



# El portal ECM

Cómo rellenar una solicitud inicial

**Agencia Española de Medicamentos y  
Productos Sanitarios**

*Madrid, 28 abril 2011*



## Novedades EudraCT v.8

- Se actualiza el formulario de solicitud inicial
- Se simplifica la obtención del N° EudraCT
- Herramienta de conversión v7 a v8
- Se mejoran las ayudas
- Se actualizan las validaciones
- Formulario para EC que solo se realicen en terceros países y formen parte de un PIP
- Herramienta de comparación de XMLv8



## Formulario solicitud inicial v.8

1. Cambia:
  - Integra los campos en la plataforma de registros públicos OMS
  - Información MI terapia avanzada
  - Información EC con menores
  - Información EC 1<sup>a</sup> administración a humanos
2. Punto verde en los campos públicos
3. Respuestas “Yes”, “No” y “Not answered”, y por defecto: “No”.
4. Campos de texto libre multilingües



## Formulario solicitud inicial v.8

### Necesario:

- Formato XML v8 (convertir las v7 en EudraCT)
- Completo y validación sin errores
- Texto libre fácilmente comprensible, en español y en inglés
- Buscar los términos en los diccionarios
- E-mail institucionales, no personales



## PROCEDIMIENTO

1. El formulario europeo (CTA) de una **solicitud inicial se cumplimenta y valida en el sitio web de EudraCT** (<https://eudract.ema.europa.eu>) donde se genera el XML del CTA.

Los nombres y direcciones de los centros de G.1/G.2 y del CEIC en H se cumplimentarán en el portal ECM cargando el XML v.8 previamente generado y validado en EudraCT.



# Convertir XML v7 -> v8

**IMPORTANT**

**Patch Release Announcement**

EudraCT V8.0.1 will be released on Tuesday 29th March 2011.

Please note to facilitate this release application downtime will be required outside business hours (From Monday 28th March 17:30 To Tuesday 29th March 9:00am UK time).

Please refer to the [patch release notes](#) for further information.

If you have any queries about the new system that are not addressed here or in the system help, please contact the [EudraCT Service Desk](#)

[Access to EudraCT](#) NEW

[New Features in v8.0](#) NEW

[v7>v8 XML Conversion](#) NEW

[EudraPharm EU CTR](#) NEW

[Supporting Documents](#) NEW

**Welcome to the Community Clinical Trial System Public Home Page**

EudraCT is a database of all clinical trials commencing in the Community from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC. This site is the sponsor and Paediatric Investigation Plan addressee (PIP addressee) interface which gives these groups access to the EudraCT application. The groups may perform the following tasks:

**Sponsor:**

- Get a EudraCT number.
- Complete the Clinical Trial Application form, save as an .xml file on your computer, print a pdf version of the Clinical Trial Application form.

**PIP Addressee:**

## Convertir XML v7 en XML v8

**Access to EudraCT Application**

**Sponsors:**

- Sponsors may create, save xml/pdf files of Clinical Trial Applications locally only after obtaining a EudraCT Number from the system (See Help on the EudraCT PUBLIC application page): [Access to EudraCT Application](#)
- Sponsors may also load locally saved Clinical Trial Applications to complete, validate, compare or use to prepare a package for submission to a National Competent Authority.

**Note:** Sponsors are unable to save xml files to the EudraCT system. Only National Competent Authorities are able to do this when you send them your xml file.

**PIP Addressees:**

**Note:** The Eudralink credentials of PIP Addressees get authenticated for access to EudraCT during the PIP application procedure. If your credentials do not give you access please contact the EudraCT Service Desk.



[https://eudract.ema.europa.eu/#v7\\_xml\\_conversion](https://eudract.ema.europa.eu/#v7_xml_conversion)



EudraCT version upgrade tool

Welcome to EudraCT version upgrade tool

In order to upgrade the version of the Clinical Trial Application, you have to:

1. Load a version 7 Clinical Trial Application XML

1º Presionar "Add"

2º Localizar archivo

3º Doble clic

ded XML will be sent.

+ Add...

Email Address

Package Security Options

- The recipient(s) must have a Eudralink account to access the package.
- The recipient(s) must enter a password.
- No password.

Update Version

Cancel



## EudraCT version upgrade tool

### Welcome to EudraCT version upgrade tool

In order to upgrade the version of the Clinical Trial Application, you have to:

- Load a version 7 Clinical Trial Application XML .
- Provide an email address to receive the XML file.

2º Indicar el nivel de protección en el correo donde se recibirá el XML corregido

File path of locally saved XML file to load

Email Address

Package Security Options

- 
- The recipient(s) must have a Eudralink account to access the package.
  - The recipient(s) must enter a password.
  - No password.

Update Version

Cancel





## EudraCT version upgrade tool

### Welcome to EudraCT version upgrade tool

In order to upgrade the version of the Clinical Trial Application, you have to:

- Load a version 7 Clinical Trial Application XML.
- Provide at least one e-mail address to which the upgraded XML will be sent.

