



## Work instructions

Title: Managing EudraCT alerts		
Applies to: Compliance and Inspection Department (P-CI)		
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### 1. Changes since last revision

New WIN.

### 2. Records

The e-mail template for EudraCT alerts in relation to centrally authorised products (CAPs) is located on the X: drive (X:\Templates\Others\Compliance and Inspection\GCP\EudraCT). Electronic copies of all records generated using this template, are saved in the GCP mailbox in Outlook ([GCP@ema.europa.eu](mailto:GCP@ema.europa.eu)).

### 3. Instructions

This WIN covers the management of the EudraCT alerts in relation to centrally authorised products (CAPs) by the Clinical and Non-Clinical Compliance Service in the Compliance and Inspections Department (P-CI-CNC). The EudraCT database contains data on clinical trials conducted in Europe and outside Europe if they are part of a Paediatric Investigational Plan (PIP). This database automatically generates an alert as soon as a change in the status of a clinical trial occurs (i.e. prematurely ended, temporarily halted, suspended, restart, end of suspension, prohibited). The clinical trial affected can be related to a product authorised via the centralised procedure (i.e. CAP) or to a product authorised via national procedures (i.e. MRP/DCP).

Actions in relation to this alert will only be taken in case it is related to a centralised product.

Whenever an alert related to a CAP is automatically transmitted by EudraCT, the information needs to be forwarded to the appointed EMA Evaluation Product Leader (EPL) for the concerned product.



If the trial concerns paediatric population, it should be forwarded separately to the paediatric PM making it clear in the subject of the e-mail that it is only for information.

Please note that if the sponsor of the trial concerned and for which the alert has been generated is not the applicant of the on-going procedure, then the information related to the alert cannot be shared with the applicant.

The frequency for sending the e-mail to the EPL is once a month. This activity is done by the responsible person in the P-CI-CNC.

### ***Abbreviations***

CAP – Centrally Authorised Product

DCP – Decentralised Procedure

MRP – Mutual Recognition Procedure

NAP – Nationally Authorised Product

NP – National Procedure

P-CI – Compliance and Inspection Department

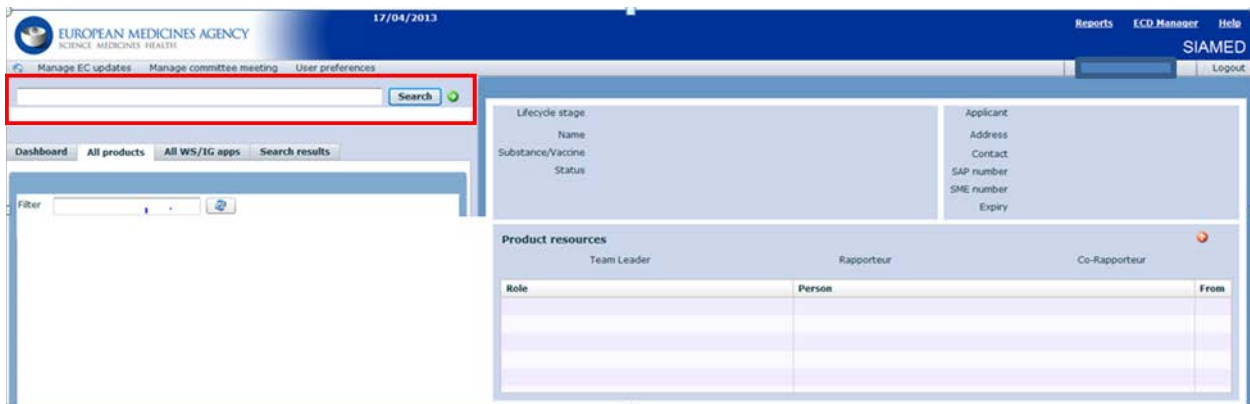
PIP – Paediatric Investigational Plan

EPL – Evaluation Product Leader

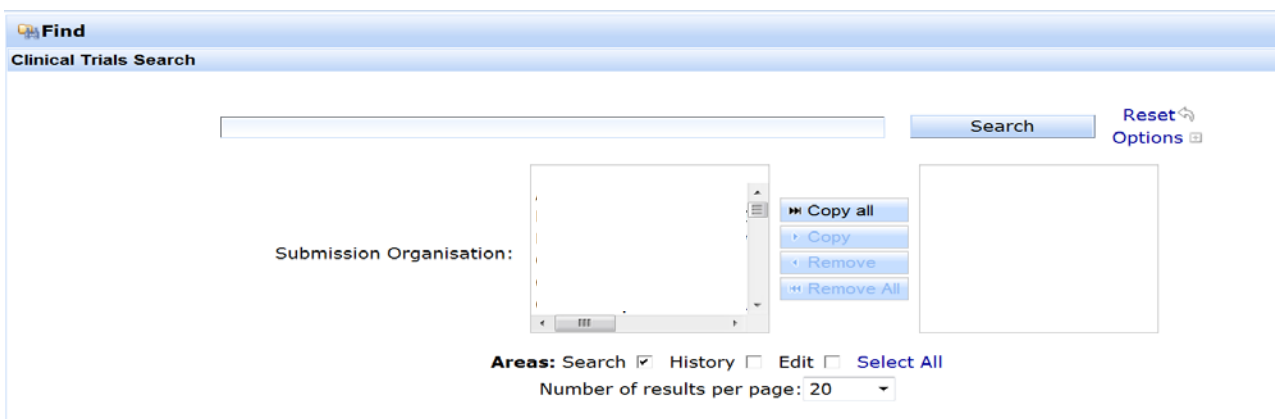
PM – Product Manager

P-CI-CNC - Clinical and Non-Clinical Compliance Service, in the Compliance and Inspections Department

**Step 1** – Upon receipt of the EudraCT alert, check if the product is a CAP by searching in SIAMED either by active substance or by product name. When found in SIAMED, identify the name of the EPL or PM for paediatric trials.



**Step 2** – Cross-check the information received in the alert against the records on the EudraCT Secure site system (<http://eudract.eudra.org>) by entering the EudraCT number in the Search text field. The EudraCT number can be found in the subject of the alert.



**Step 3** – Before forwarding the alert:

- Change the subject to specify the type of alert (i.e. prematurely ended, temporarily halted, suspended, restart, end of suspension, prohibited) and its justification.
- Include the information as per the e-mail template referred to in section 2 of this WIN.

**Step 4** – Send the e-mail to the concerned EPL/PM, as required, copying in both the GCP mailbox and product shared mailbox with an indication to inform the concerned Rapporteur to decide whether any action has to be taken.