



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 August 2015
EMA/274835/2015 Rev.3
Information Management Division

New functionalities in support of the medical literature monitoring service

User manual: EV ICHISCR Export Manager, MLM EVWEB & tracking spreadsheets

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Overview

Article 27 of Regulation (EC) No 726/2004 sets out the provisions for the monitoring of medical literature and the entry of relevant information into the EudraVigilance (EV) database by the European Medicines Agency. A detailed guide (EMA/161530/2014) further defines the scope of the activities and the applicable business processes

http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500186731.

The medical literature monitoring (MLM) service covers a range of active substances including herbal active substances as well as designated medical literature based on the use of literature reference databases. All of this information is published on MLM page of the EV website:

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/regulation/general/general_content_000633.jsp.

The outcome of the screening results is published on a daily basis as "MLM Search Results" at a dedicated area of the EudraVigilance website - Medical Literature Monitoring (MLM) box -

<https://eudravigilance.ema.europa.eu/human/restricted/PublicView/list2.asp>.

MAHs can access and download the ICSRs from EudraVigilance or a dedicated area of the EudraVigilance website via the ICSR export tool in line with the applicable formats and standards as outlined in Article 25 and 26 of the Commission Implementing Regulation (EC) No 520/2010. A list of ICSRs entered in EudraVigilance is published daily as "MLM ICSRs" at a dedicated area of the EudraVigilance website - Medical Literature Monitoring (MLM) box -

<https://eudravigilance.ema.europa.eu/human/restricted/PublicView/list2.asp>.

The ICSR export tool allows for filtering based on the following parameters: substance groups, individual substance or substance combinations, dates, pharmaceutical forms and country/region

1. Pre-requisites

1.1. Eudravigilance Registration

All of the new tools: EV ICHISCR Export Manager, MLM EVWEB & tracking spreadsheets require registration with Eudravigilance (EV). If you are not registered with EV, contact your organisation's person responsible for Eudravigilance. This is usually the QPPV or head of pharmacovigilance department. If you are unsure who is the relevant person, contact the Eudravigilance Registration team (eudravigilanceregistration@ema.europa.eu) who will be able to assist you.

1.2. Software

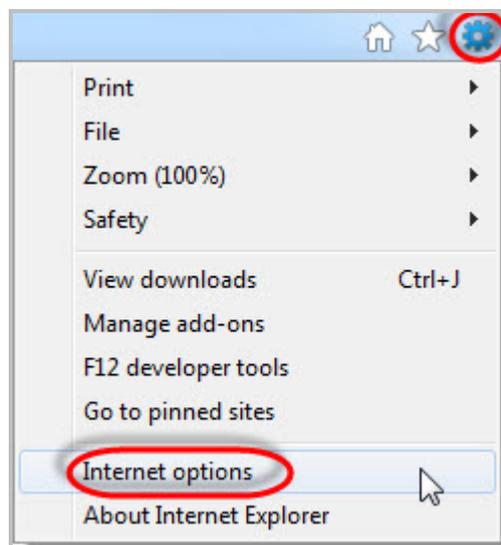
The tracking spreadsheets are published as Microsoft Excel 2007+ format spreadsheets. MLM EVWEB & the EV ICHISCR Export Manager require Internet Explorer 9 or above.

1.3. Trusted sites

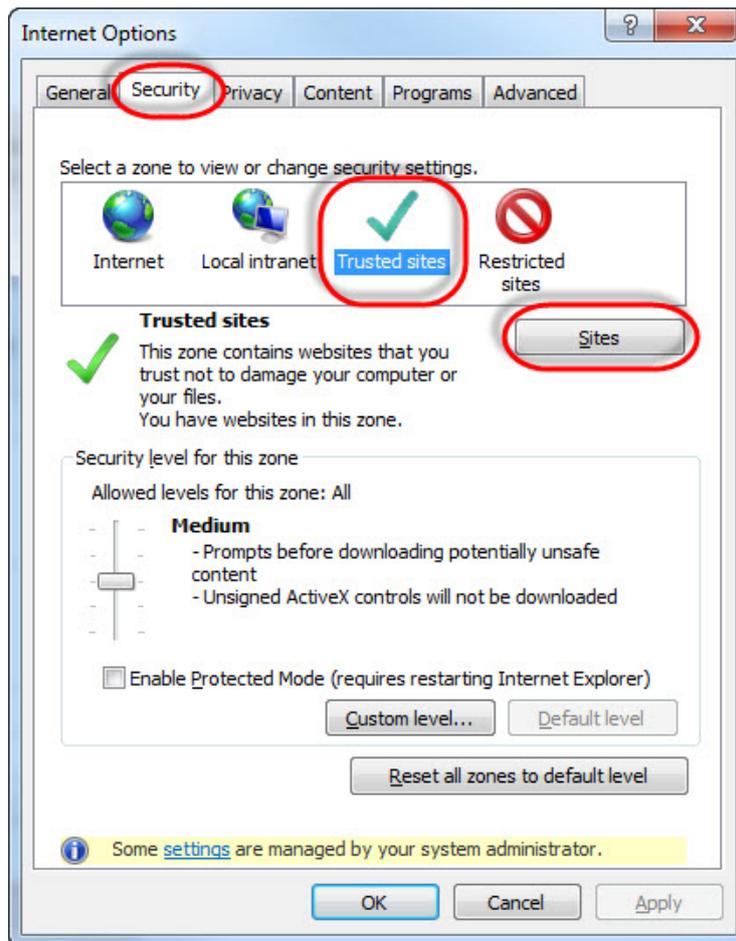
In order to download the ICSRs from the ICH ICSR Export Manager, you may need to add the Export Manager to the list of trusted sites.

To add the Export Manager to the list of trusted sites, follow the steps below:

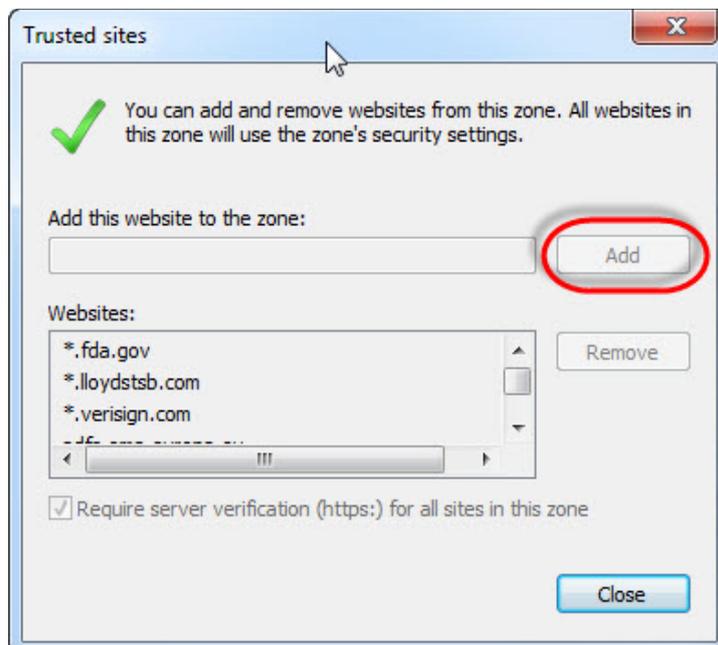
1. Navigate to the ICH ICSR Export Manager;
2. Go to Tools;



3. Click "Internet Options";
4. Click the "Security" tab;



5. Click "Trusted sites";
6. Click the "Sites" button;



7. Click the "Add" button to add this site to your list of trusted sites.

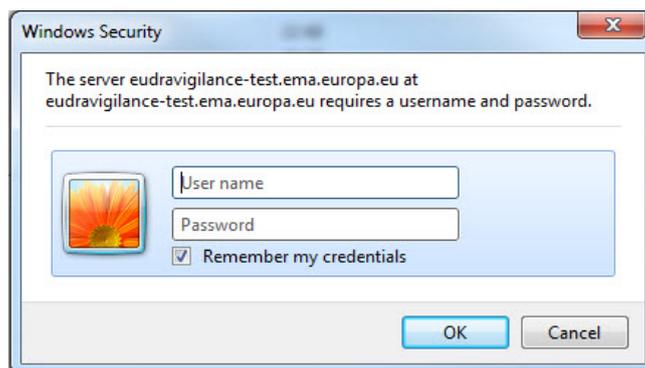
2. Accessing the new functionalities

All new functionalities are accessible from the Eudravigilance website:

<http://eudravigilance.ema.europa.eu/human/index.asp>.



In the top-right hand corner click the link "Production" (ringed in red in the image above) and, when prompted, enter your username and password.