+ Add...

3º Marcar "Update version" e indicar el e-mail para recibir el XMLv8

File path of locally saved

Bien: se recibirá un e-mail con un XMLv8 y un identificador único

Email Address

Mal: e-mail con xml v7 e identificador único.

Package Security Option

Contactar con [eudract@ema.europa.eu](mailto:eudract@ema.europa.eu)

age.

Update Version

Cancel



## XML completo y correcto

Campos nuevos:

<https://eudract.ema.europa.eu/document.html#technical>

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### Technical Information

**Release Notes** for EudraCT Version 8.0 (.pdf file) **NEW**

**EudraCT Clinical Trial Application Pick lists and Coded Values** (.xls file)

**EudraCT v8.0 Data Dictionary v3.21** (.xls) **NEW**

**New Fields in EudraCT v8.0** (.xls) **NEW** - Intended to assist users with detailed designation of existing fields.



## Por pantalla y campo



### A. Trial identification



A.1 National Competent Authority ●

Spain - AEMPS



## EudraCT supporting documentation

<https://eudract.ema.europa.eu/document.html>

### User Guides (English only)

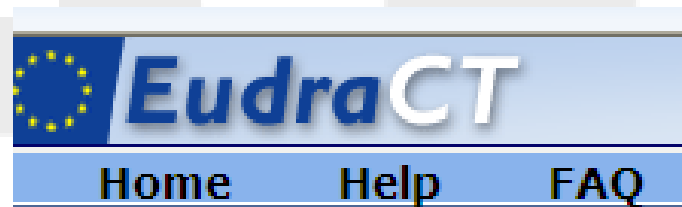
Replacement Tool tips for IE6 Users

EudraCT Frequently Asked Questions

EudraCT XML Conversion Utility User Awareness

EudraCT Validation Rules for EEA

Menú "Help"





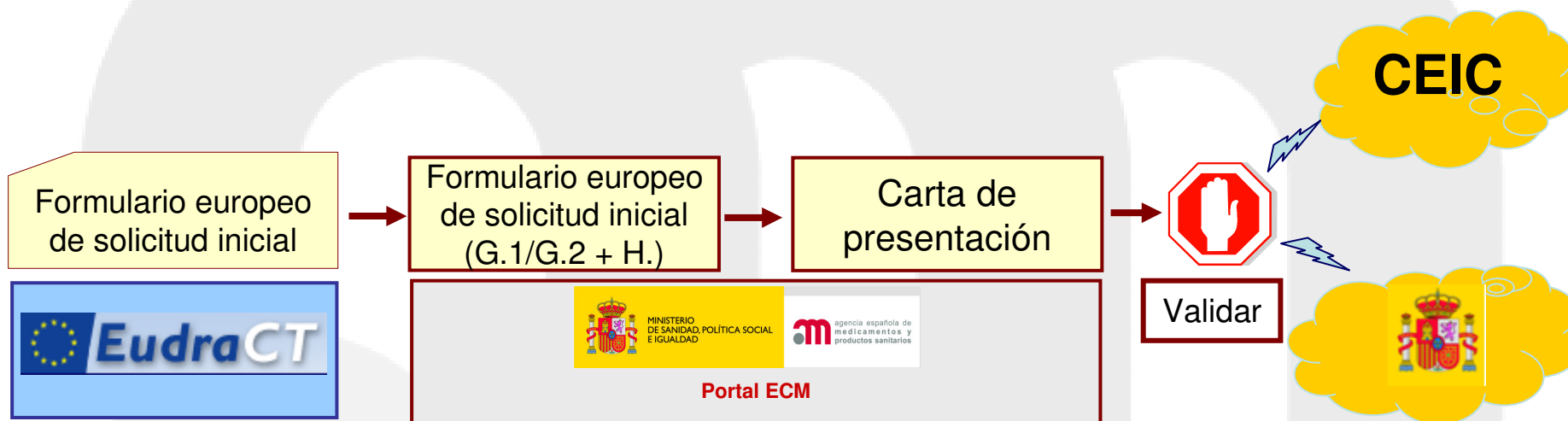
## Diccionarios en EudraCT y Portal ECM

- 1) Autoridades competentes y países
- 2) Principios activos
- 3) Formas farmacéuticas
- 4) Vías de administración
- 5) Unidades de dosificación
- 6) Área terapéutica
- 7) Centros (Hospitales y C. A. Primaria)
- 8) CEICs acreditados en España
- 9) MedDRA





## Flujo de trabajo





## Línea de soporte



[eudract@ema.europa.eu](mailto:eudract@ema.europa.eu)

[incidensayos@aemps.es](mailto:incidensayos@aemps.es)



<https://eudract.ema.europa.eu/eudract-web/index.faces>

The screenshot shows the EudraCT website interface. At the top left is the EudraCT logo with the European Union flag. Below the logo is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. On the left side, there is a 'Login' menu with a 'log-in' link. On the right side, there are 'Create' and 'Load' buttons. The main content area displays a 'Welcome to EudraCT' message, followed by instructions on how to use the system and complete forms. It mentions the EudraCT Number and provides a list of conditions for creating a new entry, including the presence of at least one investigator site in the Community and the trial being contained in an agreed Paediatric Investigation Plan (PIP) or both. A reference to Article 45(1) is also included, stating that by 26 January 2008, any paediatric studies authorized in the EU must be amended to include a PIP. The list of conditions is partially cut off at the bottom.

