Explanatory document:
Eudamed Identifier System for Clinical Investigations

Eudamed is a secure web-based portal acting as a central repository for information exchange between National Competent Authorities and the European Commission.

Eudamed is mandatory since May 2011 and must contain basic information on all ongoing Clinical Investigations.

Eudamed provides a Clinical Investigation identification number: **CIV ID**

The process to obtain the **CIV ID** is described step-by-step in the Help Function of the Eudamed application itself.

A summary of the basic principles is listed below:

An Eudamed CI entry needs a CIV ID
The CIV ID is common to a specific Clinical Investigation, independently of the countries in which the CI takes place
The same CIV ID must be used for all CI part of a multi centre CI
The CA that first receives the notification of a CI retrieves the CIV ID from Eudamed
The CA must communicate the CIV ID to the manufacturer
When receiving a CI notification the CA should systematically ask the manufacturer whether he has already and Eudamed CIV ID
The manufacturer can only have an Eudamed CIV ID if he has previously notified the same CI to another CA
The CIV ID is structured as follows: CIV-YY-MM-XXXXXX

When a CA receives a CI notification and the manufacturer does not yet have a CIV ID, the CA must obtain a Eudamed CIV ID and communicate it to the Manufacturer.

The Manufacturer must use this CI ID in all further communications related to the same CI with all national CAs.

Clinical investigation Eudamed Module Basic Principles

Recording Clinical Investigations in Eudamed is a **3-step** process:

STEP 1 – search or generate a **CIV ID**
STEP 2 – enter all details of the related Clinical Investigation
STEP 3 – confirm the Clinical Investigation

Searching or Generating a CIV ID

Before entering the details of a Clinical Investigation, a CA needs to obtain a unique CIV ID for this particular investigation.

The CA will be prompted to perform a search based on the **Manufacturer's name** and the **Protocol code**. This is a step to ensure that CA's pick up investigations that are already entered in Eudamed and to avoid that a manufacturer obtains several CIV ID for one CI.

The **Manufacturer's name** is mandatory and the **Protocol code** is optional. However, when the Protocol code is available the CA must enter this information.

If the Clinical Investigation is found, the found CIV ID will be listed in the Search results Panel and the CA must use this CIV ID to create its own country CI.

If the Clinical Investigation is not found, the CA will generate a new CIV ID before creating the Clinical Investigation.

Entering details of a Clinical Investigation

A new Eudamed Clinical Investigation is created **only** when the CA associates the CIV ID to the CI details entry.

Only at that moment the Eudamed application adds the **country code**.

The full Eudamed CIV reference looks like this: **CIV-CO-YY-MM-XXXXXX**.

Confirming the Clinical Investigation

A Eudamed record has a first status of "**proposed**". At that moment the record is only visible by the CA that has created it, the "owner" CA.

When the CA confirms the record it becomes "**confirmed**" and only at that moment the record is visible by all Eudamed users.

For multi centre CI, a search with YY-MM-XXXXXX will give the list of all countries that have already confirmed data concerning the same CI.

Eudamed users can only view Clinical Investigations that are:
1) Associated to a CIV ID and 2) Confirmed