EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Training session about IT support for safety cooperation

08 November 2021 - 14:00-17:00

An agency of the European Union

Agenda

- Demo session I (15'+15' QnA) - SUSAR screening and assessment
- Coffee break (20', 15:10-15:30)
- Demo session II (15'+15' QnA) - ASR assessment, recording and storage of assessment reports, internal/external communication
- Demo session III (15'+15' QnA) - registration of Active Substances in xEVMPD, saMS selection
- General QnA (30')

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Demo session I (15'+15' QnA)

SUSAR screening and assessment

Screening and Assessment of Suspected Unexpected Serious Adverse Reactions (SUSARs) from Interventional Clinical Trials

Objective

Describe the strategy and the EudraVigilance reports and outputs discussed and agreed within the drafting group formed for the implementation of the legal requirements established in the Commission Implementing Regulation (IR) on setting out the rules and procedures for Members States cooperation on safety assessment in clinical trials

Legal requirements (based on the draft implementing regulation)

- The SUSARs screening is defined as the systematic identification of SUSARs requiring an assessment. Such assessment will lead to a decision on the need for a notification to the MSs concerned and Reporting MSs [IR Art 2(j)].
- The safety assessing MS shall screen and assess information related to an active substance which is submitted in the EudraVigilance database as SUSARs in accordance with Article 42 of Regulation (EU) No 536/2014., including those occurring in third countries and submitted in accordance with Article 42 1. (a) of Regulation (EU) No 536/2014. [IR Art 7,1].
- The screening of the Database shall take place at least once in every 15 calendar days if the IMP does not have a marketing authorisation in the EU. The safety assessing MS may decide to decrease the frequency of the screening of SUSARs to take place at least once in every 30 days for IMPs with marketing authorization [IR Art 7, 2].
- As a risk-based approach, more frequent screening may be necessary depending on the state of knowledge of the safety profile of the active substance and the degree of deviation of their use from normal clinical practice [IR Art 7, 3].
- The screening shall be recorded by the safety assessing MS independently of the outcome of the assessment. These records including information on the date of the screening shall be available to all Member States [IR Art 7,4].
- Regarding the information systems to support the cooperation in safety assessment. The functionalities developed shall support the screening of SUSARs, including the provision of predefined reports [Art 11, 3g].

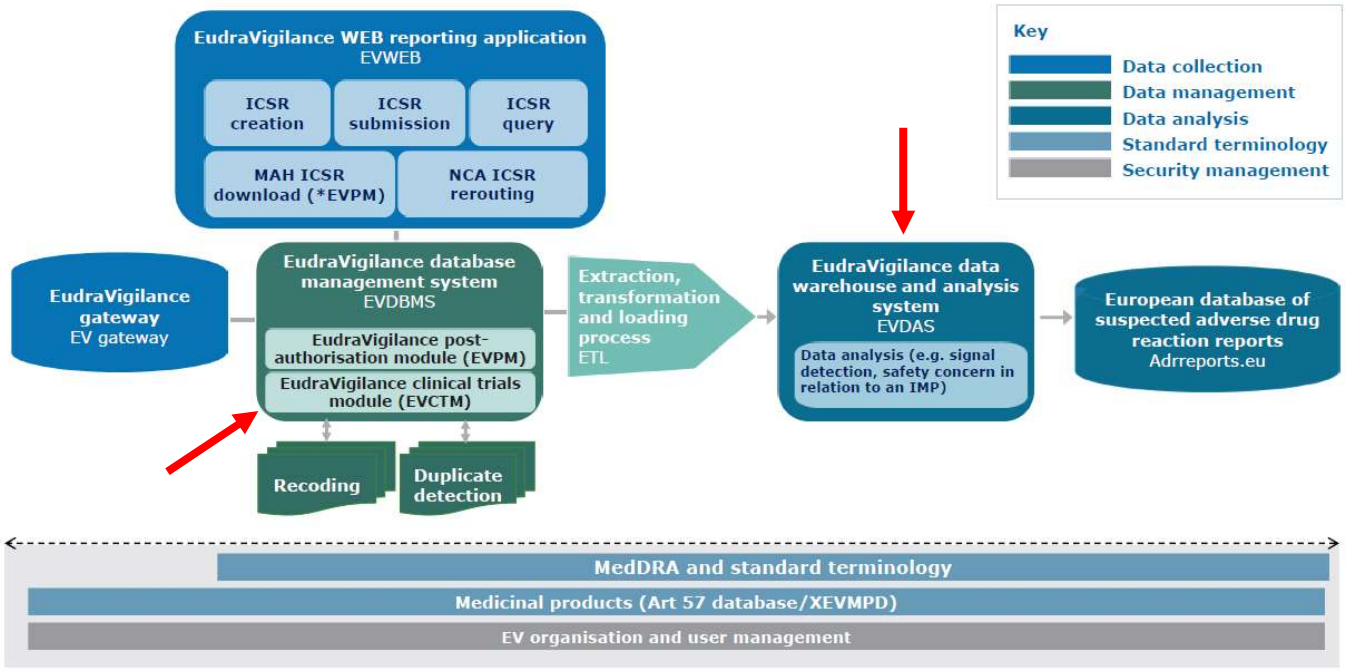
Background

SUSARs are submitted to the EudraVigilance Clinical Trials Module (EVCTM) by the sponsors according to the reporting requirements established in the Clinical Trials Legislation

The data included in the SUSARs is according to the the Individual Case Safety Report (ICSR) standard ISO EN 27953-2 , the EU ICSR Implementation Guide , and the ICH-E2B(R3) Guideline .