**EudraCT**

Home Help FAQ Contact Us About

Login

log-in

Create Load

**Welcome to EudraCT**

For further assistance on use of the system and completion of the form...

EudraCT Number:

You need a EudraCT number in order to provide a unique reference for that one individual clinical trial should be identified by one unique EudraCT number.

- There is at least one investigator site in the Community.
- The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) or both).
- The clinical trial is one of those for which information has to be submitted and amended :  
*Article 45(1): By 26 January 2008, any paediatric studies authorized in the EU must be amended to include a PIP.*
- The clinical trial is one of those for which information has to be submitted and amended.



## Obtención nº EudraCT

The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with the EudraCT logo and the text 'Home Help FAQ Contact Us About'. Below this, there is a 'Login' section with a 'log-in' link. A red box highlights the 'Create' menu, which includes options for 'Load', 'EudraCT Number', and 'Clinical Trial'. A red arrow points from a text box to the 'EudraCT Number' option. The main content area contains text explaining the need for a EudraCT number and lists conditions for its issuance.

**Home Help FAQ Contact Us About**

**Login**

log-in

**Create** **Load**

**EudraCT Number**

**Clinical Trial**

Welcome to EudraCT.

For further assistance on use of the system and comple

EudraCT Number:

You need a EudraCT number in order to provide a unique  
that one individual clinical trial should be identified by on

- There is at least one investigator site in the Comm
- The clinical trial is contained in an agreed Paediatric  
both)

Pedir N° EudraCT







# Cargar formulario

The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. Below this is a 'Login' section with a 'log-in' button. The main content area features a 'Create' button and a 'Load' button. A dropdown menu is open under the 'Load' button, showing 'Clinical Trial' with a right-pointing arrow, and two sub-options: 'EEA' and '3rd Country', both with checkboxes. The main content area contains the following text:

**Welcome to EudraCT**

For further assistance on use of the system and completion of the form, refer to the EudraCT User Guide.

EudraCT Number:

You need a EudraCT number in order to provide a unique reference for clinical trials. Each clinical trial should be identified by one unique EudraCT number.

- There is at least one investigator site in the Community.
- The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) (both).
- The clinical trial is one of those for which information has to be submitted in amended form:
  - Article 45(1): *By 26 January 2008, any paediatric studies already covered by a marketing authorisation, in respect of products authorised in the Community, shall be submitted to the competent authority for assessment to the competent authority.*
- The clinical trial is one of those for which information has to be submitted in amended form:
  - Article 46(1): *Any other marketing authorisation holder-sponsored clinical trial, the use in the paediatric population of a medicinal product covered by a marketing authorisation, whether or not they are conducted in compliance with a paediatric investigation plan, shall be submitted to the competent authority for assessment to the competent authority.*



**EudraCT**

Home Help FAQ Contact Us About

Login ⌵

log-in

Create Load

Load an XML file for an EEA Clinical Trial Application

+ Add...

File path of locally saved XML file to load

Upload Return

**Buscar y seleccionar XML**

The image shows a screenshot of the EudraCT web application. At the top, there is a navigation bar with the EudraCT logo and several menu items: Home, Help, FAQ, Contact Us, and About. Below this is a 'Login' section with a 'log-in' link. The main content area is titled 'Load' and contains the instruction 'Load an XML file for an EEA Clinical Trial Application'. A red callout box with the text 'Buscar y seleccionar XML' points to a '+ Add...' button located at the top of a large text input field. The input field contains the placeholder text 'File path of locally saved XML file to load'. At the bottom of the form, there are two buttons: 'Upload' and 'Return'.



The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. Below this is a 'Login' section with a 'log-in' link. The main content area is titled 'Clinical Trial Application Menu' and contains a list of sections: A. Trial Identification, B. Sponsor Identification, C. Applicant Identification, D. IMP Identification, D.8 Placebo Information, D.9 Site(s) where the qualified person certifies batch release, E. General Information on the Trial, F. Population of Trial Subjects, G. Clinical Trial Sites/Investigators in the Member State, and H. Competent Authority/Ethics Committee Information. On the left side, there is a sidebar with 'CTA Information' and 'CTA Sections'. The 'CTA Information' section is highlighted with a red box and contains the following details: EudraCT Number (2004-000001-22), Sponsor's Protocol Code Number (ELA-1), NCA (Spain - AEMPS), and XML File Identifier (oUx868FX9Lo/mBGRPEmW Vy#Mr/U=). The 'CTA Sections' section lists sections A through H. A red arrow points from a red-bordered box containing the text 'Identificación del ensayo' to the 'CTA Information' section.

