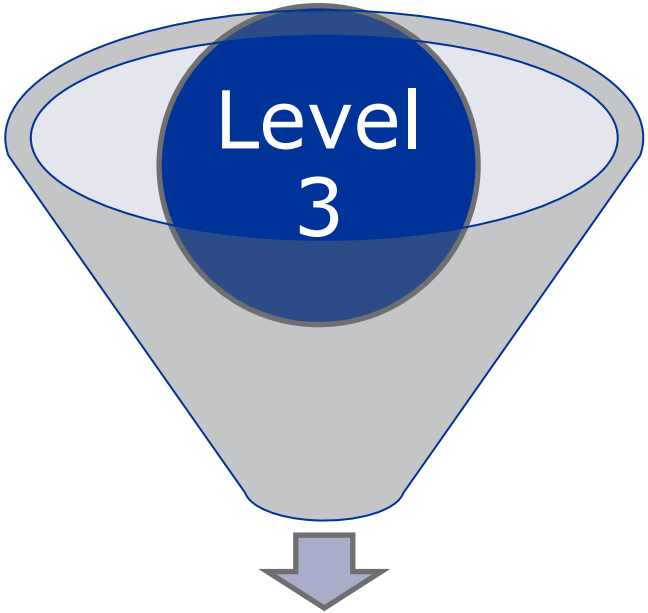


Access to Stakeholder Group I

- **Medicines regulatory authorities in EEA Member States, the European Commission and the Agency *(=>Stakeholder Group I)***

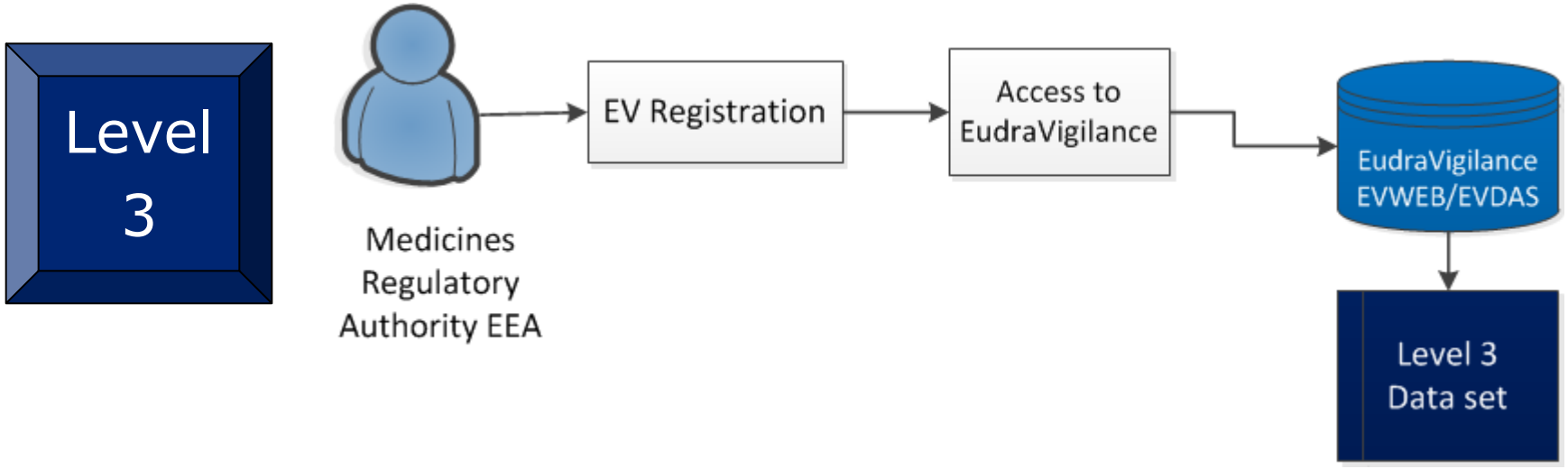
Access to Stakeholder Group I

- **Level 3 access to facilitate:**
  - Continuous monitoring of the safety of medicines
  - Evaluation of the benefits and risks of medicines authorised in the EU
  - Signal detection and validation activities related to all authorised medicines in the EU
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group I



Access to Stakeholder Group I

Level 3

- Access Authorisation
  - Based on the EudraVigilance registration process
  - For regional pharmacovigilance centres, the responsible medicines regulatory authority determines the level of access, which should be granted to these centres
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group I

- All ICSR data elements
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs for all medicinal products authorised in the EEA

Access to Stakeholder Group I

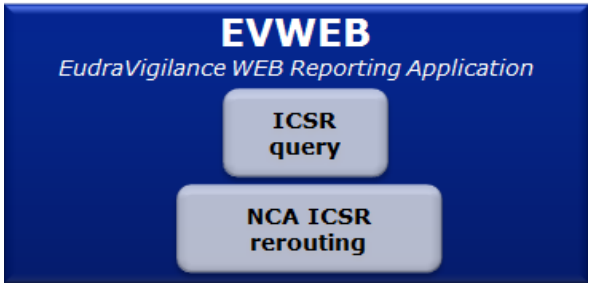
Level 3

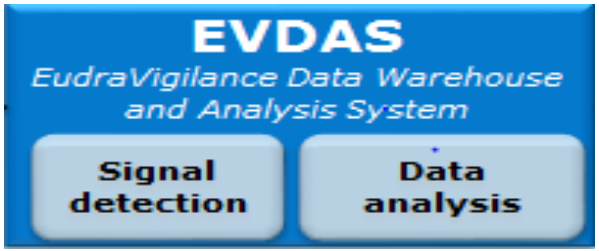
Access to all ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 3
C.1 Identification of the case safety report	20	20
C.2.r Primary source(s) of information	15	15
C.3 Information on sender of case safety information	16	16
C.4.r Literature reference(s)	2	2
C.5 Study identification	6	6
D. Patient characteristics	96	96
E.i Reaction(s)/event(s)	21	21
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13
G.k Drug(s) information	76	76
H. Narrative case summary and further information	7	7
Grand Total	272	272

Access to Stakeholder Group I

Access by EudraVigilance system component





Data outputs

- ICSR electronic (XML) format
- ICSR forms

- e-RMRs and active substance groupings
- ICSR line listings and ICSR forms
- Other data outputs based on predefined and customisable query and signal detection functionalities

Access to Stakeholder Group I

Personal data protection

- Information on EudraVigilance is to be included in privacy statements for pharmacovigilance activities

Note: An information notice for EMA's processing of ICSRs is available at the adrreports.eu portal

Access to Stakeholder Group I

Personal data protection

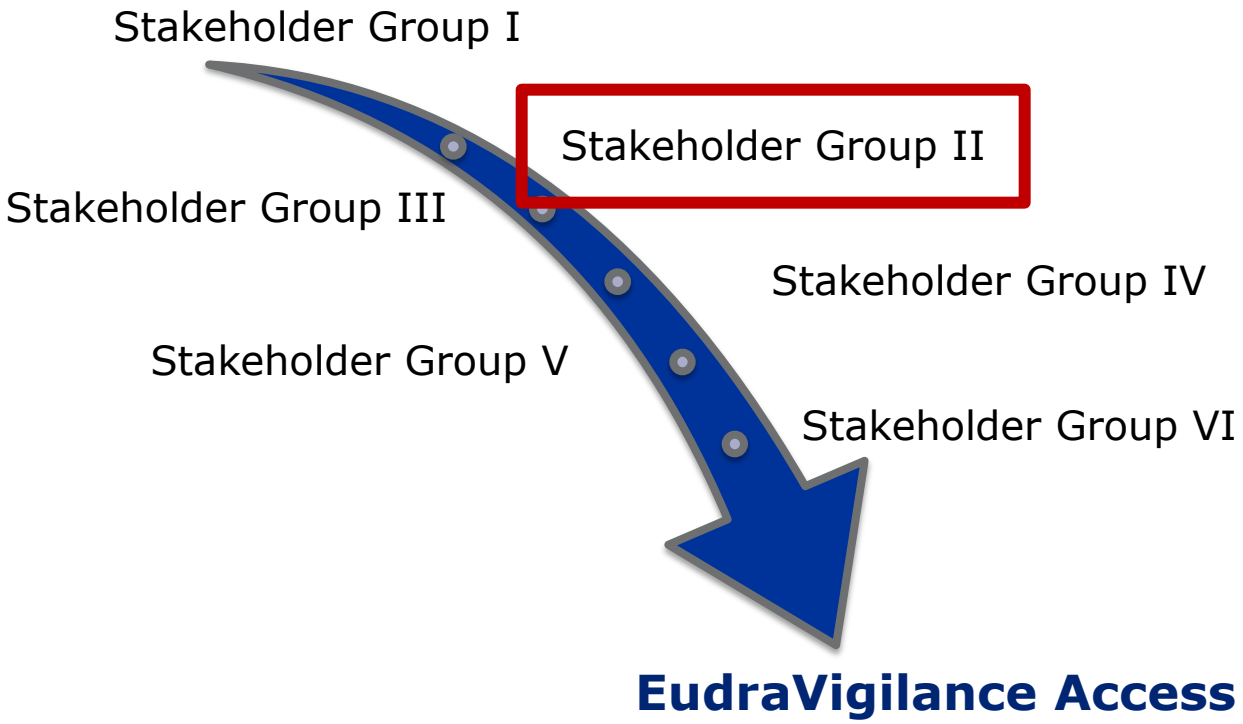
- Confidentiality of ICSRs and the personal data of the subjects need to remain protected
- Appropriate technical and organisational measures are to be implemented
- EMA has to be notified immediately of a breach of security

  -> *accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance*

Access to Stakeholder Group I

Medicines regulatory authorities, the European Commission and the Agency	
Data elements available	▸ All data elements for ICSRs submitted to EudraVigilance are accessible. This includes spontaneous reports as well as reports from all types of studies.
Access tools	▸ Access is granted via EVDAS, including data analysis and signal detection tools. ▸ In Member States, medicines regulatory authorities determine access levels for regional pharmacovigilance centres. Authorised personnel of the European Commission, regulatory authorities and the Agency are identified through the EudraVigilance registration process.
Notes	▸ Can also make use of the EudraVigilance clinical trial and post-authorisation modules.

Access to EudraVigilance

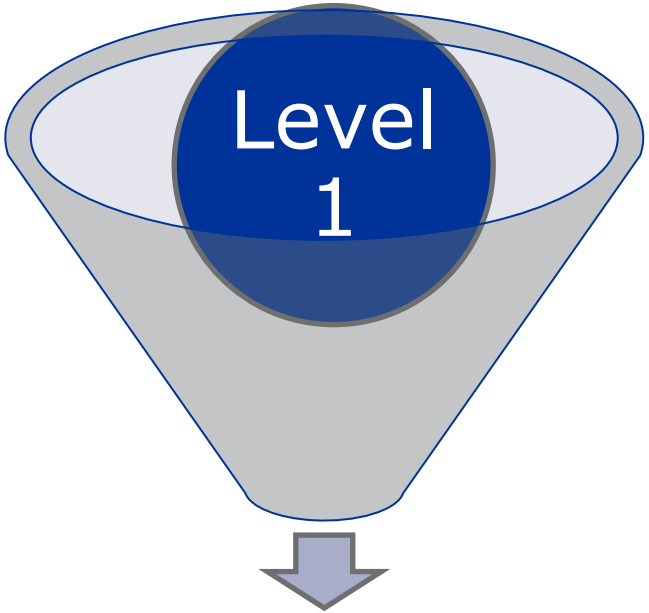


Access to Stakeholder Group II

- **Healthcare Professionals and the Public**
  (=>Stakeholder Group II)