Access to SUSARs is done via the EudraVigilance Data Analysis System (EVDAS) which is the current users' interphase to retrieve the data submitted to EudraVigilance

EudraVigilance system components

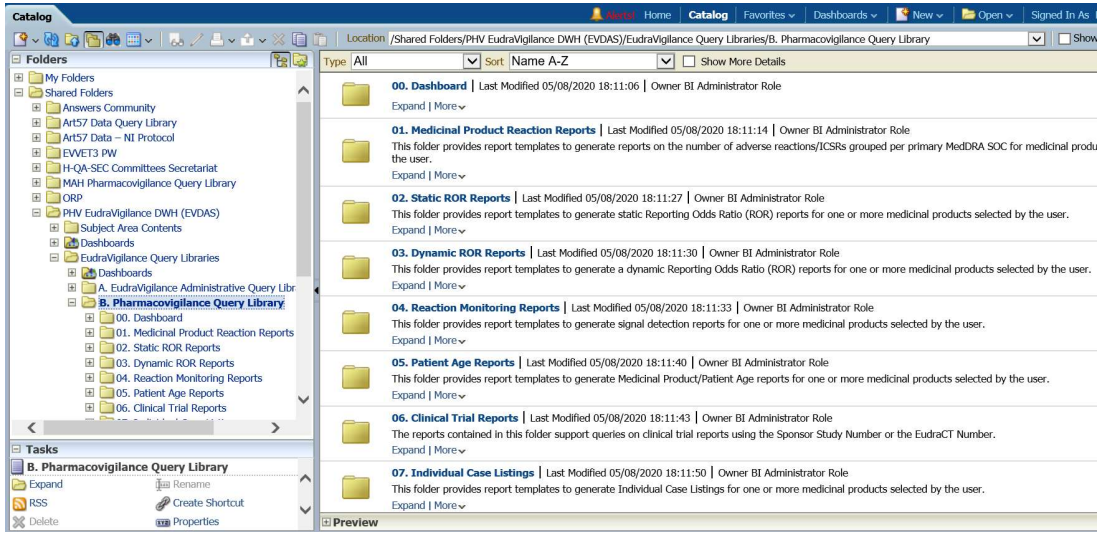


Background (post-authorisation)

- Screening of EudraVigilance data for centrally and nationally authorised medicinal products was officially put in the place following implementation of the 2010 pharmacovigilance legislation and the Implementing Regulation 520/2012.
- The tools for the screening of authorised products have been developed through years of experience and validation studies and follows a methodology that would not be applicable to the screening of SUSARs from clinical trials, nevertheless the experience, tools, EVDAS outputs used for post-authorisation have considered and used as basis to determine and agree on the strategy and tools to be implemented for the SUSAR screening.
- The strategy for the SUSAR screening have been discussed and agreed within a working group with members from the CTFG, EC and EMA.

The Clinical Trials EVDAS dashboard

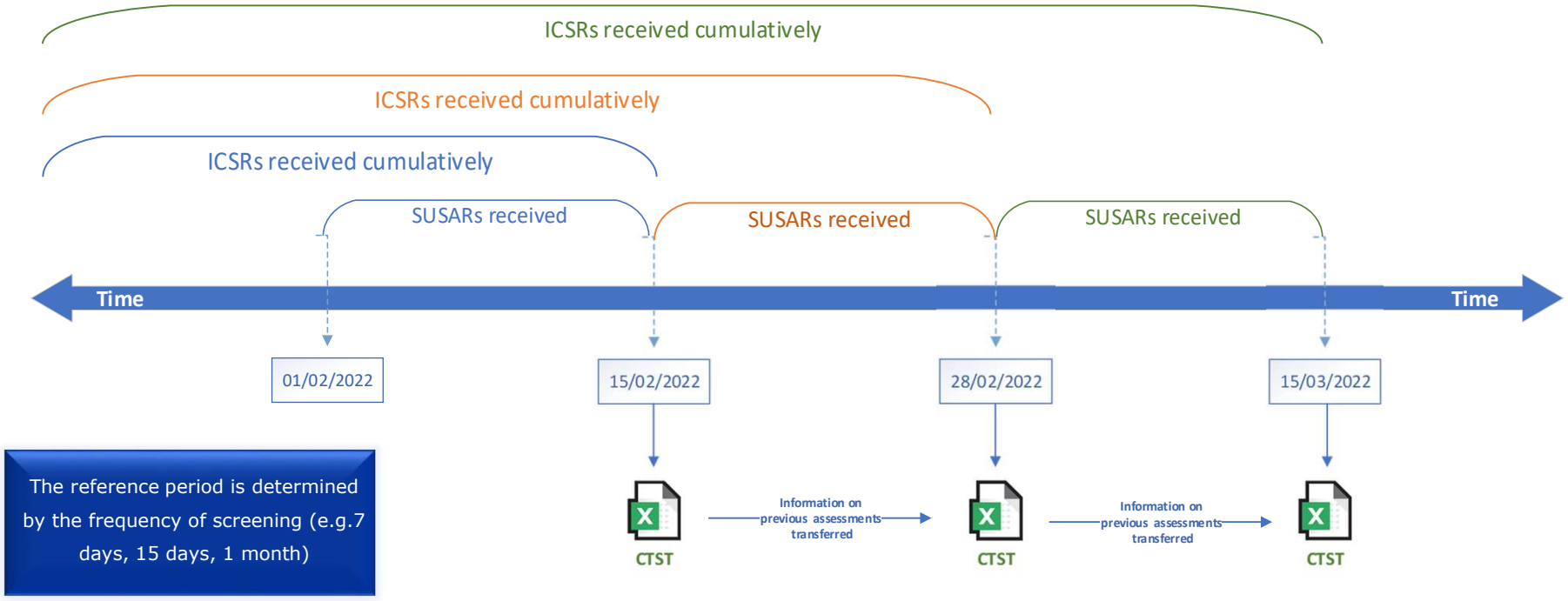
- The current EVDAS catalogue contains different reports that are used to retrieve the data filtered by different parameters.
- The proposal is to create a dedicated dashboard for clinical trials that will contain simplified reports to be used for the SUSARs screening and assessment.
- Assessors should therefore have full access to EudraVigilance in order to actively retrieve the data when needed for the assessment.
- Previous experiences with dedicated simplified reports to support the PSUR assessment and the provision of data to MAHs have been considered.



