

Automated Compliance Monitoring based on reporting timelines

Monthly Automated Reports

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

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Agenda

- Overview
- Rationale
- Key Concepts
- Examples
- Compliance Measurement
- Reports excluded from the reporting compliance
- Different time zones
- Summary

Compliance Notifications

- **What?** Up to three ICSR compliance reports (for 7/15/90-day timelines), each in separate notification emails submitted through automated reports generated by EVDAS. Within each of these compliance reports are 3 sub-reports constituting 5 outputs altogether including tables and barcharts.
- **Who?** QPPVs/RPs of all sender organisations will be automatically contacted (For Sep/Oct/Nov only top 20 MAHs who sent the most ICSRs to EV & all NCAs). From December it will be extended to include all organisations.
- **How?** By email from donotreply@ema.europa.eu
- **When?** Launched on Wednesday 3rd September 2025
- **How often?** Every month with compliance reports covering the submissions made to EV the previous month. Next notification will be on 05 Nov 2025 (today!)

But why?

1. To ensure compliance with the legal basis:

- [Directive 2001/83/EC](#), Article 107(3) – MAHs 15/90 days
- [Directive 2001/83/EC](#), Article 107(a)(4) – NCAs 15/90 days
- [Regulation \(EU\) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use](#), Article 42(2) Sponsors 7/15 days
- [Commission Implementing Regulation \(EU\) No 520/2012](#) Articles 26(2)(a) and 25(1)(f) of chapter IV
- [Regulation \(EC\) No 762/2004](#), Article 24(3) SOPs & Article 11(1)c -quality system

2. To complement your own Quality System and to assist with timely root cause analysis

3. To quickly visualise compliance and comprehend the volume of non-compliant cases

4. To understand the types of cases/timelines that are non-compliant e.g. SUSARs or post marketing cases 7/15/90-day timelines

The Batch Sender Identifier



Reports for a given organization are defined by the batch sender identifier (N.1.3). This data element identifies the origin of the ICSR reports (creator of ICH ICSR batch file), e.g. company name or regulatory authority. The identifier is unique to the sender. This is the registered sender ID. The sender ID must be a registered EDI partner of the gateway.



So if an EV Head Quarter profile has multiple affiliates and virtual affiliates with their own sender IDs, each sender (which could be an affiliate or a virtual affiliate) will each receive their own set of reports.



It is up to each parent company to decide on how they divide and manage affiliates.

ICSR Compliance Report

Division, constitution and examples

How do the ICSR submissions get divided into three potential ICSR compliance reports?

- **EVPM 15 days**
 - If **any** of the **seriousness criteria** at the **reaction level** are selected as **“true”** and the case is submitted EVPM
- **EVPM 90 days**
 - If **no seriousness criteria** are selected as **“true”** at the reaction level (NI or no selected) and the case is submitted to EVPM
- **EVCTM 7/15 days**
 - **Serious not fatal and not life-threatening ICSRs (15 days)**
 - **no related reaction** has the seriousness criteria **"Results in Death"** or **"Life-threatening"** (ICH E2B(R3) E.i.3.2a or E.i.3.2b) selected as **“True”** and they must contain at least **one related reaction** which has any of the other seriousness criteria selected as **“true”**.
 - **Serious fatal or life-threatening ICSRs (7 days)**
 - must contain **at least one related reaction** which has one or more of the seriousness criteria **"Results in Death"** or **"Life-threatening"** selected as **“true”**.
 - A related reaction is one which has the "Drug-reaction(s)/events(s) matrix" (ICH E2B(R3) G.k.9) populated with:
"1" for "EU **Method** of Assessment" (ICH E2B(R3) G.k.9.i.2.r.2.EU.1)
 - AND
"1" (**reasonable possibility**) for "EU **Result** of Assessment" (ICH E2B(R3) G.k.9.i.2.r.3.EU.1)

What exactly is contained in each compliance report?

- **Sub-Report 1: "Listing of Non-Compliant Individual Cases Submitted to EVCTM/EVPM Outside 7/15, 15 or 90 Days Reporting Period"**
- Lists ICSRs submitted to EVCTM/EVPM beyond the 7/15, 15 or 90 days reporting period for the concerned month and year.
- It is one output in table format and a column entitled 'reporting time in days' tells you the exact day it was submitted on e.g. day 16, counted from day 0.