Access to Stakeholder Group II

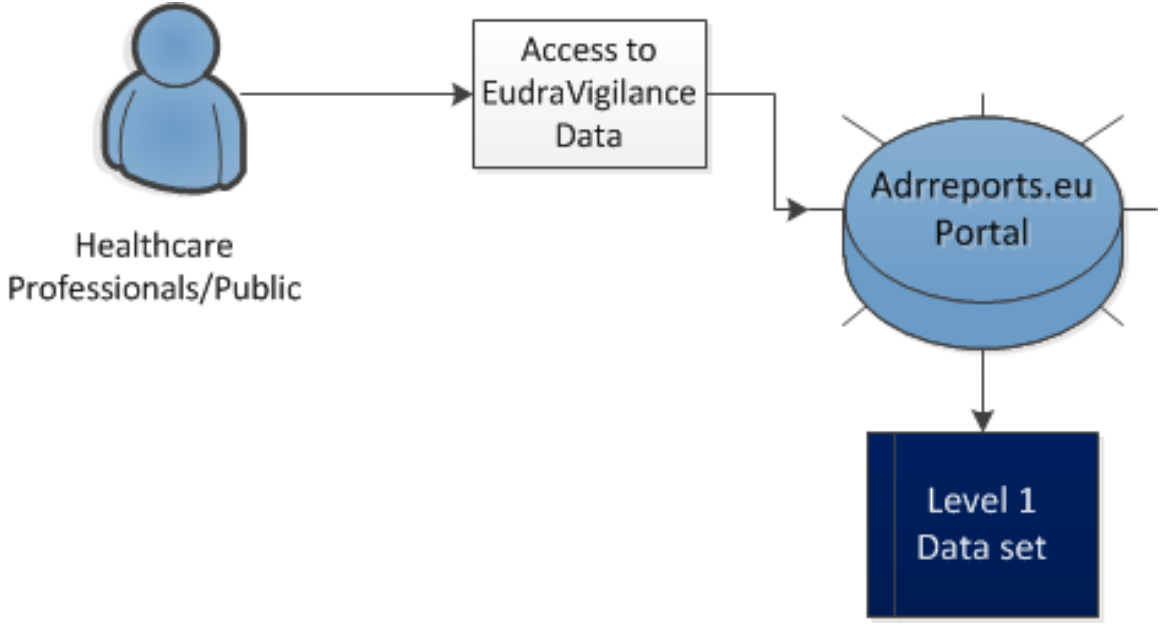
- **Level 1 access ensures:**
  - Openness to citizens, who are directly affected by the EU Regulatory Network's decisions relating to the authorisation and supervision of medicinal products including the monitoring and assessment of the safety of medicines
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group II

Level 1

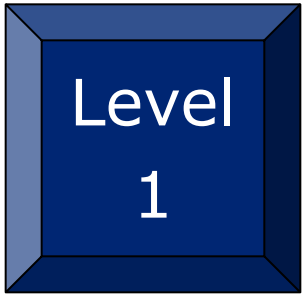


Access to Stakeholder Group II

Level 1

- Access Authorisation
  - Not required

Access to Stakeholder Group II



- Subset of ICSR data elements
  - in compliance with personal data protection law
- Report type
  - Spontaneous report
- Public Access
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group II

Level 1

Access to subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 1
C.1 Identification of the case safety report	20	3
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	4
D. Patient characteristics	96	4
E.i Reaction(s)/event(s)	21	11
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	23
H. Narrative case summary and further information	7	0
Grand Total	272	53

Access to Stakeholder Group II

Access by EudraVigilance system component

Adrreports.eu portal
Adverse Drug Reaction Reporting portal

Data outputs

- Aggregated data outputs based on predefined queries
- ICSR line listings (based on core ICSR data elements)
- ICSR forms (for individual case review)

Access to Stakeholder Group II

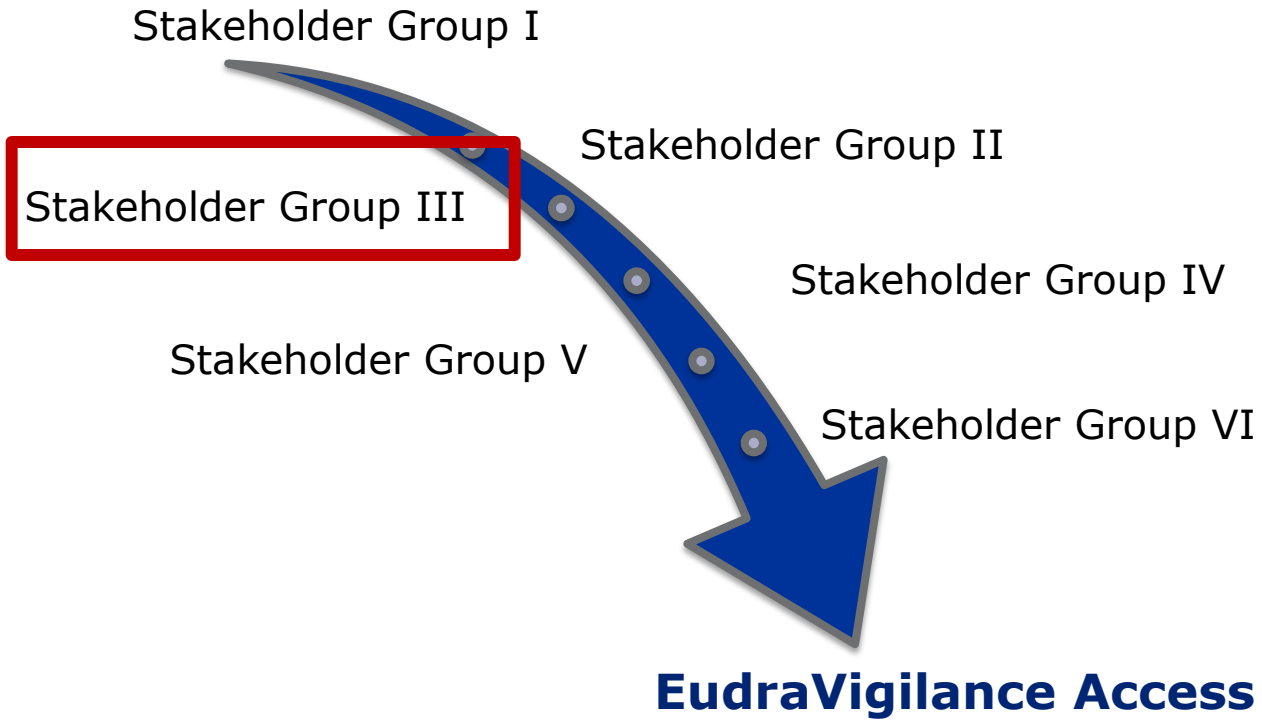
Personal data protection

- An information notice for EMA's ICSR processing is available on the adrreports.eu portal

Access to Stakeholder Group II

	Healthcare professionals and the general public
Data elements available	▸ A restricted set of data elements for spontaneous reports is available, and is provided alongside detailed guidance on the nature and interpretation of the data, including advice to patients not to change their medication without consulting a healthcare professional.
Access tools	▸ Access is by way of the Agency's adrreports.eu portal, and anyone can access data of interest.

Access to EudraVigilance

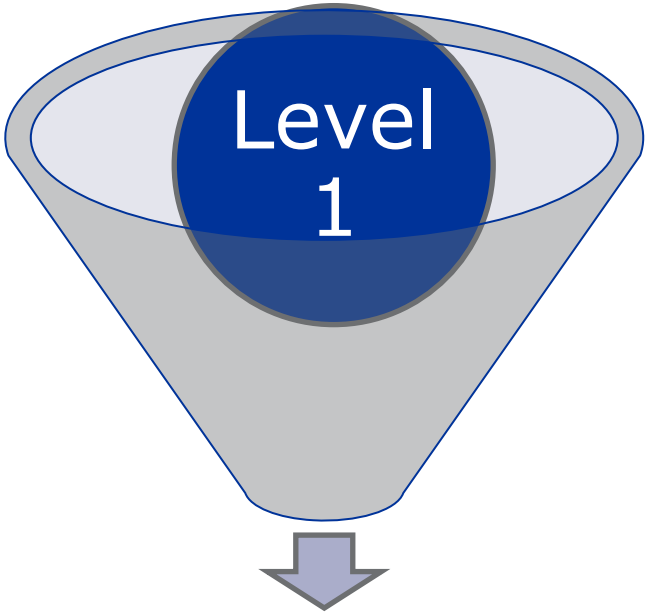


Access to Stakeholder Group III

- **Marketing Authorisation Holders**
  (=>Stakeholder Group III)

Access to Stakeholder Group III

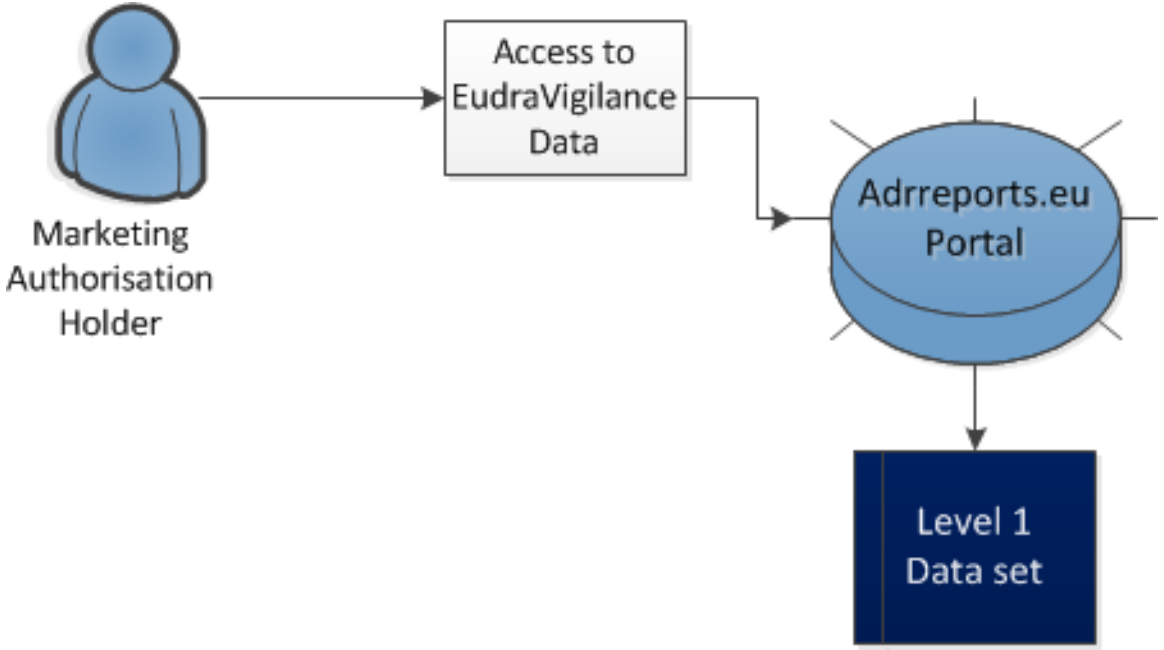
- **Level 1 access to facilitate:**
  - Monitoring of the safety of medicines following their authorisation and marketing
  - Use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group III