The Clinical Trials Summary Tabulation (CTST)

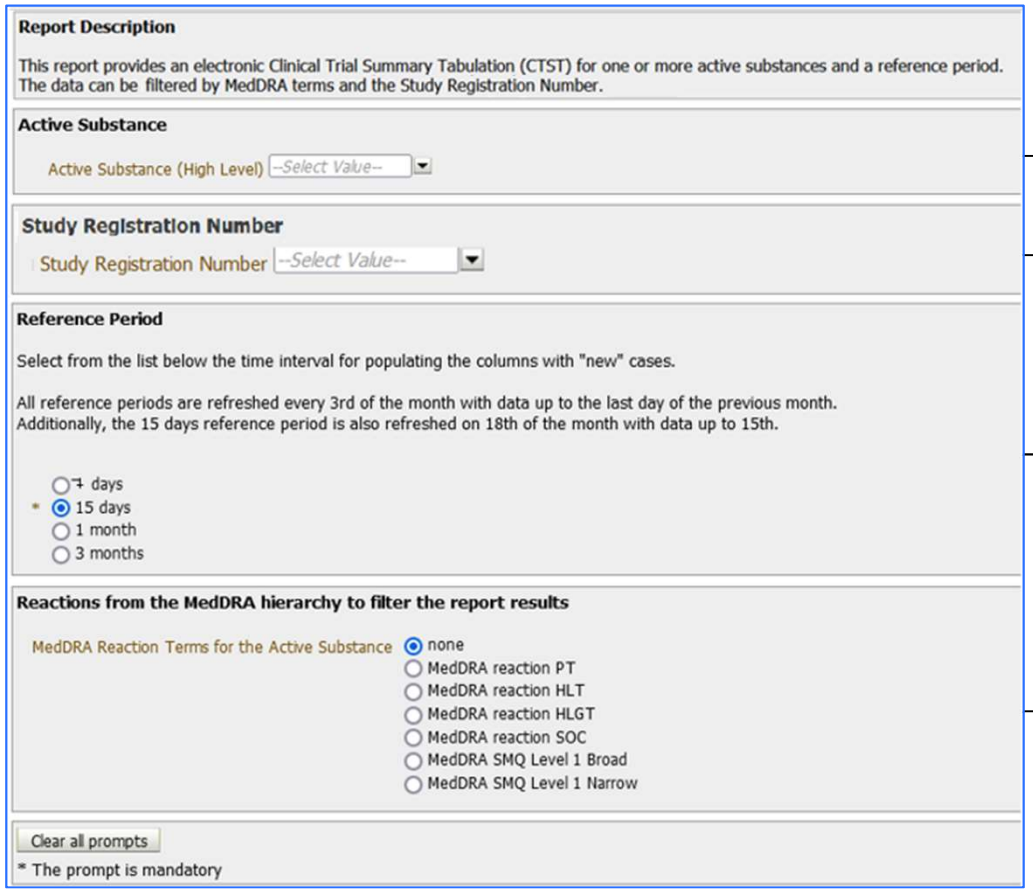
- The CTST would be the main tool for screening. The review of the SUSARs received during an specific period of time ('the reference period') in an aggregated manner ('number of cases') per drug-event combination (DEC) in the context of the cumulative data (all cases in the database for that DEC).
- The CTST will provide the number of cases for an specific active substance (using the high level hierarchy in the EVMDP (EudraVigilance Medicinal Product Dictionary) and an specific reaction using the MedDRA Preferred Term (PT).
- Although the focus of the SUSARs screening would be based on the cases from interventional clinical trials submitted to the EVCTM, the CTST will also contain an overview of the cases and statistical analysis for the DECs with cases submitted to the EVPM, since the active substances may also be used in medicinal products authorised in the EU. This will provide to the saMS an overview per active substance of the reactions reported in the clinical trial setting and in the post-marketing setting.
- The CTST permits recording the outcomes of assessment per DEC

The reference period



The reference period is determined by the frequency of screening (e.g.7 days, 15 days, 1 month)

CTST EVDAS simplified report



Based on an available list of active substances names at the highest level from EVMPD

When it is needed to filter the data for a specific study. It can be combined with the active substance

As determined by the monitoring frequency

Possibility to further filter for specific MedDRA reactions for ad-hoc analysis. For routine screening 'none' should be the option to retrieve all the data

CTST output

Drug-event combination | Clinical trials | Post-authorisation | Assessment

active substance	SOC	HLGT	HLT	SMQ Narrow	PT	IME/DME /TME	New CT	New FU CT	Tot CT	Tot EV	New/FU CT EEA	Tot CT EEA	New/FU CT Fatal	Tot CT Fatal	New/FU CT +RC	Tot CT +RC	New/FU CT Paed	Tot CT Paed	New/FU CT Geriat	Total CT Geriat	Tot Spont	Tot Obs	Tot Lit	Relative ROR (-) Paed vs Others	Paed SDR	Relative ROR (-) Ger vs Others	Geriatr SDR	ROR (-) All	SDR general	Changes	Assessment Outcome	Comments
active substance	Inv	Hepatobiliary Investigations	Liver Function Analyses	Hepatic Disorders	Alanine Aminotransferase Increased		1		15	49	0	20	0	10	0	1	0	0	1	3	9	25	1	0.50	N	0.18	Y	0.25	N	Increased	Screened without action	
active substance	Inv	Hepatobiliary Investigations	Liver Function Analyses	Hepatic Disorders	Aspartate Aminotransferase Increased		1		12	43	0	11	0	13	0	0	0	0	1	3	9	22	1	0.50	N	0.28	Y	0.29	N	Increased	Screened without action	
active substance	Inv	Hepatobiliary Investigations	Liver Function Analyses	Biliary Disorders -- Hepatic Disorders	Blood Bilirubin Increased		1		8	15	0	6	0	5	0	0	0	0	1	3	4	3	0	0.50	N	0.17	Y	0.19	Y	Increased	Screened without action	

CTST output – DEC

Active substance	SOC	HLGT	HLT	SMQ Narrow	PT	IME/DME/ TME
active substance	Gastr	Gastrointestinal Stenosis And Obstruction	Large Intestinal Stenosis And Obstruction	Gastro_perf_ulc_haem_obstr	Large Intestinal Obstruction	Ime
active substance	Infec	Infections - Pathogen Unspecified	Hepatobiliary And Spleen Infections	Biliary Disorders	Cholecystitis Infective	Ime
active substance	Infec	Infections - Pathogen Unspecified	Lower Respiratory Tract And Lung Infections	Infective Pneumonia	Pneumonia	Ime