Compliance with reporting timelines for the electronic submission of ICSRs to EudraVigilance

- ☒ 7 day timeline
- ☒ 15 day timeline
- ☒ 90 day timeline



Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

**Listing of Non-Compliant Individual Cases Submitted to
EVPM Outside 15 Days Reporting Period – September
2025**

Reporting Time in Days	EV Local Report Number	EV World Wide Unique Case Identifier	ICSRs - Initial	ICSRs - Follow-up
0			0	0
35	10020024926	SD-MLMSERVICE-20250901-PI630744-00030-1	1	0
37	10020054169	US-MLMSERVICE-20250905-PI633304-00255-1	1	0

Example: Sponsor

Organisation Sender ID: [REDACTED]

Organisation Name: [REDACTED]

Listing of Non-Compliant Individual Cases Submitted to
EVCTM Within/Outside 7/15 Days Reporting Period – June
2025

Reporting Time in Days	EV Local Report Number	EV World Wide Unique Case Identifier	Number of ICSRs fatal or life threatening - Initial	Number of ICSRs fatal or life threatening - Follow-up	Number of ICSRs not fatal and not life threatening - Initial	Number of ICSRs not fatal and not life threatening - Follow-up
0			0	0	0	0
8	100 [REDACTED]	[REDACTED]	1	0	0	0
16	100 [REDACTED]	[REDACTED]	0	0	1	0

What exactly is contained in each compliance report?

- **Sub-Report 2: "Overview of ICSRs Submission to EVCTM/EVPM Within/Outside 7/15, 15 or 90 Days Reporting Period"**
- This report provides an overview of the number of ICSRs submitted to EVCTM/EVPM within or outside the 7/15, 15 or 90 days reporting period for the concerned month and year.
- There are 2 outputs for this overview – a table and a horizontal barchart displaying the percentage and volume of cases within or outside the timelines.

Compliance with reporting timelines for the electronic submission of ICSRs to EudraVigilance