This will take you to the secure area.

EudraVigilance   [Home Restricted](#)
[Human Restricted](#) [Home Public](#)
 Restricted Area

EV Services

- ▶ **EVWEB**
- ▶ xEVMPD Export
- ▶ xEVMPD Bulk update
- ▶ EV Post

EV Registered Partners

- ▶ Manage your profile
- ▶ QPPV List
- ▶ Organisations List

Medical Literature Monitoring

- ▶ MLM Search results
- ▶ MLM ICSRs
- ▶ Archive
- ▶ ICSR Export
- ▶ Substances
- ▶ Further MLM info

User Support

- ▶ Help Desk
- ▶ EVWEB Troubleshooting
- ▶ XEVMPD product export tool user manual
- ▶ XEVMPD Data-Entry Tool (EVWEB) User Manual
- ▶ xEVMPD Bulk Update User Manual
- ▶ Change Password

Welcome to the restricted area of the EudraVigilance website
 To continue, please select one of the available functionalities from the menus on the left of the screen



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 EMA – European Medicines Agency




You will see various menus on the left of the screen. The yellow-ringed link takes you to EVWEB (which is also available directly from <https://eudravigilance.ema.europa.eu/X/?XI=6>) and the red-ringed menu contains the MLM-specific links.

3. Tracking spreadsheets

Every business day the MLM Service will publish and update the following spreadsheets:

- **MLM Search Results**, which contains the results of the searches and screening of scientific and medical literature that the Agency is monitoring;
- **MLM ICSRs**, which contains the results of the review and assessment of the returned articles and information on the management of the ICSRs created.

Both spreadsheets will be updated daily at 9AM & an article and any related cases will remain in the relevant spreadsheet until the day after it has been completed.

An article is considered completed, and is removed from the sum_screen spreadsheet the following day, once it has been assessed for inclusion/exclusion criteria.

A case is considered completed, and is removed from the sum_ICSR spreadsheet the following day, either:

- until it has been confirmed that there is no case, or once the case has been transmitted to EV and it is assessed that no follow-up is required or that follow-up was received and a follow-up version received or that no follow-up was received by the requested date of reply).

Once an article and/or the cases are completed, they will no longer appear in the daily tracking sheets, and their tracking records will only be the archive, which will be permanently available. However the cases created and transmitted to EV will be permanently available via the **Eudravigilance ICH ICSR Export Manager** (see section 4) and **MLM EVWEB** (see section 5).

All dates in the spreadsheets are in the format DD/MM/YYYY. Dates and times are in the format DD/MM/YYYY hh:mm

3.1. MLM Search Results

3.1.1. Accessing the MLM Search results spreadsheet

To access the MLM Search results click on the "MLM Search Results" link to view results in an Excel spreadsheet.



The following message is displayed:



Click "Open" to open the file, or "Save" to save the file locally.

3.1.2. Columns in the MLM Search results spreadsheet

Substance Group	Reference Database	Date & Time Of Search	Literature reference (Vancouver Style: Author(s), Title, Journal, Year:Vol:1st page-last page)	Primary Country	Lead Author	Document Object Identifier	Inclusion/exclusion criteria	Confirmed/potential ICSRs (C/P)	Serious?	Full text request date	Translation request date
ACETYSALICYLIC ACID	EMBASE	25/08/2015 09:52	Hatty CR, Banati RB. Protein-ligand and membrane-ligand interactions in pharmacology: The case of the translocator protein (TSPO). <i>Pharmacological Research</i> . 2015;100 : 58-63	AU	Hatty CR	10.1016/j.phrs.2015.07.029	Aggregated data on patients			N/A	
ACETYSALICYLIC ACID	EMBASE	25/08/2015 09:55	He JQ, Yu XP, Peng C, Li Q, Luo YW, Gao YC et al. Predictive ability of the SYnergy between percutaneous coronary intervention with TAXUS and cardiac surgery score II for long-term mortality in patients with three-vessel coronary artery disease undergoing percutaneous coronary intervention treated with second-generation drug-eluting stents. <i>Chinese Medical Journal</i> . 2015;128(16) : 2176-2182	CN	He JQ	10.4103/0366-6999.162510	Aggregated data on patients			N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 09:36	Goverde P, Taeymans K, Lauwers K, Schroë H, Vermassen F. How to ameliorate the disappointing 1-year results of bioabsorbable stents in superficial femoral artery lesions (the Belgian Remedy registry). <i>EuroIntervention</i> . 2015; :	BE	Goverde P	http://www.embase.com/search/results?su baction=viewrecord&rid=19&page=1				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 09:36	Kefer J, Zikas A, Shakir S, Gafoor S, Berti S, Santoro G et al. Left atrial appendage occlusion for stroke prevention in patients with atrial fibrillation and chronic renal failure: A substudy of the multicentre registry with the Amplatzer cardiac plug. <i>EuroIntervention</i> . 2015; :	BE	Kefer J	http://www.embase.com/search/results?su baction=viewrecord&rid=12&page=1				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 09:36	Deharo P, Pankert M, Quilici J, Bonnet JL, Cuisset T. Body mass index has no impact on platelet inhibition induced by ticagrelor after ACS, conversely to prasugrel. <i>EuroIntervention</i> . 2015; :	FR	Deharo P	http://www.embase.com/search/results?su baction=viewrecord&rid=17&page=1				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 09:36	Buzon J, Roignot O, Lemoine S, Perez P, Kimmoun A, Levy B et al. Takotsubo cardiomyopathy triggered by influenza A virus. <i>Internal Medicine</i> . 2015;54(16) : 2017-2019	FR	Buzon J	10.2169/internalmedicine.54.3606				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 10:22	Escasany AA, Iavecchia L, Safiya A, Foix DS, Ferrer MB, Gallego MS et al. Perioperative management and outcomes of patients treated with antithrombotics admitted for hip fracture surgery. <i>Basic and Clinical Pharmacology and Toxicology</i> . 2014;115(3) : 17	ES	Escasany AA	10.1111/bcpt.12300				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 10:22	Ella C, Graupera J, Barreto R, Solà E, Moreira R, Huelin P et al. Severe acute kidney injury associated with non-steroidal anti-inflammatory drugs in cirrhosis: A case-control study. <i>Journal of Hepatology</i> . 2015;63(3) : 593-600 Article Number 5640	ES	Ella C	10.1016/j.jhep.2015.04.004				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 10:22	Schroeter T, Meyer A, Lehmann S, Garbade J, Mohr FW. Complications associated with implantable cardioverter-defibrillator implantation or replacement in patients with left ventricular assist device. <i>Thoracic and Cardiovascular Surgeon</i> . 2015;63(1) :	DE	Schroeter T	10.1055/s-0035-1544276				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 10:22	Bolz J, Meves SH, Kara K, Reinacher-Schick A, Gold R, Krogias C. Multiple cerebral infarctions in a young patient with heroin-induced hyperosmophilic syndrome. <i>Journal of the Neurological Sciences</i> . 2015;356(1-2) : 193-195 Article Number 13860	DE	Bolz J	10.1016/j.jns.2015.06.031				N/A	
ACETYSALICYLIC ACID	EMBASE	26/08/2015 09:36	Niemann B, Sheybani B, Rohrbach S, Grieshaber P, Möller A, Sommerbeck S et al. Dual platelet inhibition before cardiac surgery-perioperative prospective analysis in 499 patients. <i>Thoracic and Cardiovascular Surgeon</i> . 2015;63(1) :	DE	Niemann B	10.1055/s-0035-1544342				N/A	

As you can see from the image on the previous page, the spreadsheet has the following columns:

- Substance group
 - The substance group for which the search was run that returned this article,
 - If an article is returned in more than one search, then it will appear in the spreadsheet once for each substance group, but duplicate cases will NOT be created,
 - Results are sorted by substance group;
- Reference database
 - The database against which the search was run,
For daily searches this will be Embase
For monthly searches this will be EBSCO;
- Date & time of search;
- Literature reference (Vancouver Style: Author(s). Title. Journal. Year;Vol:1st page-last page)
 - The literature reference is entered in accordance with the Vancouver Style, as described in the following article: International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. N Engl J Med. 1997; 336:309-15;
- Primary source country
 - This is the country of the lead author &, in accordance with ICH E2B(R2), the two-letter country code will form the first two characters of the WW Case Safety ID. For example, an article by an author based in Paris will see this field populated with FR,
 - In rare circumstances, this country may not correspond to the occurrence country. In such instances, the occurrence country would take precedence for the purposes of reporting;
- Lead author;
- Document Object Identifier
 - This is a unique identifier for the article & will appear in all spreadsheets to allow easy traceability,
 - If there is no DOI available then a URL for the article will be provided and if there is no URL then the internal tracking number used by the MLM Service will be provided,
 - If there are multiple cases from an article, all will have the same Document Object Identifier or URL;
- Inclusion/ exclusion criteria
 - If the cases arising from an article are **included**, then this is populated with " 5.2.1 - Valid ADR",
 - If an article is definitively excluded, then the first exclusion criterion that it meets, in accordance with those detailed in the [inclusion/exclusion criteria document](#) and the flowcharts therein, is assigned,
 - If there are potential cases in an article, then all possible exclusion criteria, in accordance with those detailed in the [inclusion/exclusion criteria document](#), are assigned;