Level 1

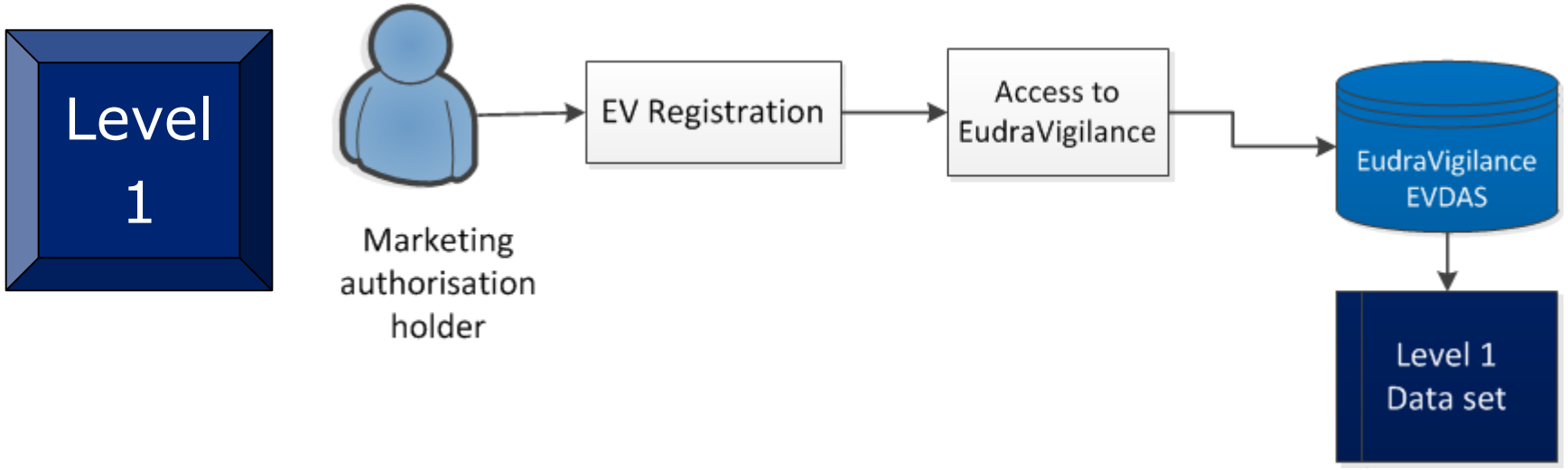


Access to Stakeholder Group III

Level 1

- Access Authorisation
  - Not required

Access to Stakeholder Group III

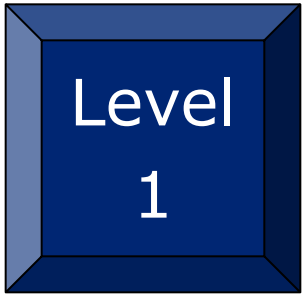


Access to Stakeholder Group III

Level 1

- Access Authorisation
  - EU Qualified Person Responsible for Pharmacovigilance (EU QPPV) (headquarter level), appointed Deputy & authorised personnel under strict responsibility of EU QPPV
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group III



- Subset of ICSR data elements
  - in compliance with personal data protection law
- Report type
  - Spontaneous report
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group III

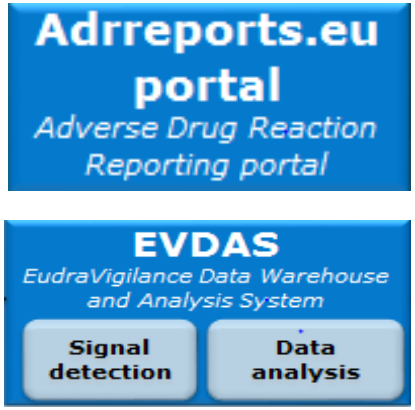
Level 1

Access to subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 1
C.1 Identification of the case safety report	20	3
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	4
D. Patient characteristics	96	4
E.i Reaction(s)/event(s)	21	11
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	23
H. Narrative case summary and further information	7	0
Grand Total	272	53

Access to Stakeholder Group III

Access by EudraVigilance system component



Data outputs

- Aggregated data outputs based on predefined queries
- ICSR line listings (based on core ICSR data elements)
- ICSR forms (for individual case review)

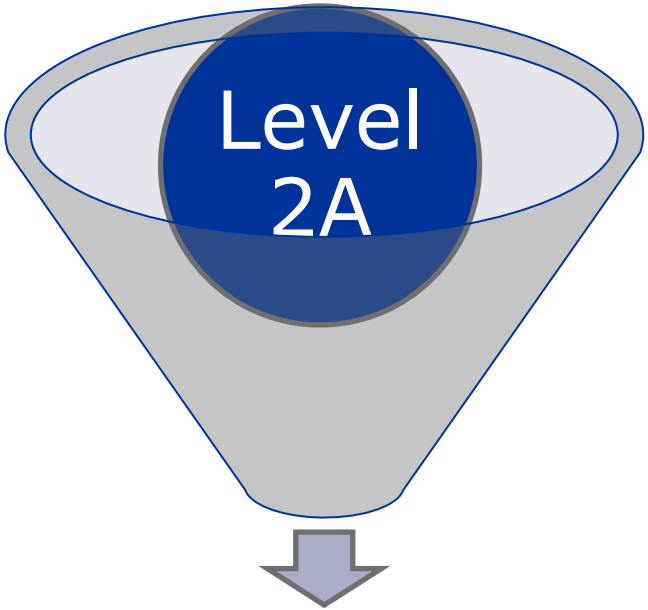
Access to Stakeholder Group III

Personal data protection

- An information notice for EMA's ICSR processing is available on the website www.adrreports.eu

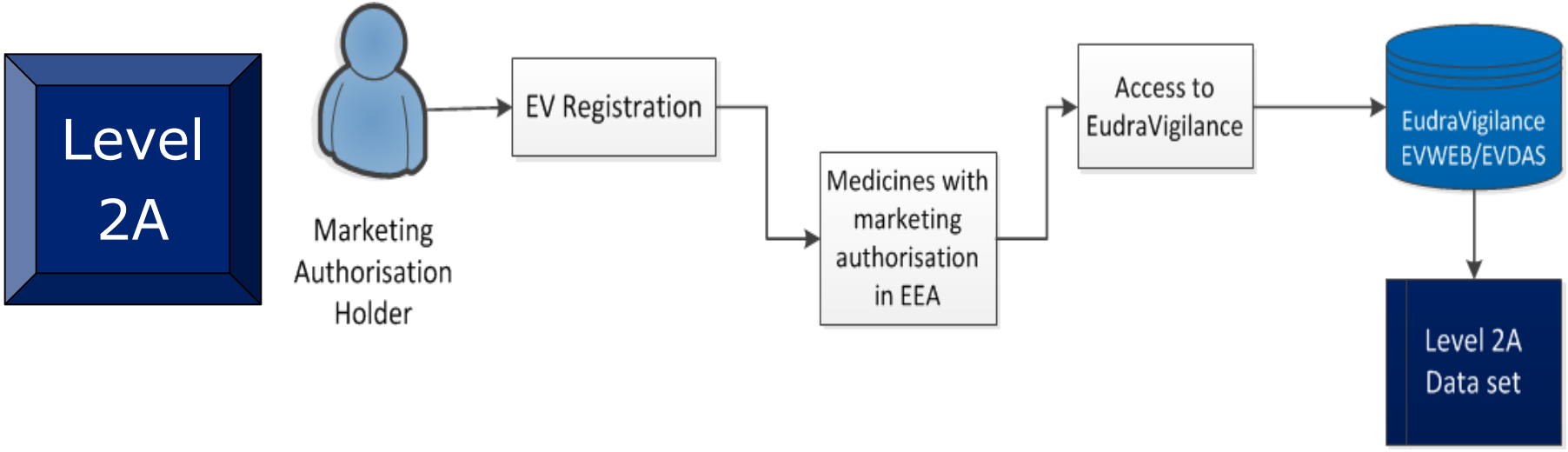
Access to Stakeholder Group III

- **Level 2A access enables:**
  - Monitoring of the safety of medicines for which a company holds marketing authorisation(s) in the EEA
  - Signal management
  - Compliance with other pharmacovigilance obligations
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group III



Access to Stakeholder Group III

Level 2A

- Authorised Personnel
  - EU Qualified Person Responsible for Pharmacovigilance (EU QPPV) (headquarter level), appointed Deputy & authorised personnel under strict responsibility of EU QPPV
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group III

- Extended subset of ICSR data elements
  - to fulfil pharmacovigilance obligations
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs for medicinal products/active substances for which company holds marketing authorisation(s) in the EEA

Access to Stakeholder Group III

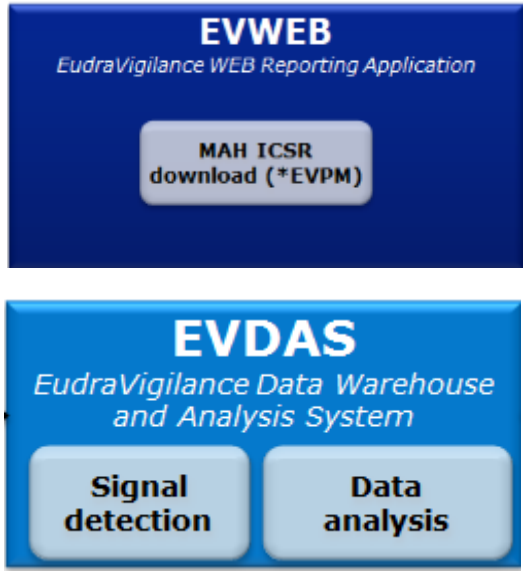
Level 2A

Access to extended subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 2A
C.1 Identification of the case safety report	20	18
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	5
D. Patient characteristics	96	87
E.i Reaction(s)/event(s)	21	21
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13
G.k Drug(s) information	76	72
H. Narrative case summary and further information	7	4
Grand Total	272	228

Access to Stakeholder Group III

Access by EudraVigilance system component



Data outputs

- ICSR electronic (XML) format

- e-RMRs and active substance groupings
- ICSR line listings
- ICSR forms

Access to Stakeholder Group III

Personal data protection

- Information is to be included on EudraVigilance in privacy statements for pharmacovigilance activities

Note: An information notice for EMA's processing is available on the website www.adrreports.eu

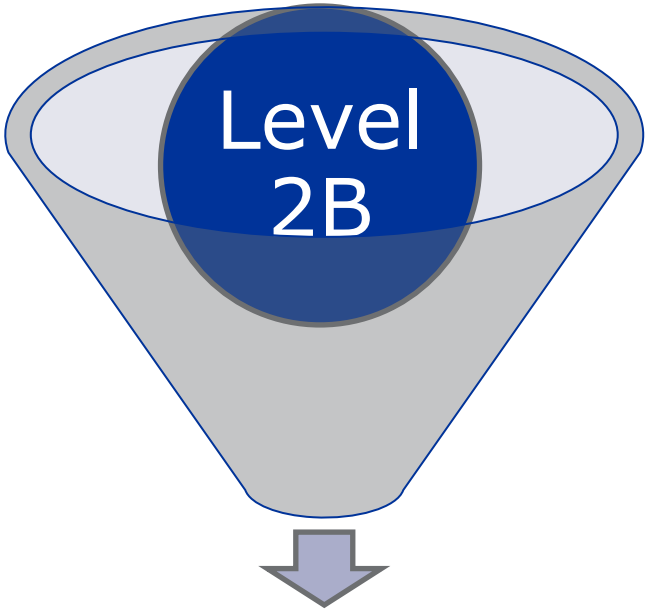
Access to Stakeholder Group III

Personal data protection

- Confidentiality of ICSRs and the personal data of the subjects need to remain protected
- Appropriate technical and organisational measures are to be implemented
- EMA has to be notified immediately of a breach of security
  -> *accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance*

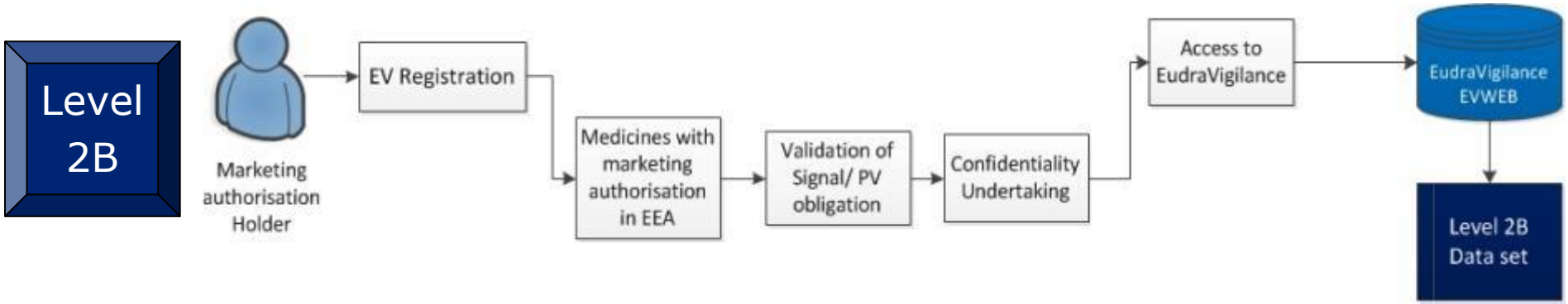
Access to Stakeholder Group III

- **Level 2B access enables:**
  - Monitoring of the safety of medicines for which a company holds marketing authorisation(s) in the EEA
  - Signal management
  - Pharmacovigilance obligations (e.g. PSUR assessment procedure, referral or signal assessment procedures)
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group III