CTST output – Clinical Trials

'New' columns (reference period)

'Tot' columns (All CT cases)

New CT	New FU CT	Tot CT	Tot EV	New/FU CT EEA	Tot CT EEA	New/FU CT Fatal	Tot CT Fatal	New/FU CT +RC	Tot CT +RC	New/FU CT Paed	Tot CT Paed	New/FU CT Geriat	Total CT Geriat
1		1	2	0	1	0	0	0	0	0	0	1	3
1		1	1	0	0	1	1.00	0	0	0	0	1	3
2		41	174	1	83	2	45.00	1	2.00	0	4	1	3

CTST output – post-authorisation

Number of cases in the EVPM			Disproportionality analysis based on spontaneous reports					
Tot Spont	**Tot Obs**	**Tot Lit**	**Relative ROR (-) Paed vs Others**	**Paed SDR**	**Relative ROR (-) Ger vs Others**	**Geriatr SDR**	**ROR (-) All**	**SDR general**
0	1	0.00	0.50	N	0.20	N	2.30	Y
0	0	0	0.50	N	0.12	N	2.30	Y
58	75	5.00	0.50	Y	0.37	N	0.49	Y

CTST output – Assessment

Standard values

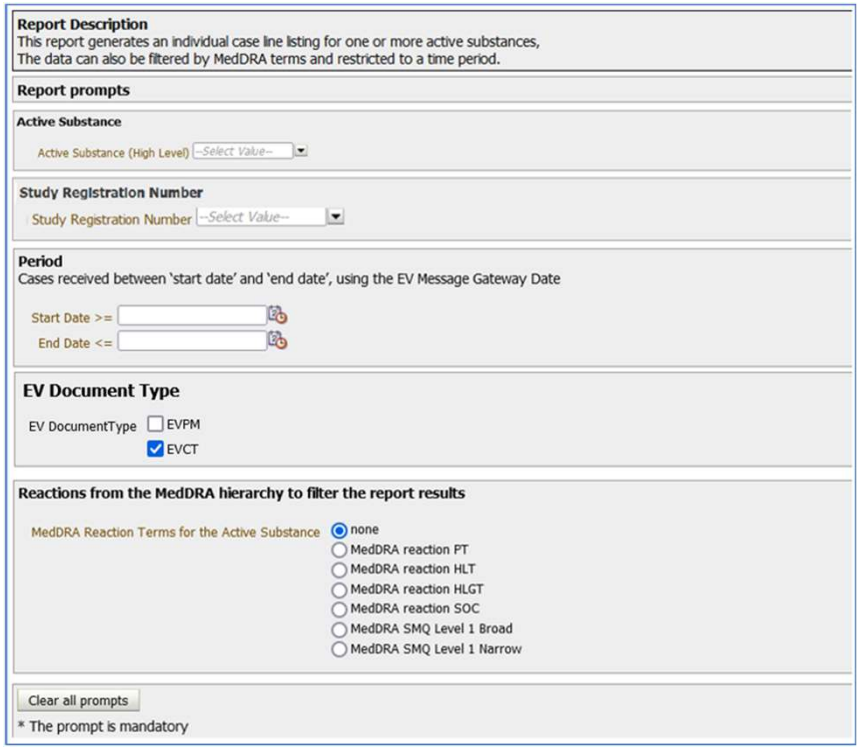
Free text to record outcomes of assessments or other comments at the DEC level

Changes	Assessment Outcome	Comments
Increased	**Screened without action**	
New	**Under assessment**	
Increased (fatal)	**Under assessment**	

These 2 columns are transferred to the next cycle CTST

Clinical Trials Line Listing (CTLL)

- Following the screening using the CSTS, assessors can retrieve the individual cases for specific DECs using the CTLL.
- The CTLL can be accessed via the EVDAS report
- Also there will be hyperlinks from the new and total EVCTM cases in the CTST to the CLL.



CTLL outcome

Specific study information

Access to the ICSR form

EV Safety Report Identifier	Case Report Number	Case version	Study registration number	Sponsor Study Number	Sender	Report Type	EV Document Type	Country	Re
EU-EC-1000[redacted]	NL-JNJFOC-20190316640	1	2013-[redacted]	123[redacted]	[redacted]	Report from studies	EVCTM ICSR(s)	Netherlands	17
EU-EC-1000[redacted]	GB-MHRA-ESUSAR-167670271001-	2	2013-[redacted]	123[redacted]	[redacted]	Report from studies	EVCTM ICSR(s)	United Kingdom	29
EU-EC-1000[redacted]	GB-JNJFOC-20181142074	3	2013-[redacted]	123[redacted]	[redacted]	Report from studies	EVCTM ICSR(s)	United Kingdom	2

ter's comments nments (first	ICSR form	E2B	Complete Narrative, reporter's
99-29#HOVON 141 eceived from an al trial	ICSR	E2B	Narrative, reporter comments and sender comments
Parkinson's. mor, anxiety, reduced n for the last year. Case	ICSR	E2B	Narrative, reporter comments and sender comments
01944-76#Ph III ed,open,parallel trial LL.This report was	ICSR	E2B	Narrative, reporter comments and sender comments

The ISCR form

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Mock-up

EVCTM_MASTER — **Individual Case Safety Report Form** — EudraVigilance

General Information

Worldwide Unique Case Identification Number	JP-Beta-lactam-3462832
Sender type	Pharmaceutical Company
Sender's Organisation	Beta-lactam antibiotics S.L.
Date Report Was First Received from Source	10/11/2002
Date of Most Recent Information	10/11/2002
Type of Report	Report from study
Primary source country	JP
Study registration number	983200163
Study Name	Open-label trial and randomized, double-blind, placebo-controlled, crossover trial of hydrogen-enriched water for mitochondrial and inflammatory myopathies
Study Type	Clinical trials
Reporter's qualification	Physician,
Case serious?	Yes
Medically confirmed?	Yes