- Confirmed/ potential ICSRs (C/P)
 - If the article contains **confirmed** ICSRs, this is populated with "C",
 - If the article contains **potential** ICSRs, this is populated with "P";
- Serious?
 - If the case is **serious**, this is populated with "Y",
 - If the case is **not serious**, this is populated with "N";
- Full text request date
 - If applicable, this is the date the full-text was requested,
 - The full text will always be requested for a confirmed ICSR;
- Translation request date
 - If applicable, this is the date the translation was requested;

3.1.3. Flow of data into and out of the MLM Search results spreadsheet

When an article has

Each day the MLM team will run the [search criteria](#) in Embase against each substance group (and on the first Monday of each month in Ebsco). The results of the searches will be entered into the Agency's tracking tool.

If a substance returns no articles, this will be recorded as "NO RESULTS RECEIVED".

If an article concerns more than one substance being monitored by the MLM service, then it will be retrieved & recorded for each substance group.

Once the articles are entered into the tracking tool, they will be screened & reviewed to see if they meet the inclusion/exclusion criteria & whether they contain any confirmed or potential ICSRs. The screening & reviewing will take place either the same day as the searching or on the next working day.

At the end of each day, the MLM Service exports the data entered into the tracking tool that day as an Excel spreadsheet & uploads it to the EMA's system, where it is virus-checked and, at 9AM the following morning, it is made available for download.

The retrieved articles will be presented in the tracking sheet and will remain there until the screening & reviewing is complete. For example, an article was retrieved on 25 August 2015. Later that day the data was extracted & uploaded. The sum_screen spreadsheet with this article was available for download from 9AM on the 26th. Also on the 26th, the article was reviewed & determined not to contain any valid ICSRs. Later that day the data was extracted & uploaded. The sum_screen spreadsheet with this article was available for download from 9AM on the 27th. In the sum_screen spreadsheet available for download the following day did not contain that article.

3.2. MLM ICSRs

3.2.1. Accessing the MLM ICSRs spreadsheet

To access the MLM ICSRs spreadsheet, click on the "MLM ICSRs" link to view results in an Excel spreadsheet.



The following message is displayed:



Click "Open" to open the file, or "Save" to save the file locally.

As you can see from the image on the previous page, the spreadsheet contains more information than the "MLM Search Results" spreadsheet. It contains the following columns:

- Substance group
 - The substance group for which the search was run that returned this article,
 - If an article is returned in more than one search, then it will appear in the spreadsheet once for each substance group, but duplicate cases will NOT be created;
- Reference database
 - The database against which the search was run,
For daily searches this will be Embase
For monthly searches this will be EBSCO;
- Date & time of search;
- Literature reference (Vancouver Style: Author(s). Title. Journal. Year; Vol: 1st page-last page)
 - The literature reference is entered in accordance with the Vancouver Style, as described in the following article: International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. N Engl J Med. 1997; 336: 309-15,
 - If an article has more than one confirmed or potential case, then the article will appear once for each case, as in the rows highlighted in yellow in the image on the previous page;
- Primary source country
 - This is the country of the lead author & the two-letter country code will form the first two characters of the WW Case Safety ID,
 - In rare circumstances, this country may not correspond to the occurrence country. In such instances, the occurrence country would take precedence for the purposes of reporting;
- Lead author;
- Document Object Identifier
 - This is a unique identifier for the article & will appear in all spreadsheets to allow easy traceability,
 - If there is no DOI available, then a URL for the article will be provided and if there is no URL then the internal tracking number used by the MLM Service will be provided,
 - If there are multiple cases from an article, all will have the same Document Object Identifier or URL;
- Inclusion/ exclusion criteria
 - If the cases arising from an article are **included**, then this is populated with " 5.2.1 - Valid ADR",
 - If an article is definitively excluded, then the first exclusion criterion that it meets, in accordance with those detailed in the [inclusion/exclusion criteria document](#) and the flowcharts therein, is assigned,

- If there are potential cases in an article, then all possible exclusion criteria, in accordance with those detailed in the [inclusion/exclusion criteria document](#), are assigned;
- Confirmed/ potential ICSRs (C/P)
 - If the article contains **confirmed** ICSRs, this is populated with "C",
 - If the article contains **potential** ICSRs, this is populated with "P";
- Serious?
 - If the case is **serious**, this is populated with "Y",
 - If the case is **not serious**, this is populated with "N";
- Full text request date
 - If applicable, this is the date the full-text was requested,
 - The full text will always be requested for a confirmed ICSR;
- Full text receive date
 - If applicable, this is the date the full-text was received;
- Translation request date
 - If applicable, this is the date the translation was requested;
- Translation receive date
 - If applicable, this is the date the translation was received;
- Suspect or interacting products/substances (semicolon delimited)
 - This contains the precise names of all substances or combinations of substances are considered suspect or interacting in each case,
 - This may include substances which are not monitored by the MLM Service as long as at least one of the substances,
 - Each different substance or substance combination will be separated by a semicolon,
 - Each substance combination will have a + between the substances,
 - Therefore a case containing both ibuprofen & a combination product containing codeine & paracetamol would see the field populated thus: Ibuprofen; Paracetamol+Codeine;
- WWID (A.1.10.1)
 - The worldwide unique case safety identifier of the case;
- Day zero
 - The day that the minimum criteria for a confirmed case were received by the MLM Service. If there is a definite case from the initial search, then day zero will be the same as as the search date;
- Transmission date (EV)
 - Date the case was first transmitted to Eudravigilance;
- Transmission date (NCA)

- Date the case was first transmitted to an NCA (as applicable);
- FU to be initiated? (Y/N)
 - If the case **does** require follow-up (FU), this is populated with "Y",
 - If the case **does not** require follow-up, this is populated with "N";
- Date FU initiated
 - If applicable, this is the date the follow-up was requested;
- Date reply requested by
 - This is the date by which a reply was requested from the author;
- Reply received? (Y/N)
 - If applicable, if a reply **was** received, this is populated with "Y",
 - If applicable, if a reply **was not** received by the date a reply was requested by, this is populated with "N";
- Date FU received
 - If applicable, this is the date the follow-up was received;
- FU creation date
 - If applicable, the date the follow-up version was created;
- FU transmission date (EV)
 - If applicable, the date the case was first transmitted to Eudravigilance;
- FU transmission date (NCA)
 - If applicable, the date the case was first transmitted to an NCA (as applicable);
- Duplicate? (Y/N)
 - If this case has been confirmed as a duplicate of another case or cases, then this will be populated with "Y"; otherwise it will be blank;
- Master WWID; Other case numbers
 - If this case has been merged under a master, then the worldwide case safety ID of the master and/or of all confirmed duplicates will be entered here, separated by a semicolon; otherwise it will be blank;
- Nullified?
 - If this case has been nullified, then this will be populated with "Y", otherwise it will be blank;
- Nullification date

3.2.3. Flow of data into and out of the MLM ICSRs spreadsheet

Once an article has been reviewed and been determined to contain one or more confirmed or potential cases, then the article will appear in the MLM ICSRs spreadsheet with one row for each case (confirmed or potential). Each case will have one row for each suspect or interacting substance the subject of monitoring by the MLM Service.

