EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of external requests on EU-CTR and EudraCT		
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1. Purpose

The purpose of this SOP is to define the procedure for the handling of requests related to the EudraCT database and EU Clinical Trials Register (EU-CTR) received from external users (e.g. from journalists, healthcare professionals, patients, the general public…).

The EU-CTR contains information on interventional clinical trials on medicinal products.

The information available dates from 1 May 2004 when national medicine regulatory authorities began populating the EudraCT database, the application that is used by national medicine regulatory authorities to enter clinical trial data.

The EU-CTR website launched on 22 March 2011 enables users to search for information which has been included in the EudraCT database. Users are able to view:

- the description of a phase II-IV adult clinical trial where the investigator sites are in the European Union (EU) member states and the European Economic Area (EEA);
- the description of any paediatric clinical trial with investigator sites in the EU and any trials which form part of a Paediatric Investigation Plan (PIP) including those where the investigator sites are outside the EU/EEA.

EudraCT is a database of all clinical trials commencing in the Community from 1 May 2004, or third country clinical trials that form part of a Paediatric Investigation Plan (PIP). The database has been established in accordance with Directive 2001/20/EC.

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2. Scope

This SOP applies to: D-CM (Press Office), P-MI-PIN, V-PD-DIS, P-PV, P-CI-CNC, I-UA-RTS and I-UA-APP.

3. Responsibilities

It is the responsibility of each Head of Sector/Section Head to ensure that this procedure is adhered to within their own sector/section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

N/A.

6. Related documents

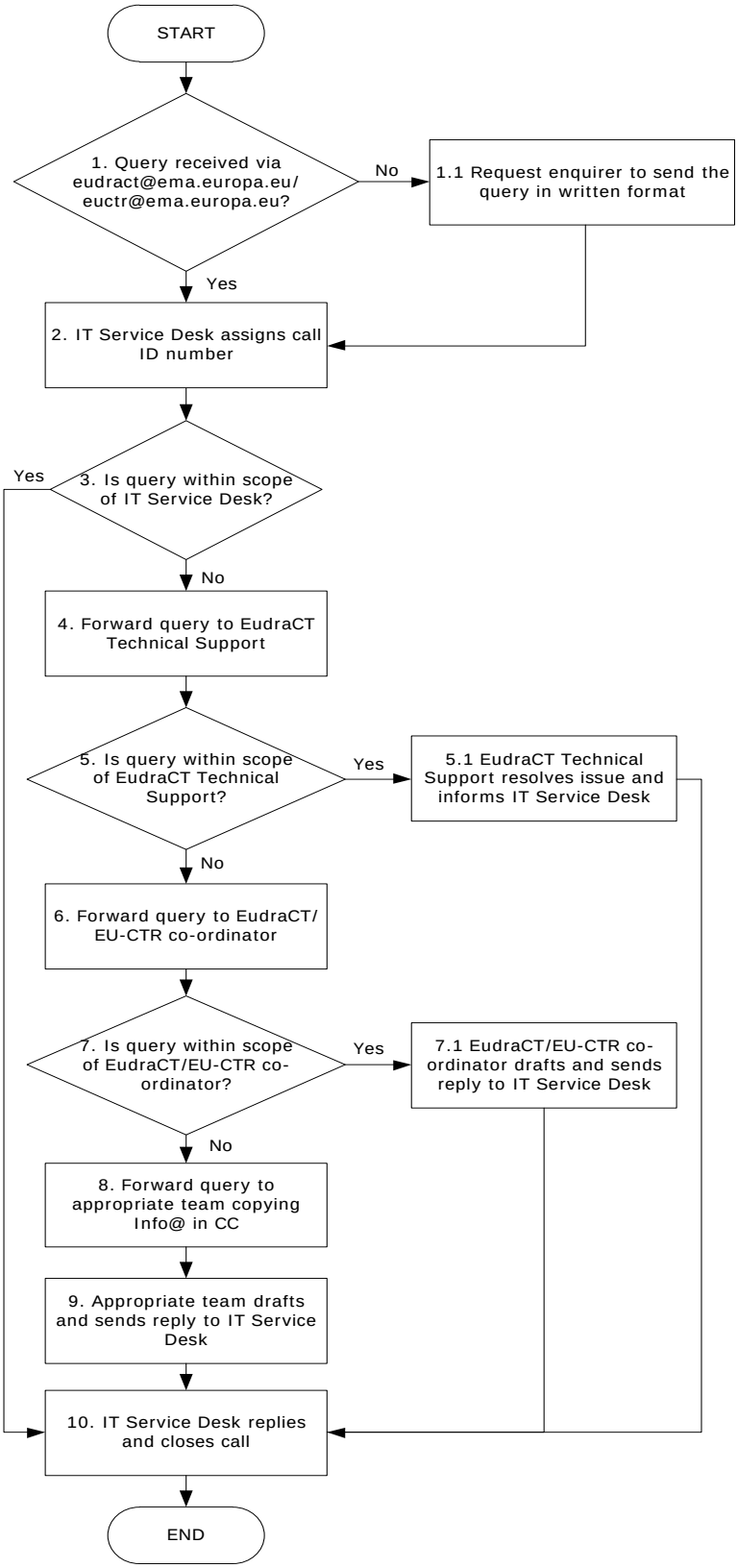
- SOP/EMA/0019 Handling of requests for Information.
- SOP/H/3386 Handling of external requests for access to information from healthcare professionals, patients and the general public.
- WIN/H/3320 Documentation of external requests for access to information and their responses from healthcare professionals, patients and the general public.