Patient

Initials	Date of Birth	Age	Age Group	Sex	Weight	Height
Karen Dinesen	15/11/1992	10	Neonate	Female	53.25 kg	102 cm

Reaction / Event

MedDRA LLT	Start Date	Stop Date	Duration	Outcome	Seriousness*
Drug reaction with eosinophilia and systemic symptoms	01/08/2002	31/08/2002		not recovered/not resolved/ongoing	death, life threat., hospital., congen.
Mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes	05/06/1980			not recovered/not resolved/ongoing	death, life threat., congen.
End stage liver disease	20/08/2002			fatal	death, disability, other
B-immunoblastic lymphoma (Kiel Classification) refractory				recovered/resolved	life threat., other

Drug Information

Role†	Drug	Start Date	Stop Date	Duration	Dose	Units in Interval	Action taken
S	Avastin 25 mg/ml RECODED	15/01/1992	01/02/1992		10 mg/kg	1 per 2w	Drug withdrawn
C	Epilim Chrono 200 mg RECODED						Dose reduced

Drug Information *(cont.)*

Info‡	Drug	Indication	Cumul. dose to 1st Reaction	Pharm. Form	Route of Admin.	Parent Route of Admin.	Batch / Lot #
	Avastin 25 mg/ml RECODED	Non-small cell lung cancer	1200 mg	Concentrate for solution for infusion	transplacental	intravenous	AO852369
	Epilim Chrono 200 mg RECODED	Clonic seizures	15 g	Prolonged Release Tablets			123654PP

Additional Information on Drug
This was an unfortunate medication error

Time-to-Onset and Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	TTO	Rechallenge?/Reaction recurred?
Drug reaction with eosinophilia and systemic symptoms	Avastin 25 mg/ml RECODED Epilim Chrono 200 mg RECODED	187d 186d	No/NA Yes/Yes
Mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes	Avastin 25 mg/ml RECODED Epilim Chrono 200 mg RECODED	125d 140d	Yes/No No/NA
End stage liver disease	Avastin 25 mg/ml RECODED Epilim Chrono 200 mg RECODED	20d 123d	Yes/No No/NA
B-immunoblastic lymphoma (Kiel	Avastin 25 mg/ml RECODED	20 hours	Yes/No

EVPM_MASTER — **Individual Case Safety Report Form** — EudraVigilance

Relevant Medical History and Concurrent Conditions

MedDRA LLT	Start Date	End Date	Continuing	Family History	Comments
Atrial fibrillation	10/10/1995		Yes	Yes	The patient was diagnosed with atrial fibrillation in another hospital and no records are in our files
Pneumothorax	04/01/1996		No		The pneumothorax was a spontaneous pneumothorax and the patient had to be intubated for more than a week.
Varicella		05/10/1999	No		It was unknown if the patient had been immunised against the virus

Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)
Unclear if the patient had surgeries in the past

Past drug history

Drug	Start Date	End Date	Indication	Reaction
Cotrimoxazole	01/08/1994	31/09/1994	Acute pulmonary histoplasmosis	Eye disorder
Acetylsalicylic acid	05/05/1993		Headache	Gastrointestinal disorder

Death

Date of Death	Reported Cause	Autopsy done?	Autopsy-determined Cause of Death
31/08/2002	Pancreatic cancer		Pancreatic cancer resectable

Case Narrative

"Multis post annis respiciebat nee accendi regendos. Colonel Aureliano Buendia erattMerimerit ut perspiciantur distant pater eius diei cum glacis flumen equitatur. Tunc MACONDOet aedificavit civitatem luto Canabrava viginti domibus limpidae aquae fluminis ripa tutaquod lectum decurrerent polito lapide candido et enormi sicut ovarchehistoric. Multa nomina tam recenti re mundi, etseñalarias interuent mentio ille digitus. Familiae quotannis mense Martioet adpropinquaverunt castello castrametati essent gypsies pannosi et tibiis ingenti tumultukettledrums deret eo nova. Primum adduxerunt magnes. Gravitas cum avpsvindomitae barbam et passer manus quae inferebant nomine Melquiades fecit.Ipse palam ostendit quid micum audax sapientum octavusAlcumistae certi est. Abiit domum ad domum et omnes trahentes conflatiles duos ingotsabhorrent mundi videt lebetes et mortaria uere forcipes atque prominentibus trullis ferreis vestri site,et reddat trabes inde ab
clavis et desperatio irrumpet trying efficta est.maior etiam objecta diu ubi acerrima ex humiliati suntappetenda et secum trahens turbulentis post confusionem Melquiades 'magicalis vincirent.""Nihil habent -preponaba the gypsy vita circa omnes acerbam accentut experrecta animas eorum. ""José Arcadio Buendia, cuius
effrenata imaginatio semper superprediturusquedum veniatur supra naturae miracula magica ingenio putaverunt posseutuntur, de terra aurum credidi neotericis inventum. Melquiades, qui fulthominem probum existimares, monuit: ""Quod bonum."" Sed quia noluerunt obaedire Buendia Arcadio Josétum probitate nomades mulae ita mutato par duorum hircorumingots magnetem. Ursula Iguarán uxore animalia crescunt exterminaveruntPauperes vero earum a domesticis holdings, occurrere non potuit, dissuaderent. ""Cito Nam aurum satisstruere domum ""inquit viro. Aliquot menses demonstrare laborantessuccessu opinationem suam. Inch regionis abdita cuncta rimata est. ut alveo trahentestum ferri et recitatio voce ad famam Melquiades. Hoc solum est achievedUnearth erat an armour quintodecimo saeculo cum omnibus frusta naciam partes cadmiae,cui interiora adeo erat cavae resiliens inormi saxo satiemini hederam. IngressoBuendia Arcadio et quatuor hominibus expeditio managed sumere arma seorsum.Invenerunt in osseus calcified pendentis super collum eius vas aerisMulieres cum Crispum.In marcii nomades reversus. Hoc tempore magnificantes speculum uenarum magnitudine adtulissentdrum quos Amsterodamensem Judaeorum inventum tardus prodiderit. Sederunt unumGloria statuitque simul uenarum finem castellum ad ostium tabernaculi. Ryquinis reales, videre possent gypsy at digitis uenarum inspicere.""Removeatur Science has distantias», super Melquiades. ""Mox homoVides quid usquam gentium domi relicto. ""A mendieDemonstratio magnificantes vitrum cum giganteas incendio micam fecit: multum illiin medio plateae et paleas videlicet radios succenderuntsolar. José Buendia Arcadio qui ad consolacionem inciti magnetesIpse armatus Inventionem multumque fatigatus nova belli usu. Melquiades cursus temptaretsuaderet illi. Duo accepit magnetem ingots Tandem autem, et tres,