For example, if an article contains 2 cases, the first of which has a suspect drug of paracetamol and the second of which has both paracetamol & ibuprofen as suspect, then there will be one row for the first case & 2 rows for the second case, making a total of 3 rows for the article

Once assessed as confirmed (C) or potential (P) a case will stay in the MLM ICSRs spreadsheet until the day after it has been completed. A case is considered completed in the following situations:

- Potential cases will always have follow-up sought (including requesting the full-text article if it has not yet been received). Once received, this date will be added to the spreadsheet and the potential case will be reassessed and the status amended to either confirmed or non-valid:
 - For a once-potential case that is now confirmed, the date of receipt of the FU which permitted confirmation is day zero for reporting timelines,
A confirmed case stays in the spreadsheet until completed (see below),
 - Once a case is changed to non-valid, the final exclusion criterion must be entered in the tracking tool,
 - The rejected (non-valid) case will appear in the spreadsheet extracted that day with the exclusion criterion,
 - It will no longer be available in the sum_ICSR spreadsheet for the following days, but the previous days' sheets in the archive will retain the record of the case & the decisions taken;
- The day a confirmed cases is transmitted to EV (and the relevant NCA, if applicable), the following columns are populated for the case:
 - Suspect or interacting products/substances (semicolon delimited),
 - WWID (A.1.10.1),
 - Day zero,
 - Transmission date (EV),
 - Transmission date (NCA),
 - FU to be initiated? (Y/N),
 - Date FU initiated,
 - Date reply requested by;
- This data will be extracted into that day's spreadsheet, which will be available from 9AM the following day
 - That day's spreadsheet will be available permanently in the archive;
- If no follow-up was required, then the transmitted case will be considered closed and will not appear in subsequent spreadsheets unless follow-up or duplicates are received or a correction made
 - If a correction was made, then there should be a footnote added to the bottom of the spreadsheet explaining why the case has returned & was corrected;
- A confirmed case transmitted to EV which requires follow-up will stay in the spreadsheet until either:
 - FU has been received, processed & a follow-up version transmitted to EV,

- FU has been received, but contained no new information,
- The date by which a reply was requested has passed;
- The day that follow-up is received, the field "Reply received? (Y/N)" will be populated with Y & the field "Date FU received" is populated with that date
 - The tracking sheet for that day will contain this information & it will remain in the tracking sheet with the case for as long as the case remains there;
- If the follow-up contains no new information (an unlikely, but not impossible, scenario), then no follow-up version will be created and the following day the case will disappear from the tracking sheet;
- If the follow-up does contain new information, then a follow-up version will be created & on the day that the follow-up is transmitted the fields "FU creation date", "FU transmission date (EV)" and, if applicable, "FU transmission date (NCA)" will be populated
 - This information will appear in that day's MLM ICSRs spreadsheet, which will be available the following day from 9AM,
 - Once the follow-up has been sent, the case will not appear in subsequent days' tracking sheets, but the previous sheets will remain in the archive as a record of what happened;
- If no follow-up is received by the date that FU was requested, then on the following day the field "Reply received? (Y/N)" will be populated with N, thus closing the case. This will appear in that day's MLM ICSRs spreadsheet, which will be available the following day from 9AM
 - This case will not appear on subsequent days' spreadsheets, but the record of what happened will remain in the previous days' spreadsheets in the archive.

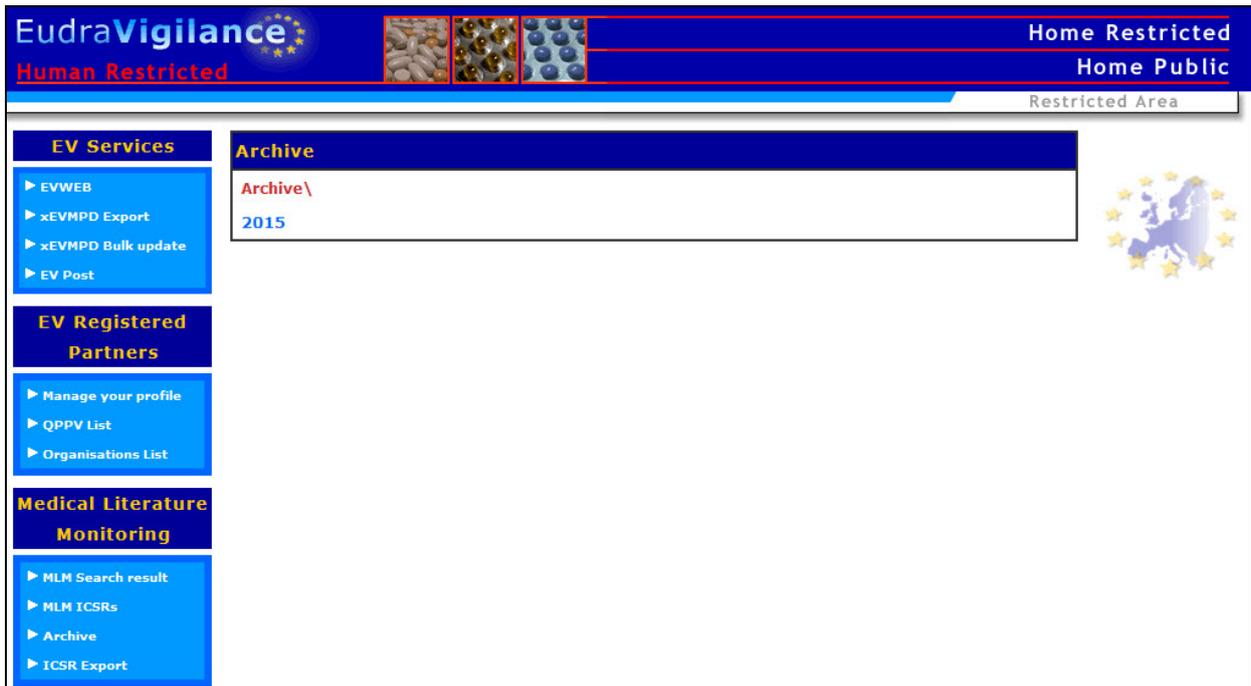
3.3. Archive

The archive is a record of each day's tracking sheets, both MLM Search results & MLM ICSRs. The spreadsheets, once archived, are not updated & form a permanent record of the information available to MAHs on each day.

To access the archives of daily sheets, click on the "Archive" link to view results in an Excel spreadsheet.



The following screen will appear



Select the required year...

Archive

Archive\2015

June
July
August



Select a month to access that month's archive of daily tracking sheets

Archive

Archive\2015\August

[sum_ICSR_2015_08_03.xlsx](#)
[sum_ICSR_2015_08_04.xlsx](#)
[sum_ICSR_2015_08_05.xlsx](#)
[sum_ICSR_2015_08_06.xlsx](#)
[sum_ICSR_2015_08_07.xlsx](#)
[sum_ICSR_2015_08_10.xlsx](#)
[sum_ICSR_2015_08_11.xlsx](#)
[sum_ICSR_2015_08_12.xlsx](#)
[sum_ICSR_2015_08_13.xlsx](#)
[sum_ICSR_2015_08_14.xlsx](#)
[sum_ICSR_2015_08_17.xlsx](#)
[sum_ICSR_2015_08_18.xlsx](#)
[sum_ICSR_2015_08_19.xlsx](#)
[sum_ICSR_2015_08_20.xlsx](#)
[sum_ICSR_2015_08_21.xlsx](#)
[sum_ICSR_2015_08_24.xlsx](#)
[sum_ICSR_2015_08_25.xlsx](#)
[sum_ICSR_2015_08_26.xlsx](#)
[sum_screen_2015_08_03.xlsx](#)
[sum_screen_2015_08_04.xlsx](#)
[sum_screen_2015_08_05.xlsx](#)
[sum_screen_2015_08_06.xlsx](#)
[sum_screen_2015_08_07.xlsx](#)
[sum_screen_2015_08_10.xlsx](#)
[sum_screen_2015_08_11.xlsx](#)
[sum_screen_2015_08_12.xlsx](#)
[sum_screen_2015_08_13.xlsx](#)
[sum_screen_2015_08_14.xlsx](#)
[sum_screen_2015_08_17.xlsx](#)
[sum_screen_2015_08_18.xlsx](#)
[sum_screen_2015_08_19.xlsx](#)
[sum_screen_2015_08_20.xlsx](#)
[sum_screen_2015_08_21.xlsx](#)
[sum_screen_2015_08_24.xlsx](#)
[sum_screen_2015_08_25.xlsx](#)
[sum_screen_2015_08_26.xlsx](#)



Archived MLM Search Results spreadsheets will have file names beginning "sum_screen". Archived MLM ICSRs spreadsheets will have file names beginning "sum_icsr".