Access to Stakeholder Group III

Level 2B

- Access authorisation
  - EU QPPV (headquarter level), appointed Deputy & authorised personnel under strict responsibility of EU QPPV
  - Confirmation that either:
    - The initial signal management steps as outlined in GVP Module IX “Signal Management” have been performed, including a reference to the corresponding e-RMR, if applicable
    - A review of ICSR data is warranted in the context of a pharmacovigilance assessment procedure such as the PSUR as outlined in GVP Module VII or when required by the PRAC in a referral or signal assessment procedure

Access to Stakeholder Group III

Level 2B

- Access authorisation
  - Confidentiality Undertaking signed by the EU QPPV and where different, by the Deputy appointed by the EU QPPV or any other personnel, under the strict responsibility of the EU QPPV
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group III

- Extended subset of ICSR data elements including case narratives
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs for medicinal products for which company holds marketing authorisation(s) in the EEA

Access to Stakeholder Group III

Level 2B

Access to all ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 2B
C.1 Identification of the case safety report	20	18
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s)	2	1
C.5 Study identification	6	5
D. Patient characteristics	96	87
E.i Reaction(s)/event(s)	21	21
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13
G.k Drug(s) information	76	72
H. Narrative case summary and further information	7	7
Grand Total	272	230

Access to Stakeholder Group III

Access by EudraVigilance system component

Data outputs

- ICSR electronic (XML) format

Access to Stakeholder Group III

Access by EudraVigilance system component

For the MAH ICSR (EVPM) L2B access the following applies:

- If a user requests L2B access the user is prompted to enter a reason for the L2B request along with agreeing to a confidentiality agreement stating there is a legitimate need for the L2B request
- This information is maintained for audit and tracking purpose
- Once confirmed, the user can proceed with the L2B request

Access to Stakeholder Group III

Personal data protection

- Information to be included on EudraVigilance in privacy statements for pharmacovigilance activities

  Note: An information notice for EMA's processing is available on the website www.adrreports.eu

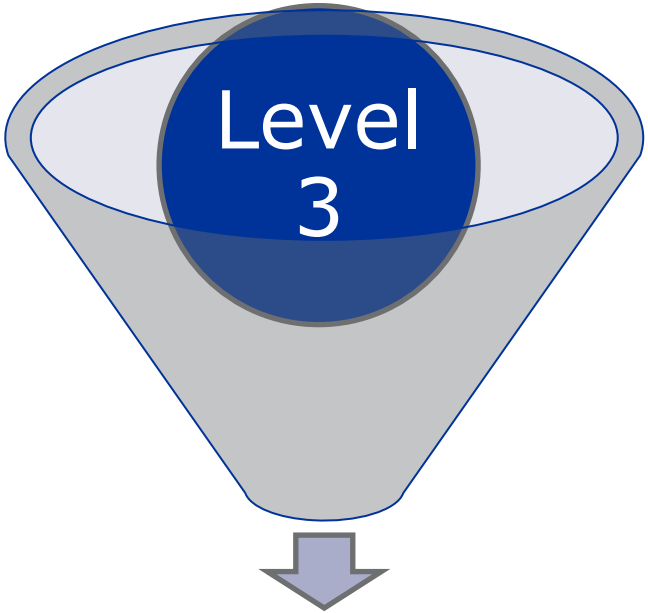
Access to Stakeholder Group III

Personal data protection

- Confidentiality of ICSRs and the personal data of the subjects need to remain protected
- Appropriate technical and organisational measures are to be implemented
- EMA has to be notified immediately of a breach of security
  -> *accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance*

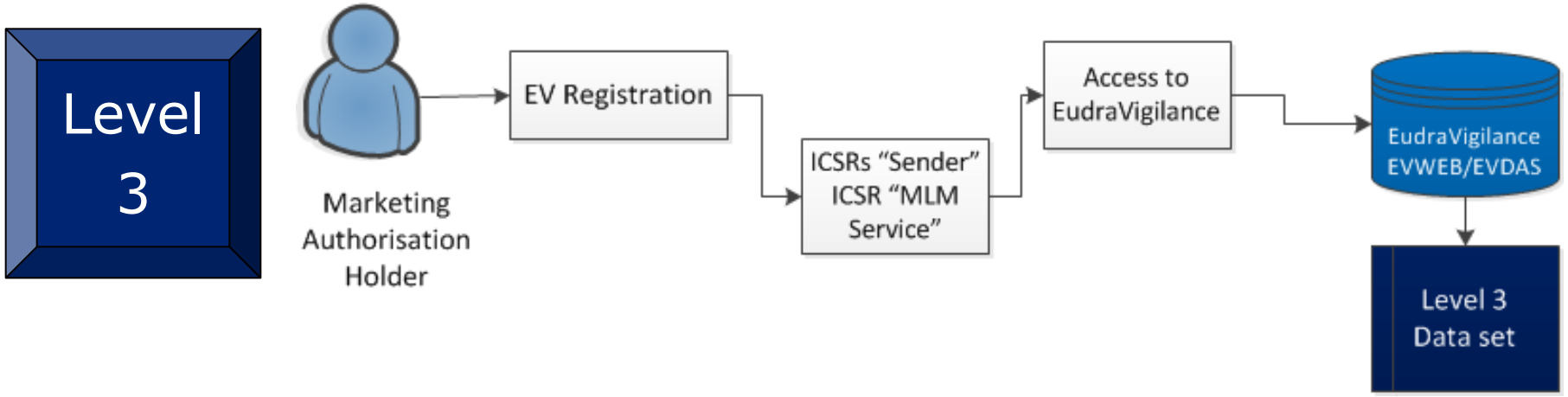
Access to Stakeholder Group III

- **Level 3 access enables:**
  - Continuous monitoring of the safety of medicines
  - Evaluation of the benefits and risks of medicines authorised in the EU
  - Signal detection and validation activities
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group III



Access to Stakeholder Group III

Level 3

- Access authorisation
  - EU QPPV (headquarter level), appointed Deputy & authorised personnel under strict responsibility of EU QPPV
  - Restricted to
    - ICSRs that were sent by the MAH to EVPM (“Sender-based” access)
    - Reports originating from the Agency’s medical literature monitoring activities pursuant to Article 27 of Regulation (EC) 726/2004
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group III

Level 3

- All ICSR data elements
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs that a MAH submitted (“Sender-based”) to EVPM
- ICSRs originating from the Agency’s medical literature monitoring activities pursuant to Article 27 of Regulation (EC) 726/2004

Access to Stakeholder Group III

Level 3

- Access authorisation
  - Based on the EudraVigilance registration process
  - EU QPPV (headquarter level), appointed Deputy & authorised personnel under strict responsibility of EU QPPV
  - Authorised personnel to be registered with EudraVigilance and to hold a valid user ID and password

Access to Stakeholder Group III

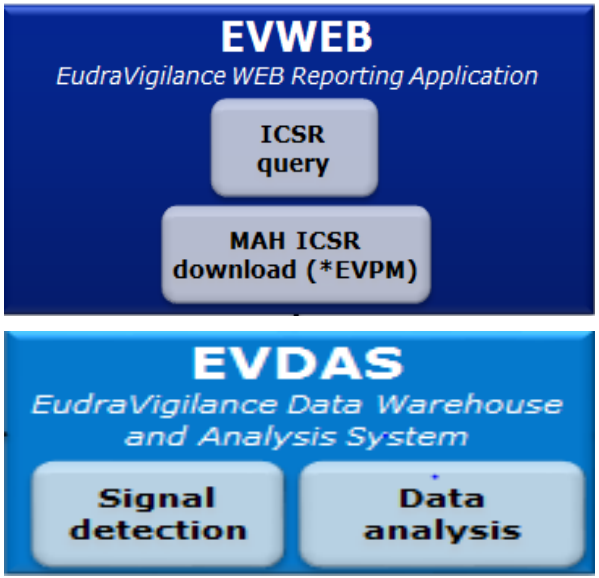
Level 3

Access to all ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	[redacted] Level 3
C.1 Identification of the case safety report	20	20
C.2.r Primary source(s) of information	15	15
C.3 Information on sender of case safety information	16	16
C.4.r Literature reference(s)	2	2
C.5 Study identification	6	6
D. Patient characteristics	96	96
E.i Reaction(s)/event(s)	21	21
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13
G.k Drug(s) information	76	76
H. Narrative case summary and further information	7	7
Grand Total	272	272

Access to Stakeholder Group III

Access by EudraVigilance system component



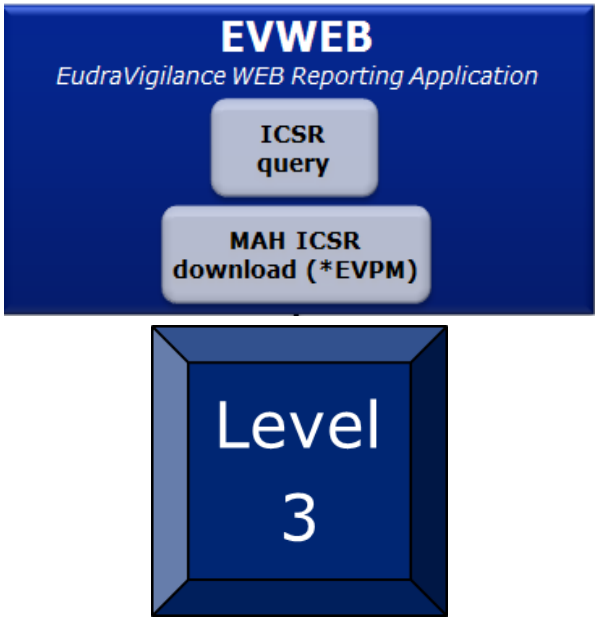
Data outputs

- ICSR electronic (XML) format
- ICSR forms

- e-RMRs and active substance groupings
- ICSR line listings
- ICSR forms

Access to Stakeholder Group III

Access by EudraVigilance system component



- **ICSR query** – for Level 3 allows MAHs to retrieve MLM ICSRs and ICSRs they submitted to EVPM (“Sender- based”)
- **MAH ICSR download** – for Level 3 allows to download MLM ICSRs

Access to Stakeholder Group III

Personal data protection

- Information to be included on EudraVigilance in privacy statements for pharmacovigilance activities

  Note: An information notice for EMA's processing is available on the website www.adrreports.eu