**EudraCT**

Home Help FAQ Contact Us About European Clinical

Login log-in

**CTA Information**

**EudraCT Number**  
2004-000001-22

**Sponsor's Protocol Code Number**  
ELA-1

**NCA**  
Spain - AEMPS

**XML File Identifier**  
oUx868FX9Lo/mBGRPEmW Vy#Mr/U=

**CTA Sections**

- # Sections Index
- # Section A
- # Section B
- # Section C
- # Section D
- # Section D.8
- # Section D.9
- # Section E
- # Section F
- # Section G
- # Section H

**Validate** **Compare** **Save as XML** **Switch XML** **Save PDF**

**Clinical Trial Application Menu**

- A. Trial Identification
- B. Sponsor Identification
- C. Applicant Identification
- D. IMP Identification
- D.8 Placebo Information
- D.9 Site(s) where the qualified person certifies batch release
- E. General Information on the Trial
- F. Population of Trial Subjects
- G. Clinical Trial Sites/Investigators in the Member State
- H. Competent Authority/Ethics Committee Information

**Identificación del ensayo**



The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. Below this is a header area with the EudraCT logo and a search bar. The main content area is divided into two columns. The left column contains a sidebar with sections for Login, CTA Information, and CTA Sections. The right column contains a Clinical Trial Application Menu with various sections listed. A red box highlights the XML File Identifier in the sidebar, and a red arrow points from a larger red box containing the text 'Identificador del XML' to this field.

**EudraCT**  
Home Help FAQ Contact Us About European Clinical

Login [log-in](#)

**CTA Information**

**EudraCT Number**  
2004-000001-22

**Sponsor's Protocol Code Number**  
ELA-1

**NCA**  
Spain - AEMPS

**XML File Identifier**  
oUx868FX9Lo/mBGRPEmW  
VyHMr/U=

**CTA Sections**

- Sections Index
- Section A
- Section B
- Section C
- Section D
- Section D.8
- Section D.9
- Section E
- Section F
- Section G
- Section H

**Clinical Trial Application Menu**

- A. Trial Identification
- B. Sponsor Identification
- C. Applicant Identification
- D. IMP Identification
- D.8 Placebo Information
- D.9 Site(s) where the qualified person certifies batch release
- E. General Information on the Trial
- F. Population of Trial Subjects
- G. Clinical Trial Sites/Investigators in the Member State
- H. Competent Authority/Ethics Committee Information

**Identificador del XML**



The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. Below this is a login section and a toolbar with icons for Validate, Compare, Save as XML, Switch XML, and Save PDF. The main content area is titled "Clinical Trial Application Menu" and contains a list of sections: A. Trial Identification, B. Sponsor Identification, C. Applicant Identification, D. IMP Identification, D.8 Placebo Information, D.9 Site(s) where the qualified person certifies batch release, E. General Information on the Trial, F. Population of Trial Subjects, G. Clinical Trial Sites/Investigators in the Member State, and H. Competent Authority/Ethics Committee Information. On the left side, there is a sidebar with "CTA Information" and "CTA Sections". The "CTA Sections" sidebar lists: Sections Index, Section A, Section B, Section C, Section D, Section D.8, Section D.9, Section E, Section F, Section G, and Section H. A red box highlights the "Clinical Trial Application Menu" and the "CTA Sections" sidebar. A red arrow points from the text box below to the "CTA Sections" sidebar, and another red arrow points from the text box to the "Clinical Trial Application Menu".

**EudraCT**  
Home Help FAQ Contact Us About European Clinical

Login  
log-in

**CTA Information**  
EudraCT Number  
2004-000001-22  
Sponsor's Protocol Code Number  
ELA-1  
NCA  
Spain - AEMPS  
XML File Identifier  
oUx868FX9Lo/mBGRPEmW  
Vy#Mr/U=

**CTA Sections**  
# Sections Index  
# Section A  
# Section B  
# Section C  
# Section D  
# Section D.8  
# Section D.9  
# Section E  
# Section F  
# Section G  
# Section H

**Clinical Trial Application Menu**  
A. Trial Identification  
B. Sponsor Identification  
C. Applicant Identification  
D. IMP Identification  
D.8 Placebo Information  
D.9 Site(s) where the qualified person certifies batch release  
E. General Information on the Trial  
F. Population of Trial Subjects  
G. Clinical Trial Sites/Investigators in the Member State  
H. Competent Authority/Ethics Committee Information