Demo session II (15'+15' QnA)

ASR assessment, recording and storage of assessment reports, internal/external communication

Recording and storage of SUSARs assessment reports

Session II - CTIS

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Live demo of the CTIS system for ASR assessment, recording and storage of assessment reports, communication MSs/sponsors

Session II – cooperation in safety assessment

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Recording and storage of SUSARs/assessment reports:

- creation of a **new repository** (SharePoint) for storing CT summary tabulation, line listing, SUSARs' assessment reports and reference list for active substance/saMS (safety assessing Member States)

- repository structured by active substances

- accessible by all MSs and relevant Ethics Committees (Article 44.3) and the European Commission

- access managed by CTIS MS administrator(s) via the EMA Account Management platform

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Demo session III (15'+15' QnA)

Registration of Active Substances in xEVMPD (extended EudraVigilance Medicinal Product Dictionary)

saMS selection

Session III - Active Substances in xEVMPD

- **Objective**: describe the data flow of active substance information from data population and validation to use in CTIS
- **IT systems**
  - SMS (Substance Management System)
  - xEVMPD (extended EudraVigilance Medicinal Product Dictionary)
  - CTIS

Session III - Active Substances in xEVMPD

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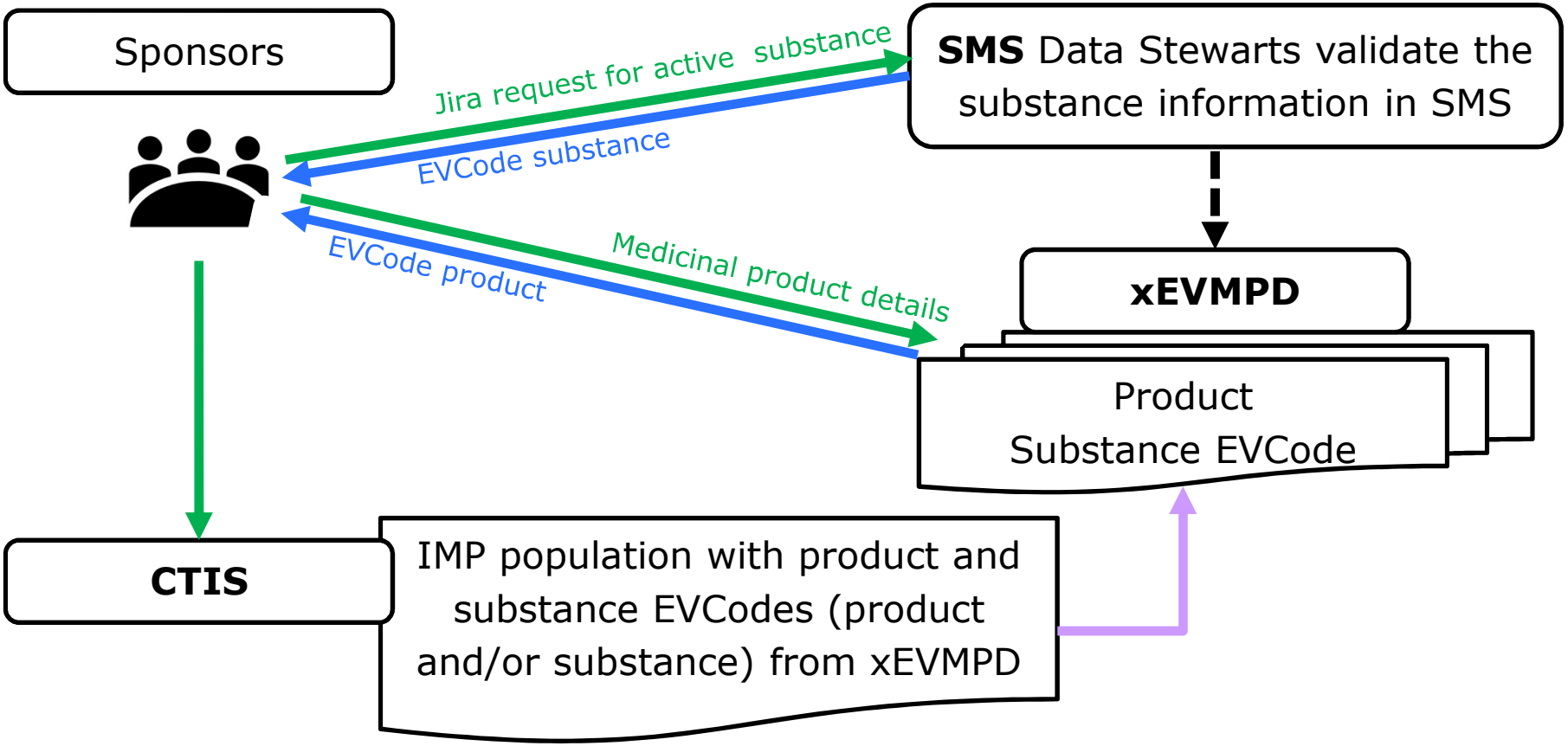
- Management of Active Substances is hosted by EMA and managed by EMA Data Stewards in the SMS system (Substance Management System)
- SMS is part of the "SPOR data management services" for master data management
- SMS data is used by EMA and by external stakeholders, via its consuming systems (e.g. EUTCT, IRIS, xEVMPD, etc.) and the SMS API (NCAs only) to support regulatory processes
- Each substance has a primary ID i.e. SMS ID and a secondary ID i.e. EVCodes in the xEVMPD
- xEVMPD substance information is used by sponsors in CTIS and coming from the SMS system
- Requests to SMS for new substances or update of substance information are managed by the Data Stewart via EMA Service Desk