Access to Stakeholder Group III

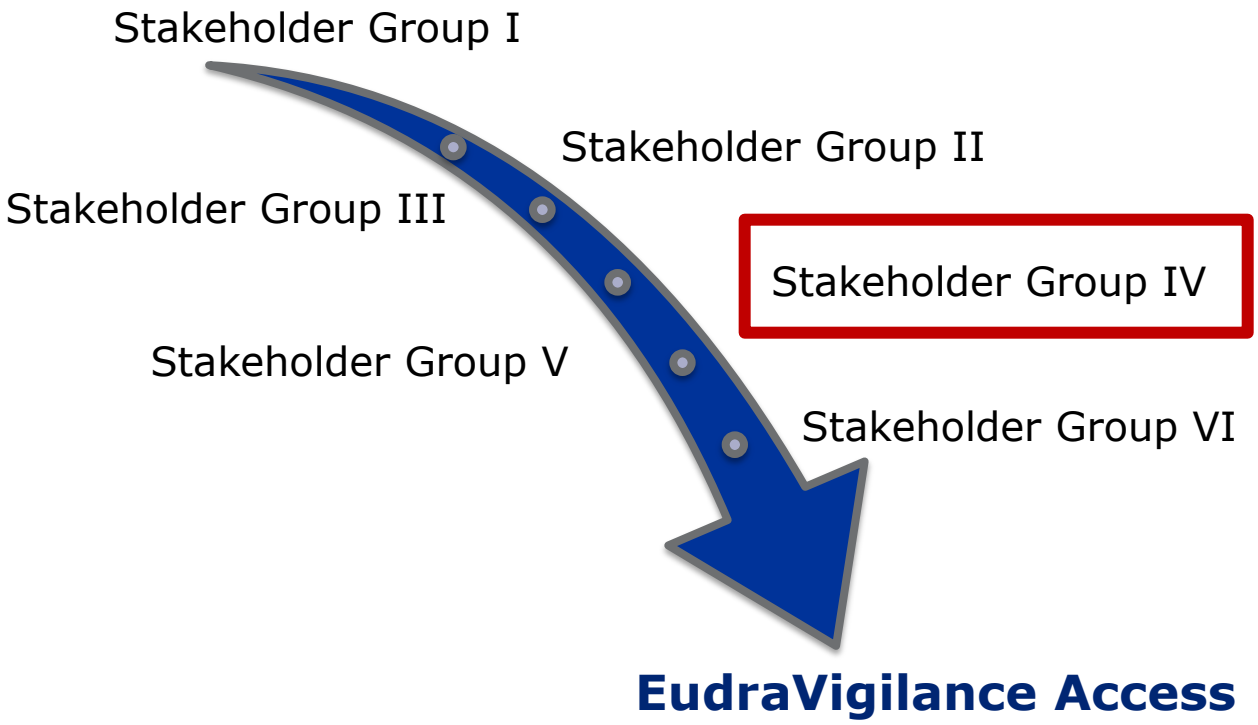
Personal data protection

- Confidentiality of ICSRs and the personal data of the subjects need to remain protected
- Appropriate technical and organisational measures are to be implemented
- EMA has to be notified immediately of a breach of security
  -> *accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance*

Access to Stakeholder Group III

	Marketing authorisation holders
Data elements available	▸ Can access a defined set of ICSR data elements for medicines for which they hold a marketing authorisation in the EEA, in compliance with EU personal data protection legislation. ▸ This includes cases related to spontaneous reports and reports from non-interventional studies. ▸ Senders of ICSRs have access to all data elements for cases they have submitted to EudraVigilance.
Access tools	▸ Access is by EVDAS, which includes the use of signal detection and data analysis functionalities. The EU qualified person for pharmacovigilance (or the appointed deputy) nominates authorised personnel through the EudraVigilance registration process. ▸ For access to case narratives required for the validation of a signal or in the context of other pharmacovigilance assessment procedures, a confidentiality undertaking is required. Details are outlined in the policy.

Access to EudraVigilance



Access to Stakeholder Group IV

- **Academia**
  (=>Stakeholder Group IV)

Access to Stakeholder Group IV

'Academia' or 'Academic sector'

consisting of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest

References: 25 MSCA Standard Eligibility Conditions: Extract from the MSCA part of the main Work Programme" of 10 December 2013

Access to Stakeholder Group IV

'Non-profit organisation' or 'non-profit legal entity'

a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members

Reference*: REGULATION (EU) no 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006*

Access to Stakeholder Group IV

'Legal entity'

any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations

Reference: REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

Access to Stakeholder Group IV

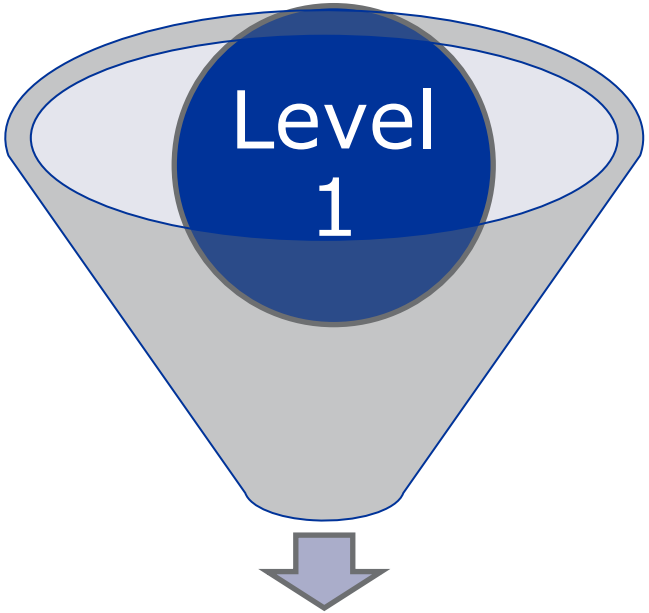
'International European interest organisation'

an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe

Reference: REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

Access to Stakeholder Group IV

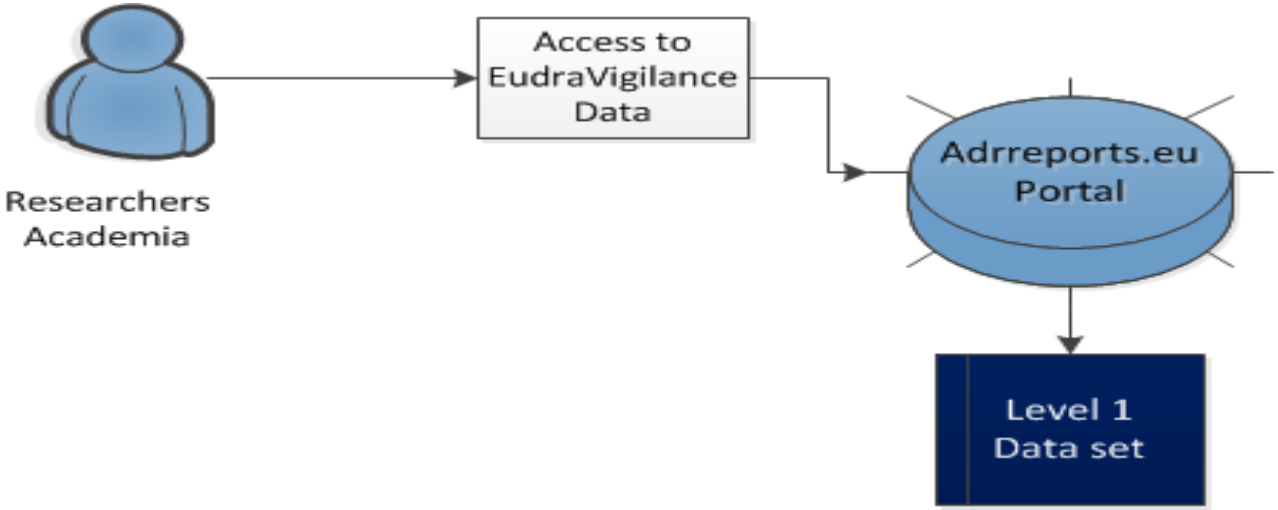
- **Level 1 access to facilitate:**
  - Use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group IV

Level 1

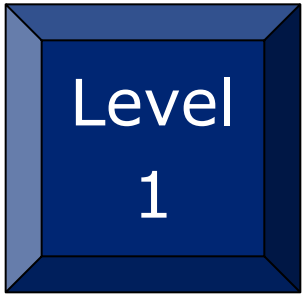


Access to Stakeholder Group IV

Level 1

- Access Authorisation
  - Not required

Access to Stakeholder Group IV



- Subset of ICSR data elements
  - in compliance with personal data protection law
- Report type
  - Spontaneous report
- Public Access
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group IV

Level 1

Access to subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 1
C.1 Identification of the case safety report	20	3
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	4
D. Patient characteristics	96	4
E.i Reaction(s)/event(s)	21	11
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	23
H. Narrative case summary and further information	7	0
Grand Total	272	53

Access to Stakeholder Group IV

Access by EudraVigilance system components

Adrreports.eu portal
Adverse Drug Reaction Reporting portal

Data outputs

- Aggregated data outputs based on predefined queries
- ICSR line listings (based on core ICSR data elements)
- ICSR forms (for individual case review)

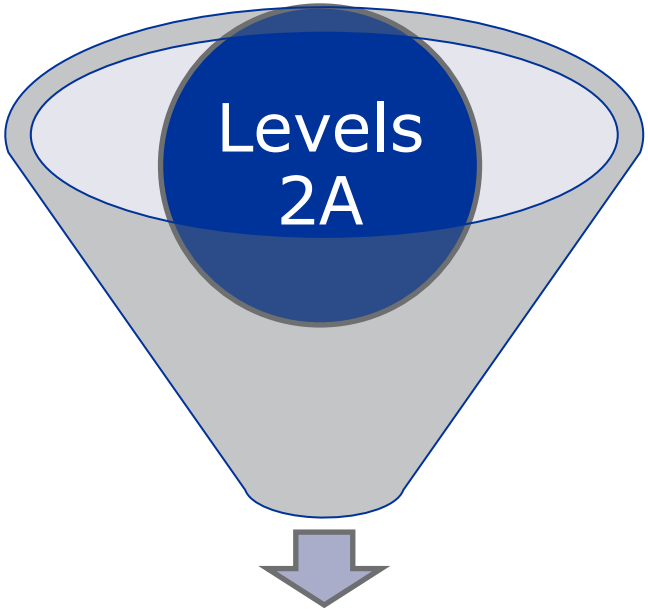
Access to Stakeholder Group IV

Personal data protection

•An information notice for EMA's ICSR processing is available on the website www.adrreports.eu

Access to Stakeholder Group IV

- **Level 2A access to facilitate:**
  - Use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research as per access principles
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group IV

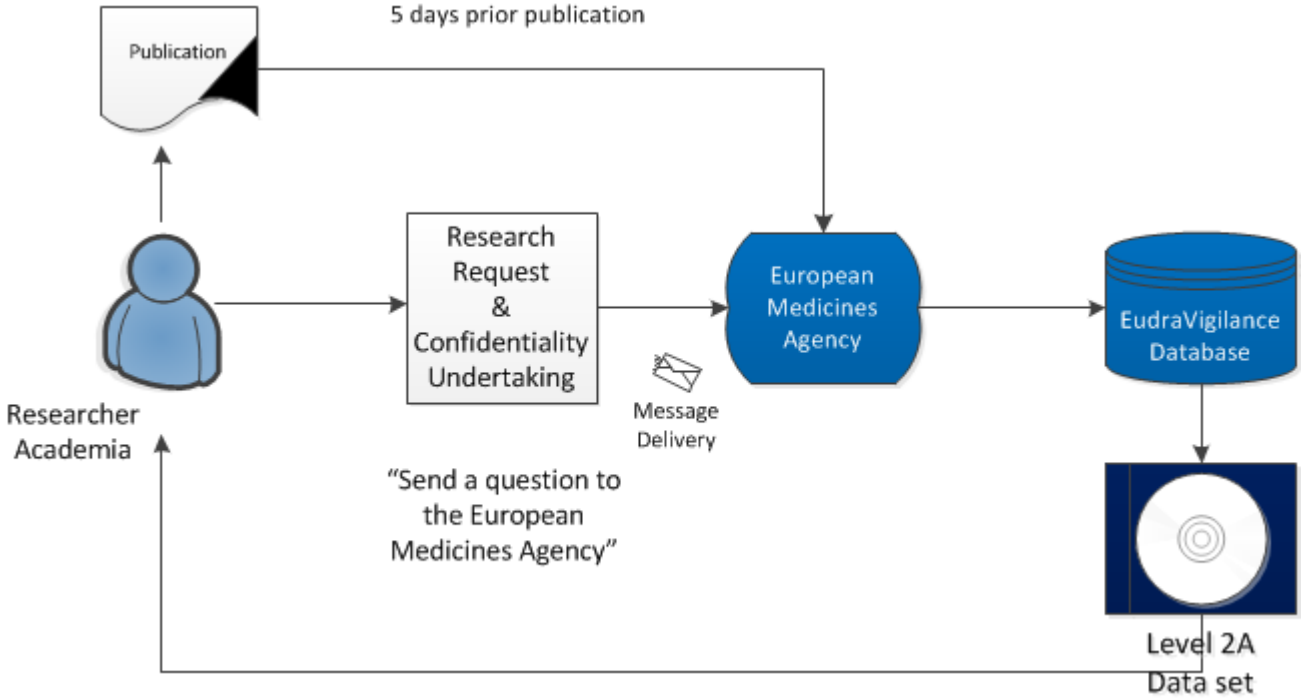
Access principles

Level 2A

- Research efforts should aim to directly advance public health and work which is intended to improve procedures for protecting public health
- The data to be provided by EMA should be sufficient to carry out work to protect public health and should observe EU legislation on protection of personal data
- Researchers should submit a research request and confidentiality undertaking to the EMA -> the research request is needed to prepare the data set required for the research
- The academic researchers should make all possible efforts to publish their research outcome
- For information purposes, a copy of any associated articles should be provided to EMA at least 5 business days ahead of publication