4. Eudravigilance ICH ICSR Export Manager

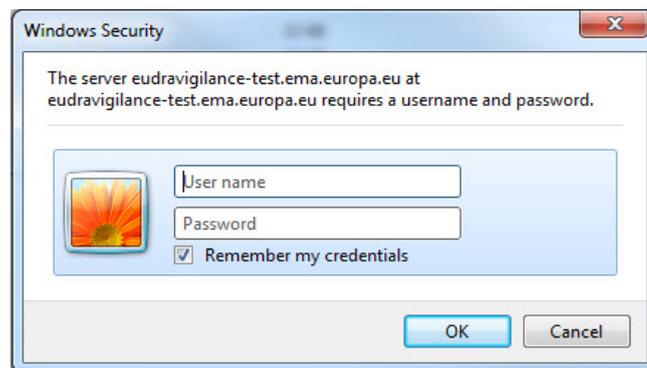
4.1. Log in

There are two methods to access the ICSR Export Manager: Either you can follow the steps described in section 2, above, and click on the ICSR Export link



Or you can do the following:

1. Go to <https://eudravigilance.ema.europa.eu/icsrex>.



2. A screen is displayed prompting you to enter your user name and password:



3. Enter your username and password and click **OK**.

The main screen is displayed as follows:

Filters Click the filter name to display / hide the filter. The filter name is highlighted once a selection is made. The selection will be filtered on only when it is highlighted in the list. [Save Filters](#) [Load Filters](#) pdassep (AAA) HUMAN PRODUCTION V. 7.11.5.1

Active Substance Group

Active Substance Combination

Start Date*

Official Receive Date (Date the ICSRs were entered into EV) 2015-03-11

End Date*

Official Receive Date (Date the ICSRs were entered into EV) 2015-03-26

Country of Occurrence

Country of Occurrence (Groups)

Dosage Form

Active Filters Click on the name of the filter to disable/enable it. **Start Date End Date**

Request Name Initial Case Count

Request Name	Size	Status
Requested on 18/03/2015 16:18, ICHCSR	3 (3 KB)	Completed
allcountries5only (on 18/03/2015 12:53), ICHCSR	5 (3 KB)	Completed
3-18march59records (on 18/03/2015 12:23), ICHCSR	59	Cancelled
3-18march59records (on 18/03/2015 12:23), ICHCSR	59 (186 KB)	Completed
KO_Cntry,dosform&com (on 18/03/2015 11:09), ICHCSR	3 (3 KB)	Completed

4.2. Filters

The ICSR Export Manager allows for filtering on the following criteria as a primary means of exclusion:

- Active substance name of suspect or interacting drugs;
- Date of case transmission to EV;
- Country of occurrence of the adverse reaction or, if this is not specified, Primary source country;
- Pharmaceutical form.

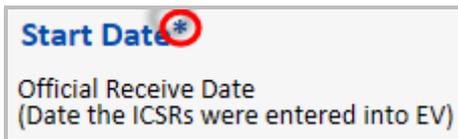
Within an individual filter, any selections you make will expand your search (an "OR" operator is applied), so if you select both France & Germany as the countries of occurrence, then cases occurring in either France or Germany will be returned.

Among different filters, any selections you make will contract your search (an "AND" operator is applied), so if you select the country of occurrence as Spain and the active substance group as Paracetamol, then only ICSRs occurring in Spain where paracetamol was the suspect or interacting drug will be returned.

Please Note: There is a filter limit of 1000 selections in total for any given search. If you require more than 1000 selections you will need to perform another query.

4.2.1. Mandatory filters

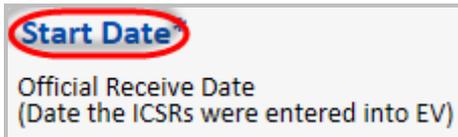
Mandatory filters are marked with an asterisk



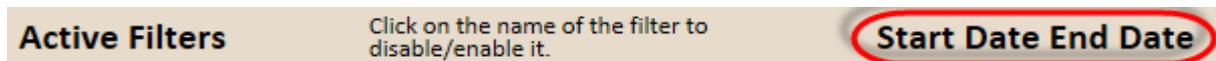
These are the date filters and will be auto-populated. If you delete a date and do not enter a new one, then you will not be able to run your query.

4.2.2. Active filters

Active filters (those with data selected) have the filter title in bold blue text.



Active filters are also listed in the Active filters bar



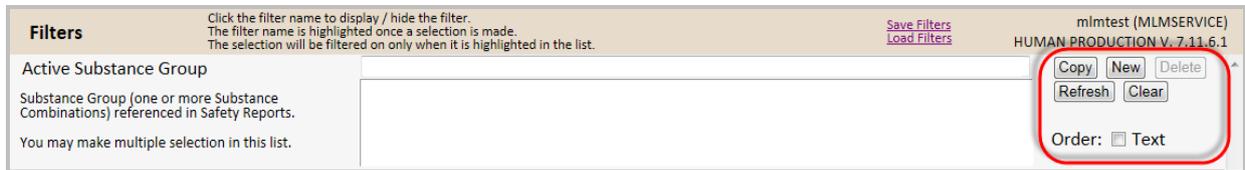
4.2.3. Show/hide filters

By default, when you log on inactive filters (ringed in red in the image below) only have their titles displayed, whereas active filters (ringed in green in the image below) are displayed

Click the filter name and it will be displayed.

4.2.4. Filter button functions

All filters in the EudraVigilance ICSR Export manager have some, or all, of the following buttons on the right-hand side of the filter:



Button	Function
Copy	creates a copy of this iteration of the filter
New	Creates a new iteration of the filter
Delete	Deletes this iteration of the filter
Refresh	Clears the searched-for data and loads the first 50 items in alphabetical order
Clear	Clears the selections made for that iteration of the filter

Some filters also have an "Order" option. These allow you to choose to order the returned results alphabetically either by the name or by the code (in the case of the country of occurrence filter).

4.3. Active Substances being monitored

The Active substance groups, as described in Chapter 1 of the detailed guide on literature monitoring, are available from the [dedicated MLM Service page](#) of the EMA Website and from the Medical Literature Monitoring menu on the Eudravigilance website.



Each group includes all substances including various salts, and substance combinations under the group.

For example, the Paracetamol substance group contains paracetamol on its own, and paracetamol in combination with everything that it is in combination with in the xEVMPD; however if a substance is included as part of a combination with another monitored substance, then the specific combination will be found under the earliest combination group. For example the combination of paracetamol & codeine

is under the Paracetamol substance group, and not the Codeine group, because the Paracetamol is ranked before the Codeine group. Therefore, if you want case with codeine as a suspect or interacting drug, whether alone or in combination, you will need to select the Codeine substance group &, in a separate query, all substance combinations containing codeine from higher-ranked groups. You should do this as two separate filters, since selecting the CODEINE active substance group & the PARACETAMOL, CODEINE active substance combination in the same query will return only cases where both a substance under the codeine group **AND** the combination product were considered suspect or interacting.

Conversely, when selecting **only** multiple active substance groups **or only** multiple active substance combinations, an "OR" operator is applied. Therefore, if you select active substance group PARACETAMOL and then active substance group CODEINE, the search will return all cases containing **either** paracetamol **or** codeine.

The substance groups are ranked by the greatest number of MAHs that hold MAs for a product containing this substance.

If selecting only combinations, you will need to carefully select from the list of substances before entering your filtering criteria. You will not need to do this every time, since, as described in section 4.10, below, you can save & load filters.

4.3.1. Active Substance Group

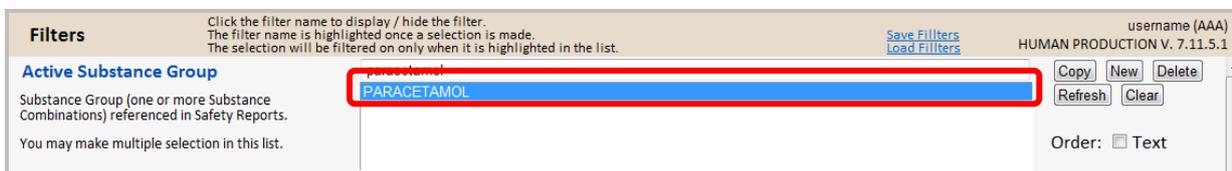
Searching on Active Substance Groups is optional. If you wish to retrieve cases concerning all substances, do not filter of this criterion.

To search on an active substance group, enter the name, or part of the name, of the desired substance into the search box (ringed in red in the image below) and press Enter



When the substance is returned, click the desired substance group name to select it & activate the filter, as shown in the image below.

Even if only one active substance group is returned, you still need to click it to select it.



Note how the filter name "Active substance Group" is in bold blue text because it is now active

To filter on multiple substance groups you can either return multiple substances and select these within the same iteration, or create multiple iterations each with a single substance group selected.

Note: Tick the check box "Order: Text" to view the substance names in alphabetical order.

To return multiple substances, click in the Active Substance Group field and either:

- type the first letters of the substance to search on and press **Enter**;

- type * as a wildcard and press **Enter**;
- click "Refresh" to return the first 50 substance groups alphabetically

When your substance groups have returned, highlight the required substance and press **Enter** (or double click on the substance group) to populate the field. Hold down the **Ctrl** key and click the mouse button to highlight and select more than one substance.