Validate Compare Save as XML Switch XML Save PDF

Puntos de entrada a cada sección del formulario europeo



The screenshot shows the EudraCT website interface. At the top, there is a navigation bar with links for Home, Help, FAQ, Contact Us, and About. Below this is a header area with the EudraCT logo and a navigation menu. The main content area is titled "Clinical Trial Application Menu" and contains a list of sections: A. Trial Identification, B. Sponsor Identification, C. Applicant Identification, D. IMP Identification, D.8 Placebo Information, D.9 Site(s) where the qualified person certifies batch release, E. General Information on the Trial, F. Population of Trial Subjects, G. Clinical Trial Sites/Investigators in the Member State, and H. Competent Authority/Ethics Committee Information. To the right of the menu, there is a toolbar with five function buttons: Validate, Compare, Save as XML, Switch XML, and Save PDF. An orange arrow points from a red-bordered box labeled "Botones de función" to the "Switch XML" button.

**EudraCT**

Home Help FAQ Contact Us About

European Clinical

Login

log-in

**CTA Information**

**EudraCT Number**  
2004-000001-22

**Sponsor's Protocol Code Number**  
ELA-1

**NCA**  
Spain - AEMPS

**XML File Identifier**  
oUx868FX9Lo/mBGRPEmW  
Vy#Mr/U=

**CTA Sections**

- # Sections Index
- # Section A
- # Section B
- # Section C
- # Section D
- # Section D.8
- # Section D.9
- # Section E
- # Section F
- # Section G
- # Section H

**Validate** **Compare** **Save as XML** **Switch XML** **Save PDF**

**Clinical Trial Application Menu**

- A. Trial Identification
- B. Sponsor Identification
- C. Applicant Identification
- D. IMP Identification
- D.8 Placebo Information
- D.9 Site(s) where the qualified person certifies batch release
- E. General Information on the Trial
- F. Population of Trial Subjects
- G. Clinical Trial Sites/Investigators in the Member State
- H. Competent Authority/Ethics Committee Information

**Botones de función**



**draCT** Help FAQ Contact Us About European Clinical Trials Database

Validate Compare Save as XML Switch XML Save PDF Package

### A. Trial identification

A.1 National Competent Authority • Spain - AEMPS

A.2 EudraCT Number • 2004-000001-22

A.3 Full title of the trial •

A.3.1 Title of the trial for lay people, in easily understood, i.e. non-technical, language •

**Campos multilingües**

English +

Spanish ✖

English +

Annotations: Annotations Index Annotations A Annotations B Annotations C Annotations D Annotations D.8 Annotations D.9 Annotations E Annotations F Annotations G Annotations H





Al final de cada página o sección pulsar siempre **'Continue'** o **'Done'** para guardar datos

A.6 Is this a resubmission?

No

Indicate the resubmission letter or else select 'First submission'

First Submission

A.7 Is the trial part of a Paediatric Investigation Plan? ●

Yes  No  Not Answered


A.8 EMEA Decision number of Paediatric Investigation Plan ●

P/000/2010

Done



Existe la posibilidad de marcar ciertos campos como "No contestado"

 Validate


## D.1/D.2 IMP Identification and Status Details



D.1.2 and D.1.3 Category ●

Test



D.2 Status of the IMP to be used in the clinical trial 

D.2.1 Has the IMP to be used in the trial a marketing authorisation? ●




Yes



No



Not Answered 

D.2.1.1 If 'Yes', specify the product to be used in the trial 



## Agregar medicamento

The screenshot shows the 'D. IMP Identification' section of a web application. At the top, there are three buttons: 'Validate', 'Compare', and 'Save as XML'. Below this is a section titled 'D. IMP Identification' with a help icon. A red-bordered box labeled 'Agregar medicamento' has an arrow pointing to a green plus icon followed by the text 'Add IMP'. Below this is the 'IMP Details' section, which contains a table with one row: 'IMP' and 'No IMP name was specified'. To the right of the table are four buttons: 'Edit IMP', 'Delete IMP', 'Copy IMP', and 'Search active subs'. A red-bordered box labeled 'Agregar principio activo' has an arrow pointing to the 'Search active subs' button. At the bottom of the interface is a 'Return' button.

Validate Compare Save as XML

D. IMP Identification

Agregar medicamento

+ Add IMP

IMP Details

|     |                           |          |            |          |                    |
|-----|---------------------------|----------|------------|----------|--------------------|
| IMP | No IMP name was specified | Edit IMP | Delete IMP | Copy IMP | Search active subs |
|-----|---------------------------|----------|------------|----------|--------------------|

Return

Agregar principio activo



Opciones de búsqueda:

“Contiene”, “igual” o “empieza con”

Contact Us About Europe

Validate Compare Save as XML Switch XML Save

**D. MPD Active Substance Search Criteria**

Active substance name contains equals starts with

CAS Number

CBD (Chemical/Biological Description)