☒ 7 day timeline

☒ 15 day timeline

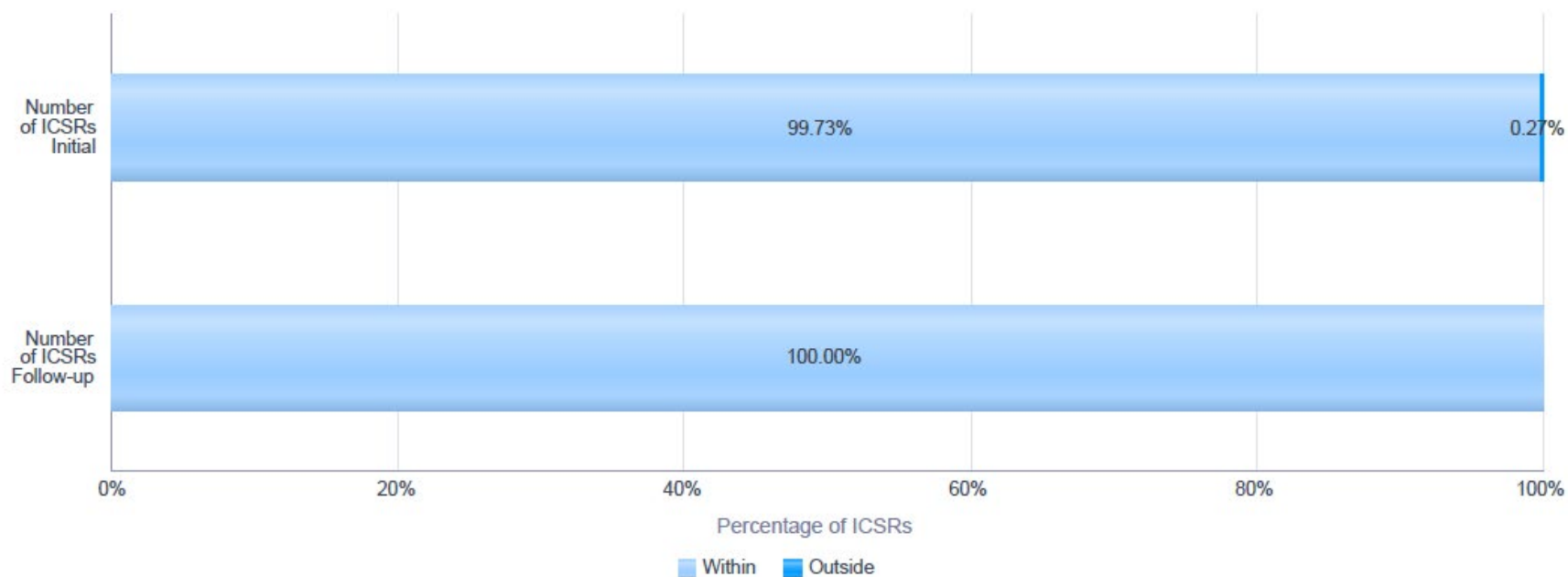
☒ 90 day timeline



Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

**Overview of ICSRs Submission to EVPM Within/Outside
15 Days Reporting Period – September 2025**



Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

**Overview of ICSRs Submission to EVPM Within/Outside
15 Days Reporting Period – September 2025**

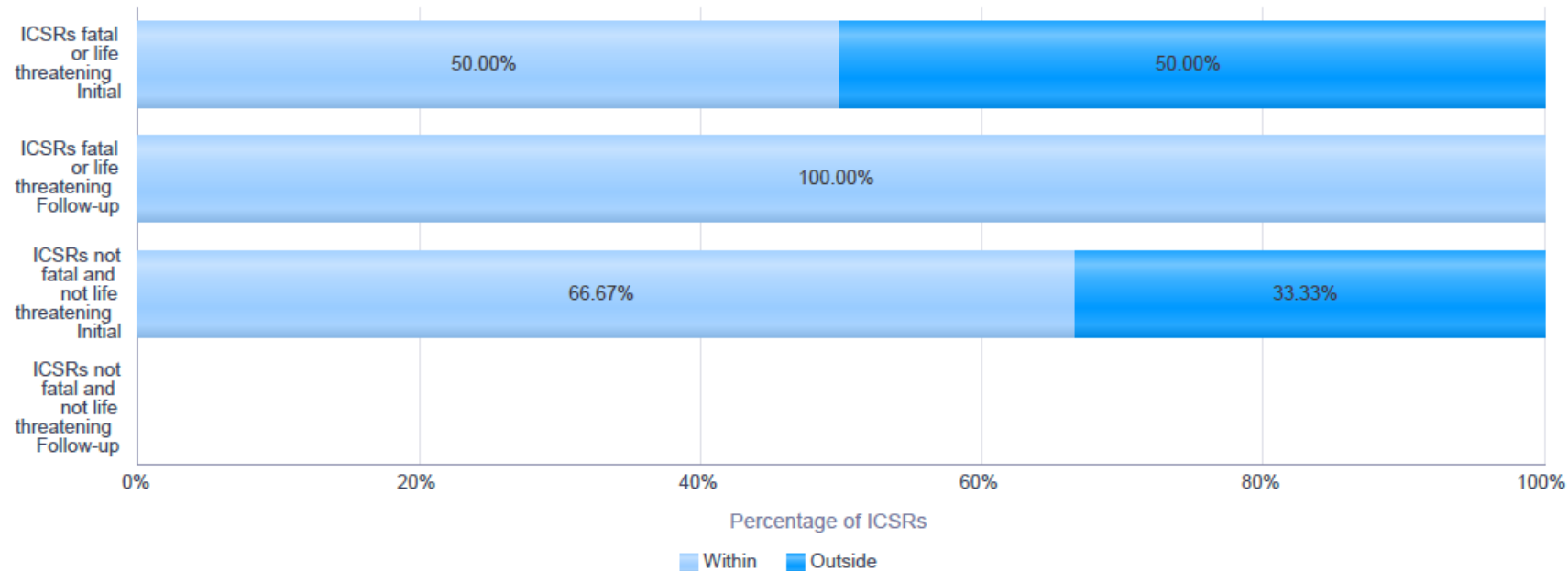
15 Days Reporting Period	Number of ICSRs - Initial	Number of ICSRs - Follow-up
Within	731	365
Outside	2	0

Example: Sponsor

Organisation Sender ID: [REDACTED]

Organisation Name: [REDACTED]