Access to Stakeholder Group IV

Level 2A



Access to Stakeholder Group IV

Main process steps

Level 2A

•Researcher to submit research request via *"Send a question to the European Medicines Agency"*; this request should include

a. Name and contact details of a nominated person for the research organisation (see EV Access Policy for details)
b. "Confidentiality undertaking for academia" to be signed by the nominated person of the research organisation and all members of the research team

Access to Stakeholder Group IV

Level 2A

c. Research request, which should address:

Primary research question

Methodology to be used

Way that the results will impact on public health

Name and contact details of the person nominated by the academic institution to safeguard the EudraVigilance data for the research purpose

A proposed privacy check to be performed by the academic institution prior to any publication to prevent a release of personal data and the possible re-identification of data subjects (e.g. patients, reporters)

Access to Stakeholder Group IV

Level 2A

- Data may not be transferred to any third party

Access to Stakeholder Group IV

Level 2A

Process steps for granting L2A access

•Review if the research request by an EMA panel with representatives from the Pharmacovigilance and Business Data and Analytics Department -> *for the purpose of preparing the ICSR data set required for the research*

–EMA will not review the validity or soundness of the research proposal and will apply a standard timescale for response to requests
–EMA may comment on the proposed data privacy check approach in the context of publications related to the research request
–The data quality will be the best available to the Agency at the time of request
–Explanations essential for the interpretation of the EudraVigilance data set for which access is provided, will be also made available by EMA where applicable

Access to Stakeholder Group IV

Level 2A

Process steps for granting L2A access

- EMA provides Level 2A data set as per research request to nominated person by the academic institution
- Nominated person by the academic institution provides a copy of any research associated articles to the EMA at least 5 business days ahead of publication for information purpose

Access to Stakeholder Group IV

Level 2A

- Authorised Personnel
  - Nominated person by the academic institution to safeguard the EudraVigilance data
  - Note: subject to submission of a research request and signed “confidentiality undertaking for academia” by the nominated person requesting access to the ICSR data set Level 2A and all members of the research team working with the data

Access to Stakeholder Group IV

Level 2A

- Extended subset of ICSR data elements
  - Use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research as per access principles
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- Substances or class of substances subject to research

Access to Stakeholder Group IV

Level 2A

Access to extended subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 2A
C.1 Identification of the case safety report	20	18
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	5
D. Patient characteristics	96	87
E.i Reaction(s)/event(s)	21	21
F.r Results of tests and procedures relevant to the investigation of the Patient	13	13
G.k Drug(s) information	76	72
H. Narrative case summary and further information	7	4
Grand Total	272	228

Access to Stakeholder Group IV

Access by EudraVigilance system component

Data outputs

- Ad-hoc preparation of data set by EMA based on receipt of a research request and confidentiality undertaking
- Data format will depend on research request

Access to Stakeholder Group IV

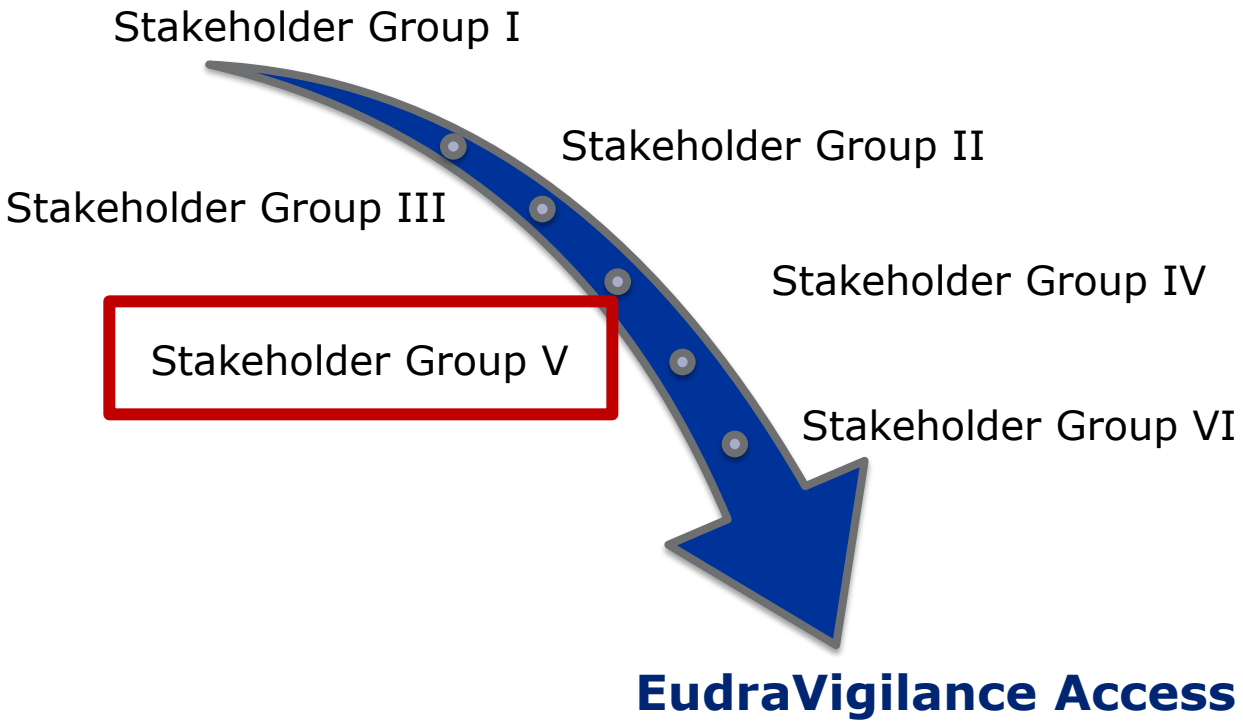
Personal data protection

- Confidentiality of ICSRs and the personal data of the subjects need to remain protected
- Appropriate technical and organisational measures are to be implemented
- EMA has to be notified immediately of a breach of security *-> accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance*

Access to Stakeholder Group IV

Academia	
Data elements available	▸ In the interest of supporting efforts to improve public health through research, a defined set of data for spontaneous reports is available to academic institutions. ▸ Where a research request is submitted, an extended data set can be provided by the Agency following receipt of a signed confidentiality undertaking. Details are outlined in the policy.
Access tools	▸ Access is granted through the adrreports.eu portal.

Access to EudraVigilance

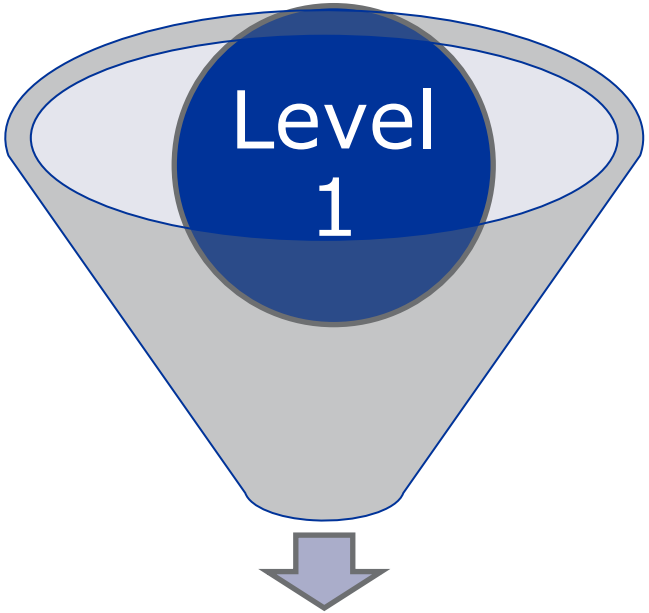


Access to Stakeholder Group V

- **World Health Organisation – Uppsala Monitoring Centre *(=>Stakeholder Group V)***

Access to Stakeholder Group V

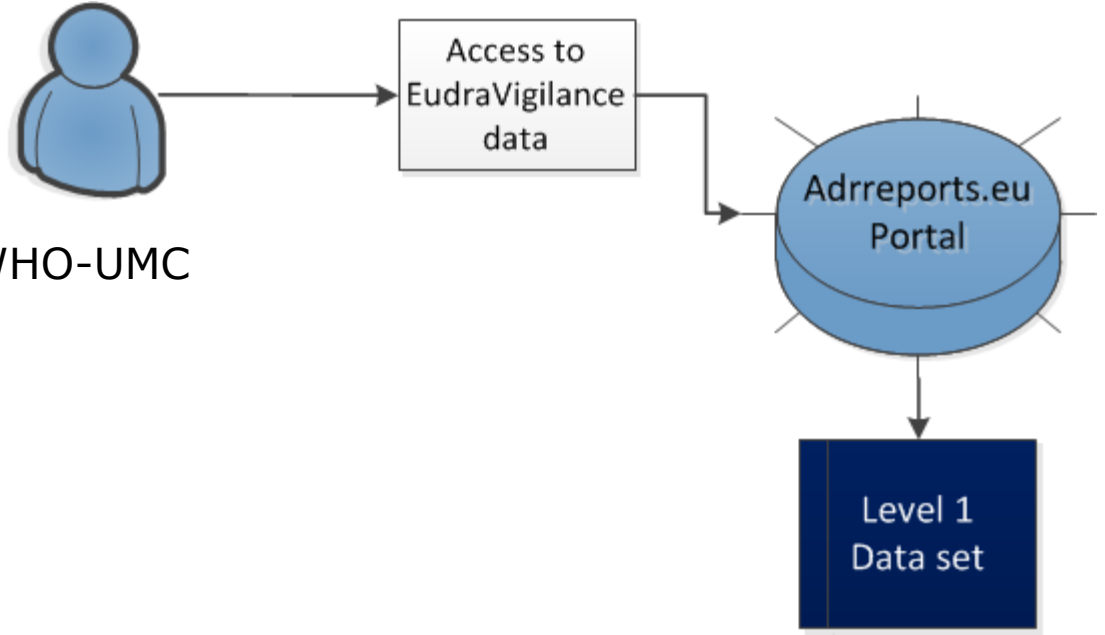
- **Level 1 access to provide:**
  - Monitoring of the safety of medicines
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group V

Level 1



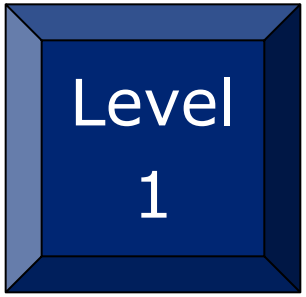
WHO-UMC

Access to Stakeholder Group V

Level 1

- Access Authorisation
  - Not required

Access to Stakeholder Group V



- Subset of ICSR data elements
  - in compliance with personal data protection law
- Report type
  - Spontaneous report
- Public Access
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group V

Level 1

Access to subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 1
C.1 Identification of the case safety report	20	3
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	4
D. Patient characteristics	96	4
E.i Reaction(s)/event(s)	21	11
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	23
H. Narrative case summary and further information	7	0
Grand Total	272	53

Access to Stakeholder Group V

Access by EudraVigilance system component

Adrreports.eu portal
Adverse Drug Reaction Reporting portal

Data outputs

- Aggregated data outputs based on predefined queries
- ICSR line listings (based on core ICSR data elements)
- ICSR forms (for individual case review)