EV Code

Search Return



Todo medicamento debe tener debajo identificados sus principios activos

Contact Us About



Validate



Compare



Save as XML



Switch XML



Save PDF



Package

D. IMP Identification



+ Add IMP

IMP Details

IMP

APIRETAL 500 mg comprimidos bucodispersables / Chewable/dispersible tablet

Edit IMP

Delete IMP

Copy IMP

Search active substance

Add active substance






**Active Substance: 103-90-2/PARACETAMOL/  
based on MPD record: SUB09611MIG**





- Para buscar el principio activo pulsar “Search”
- Para seleccionar la sustancia activa marcar 


Contact Us About Europe

 Validate  Compare  Save as XML  Switch XML  Save

### D. MPD Active Substance Search Criteria

|                                       |                                     |  |
|---------------------------------------|-------------------------------------|--|
| Active substance name                 | <input type="text" value="equals"/> | <input type="text" value="paracetamol"/> |
| CAS Number                            | <input type="text"/>                | <input type="text"/>                     |
| CBD (Chemical/Biological Description) | <input type="text"/>                | <input type="text"/>                     |
| EV Code                               | <input type="text"/>                | <input type="text"/>                     |

Displaying 1-1 of 1 matching results.

| MPD Search Results |          |           |             |       |   |
|--------------------|----------|-----------|-------------|-------|---|
| Substance Name ↕   | Source ↕ | CAS No. ↕ | EV Code ↕   | CBD ↕ |   |
| PARACETAMOL        | INN      | 103-90-2  | SUB09611MIG |       |  |

<<< >>>



1º “Search active substance”

Sólo si no se encuentra, emplear “Add active substance”

Contact Us About

Validate Compare Save as XML Switch XML Save PDF Package

D. IMP Identification

?

+ Add IMP

| IMP Details |   |          |            |          |                         |                             |
|-------------|---|----------|------------|----------|-------------------------|-----------------------------|
| IMP         | APIRETAL 500 mg comprimidos bucodispersables /Chewable/dispersible tablet | Edit IMP | Delete IMP | Copy IMP | Search active substance | <b>Add active substance</b> |

Return



Medicamento

Principio activo

-in

### Information

draCT Number

04-000001-22

Sponsor's Protocol  
Identification Number

A-1

NA

Application - AEMPS

Application XML Identifier

### Sections

Sections Index

Section A

Section B

Section C

Section D

## D. IMP Identification



+ Add IMP

### IMP Details

IMP CETROHEMADEXMOS/CTM2010/Powder for oral solution



Edit IMP



Delete IMP



Copy IMP



Search active substance



Add active substance

Active Substance: N/A/celulas pro-ELA/Células troncales hematopoyéticas autólogas adultas

IMP Hormona crecimiento humano/Concentrate for solution for injection



Edit IMP



Delete IMP



Copy IMP



Search active substance



Add active substance

Active Substance: RECOMBINANT HUMAN GROWTH HORMONE/HUMAN GROWTH HORMONE/based on MPD record: SUB20678

Return





# Identificación del placebo



Validate



Compare



Save as XML



Switch XML



Save PDF

## D.8 Placebo Information



[+ Add placebo](#)

| Details                        |   |  |
|--------------------------------|---|--|
| <b>Related IMP(s)</b>          | CETROHEMADEXMOS/CTM2010/Powder for oral solution                                |  |
| <b>Pharmaceutical form</b>     | Oral powder   |  |
| <b>Route of administration</b> | Ocular use  |  |
| <b>Related IMP(s)</b>          | HormonPlus(R)/Hormona crecimiento humano/Concentrate for solution for injection |  |
| <b>Pharmaceutical form</b>     | Solution for injection/infusion   |  |
| <b>Route of administration</b> | Intravenous use   |  |

[Return](#)



## D.8 Information on the Placebo

D.8.3 Pharmaceutical form●

Solution for injection/infusion

D.8.4 Route of administration●

Intravenous use

D.8.5 Which IMP(s) is it a placebo for?

IMP:CETROHEMADXMOS/CTM2010/Powder for oral solution

IMP:HormonPlus(R)/Hormona crecimiento humano/Concentrate for solution for injection

D.8.5.1 Composition, apart from the active substance(s):

D.8.5.2 Is it otherwise identical to the IMP?

Yes  No  Not Answered

D.8.5.2.1 If composition is not otherwise identical, specify the major ingredients

Poner aquí las diferencias

Done



Investigador  
**Nombre:** rellenar en EudraCT  
**Dirección:** rellenar en portal ECM

## G. Clinical Trial Sites/Investigators in the Member State

+ Add Investigator?

Investigator Name

HOSPITAL CENTRAL

Häuse



+ Add Central Technical Facility?

No Central Technical Facilities have been added for this application

+ Add Trial Network?

No Trial Networks have been added for this application

+ Add Sponsor's Subcontractor Facilities?

No Sponsor's Subcontractor Facilities have been added for this application



Return



## Redes del ensayo

### G. Clinical Trial Sites/Investigators in the Member State

+ Add Investigator?

| Investigator Name |       |  |
|-------------------|-------|--|
| HOSPITAL CENTRAL  | Häuse |   |

+ Add Trial Network?