7. Definitions

EudraCT/EU-CTR co-ordinator:	EMA staff member who manages EudraCT/EU-CTR queries.
D-CM:	Communications Sector, Directorate.
EU-CTR:	European Clinical Trials Register.
EudraCT:	European Electronic Database of Clinical Trials.
EVMPD:	EudraVigilance Medicinal Products Dictionary.
I-UA-APP:	Application Support Section, ICT User and Application Support Sector, Information and Communications Technology Unit.

I-UA-RTS:	User Registration, Training and Service Desk Section, ICT User and Application Support Sector, Information and Communications Technology Unit.
P-CI–CNC:	Clinical and Non-Clinical compliance Section, Compliance and Inspection Sector, Patient Health Protection Unit.
P-MI-PIN:	Public Information and Stakeholder Networking Section, Medical Information Sector, Patient Health Protection Unit.
P-PV:	Pharmacovigilance and Risk Management Sector, Patient Health Protection Unit.
SUSAR:	Suspected Unexpected Serious Adverse Reactions.
V-PD-DIS:	Document and Information Services Section, Product Data Management Sector, Veterinary Medicines and Product Data Management Unit.

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
	Start	
1.	Receive query on EudraCT/EUCTR from external user. Is query received via eudract@ema.europa.eu / euctr@ema.europa.eu? If yes, go to step 2. If no (query received by P-CI-CNC via phone call), go to step 1.1.	IT Service Desk
1.1	Request enquirer to send the query in written format to the relevant e-mail address (eudract@ema.europa.eu or euctr@ema.europa.eu).	P-CI-CNC
2.	Acknowledge receipt of request and assign call ID number through the InfraEudra system.	IT Service Desk
3.	*1st Line* Is query within scope of IT Service Desk? If yes, go to step 10. If no, go to step 4.	IT Service Desk
4.	Forward query to EudraCT Technical Support.	IT Service Desk
5.	*2nd Line* Is query within scope of EudraCT Technical Support? If yes, go to step 5.1. If no, go to step 6.	EudraCT Technical Support
5.1	Resolve technical issue and inform IT Service Desk by e-mail. Then go to step 9.	EudraCT Technical Support
6.	Forward query to EudraCT/EU-CTR co-ordinator.	EudraCT Technical Support
7.	*3rd Line* Is query within scope of EudraCT/EU-CTR co-ordinator? If yes, go to step 7.1. If no, go to step 8.	EudraCT/EU-CTR co-ordinator
7.1	Draft reply and send it to IT Service Desk via eudract@ema.europa.eu keeping the original call number in the email's subject. Then go to step 10.	EudraCT/EU-CTR co-ordinator
8.	Forward query to appropriate team/section/sector (D-CM/P-MI-PIN/P-PV/V-PD-DIS) copying Info@ in CC	EudraCT/EU-CTR co-ordinator
9.	Draft reply and send it to IT Service Desk via eudract@ema.europa.eu keeping the original call number in the email's subject and copying Info@ in CC.	D-CM/P-MI-PIN/P-PV/V-PD-DIS
10.	Send reply to external user and close call using the InfraEudra system.	IT Service Desk

Step	Action	Responsibility
	End	

10. Records

Electronic copies of the requests and their responses are kept by IT Service Desk in the InfraEudra system.