4.3.2. Active Substance Combination

Searching on active substance combinations is performed in the same manner as for active substance groups; however there are many more combinations than groups and so you may need to use more iterations of the field to be able to select all of your substance combinations.

While it is possible to combine searches for groups and combinations at the same time, as is shown in the image below, it is not recommended. If you search for both a substance group & a substance combination, then only ICSRs containing both will be returned.

To return ICSRs containing either a substance group (or groups) or a specific substance combination (or combinations), you would need to make two or more different queries.

Active Substance Group Substance Group (one or more Substance Combinations) referenced in Safety Reports. You may make multiple selection in this list.	CO-TRIMOXAZOLE CODEINE COLECALCIFEROL	<input type="button" value="Copy"/> <input type="button" value="New"/> <input type="button" value="Delete"/> <input type="button" value="Refresh"/> <input type="button" value="Clear"/> Order: <input type="checkbox"/> Text
Active Substance Combination Substance Combination referenced in Safety Reports. You may make multiple selection in this list.	PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE, CODEINE PHOSPHATE HEMIHYDRATE	<input type="button" value="Copy"/> <input type="button" value="New"/> <input type="button" value="Delete"/> <input type="button" value="Refresh"/> <input type="button" value="Clear"/> Order: <input type="checkbox"/> Text

Note how both filter names are in bold blue text indicating that both are active.

4.4. Start and End Dates

The start and end dates are the dates that the ICSRs were transmitted to Eudravigilance by the MLM service.

These dates are mandatory and must be populated. When changing the date, click in the field to bring up the calendar. Do not use the backspace button or you are returned to the previous screen and your changes could be lost.

Start Date* Official Receive Date (Date the ICSRs were entered into EV)	2015-03-03	<input type="button" value="Clear"/>																																																								
End Date* Official Receive Date (Date the ICSRs were entered into EV)	<table border="1"> <tr> <td colspan="7">[Close]</td> </tr> <tr> <td colspan="7">March 2015</td> </tr> <tr> <td>Sun</td><td>Mon</td><td>Tue</td><td>Wed</td><td>Thu</td><td>Fri</td><td>Sat</td> </tr> <tr> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td> </tr> <tr> <td>8</td><td>9</td><td>10</td><td>11</td><td>12</td><td>13</td><td>14</td> </tr> <tr> <td>15</td><td>16</td><td>17</td><td>18</td><td>19</td><td>20</td><td>21</td> </tr> <tr> <td>22</td><td>23</td><td>24</td><td>25</td><td>26</td><td>27</td><td>28</td> </tr> <tr> <td>29</td><td>30</td><td>31</td><td></td><td></td><td></td><td></td> </tr> </table>	[Close]							March 2015							Sun	Mon	Tue	Wed	Thu	Fri	Sat	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31					<input type="button" value="Clear"/>
[Close]																																																										
March 2015																																																										
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29	30	31																																																								
Country of Occurrence																																																										
Country of Occurrence (Groups)																																																										
Dosage Form																																																										

To change the year use the << and >> arrows. To change the month use the < and > arrows.

Note: The start and end dates cannot be more than 15 days apart, but you can search for any ≤15-day time period.

4.5. Country of Occurrence

In accordance with the exclusion criteria detailed in GVP Module VI, Chapter VI.C.2.2, "exclusion based on the primary source country or country of origin of the adverse reaction is possible if the marketing authorisation holder can demonstrate that the suspected medicinal product has never been supplied or placed on the market in that territory or that the product is not a travel medicine (e.g., anti-malarial medicinal product)."

To filter on the country of occurrence, click the filter name and select a country or countries from the drop-down menu where the ICSR occurred.

Country of Occurrence

Filter on Occurrence Country (A.1.2) or, if not populated, Primary Source Country (A.1.1)

You may make multiple selection in this list.

AF - Afghanistan
AL - Albania
DZ - Algeria
AS - American Samoa
AD - Andorra

Refresh Clear

Order: Code

Hold down the **Ctrl** key and click the mouse button to highlight and select more than one country.

Please Note: If a country or region is selected in error use the **Clear** button to remove it and select another one.

If the occurrence country has not been specified, it will not be populated in field A.1.2 of the ICSR. If it is not populated, then the ICSR Export manager will filter on the Primary source Country (A.1.1), which is a mandatory field in Eudravigilance.

4.6. Country of occurrence (Groups)

You can also select a region grouped by EU, EEA or non-EU or non-EEA.

Country of Occurrence (Groups)

Country Codes of Occurrence (Groups).
Single selection list.

EU
EEA
Non EU
Non EEA

Clear

Note: Since the country of occurrence and the country of occurrence (group) filters combine using an "AND" operator, it is imperative not to filter on both sections in the same query. If you were to select the group "EEA" & the country "Japan", then you would get no cases returned.

4.7. Dosage form

In accordance with the exclusion criteria detailed in GVP Module VI, Chapter VI.C.2.2, "With regard to the collection and recording of reports of suspected adverse reactions, marketing authorisation holders responsibilities apply to reports related to medicinal products (see VI.A.2.2) for which ownership cannot be excluded on the basis of ... **pharmaceutical form** ..." Therefore, the ICHICSR Export Manager permits filtering on pharmaceutical form, amongst others.

Unlike the other filtering criteria, pharmaceutical form (B.4.k.7) is not a mandatory field in ICSRs and is frequently not populated. Therefore, the dosage form filter will return all ICSRs meeting the other filtering criteria where the selected dosage forms were populated and all ICSRs meeting the other filtering criteria where the dosage form was not populated.

Filtering on dosage form works in the same manner as filtering on active substance groups or combinations.

Dosage Form

Dosage Forms referenced in Safety Reports.

You may make multiple selection in this list.

tab
TABLET
TABLET AND POWDER FOR ORAL SOLUTION
TABLET AND SOLVENT FOR RECTAL SUSPENSION
TABLET FOR ORAL SUSPENSION
TABLET FOR RECTAL SOLUTION

Copy New Delete
Refresh Clear

Order: Text

4.8. Active filters

Active filters are those where criteria have been selected for that filter.

The images below show two examples of selected filtering criteria and the resultant active filters bar.

The screenshot shows the Eudravigilance ICHCSR Export Manager interface. The 'Filters' section on the left has 'Start Date' and 'End Date' highlighted in bold blue text. The 'Active Filters' bar at the bottom also shows 'Start Date End Date' in bold blue text. The main content area displays a list of requests with columns for Request Name, Size, and Status.

Request Name	Size	Status
Requested on 16/03/2015 16:47, ICHCSR	2 (3 KB)	Completed
Requested on 16/03/2015 15:27, ICHCSR	2 (2 KB)	Completed
Requested on 16/03/2015 15:27, ICHCSR	2 (2 KB)	Completed
Requested on 16/03/2015 14:43, ICHCSR	59 (186 KB)	Completed
4dosageform (on 16/03/2015 12:49), ICHCSR	4 (3 KB)	Completed

Note how in the above image the only filter names in bold blue text are "Start Date" & "End Date" and that these are the only filters in the "Active Filters" bar.

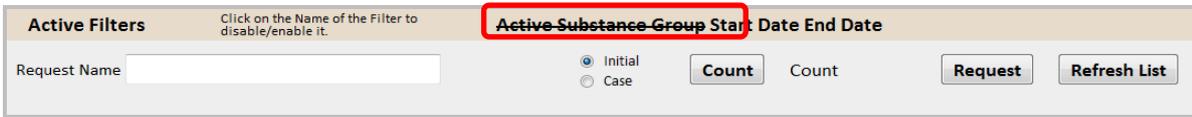
The screenshot shows the Eudravigilance ICHCSR Export Manager interface with more filters selected. 'Active Substance Group', 'Active Substance Combination', 'Start Date', and 'End Date' are highlighted in bold blue text in the 'Filters' section. The 'Active Filters' bar at the bottom shows 'Active Substance Group Active Substance Combination Start Date End Date' in bold blue text. The main content area displays a list of requests with columns for Request Name, Size, and Status.

Request Name	Size	Status
Requested on 18/03/2015 16:18, ICHCSR	3 (3 KB)	Completed
allcountriesOnly (on 18/03/2015 12:53), ICHCSR	5 (3 KB)	Completed
3-18march59records (on 18/03/2015 12:23), ICHCSR	59	Cancelled
3-18march59records (on 18/03/2015 12:23), ICHCSR	59 (186 KB)	Completed
KO_Cntry.dosform&com (on 18/03/2015 11:09), ICHCSR	3 (3 KB)	Completed

Note how in the above image the filter names in bold blue text are "Active Substance Group", "Active Substance Combination", "Start Date" & "End Date" and that these are the all in the "Active Filters" bar.