No Trial Networks have been added for this application

+ Add Central Technical Facility?

No Central Technical Facilities have been added for this application

+ Add Sponsor's Subcontractor Facilities?

No Sponsor's Subcontractor Facilities have been added for this application



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Servicios técnicos centrales

## G. Clinical Trial Sites/Investigators in the Member State

+ Add Investigator?

| Investigator Name |       |  |
|-------------------|-------|--|
| HOSPITAL CENTRAL  | Häuse |   |

+ Add Trial Network?

No Trial Networks have been added for this application

+ Add Central Technical Facility?

No Central Technical Facilities have been added for this application

+ Add Sponsor's Subcontractor Facilities?

No Sponsor's Subcontractor Facilities have been added for this application



Return



Tareas subcontratadas

## G. Clinical Trial Sites/Investigators in the Member State

+ Add Investigator?

| Investigator Name |       |  |
|-------------------|-------|--|
| HOSPITAL CENTRAL  | Häuse |   |

+ Add Trial Network?

No Trial Networks have been added for this application

+ Add Central Technical Facility?

No Central Technical Facilities have been added for this application

+ Add Sponsor's Subcontractor Facilities?

No Sponsor's Subcontractor Facilities have been added for this application

Return



## Login

[log-in](#)

## CTA Information

### EudraCT Number

2004-000001-22

### Sponsor's Protocol Code Number

ELA-1

### NCA

Spain - AEMPS

[update XML identifier](#)

## CTA Sections

- [Sections Index](#)
- [Section A](#)
- [Section B](#)
- [Section C](#)
- [Section D](#)
- [Section D.8](#)
- [Section D.9](#)
- [Section E](#)
- [Section F](#)
- [Section G](#)
- [Section H](#)

Validate Compare Save

## H. Competent Authority/Ethics Committee Information



National Competent Authority  
Ethics Committee

H:  
Rellenar datos de  
situación de la  
autorización AEMPS y  
del dictamen del CEIC

En el portal ECM se  
rellenará nombre y  
dirección del CEIC



# Validación

## Application Validation Results

Validation Date and Time: 2011-02-28 13:03:34 GMT

This is the list of inconsistencies found in your application. Please go back and correct the inconsistencies before submission.

Expand All / Collapse All

Expandir

Total: 6 Failed

- ▶ Section D
- ▶ Section D8

▶ PL1

▶ D.8 Information on the Placebo

**FIELD:** D.8 Trial has placebo

**RULE ID:** FEAT6.2.1.28

**DESCRIPTION:** FIELD and if it is "Yes" D.8.5.2.1 should be completed.- D.8.5 Which IMP(s) is it a placebo for? should refer to a valid IMP Name.

▶ Section E

▶ Section G

Informe de validación en PDF

Save As PDF

Return





### CTA Information

#### EudraCT Number

2004-000001-22

#### Sponsor's Protocol Code Number

ELA-1

#### NCA

Spain - AEMPS

#### XML File Identifier

oUx868FX9Lo/mBGRPEmWVyHMr/U=

### D. IMP Identification Index

| TRADE NAME | PRODUCT NAME           | PRODUCT CODE   |
|------------|------------------------|----------------|
|            | <b>CETROHEMADEXMOS</b> | <b>CTM2010</b> |

#### D.1/D.2 IMP Identification and Status Details

| FIELD                  | RULE ID      | DESCRIPTION   |
|------------------------|--------------|---|
| <b>D2.1 IMP has MA</b> | FEAT6.2.2.7a | If 'D.2.1 IMP has MA' is answered "No" the applicant should then go to D.2.3, and need not answer further questions in D.2.1 or D.2.2.          |
| <b>D2.1 IMP has MA</b> | FEAT6.2.2.7c | If D.2.1 is "Not Answered" then D.2.1 subquestions should be blank and the IMP should be defined by completing any of the subquestions of D.2.2 |

| TRADE NAME           | PRODUCT NAME                      | PRODUCT CODE |
|----------------------|-----------------------------------|--------------|
| <b>HormonPlus(R)</b> | <b>Hormona crecimiento humano</b> |              |

#### D.1/D.2 IMP Identification and Status Details

| FIELD                  | RULE ID      | DESCRIPTION   |
|------------------------|--------------|---|
| <b>D2.1 IMP has MA</b> | FEAT6.2.2.7c | If D.2.1 is "Not Answered" then D.2.1 subquestions should be blank and the IMP should be defined by completing any of the subquestions of D.2.2 |

