EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

EudraCT v.10.5.0.0

Release notes

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Contents

1. Introduction

This document lists and briefly describes changes done in the EudraCT application / database.

1.1. Version: version number 10.5.0.0

1.2. Version Goal: Production

2. Related Documents

The following documents are related to these release notes:

N/A

2.1. What's New

The following functionality is new in this release:

Mark a trial as prematurely ended in the system. It can be done as follow:

1. Logging into https://eudract.ema.europa.eu/results-web/ and have a trial assigned.
2. Go to Your Page. Under Options, select trial to Edit.
3. Attach summary document (under summary attachments section).
4. Click on Post Results.
5. Select "Do not include the full data set".

The message from the following screen has been modified.

Instead of:

You will now be asked up to 4 questions about the clinical trial. Provide an answer to each question to ascertain whether the modality of posting used (one or more summary attachments only) is permitted.

- *Is this clinical trial part of an agreed pediatric investigation plan (PIP)? Yes/No*

It is:

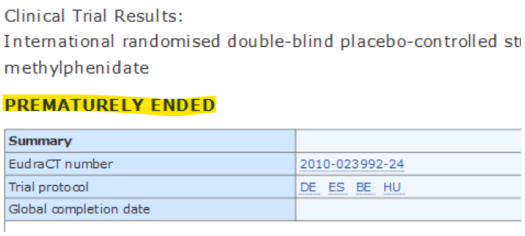
You will now be asked a few questions about the clinical trial. Provide an answer to each question to ascertain whether the modality of posting used (summary attachments or full data set of results) is permitted.

- *Has this clinical trial ended prematurely (e.g. the trial never started or the trial started but was interrupted prematurely)? Yes/No*

If NO, the system validations, logic, pre-requisites/conditions behind these questions remain the same.

If YES, the system skips the subsequent questions, the logic, pre-requisites / conditions behind those questions. And system takes the user directly to Agreement.

Once the terms of agreement are accepted, the user clicks on “post” and the screen “post results-success” is shown. After two weeks, in clinicaltrialsregister.eu, when clicking on “View Results” for the relevant trial, the trial appears marked as PREMATURELY ENDED.


Clinical Trial Results:
International randomised double-blind placebo-controlled st
methylphenidate

PREMATURELY ENDED

Summary	
EudraCT number	2010-023992-24
Trial protocol	DE ES BE HU
Global completion date	

2.2. Bugs Fixed

The following bugs have been fixed:

Ref Number	Description
ECTRESIII-2375	Upload of Clinical Trial Application XML failing
ECTRESIII-2380	The radio button NO is auto-selected when "Modality of Posting" screen is displayed
ECTRESIII-2381	Trial status in Clinical Trial Register displayed as 'Ongoing' instead of 'Prematurely Ended'
ECTRESIII-2382	The result displayed in CTR has blank field for answers skipped when YES selected for "Has this clinical...."
SD-443478	Unavailability to complete the UAT on prematurely ended trials

3. Change Requests

The following change requests have been implemented for this release:

Ref Number	Description
SD-376939	Remove restriction that obliges sponsors to upload full set of results (if trial ended prematurely)