Overview of ICSRs Submission to EVCTM Within/Outside
7/15 Days Reporting Period – June 2025



Example: Sponsor

Organisation Sender ID: [REDACTED]

Organisation Name: [REDACTED]

**Overview of ICSRs Submission to EVCTM Within/Outside
7/15 Days Reporting Period – June 2025**

7/15 Days Reporting Period	Number of ICSRs fatal or life threatening - Initial	Number of ICSRs fatal or life threatening - Follow-up	Number of ICSRs not fatal and not life threatening - Initial	Number of ICSRs not fatal and not life threatening - Follow-up
Within	1	3	2	0
Outside	1	0	1	0

What exactly is contained in each compliance report?

- **Sub-Report 3: "Overview of Submission Timelines of ICSRs to EVCTM/EVPM: 7/15, 15 or 90 Days Reporting Period".**
- This report provides an overview of the number of ICSRs submitted to EVCTM/EVPM for the concerned month and year in relation to their reporting timelines. It shows both initials and follow up and the 'reporting time in days' tells you the exact day it was submitted on e.g. day 6, counted from day 0.
- For reports submitted to EVCTM the barchart separates the initial/fup ICSR submissions into life-threatening/fatal SUSARs or a non-life-threatening/fatal SUSARs.
- There are 2 outputs for this overview – a table and a barchart.

Compliance with reporting timelines for the electronic submission of ICSRs to EudraVigilance

☒ 7 day timeline

☒ 15 day timeline

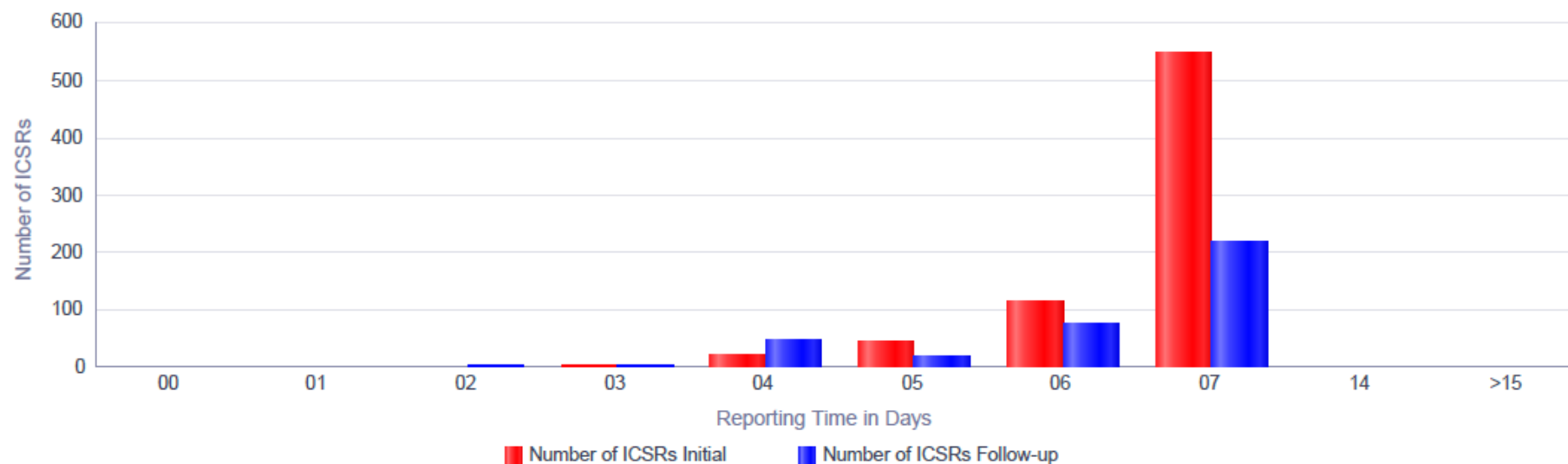
☒ 90 day timeline



Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

Overview of Submission Timelines of ICSRs to EVPM: 15 Days Reporting Period – September 2025