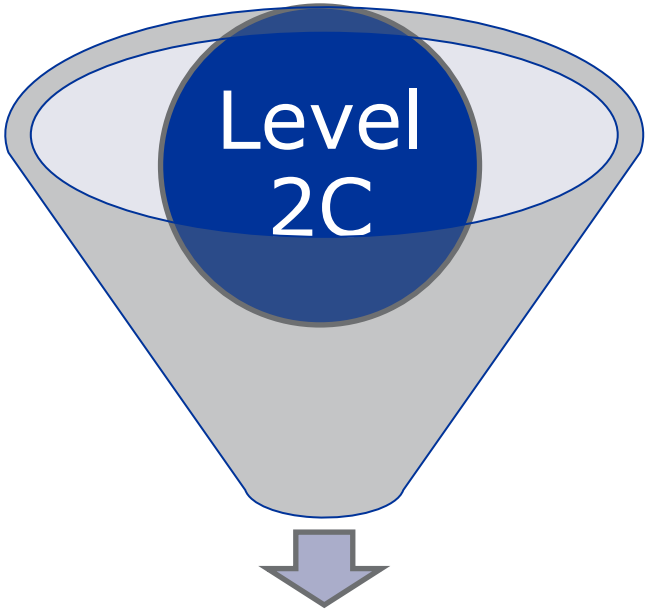
Access to Stakeholder Group V

Personal data protection

- An information notice for EMA's ICSR processing is available on the adrreports.eu portal

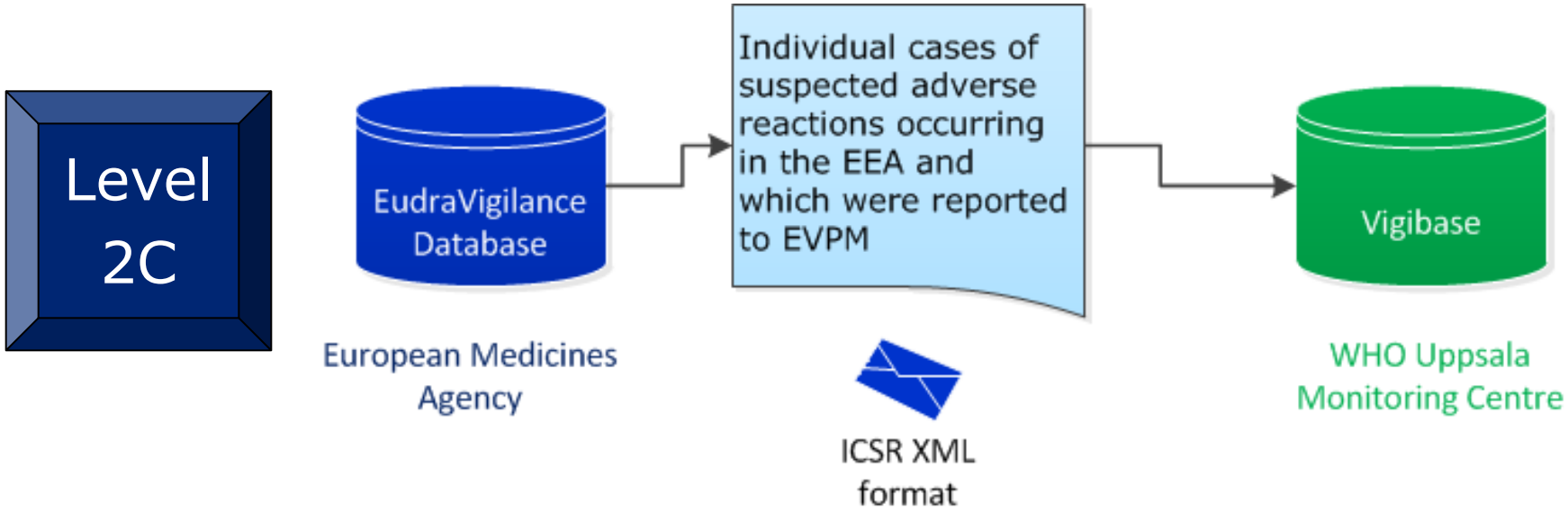
Access to Stakeholder Group V

- **Level 2C access to facilitate:**
  - Public health protection
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group V



Access to Stakeholder Group V

Level 2C

- **Authorised Personnel**
  - WHO-UMC authorised personnel as per “data transfer arrangement*” between the Agency and WHO-UMC

**Modalities for making available EU adverse reaction reports to VigiBase and arrangements for the data transfer and use, taking into account the principle of data quality, purpose limitation and adequate safeguards for the protection of personal data*

Access to Stakeholder Group V

Level 2C

- Extended subset of ICSR data elements
  - Subset of ICSR data elements in support of public health protection and in accordance with EU data protection legislation
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs reported to EVPM (occurrence in EEA) for substances/medicinal products authorised in the EEA

Access to Stakeholder Group V

Level 2C

Access to extended subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 2C
C.1 Identification of the case safety report	20	16
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	5
D. Patient characteristics	96	16
E.i Reaction(s)/event(s)	21	18
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	71
H. Narrative case summary and further information	7	0
Grand Total	272	134

Access to Stakeholder Group V

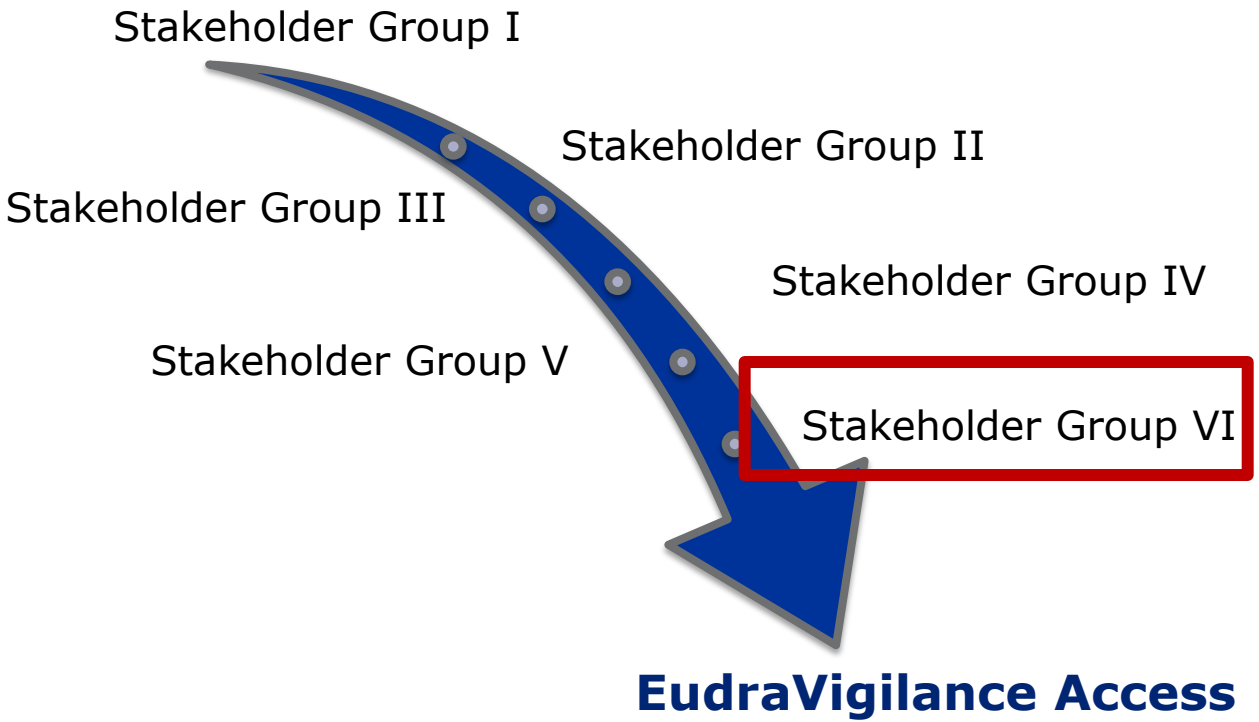
Personal data protection

- As defined in the data transfer arrangement

Access to Stakeholder Group V

World Health Organization - Uppsala Monitoring Centre (WHO-UMC)	
Data elements available	▸ The Agency provides the WHO-UMC with a defined set of data elements for ICSRs originating from within the EEA in accordance with EU personal data protection law. This includes spontaneous reports and reports of non-interventional studies.
Notes	▸ The circumstances for the data provision are set out in a data transfer arrangement. Details are outlined in the policy.

Access to EudraVigilance

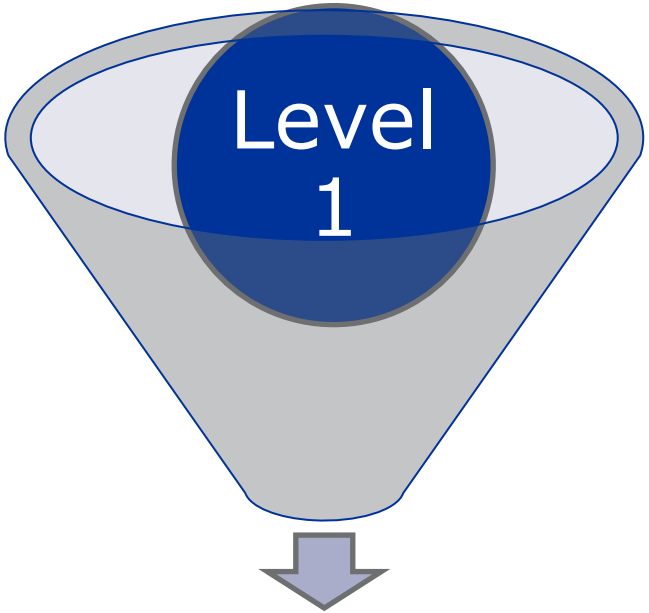


Access to Stakeholder Group VI

- **Medicines regulatory authorities in third countries *(=>Stakeholder Group IV)***

Access to Stakeholder Group VI

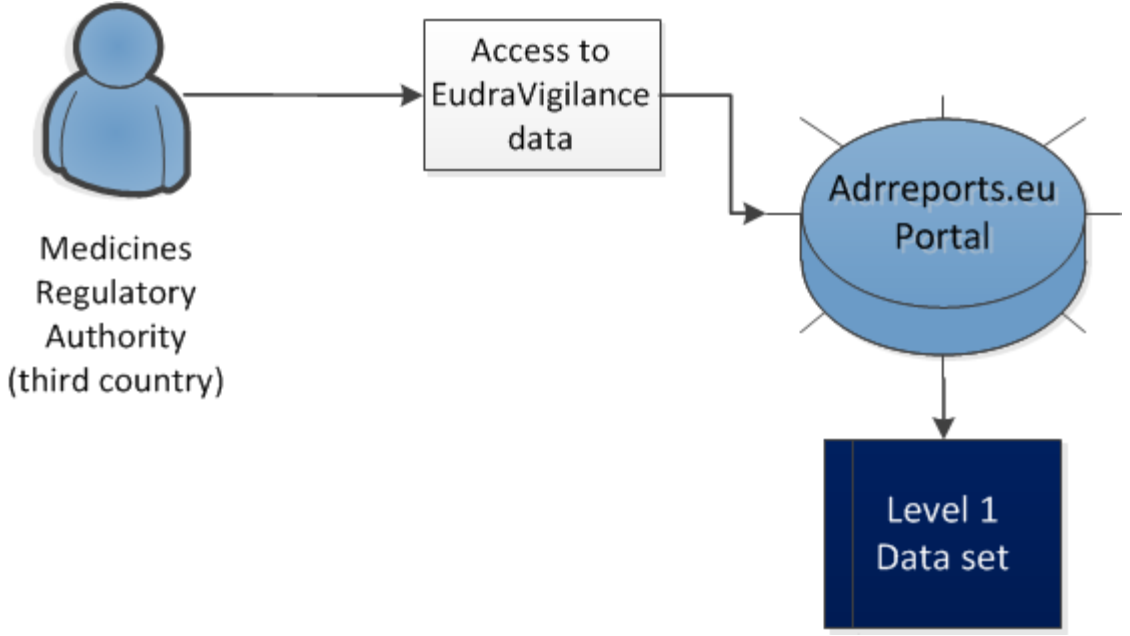
- **Level 1 access to provide:**
  - Monitoring of the safety of medicines
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group VI