### D8. Placebo Identification Index

| PLACEBO ID |
|------------|
| <b>PL1</b> |

#### D.8 Information on the Placebo

| FIELD                        | RULE ID      | DESCRIPTION  |
|------------------------------|--------------|--|
| <b>D.8 Trial has placebo</b> | FEAT6.2.1.28 | For any placebo, subquestions in D.8 is MANDATORY and should be completed. - D.8.5.2 is a MANDATORY FIELD and if it is "Yes" D.8.5.2.1 should be completed.- D.8.5 Which IMP(s) is it a placebo for? should refer to a valid IMP Name. |

XML File Identifier : oUx868FX9Lo/mBGRPEmWVyHMr/U=



## CONSIDERACIONES sobre EudraCT

**Con carácter general, si EudraCT no indica errores en la solicitud la solicitud será válida en España, teniendo en cuenta que:**

- A.** La autoridad Competente deberá definirse “Spain-AEMPS”
- B.** Sólo se admite UN PROMOTOR
- D.2.1/D.2.2:** Cuando el medicamento no se defina según marca comercial
  - D.2.1 debe marcarse “Sí”, dejar subpreguntas D.2.1.X = “No” e indicar país autorización.
  - D.2.1.2** Si el medicamento está autorizado y registrado en España pero se utiliza el de otro país del EEE, se indicará el medicamento del otro país.
  - D.2.1.2** Si el medicamento está autorizado en la EEE por procedimiento centralizado y está inscrito en España se indicará “España”
- G.1/G.2** Datos investigador: nombre y apellidos, datos contacto, departamento
- H.2** Datos de AEMPS se escriben en EudraCT
- H.2** Datos de dictamen CEIC o autorización AEMPS se escriben en EudraCT



## CONSIDERACIONES sobre EudraCT

# ERRORES CONOCIDOS que se admiten en la solicitud

**D.2.1, D.3.6, D.3.11.4, E.8.2.4, E.8.5, E.8.6,  
E.8.9, F.1.1, G.3 ó G.5**



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European Clinical Trials Database

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ation

**Ayuda sección**

Number  
0001-22

's Protocol  
number

AEMPS  
ML identifier

ions

- ons Index
- on A
- on B
- on C
- on D
- on D.8
- on D.9
- on E
- on F
- on G
- on H

### A. Trial identification

A.1 National Competent Authority

Spain - AEMPS

A.2 EudraCT Number

2004-000001-22

A.3 Full title of the trial

A PHASE I/II CLINICAL TRIAL ON THE USE OF BONE MARROW'S AUTOLOGOUS STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS

English

ENSAYO CLÍNICO EN FASE I/II DE UTILIZACIÓN DE LAS CÉLULAS TRANCALES DE MÉDULA ÓSEA AUTÓLOGAS EN PACIENTES CON ESCLEROSIS LATERAL AMIOTRÓFICA

Spanish

A.3.1 Title of the trial for lay people, in easily understood, i.e. non-technical, language

CLINICAL TRIAL ON THE USE OF BONE MARROW OWN-PATIENT'S STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS

English



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**Validate** **Compare** **Save as XML** **Ayuda campos** **Package**

### A. Trial identification

A.1 National Competent Authority •  ?

A.2 EudraCT Number •  ?

A.3 Full title of the trial •

|   |  |         |
|---|--|---------|
| A.3.1 Title of the trial for lay people, in easily understood, i.e. non-technical, language • | A PHASE I/II CLINICAL TRIAL ON THE USE OF BONE MARROW'S AUTOLOGOUS STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS                 | English |
|   | ENSAYO CLÍNICO EN FASE I/II DE UTILIZACIÓN DE LAS CÉLULAS TRANCALES DE MÉDULA ÓSEA AUTÓLOGAS EN PACIENTES CON ESCLEROSIS LATERAL AMIOTRÓFICA | Spanish |
|   | CLINICAL TRIAL ON THE USE OF BONE MARROW OWN-PATIENT'S STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS                             | English |

*Note: A red box labeled "Ayuda campos" with an arrow points to the help icon next to the National Competent Authority field.*



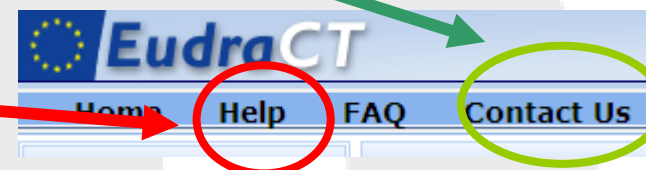
## Contacto

- Incidencias y ayuda EudraCT



[eudract@ema.europa.eu](mailto:eudract@ema.europa.eu) / Menú “Contact Us”

⇒ Ayuda: Menú “Help”



Incidencias técnicas y sugerencias portal ECM:



⇒ [incidensayos@aemps.es](mailto:incidensayos@aemps.es)

- Incidencias con solicitudes ya enviadas al CEIC:

- CEIC de referencia

- Otras preguntas sobre el ensayo:

- Solicitudes a la AEMPS: [aecaem@aemps.es](mailto:aecaem@aemps.es)
- Solicitudes al CEIC: CEIC de referencia