Example: MLM Service

Organisation Sender ID: MLMSERVICE
Organisation Name: EMA MLMSERVICE

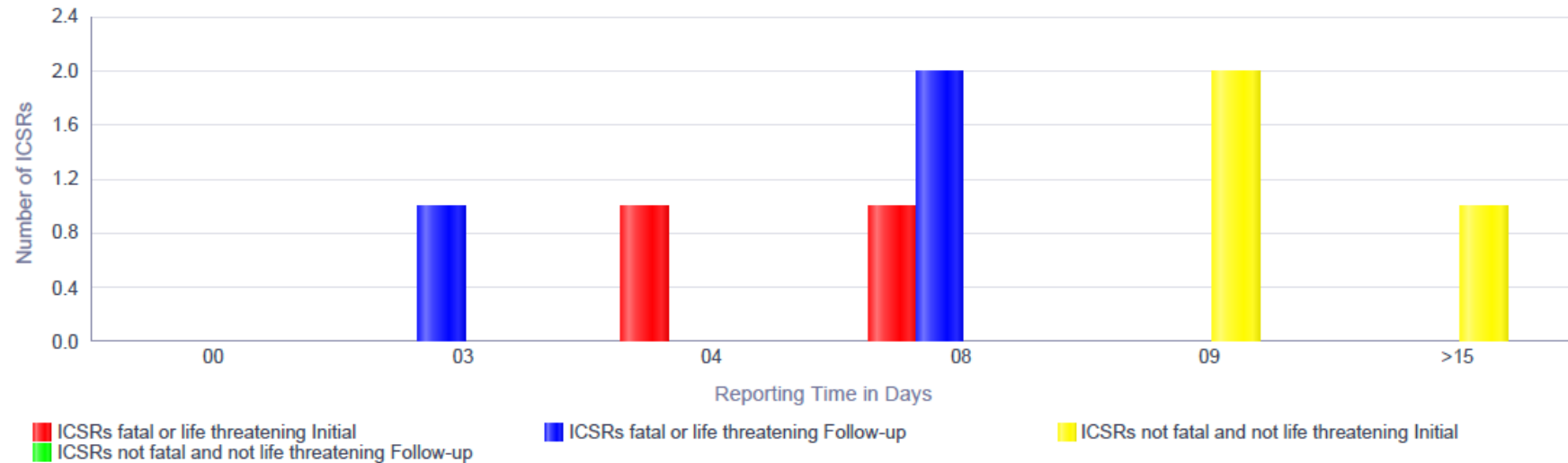
**Overview of Submission Timelines of ICSRs
to EVPM: 15 Days Reporting Period – September 2025**

Reporting Time in Days	Number of ICSRs - Initial	Number of ICSRs - Follow-up
00	0	1
01	0	1
02	0	3
03	5	3
04	21	47
05	45	18
06	113	74
07	546	218
14	1	0
>15	2	0

Example: Sponsor

Organisation Sender ID: [REDACTED]
Organisation Name: [REDACTED]

Overview of Submission Timelines of ICSRs
to EVCTM: 7/15 Days Reporting Period – June 2025



Example: Sponsor

Organisation Sender ID: [REDACTED]

Organisation Name: [REDACTED]

Overview of Submission Timelines of ICSRs
to EVCTM: 7/15 Days Reporting Period – June 2025

Reporting Time in Days	Number of ICSRs fatal or life threatening - Initial	Number of ICSRs fatal or life threatening - Follow-up	Number of ICSRs not fatal and not life threatening - Initial	Number of ICSRs not fatal and not life threatening - Follow-up
00	0	0	0	0
03	0	1	0	0
04	1	0	0	0
08	1	2	0	0
09	0	0	2	0
>15	0	0	1	0

Compliance measurements
Exclusions
Time zones
Questions

How is compliance measured?

The compliance is calculated per each ICSR as the difference between the data element "Date (of receipt) of most recent information for this report" (ICH E2B(R3) C.1.5) and the "EudraVigilance Gateway date".

This image shows how to find the gateway date in EVWEB

The screenshot displays the EVWEB interface for searching ICSRs. The 'ICSRs' tab is selected in the top navigation bar. Below the navigation bar, the 'Search for:' section has 'ICHICSR messages' selected. A search bar is present to the right. Below the search bar, a message states: 'The ICSR search section gives access to all ICSRs (both EEA and Non-EEA) at either level 1 (public), level 2A (if the ICSR is associated with your XEVMPD data) or level 3 (if your organisation sent the case). You should NOT use this section to routinely retrieve cases to fulfil your pharmacovigilance obligations. To obtain cases with Level 2A access to fulfil your pharmacovigilance obligations you should use the section "ICSR Download".'