Session III - Active Substances in xEVMPD



Session III - Active Substances in xEVMPD

SMS manages the following substance data fields:

- SMS ID (also known as EUTCT ID)
- Domain (i.e. Human or Veterinary)
- Data classification (i.e. Public or Restricted)
- Molecular formula
- Substance Names
    - Preferred term (English or Latin)
    - Aliases (English or Latin)
    - Translations (EU official langages)
- Substance name reference source (for preferred term and aliases)
- Substance codes (e.g. EV Code, CAS)

Session III - Active Substances in xEVMPD

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In **SMS**, the choice of the preferred term for a chemical substance depends on the substance names available at the time of registration

Preferred term hierarchy:

1. European Pharmacopoeia (Ph. Eur.)
2. Recommended International Non-Proprietary Name
3. Other official name type with EU jurisdiction
4. Common name mentioned in the SmPC or PiL
5. International Union of Pure and Applied Chemistry name
6. Other systematic name
7. Company code

In addition, the following sources can also be used for registering aliases:

- Proposed INN
- United States Approved Name
- United States Pharmacopoeia
- Japanese Approved Name
- Official name in other jurisdiction

Session III - Active Substances in xEVMPD

SMS has two "Data Classification" fields at different levels to prevent disclosure of confidential substance information:

- **Substance name level**
  - **Public**: Name publicly visible in the consuming systems
  - **Restricted**: Name only visible to EMA DS in SMS and to NCAs via SMS API

- **Substance level**
  - **Public**: All substance information is publicly visible in the consuming systems
  - **Restricted**: Molecular formula and "restricted" names are only visible to EMA DS in SMS and to NCAs via SMS API

- The preferred term is always registered as "Public"
- Official names (e.g. INN, USAN) are always public
- Requestors can suggest a name to be registered as "Restricted", however, the final decision is made by the SMS DS, after confirming if the name is publicly available or not; *the requestor will be informed*
- The information available in the xEVMPD is based on this classification

Session III - Active Substances in xEVMPD

SMS Request process

1. Submission

Requestor

Submit SMS CR in EMA Service Desk portal

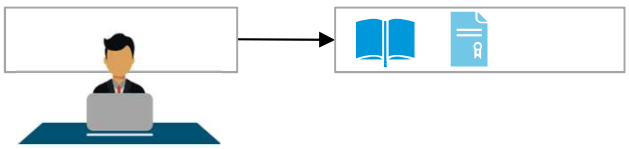
- Add Substance
- Update Substance

- Substance Request form
- Supporting document (SmPC, IB, etc.)

2. Validation

EMA Data Stewards

Guidance/references



Data Stewards validate all SMS CRs using guidance/references

- Data Cleansing Manual
- EMA Substance Naming Rules
- External Sources of Information

3. Approval/ Rejection

EMA Data Stewards

- New substances (<20): 5-10 working days
- Translations (<20): 10-15 working days
- Bulk requests (>20): No guaranteed SLA
  - Priority to be given to new substances

SMS CR approved = data updated in the SMS and published in consuming systems

SMS CR rejected = reasons explained to requestor via EMA Service Desk

Session III - Active Substances in xEVMPD

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Scenario 1

Sponsor A: requests the creation of a substance for Development Medicinal Product submission

- According to the IB and substance form:
  - PT (Public): *ABC-123*
  - Class (Public): *Chemical*
  - Molecular formula (Restricted): *Cx1Hy1Oz1*
  - Alias (Restricted): *[Chemical name XYZ]*

- ❖ Confidentiality: No information/company code is available in the public domain
- ❖ Duplicate detection: No substance records matching in SMS
- ❖ Action: Substance record is created in SMS => EV CODE 1

Scenario 2

Sponsor B: requests the creation of a substance for Development Medicinal Product submission

- According to the IB and substance form:
  - PT (Public): *DEF-456*
  - Class (Public): *Chemical*
  - Molecular formula (Restricted): *Cx1Hy1Oz1*
  - Alias (Restricted): *[Chemical name XYZ]*

- ❖ Confidentiality: No information/company code is available in the public domain
- ❖ Duplicate detection: EV CODE 1 is matching current information
- ❖ Action: Substance record is updated in SMS => EV CODE 1 to be referenced (new company code entered as Alias; both company codes will be made public)

Session III - Active Substances in xEVMPD

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SMS data stewards conduct regular data enrichment exercises in order to prevent change requests and improve data quality in SMS:

- Proposed INN Lists (twice per year)
- Recommended INN Lists (twice per year)
- USANs that aren't INN (once per year, in December)

As outcome of these enrichments:

- New substances are created
- Substances are updated: official name (INN/USAN) and company codes

Session III - Active Substances in xEVMPD - Summary

- **SMS** (Substance Management System) process in place to register and validate active substances, avoiding duplicate entries
- **SMS** information is kept up-to-date by sponsors (via request) and by SMS team (via periodic review)
- **xEVMPD** contains validated and up-to-date substance information from SMS as well as development medicinal products recorded by sponsors
- **CTIS** allows sponsors record to select the IMPs details - active substances and development medicinal products information - from the xEVMPD
- **SUSARs**'s reported drug/substances are matched against the xEVMPD's product/substance information
- **CTST/CTLL** are run using active substances from the xEVMPD

Demo session III (15'+15' QnA)

Registration of Active Substances in xEVMPD (extended EudraVigilance Medicinal Product Dictionary)

saMS selection

Session III – saMS selection

- **Objective**: describe the process to support the saMS (safety assessing Member State) selection/re-selection process
- **Background**: the saMS selection process implemented in CTIS needs to be reviewed and amended post go-live as the current functionalities do not support the desired to-be process

Article 11(5): *The Agency together with Member States and the Commission shall develop information system support for safety assessing Member State selection and re-selection according to Article 3 and 5 by the end of the transition period as laid down in Regulation (EU) 536/2014.*