Level 1

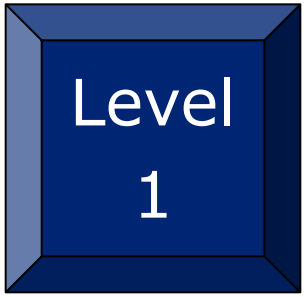


Access to Stakeholder Group VI

Level 1

- Access Authorisation
  - Not required

Access to Stakeholder Group VI



- Subset of ICSR data elements
  - in compliance with personal data protection law
- Report type
  - Spontaneous report
- Public Access
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group VI

Level 1

Access to subset of ICSR data elements described in the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 1
C.1 Identification of the case safety report	20	3
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s) .	2	1
C.5 Study identification	6	4
D. Patient characteristics	96	4
E.i Reaction(s)/event(s)	21	11
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	23
H. Narrative case summary and further information	7	0
Grand Total	272	53

Access to Stakeholder Group VI

Access by EudraVigilance system component

Adrreports.eu portal
Adverse Drug Reaction Reporting portal

Data outputs

- Aggregated data outputs based on predefined queries
- ICSR line listings (based on core ICSR data elements)
- ICSR forms (for individual case review)

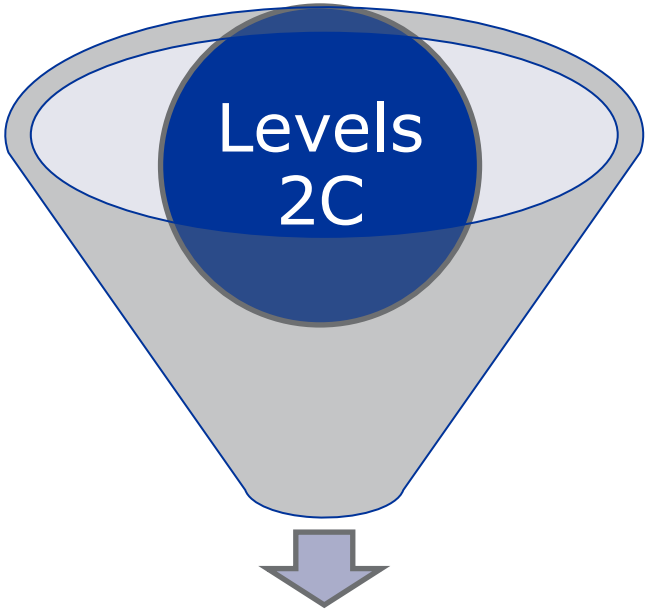
Access to Stakeholder Group VI

Personal data protection

- An information notice for EMA's ICSR processing is available on the adrreports.eu portal

Access to Stakeholder Group VI

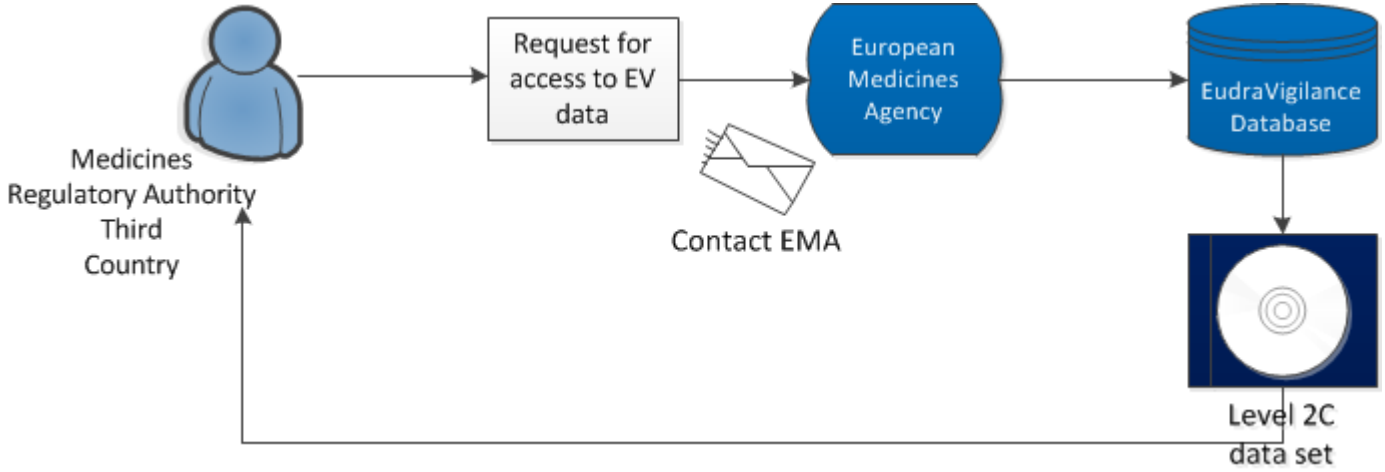
- **Level 2C access to facilitate:**
  - Evaluation of a safety issue related to medicines
- **Compliance with personal data protection requirements**



EudraVigilance Access

Access to Stakeholder Group VI

Level 2C



Access to Stakeholder Group VI

Main process steps

- Medicines Regulatory Authority (third country) submits "Request for access to EudraVigilance data"
- EMA provides Level 2C data set as per request to nominated contact of Medicines Regulatory Authority in third country

Access to Stakeholder Group VI

Level 2C

- Access authorisation
  - Nominated contact of the medicines regulatory authority
  - Transfer of data will comply with applicable data protection legislation

Access to Stakeholder Group VI

Level 2C

- Extended subset of ICSR data elements
  - Subset of ICSR data elements (as for WHO UMC)
- Report types
  - Spontaneous report
  - Report from study (individual patient use, other studies)
  - Other
  - Not available to sender
- ICSRs for medicinal products authorised in the EEA

Access to Stakeholder Group VI

Level 2C

Access to extended subset of ICSR data elements based on the ICH E2B(R3) ICSR Implementation Guide

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Level 2C
C.1 Identification of the case safety report	20	16
C.2.r Primary source(s) of information	15	4
C.3 Information on sender of case safety information	16	3
C.4.r Literature reference(s)	2	1
C.5 Study identification	6	5
D. Patient characteristics	96	16
E.i Reaction(s)/event(s)	21	18
F.r Results of tests and procedures relevant to the investigation of the Patient	13	0
G.k Drug(s) information	76	71
H. Narrative case summary and further information	7	0
Grand Total	272	134

Access to Stakeholder Group VI

Personal data protection

- Transfer of data to medicines regulatory authorities in third countries in compliance with applicable data protection legislation

Access to Stakeholder Group VI

Medicines regulatory authorities in third countries	
Data elements available	A defined set of ICSR data elements identical to the one made available to WHO is provided to nominated contacts following receipt of a request, e.g. in the context of the evaluation of a safety issue related to a medicine.

Session summary

In this session you obtained an understanding:

- Which factors are essential in organising the provision of access
- How each stakeholder group obtains access to EudraVigilance
- Which data can be accessed by each stakeholder group

Overview Module PhV-M4

- Introduction to this training module
- Scope, legal background, principles, objectives
- Access to EudraVigilance by stakeholder group
- **How to get supporting information**

Where can I get support if needed?

EudraVigilance Registration

- Email - eudravigilanceregistration@ema.europa.eu
- Tel - 44 (0) 20 3660 7523

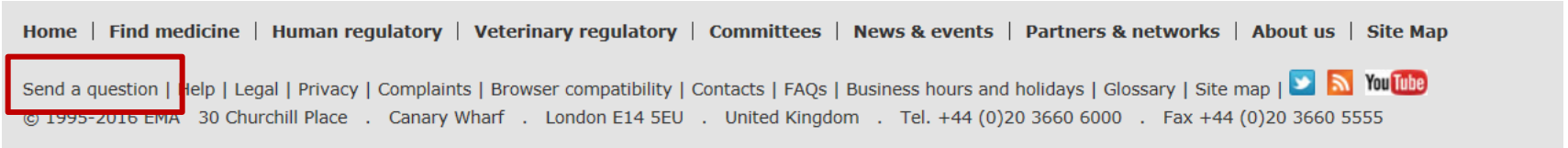
EudraVigilance Operations and IT Operations

- Visit the EMA Service Desk portal: https://servicedesk.ema.europa.eu
- For **urgent** technical matters, telephone: +44 (0)20 3660 8520

Where can I get support if needed?

Pharmacovigilance operations

- Send a question to EMA (accessible from the EMA homepage)



Reference Documents (1)

Reference	Document title
Regulation 726/2004	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013)
Directive 2001/83/EC	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version: 16/11/2012)

Reference Documents (2)

Reference	Document title
23 August 2011 EMA/759287/2009 corr.	EudraVigilance access policy for medicines for human use (revision 1)
17 December 2015 EMA/759287/2009 Revision 2	European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (EudraVigilance Access Policy)

Overview Module PhV-M4

- Introduction to this training module
- Scope, legal background, principles, objectives
- Access to EudraVigilance by stakeholder group
- How to get supporting information

Summary of PhV-M4

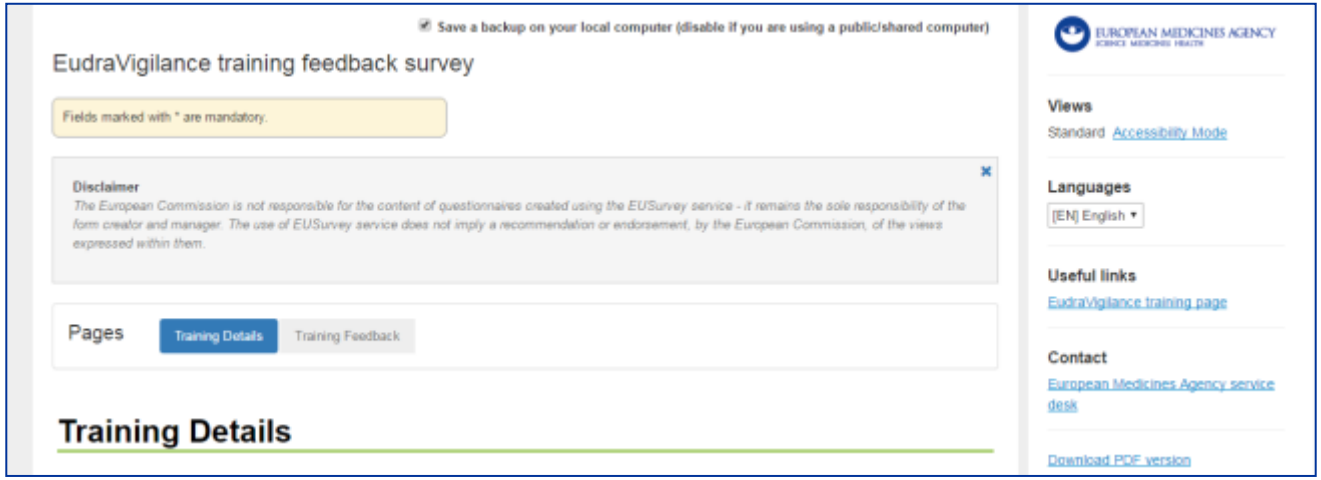
We are now at the end of the training module PhV-M4, which provided you the knowledge to:

- Understand the legal background, scope and the key principles outlined in revision 2 of the EudraVigilance Access Policy
- Describe the levels of access provided to stakeholders based on six stakeholder groups
- Recognise how access will be granted to EudraVigilance data
- Describe the impact of obtaining access to EudraVigilance data
- Understand where to obtain supporting information

Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.

- The survey is accessible via this link.



Acronyms

Acronym	Description
EEA	European Economic Area
eRMRs	Electronic Reaction Monitoring Reports
EU	European Union
EV	EudraVigilance
EVPM	EudraVigilance Post-Authorisation Module

Acronyms

Acronym	Description
GVP	Guideline on good pharmacovigilance practices
ICSR	Individual Case Safety Reports
ID	Identification
IG	Implementation Guide
MAH	Marketing authorisation holder
PhV	Pharmacovigilance
QPPV	Qualified Person responsible for Pharmacovigilance

Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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