The 'Criteria (0)' section shows 'No criteria added, click "More criteria" to add some!'. The 'Fields (6)' section is expanded, showing a table of search results. The table has columns for 'Message Number', 'Message Date', 'Message Received Date', and 'Document Type'. The 'Message Received Date' column shows the value '2025/08/11 10:59:38'. Below the table, there are fields for 'Message Acknowledgment Code' (Application Acknowledgment Accept (message successfully processed, n...)) and 'Sender Identifier' (EVHUMANWT).

Message Number	Message Date	Message Received Date	Document Type
		2025/08/11 10:59:38	

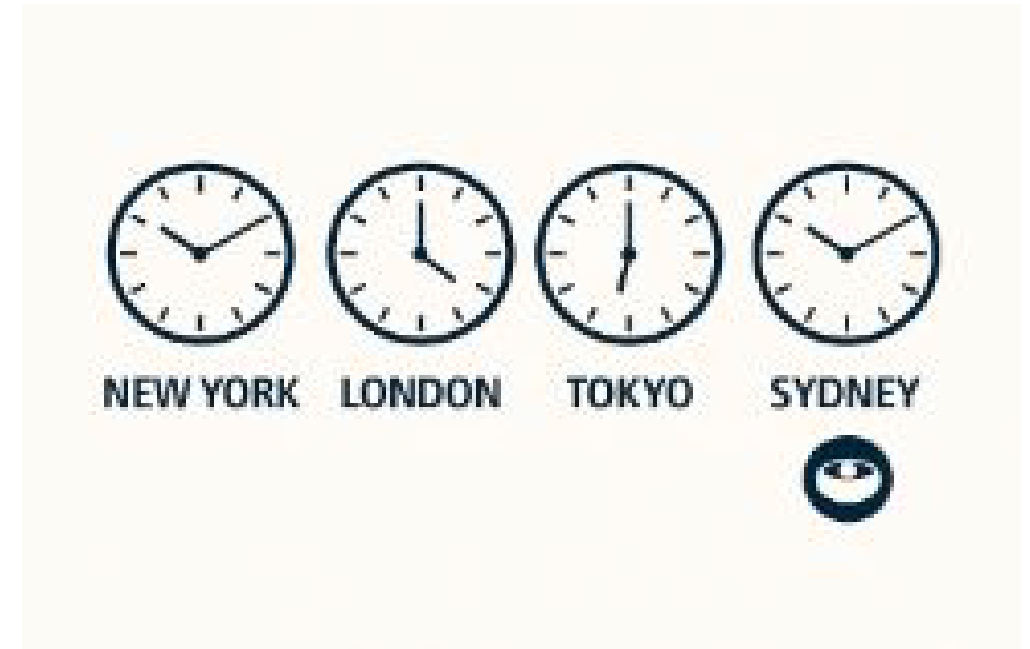
Are any ICSRs excluded from the compliance notification?

Yes:

1. **"Error reports"**: ICSRs for which the sender received an acknowledgement code "CR" in data element "Acknowledgment Code for a ICSR Message" (ICH E2B(R3) ACK.B.r.6);
2. **"Nullification reports"**: ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "1";
3. **"Amendment reports"**: ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "2".

What about different time zones?

- Please be mindful of potential time zone differences when submitting a case to EV, as close of business in your location could mean the deadline has already passed for EMA.
- The official EV gateway date should be checked
- In ICSR submissions you can include the time zone from which you are making your submissions.
- We allow 12h (+12:00) exceeding the current CE(S)T time.
- For example, if you are in the UTC +12 time zone and you submit your ICSR to EV at 11:55am on day 16 then it will be on time (if you include the time offset).
- This is detailed in note 5 of the EV business rules, See the EU Individual Case Safety Report (ICSR) Implementation Guide, section I.C.4.1 Business Rule Notes, Table 35.



Questions?

- Please see the FAQ section of the Compliance notifications explanation and Q&A document.
- If you still have a question, then please submit it using the [EMA Service Desk: ICSR compliance notification question](#) form.





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Thank you

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