- **IT systems**: the saMS selection/re-selection will take place outside of CTIS and will be supported by newly setup IT applications

Session III – saMS selection

- The process to support the saMS selection/re-selection process for the go-live and during the transition period is currently being drafted by the Drafting group
- As the saMS selection/re-selection will take place outside of CTIS, the process will be supported by **new IT applications** e.g.:
  - a new repository accessible by all MSs which will allow:
    - to record the expression and the assessment of interest for saMS selection
    - to record and consult the list of active substances and saMS (*Article 11(3)b & c: recording & searchable listing)*
  - a new EudraMail mailbox to facilitate communication between MSs

Session III – saMS selection

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- The saMS selection/re-selection process will also be supported by **business processes** (workaround)
- The Drafting group is currently capturing the detailed business process (flowchart and guidance)
- Business Intelligence reports and/or ad-hoc analysis will be developed in Q4/Q1 to identify active substances and changes over time (e.g. new substance, changes in the number of MS Concerned (mono-national to multi), change of active substance name, active substance 'not active' anymore as clinical trial has concluded, etc…)
- Some actions will be supported by the "secretariat/RMS" - while these actions should be carried out by the RMS in accordance with the IR, the secretariat will provide support as an interim solution under the Joint Action
- The EMA will support the management of the active substances and saMS reference list for go-live/post go-live

Session III – saMS selection

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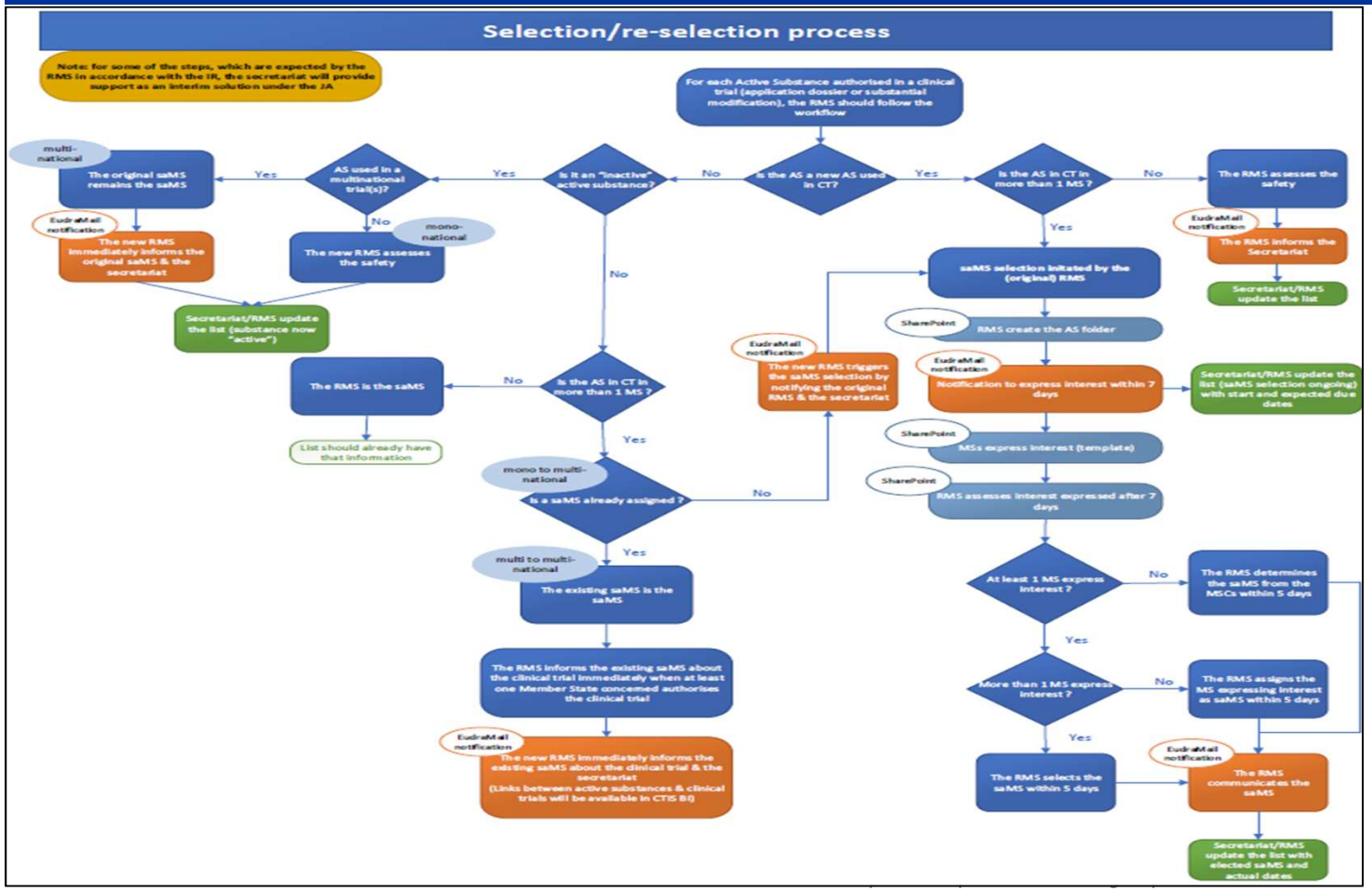

Based on Chapter II – Coordinated Safety Assessment

Article 3:Selection of the safety assessing Member State

-> re-selection not shown

-> expression/assessment of interest in the new repository (template)

Session III – saMS selection - Summary

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- The business process is being developed by the Drafting group for saMS selection/re-selection for go-live
- Process/guidance will be included in the best practice
- It will be supported by new IT applications e.g. repository for collaboration, EudraMail for communication
- It will be supported by business intelligence reports that will be iteratively developed (before and after go-live to use production data) to identify active substances and changes over time, allowing MSs to trigger the saMS selection process when required
- The EMA will support the creation/management of the active substances and saMS reference list (until task taken over by the Joint Action)

General QnA (30')

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Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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