4.8.1. Disabling filters

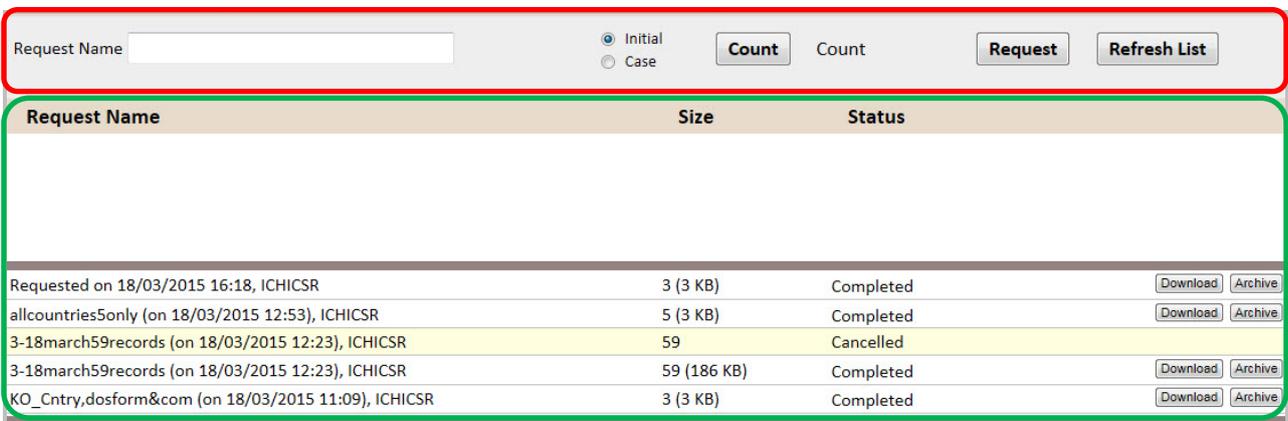
To disable a filter, so that the selections made remain in the filter in the ICHICSR Export Manager, but that criterion is not filtered on, click the filter name in the Active Filters bar, as in the image below.



As you can see, a disabled filter is marked by strikethrough text in the Active Filters bar, indicating that although populated, it is inactive.

4.9. Requests

The requests section consists of both the requests you wish to make (ringed in red) and the requests previously made (ringed in green)



Requests currently in progress appear above the already processed requests.

The requests section has the following functionalities

Function	Description
Request Name	A name given to the request to distinguish it from other requests. If request name is not populated, the system will automatically name the request in the format "Requested on DD/MM/YYYY hh:mm, ICHICSR"
Initial/Case	Initial returns only the first version of a valid individual case (the initial ICSR). A case which is subsequently nullified will not have the initial version returned. Case returns the latest version of a case, whether active or nullified. If a case only has one ICSR, then this will be returned. Note: Error cases will never be returned. If you are performing searches daily, then "Case" should normally be selected.
Count	Displays the total number of unique ICSRs that meet the filtering criteria. Note: If an ICSR meets more than one criterion (e.g. suspect drugs are paracetamol & codeine and both of these were filtered on), then it will only be counted once.

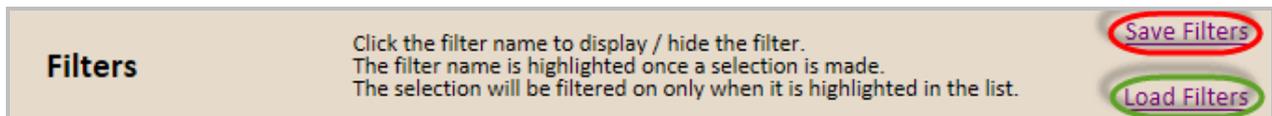
Function	Description
Request	Downloads the ICSRs.
Refresh List	Refreshes the list of all ICSRs.
Download	Downloads the export file.
Archive	When a file is archived, it is removed from the list.

4.10. Save & Load Filters

The ICHICSR Export Manager permits users to save & load filters. The saved filters can be stored locally, shared with colleagues and can be loaded on any logged-in computer.

4.10.1. Save Filters

To save a filter, first make your desired selection. Then click the **"Save Filters"**, ringed in red in the image below



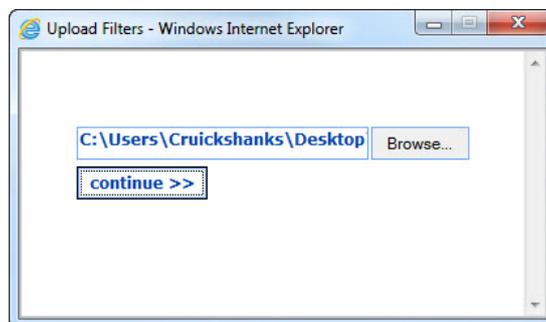
A file save dialogue is displayed. Enter a name for the file and click **OK**.

Do not change the file type or the file language (Unicode UTF-8), otherwise reloading the filter will not work.

Please note: The file name needs to end ".xml" for the filters to load again.
If you are not offered saving as XML, then you will need to manually add it to the file name.

4.10.2. Load Filters

1. To load predefined filters, click **Load Filters** (ringed in green in the image above) and locate the filters by clicking the **Browse** button in the popup window.



2. Locate the file, click **continue>>** and the saved filters are loaded.

5. MLM EVWEB

In addition to the ICSR Export Manager, MAHs & NCAs can access and download ICSRs via EVWEB.

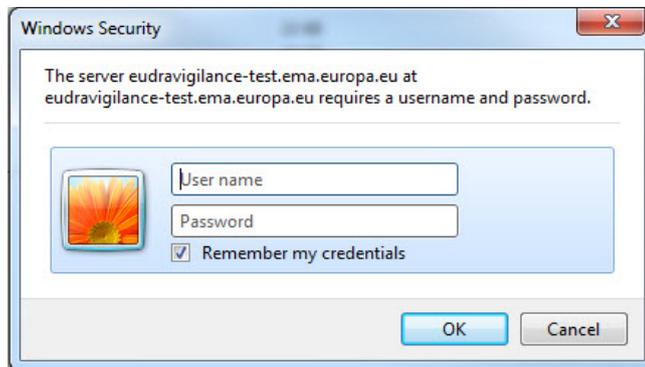
EVWEB offers more filtering options (56 different filters) and can return all ICSRs of all cases, including error cases, but is not optimised for batch downloading, unlike the ICSR Export Manager.

MLM EVWEB permits users to download all MLM ICSRs, without access controls, unlike all other sections of EVWEB.

5.1. Logging In

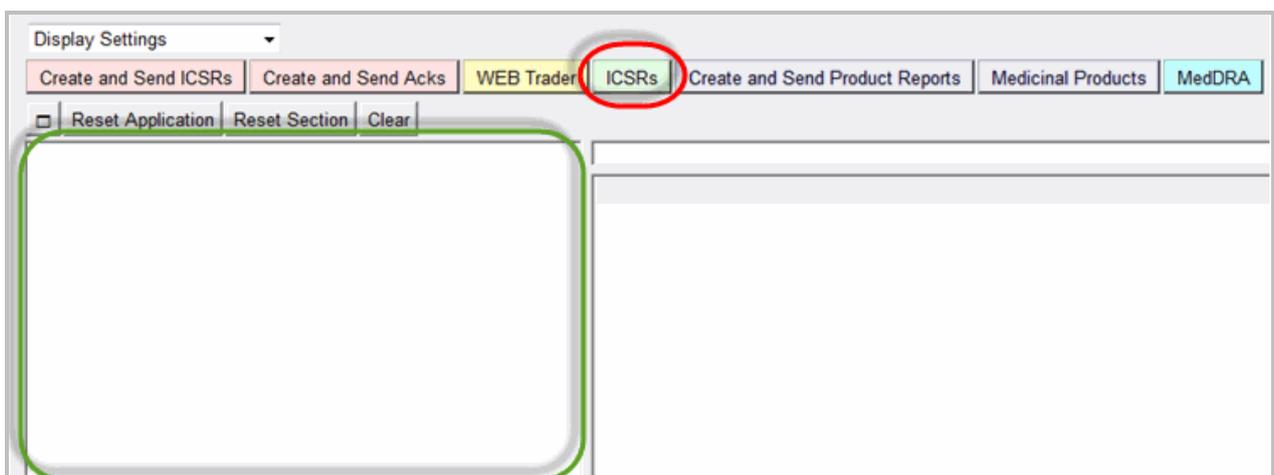
You can either access MLM EVWEB via the method described in section 2, above, or as follows:

1. Go to <https://eudravigilance.ema.europa.eu/X/?6>
2. A screen is displayed prompting you to enter your user name and password:



3. Enter your username and password and click OK.

Once you have logged-in, you will see the following screen



5.2. Using MLM EVWEB

To run a query in MLM EVWEB, follow the steps below:

1. Click the green **ICSRs** Button (ringed in red in the image above);
2. The tree view will be populated in the area ringed in green in the above;

3. Click on the + next to "Queries" (ringed in orange);
4. The tree-view menu will expand;
5. Click on the + next to "MLM Reports" (ringed in green);
6. The tree-view menu will expand further;
7. Click "**Conditions**" (ringed in blue);
8. Select the desired filtering conditions from the active area (ringed in purple)
 - 8.1. Note 1: the image below does not contain all filtering conditions),
 - 8.2. Note 2: all of the MLM EVWEB filters use an "AND" condition. This means that every additional option you select adds another filter to your query
 - 8.3. Note 3: the data in EVWEB is precisely as entered, so the search will only return results where precisely what you select has been entered in the ICSRs;
9. Click "**Run**" (ringed in black)

Display Settings

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA

Reset Application Reset Section Clear E R Run Run to Excel

Safety Reports (-)
 ICHICSR Messages (-)
 Queries
 Case Tracking List
 All Reports
 MLM Reports
 Fields
 Conditions (AND)
 Results
 Reports with Warnings
 Reports with Errors
 ICHICSR Messages
 Statistics

Description	Name/Value
Reporting Type	<input type="checkbox"/>
Local Report Number (Matches)	<input type="checkbox"/>
Blinded Suggestion	<input type="checkbox"/>
Blinded	<input type="checkbox"/>
Blinded (Manual Recode Status)	<input type="checkbox"/>
Message Receive date	<input type="checkbox"/>
Message Receive date (From)	<input type="checkbox"/>
Message Receive date (Up to)	<input type="checkbox"/>
Transmission date	<input type="checkbox"/>
Transmission date (From)	<input type="checkbox"/>
Transmission date (Up to)	<input type="checkbox"/>
Primary Source Country	<input type="checkbox"/>
Occurrence Country	<input type="checkbox"/>
Reporter Country	<input type="checkbox"/>
Study Name (Matches)	<input type="checkbox"/>
Study Number (Matches)	<input type="checkbox"/>
Study Type	<input type="checkbox"/>
Medicinal product (Matches)	<input type="checkbox"/>
Active substance (Matches)	<input type="checkbox"/>
Drug characterization	<input type="checkbox"/>
Product Scientific Name (Matches)	<input type="checkbox"/>
Drug Indication (code)	<input type="checkbox"/>

5.2.1. Searching for specific cases using EVWEB

If you wish to download a specific case or cases via EVWEB, follow the steps below:

1. Tick the box next to the filtering option "Case number (Matches)", ringed in red in the screenshot below;

The screenshot shows the EVWEB interface with a sidebar on the left containing a tree view of navigation options: Safety Reports (-), ICHICSR Messages (-), Queries, Case Tracking List, All Reports, MLM Reports (with sub-items: Fields, Conditions (AND), Results), Reports with Warnings, Reports with Errors, and ICHICSR Messages. The main panel on the right contains a table with two columns: 'Description' and 'Name/Value'. The table lists various filtering criteria with checkboxes. The 'Case number (Matches)' checkbox is checked and highlighted with a red circle and a blue bar. Other criteria include Reaction System Organ Class (Matches), Outcome, Safety Report ID (Matches), Safety Report Version (Matches), Report Type, Sender Identifier (Matches), Results in death?, Caused/Prolonged Hospitalization?, Disabling/Incapacitating?, Congenital Anomaly?, Other medically important condition?, Report Classification (Not Classified ()), Report Correctness, Case Correctness, Case type, and Receive date.

2. Press **Enter** and the blue area in the image above will become editable, as in the image below;

This screenshot is identical to the previous one, but the 'Case number (Matches)' checkbox is now active, and a text input field is visible next to it, highlighted with a red circle. The input field is currently empty.

3. Type or paste in the case number (world-wide unique case identifier ICH E2B(R2) A.1.10.2) of the case you require;

- 3.1. If you require more than one case, then you can separate the case numbers using | as shown in the image below.

The | symbol is on the same key as the \ symbol on a standard UK keyboard.

Description	Name/Value
Reaction System Organ Class (Matches)	<input type="checkbox"/>
Outcome	<input type="checkbox"/>
Safety Report ID (Matches)	<input type="checkbox"/>
Safety Report Version (Matches)	<input type="checkbox"/>
Report Type	<input type="checkbox"/>
Sender Identifier (Matches)	<input type="checkbox"/>
Results in death ?	<input type="checkbox"/>
Caused/Prolonged Hospitalization ?	<input type="checkbox"/>
Disabling/Incapacitating ?	<input type="checkbox"/>
Congenital Anomaly ?	<input type="checkbox"/>
Other medically important condition ?	<input type="checkbox"/>
Report Classification	<input type="checkbox"/> Not Classified ()
Report Correctness	<input type="checkbox"/>
Case Correctness	<input type="checkbox"/>
Case type	<input type="checkbox"/>
Case number (Matches)	<input checked="" type="checkbox"/> AT-MLMSERVICE-TESTCASE-20150427-02 CZ-MLMSERVICE-TESTCASE-20150427-04
Receive date	<input type="checkbox"/>
Receive date (From)	<input type="checkbox"/>
Receive date (Up to)	<input type="checkbox"/>
Receipt Date	<input type="checkbox"/>

Note the symbol separating the case numbers in the red-ringed area

4. Click **Run**;
5. All versions of your case(s) will be returned, as in the image below;

Num	Local Report Number	Transmission date	Primary Source Country	Safety Report ID	Report Type	Case type	Case number
<input type="checkbox"/> 0001	EU-EC-2348791	27/03/2015	Czech Republic (CZ)	CZ-MLMSERVICE-TESTCASE-20150427-04	Report from studies (2)	Marketing Authorisati...	CZ-MLMSERVICE-TESTCASE-20150427-04
<input type="checkbox"/> 0002	EU-EC-2348684	27/03/2015	Czech Republic (CZ)	CZ-MLMSERVICE-TESTCASE-20150427-04	Report from studies (2)	Marketing Authorisati...	CZ-MLMSERVICE-TESTCASE-20150427-04
<input type="checkbox"/> 0003	EU-EC-2348682	11/02/2015	Austria (AT)	AT-MLMSERVICE-TESTCASE-20150427-02	Spontaneous (1)	Marketing Authorisati...	AT-MLMSERVICE-TESTCASE-20150427-02

6. Tick the box(es) of the desired ICSR(s) (ringed in red in the image below);

Num	Local Report Number	Transmission date	Primary Source Country	Safety Report ID	Report Type	Case type	Case number
<input checked="" type="checkbox"/> 0001	EU-EC-2348791	27/03/2015	Czech Republic (CZ)	CZ-MLMSERVICE-TESTCASE-20150427-04	Report from studies (2)	Marketing Authorisati...	CZ-MLMSERVICE-TESTCASE-20150427-04
<input type="checkbox"/> 0002	EU-EC-2348684	27/03/2015	Czech Republic (CZ)	CZ-MLMSERVICE-TESTCASE-20150427-04	Report from studies (2)	Marketing Authorisati...	CZ-MLMSERVICE-TESTCASE-20150427-04
<input type="checkbox"/> 0003	EU-EC-2348682	11/02/2015	Austria (AT)	AT-MLMSERVICE-TESTCASE-20150427-02	Spontaneous (1)	Marketing Authorisati...	AT-MLMSERVICE-TESTCASE-20150427-02

7. To export the ICSR(s), click **Export** (ringed in purple in the image above) & select the format you want from the Export menu (see the image below);

Choose one of the available Commands

Press A - Z to find initial letter
Press Enter to select, Escape to clear

- Multi XML Files
- One XML File
- Multi RTF Files
- One RTF File
- Multi Printable Files
- One Printable File
- Multi CIOMS Files
- One CIOMS File

8. To review the cases before exporting, click **Load** (ringed in blue in the image above step 7) and they will appear in the tree-view for you to review.

6. List of acronyms used in the document

Acronym	Meaning
EV	Eudravigilance
EVWEB	Eudravigilance Web application
FU	Follow-up
ICH	International Conference on Harmonisation
ICSR	Individual case Safety Report
MLM	Medical Literature Monitoring
NCA	National Competent Authority of an EEA Member State
XML	Extensible Markup Language