



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^a 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



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 the email address of the recipient(s) of 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

age.

Update Version

Cancel



XML completo y correcto

Campos nuevos:

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

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"





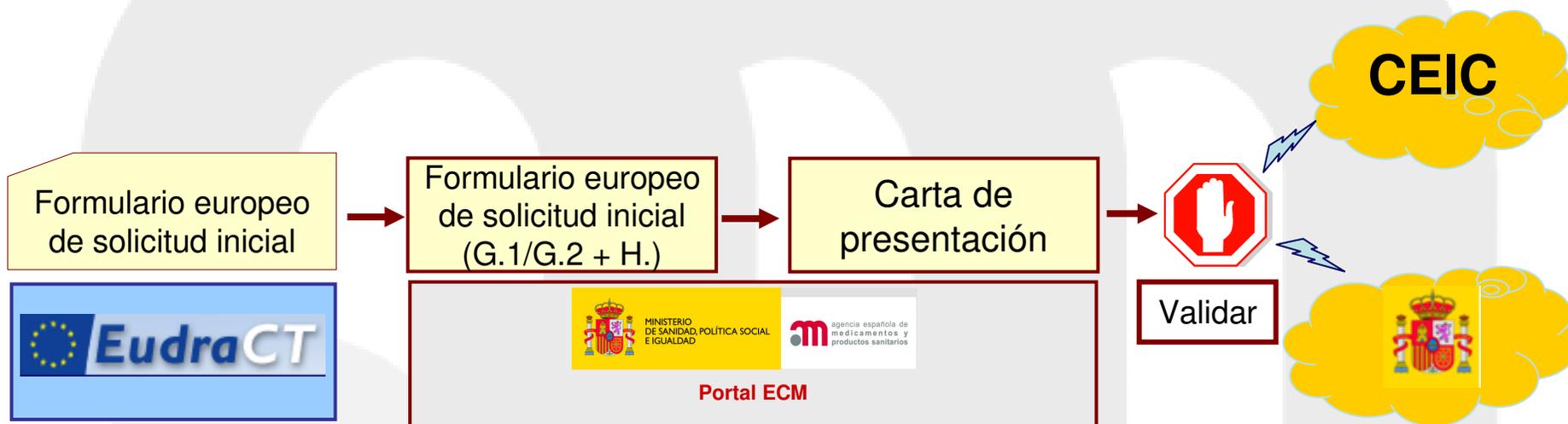
Diccionarios en EudraCT y Portal ECM

- 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

incidensayos@aemps.es



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

The screenshot displays the EudraCT web application interface. At the top left is the EudraCT logo, featuring the European Union flag. Below the logo is a navigation menu with links for Home, Help, FAQ, Contact Us, and About. A 'Login' dropdown menu is open, showing a 'log-in' link. To the right of the login menu are 'Create' and 'Load' buttons. The main content area is titled 'Welcome to EudraCT' and contains the following text: '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 are three types of clinical trials that require a 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 to the EMA. amended : Article 45(1): By 26 January 2008, any paediatric studies authorised in the Community of entry into force, in respect of products authorised in the Community by the marketing authorisation holder for assessment to the EMA. • The clinical trial is one of those for which information has to be submitted to the EMA.'



Obtención nº EudraCT

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, 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 requirements 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 complete the following information:

EudraCT Number:

You need a EudraCT number in order to provide a unique identifier for each clinical trial. That one individual clinical trial should be identified by one of the following:

- There is at least one investigator site in the Community
- The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) (both)

Pedir Nº EudraCT



Rellenar formulario en blanco

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 features a 'Create' button and a 'Load' button. A dropdown menu is open under 'Create', showing 'EudraCT Number' with a sub-menu containing 'Clinical Trial', 'EEA', and '3rd Country'. The 'Clinical Trial' option is selected, and the 'EEA' and '3rd Country' options are checked. Below the menu, there is a 'Welcome to EudraCT' message and a link to 'Help'. The main text explains the need for an EudraCT number and provides a list of conditions for its use, including references to Article 45(1) and Article 46(1) of the EU Clinical Trials Directive.

EudraCT

Home Help FAQ Contact Us About

Login

log-in

Create Load

EudraCT Number

Clinical Trial

EEA

3rd Country

Welcome to EudraCT

For further assistance on use of the system and completion of the form, refer to 'Help'

EudraCT Number:

You need a EudraCT number in order to provide a unique reference for clinical trials in 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) (it may be either a PIP or a PIP and a PIP).
- The clinical trial is one of those for which information has to be submitted in accordance with Article 45(1) of the Directive:

Article 45(1): *By 26 January 2008, any paediatric studies already completed or in progress, in respect of products authorised in the Community and for which a marketing authorisation holder has submitted an application for assessment to the competent authority, shall be submitted to the competent authority within a period of 18 months from the date of entry into force of this Directive.*

- The clinical trial is one of those for which information has to be submitted in accordance with Article 46(1) of the Directive:

Article 46(1): *Any other marketing authorisation holder-sponsored studies, whether or not they are conducted in compliance with an agreed paediatric investigation plan, shall be submitted to the competent authority within a period of 18 months from the date of entry into force of this Directive.*

The EudraCT Number must be included on all Clinical Trial applications within the Community (e.g. SUSAR reports, PIP).



Cargar formulario

The screenshot shows the EudraCT website interface. At the top left is the EudraCT logo. Below it is a navigation bar with links: Home, Help, FAQ, Contact Us, and About. On the left side, there is a 'Login' button with a dropdown menu containing 'log-in'. In the main content area, there are two buttons: 'Create' and 'Load'. The 'Load' button is highlighted, and a dropdown menu is open below it, showing 'Clinical Trial' with a right-pointing arrow. Under 'Clinical Trial', there are two options: 'EEA' and '3rd Country', both with checkboxes. Below the buttons, the text reads 'Welcome to EudraCT'. This is followed by a paragraph: 'For further assistance on use of the system and completion of the form, refer to...'. Then, 'EudraCT Number:' is displayed. Below that, another paragraph states: 'You need a EudraCT number in order to provide a unique reference for clinical trials that one individual clinical trial should be identified by one unique EudraCT number'. A bulleted list follows, detailing requirements for clinical trials. The first three items are: 'There is at least one investigator site in the Community.', 'The clinical trial is contained in an agreed Paediatric Investigation Plan (PIP) (both).', and 'The clinical trial is one of those for which information has to be submitted in amended form:'. The last item is: 'The clinical trial is one of those for which information has to be submitted in amended form:'. Under the last item, there are two sub-points: 'Article 45(1): By 26 January 2008, any paediatric studies already covered by the marketing authorisation holder for assessment to the competent authority...' and 'Article 46(1): Any other marketing authorisation holder-sponsored studies for the use in the paediatric population of a medicinal product covered by the marketing authorisation, whether or not they are conducted in compliance with a paediatric investigation plan, shall be submitted to the competent authority with amended information.'



The screenshot shows the EudraCT web application interface. At the top left is the EudraCT logo. Below it is a navigation menu with 'Home', 'Help', 'FAQ', 'Contact Us', and 'About'. On the left side, there is a 'Login' section with a 'log-in' link. The main content area has a 'Load' button with a green upload icon. Below the 'Load' button, the text reads 'Load an XML file for an EEA Clinical Trial Application'. A large red callout box with rounded corners contains the text 'Buscar y seleccionar XML' in red. A red arrow points from this box to a '+ Add...' button located at the top of a large empty text input field. Below the input field, the text 'File path of locally saved XML file to load' is visible. 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 lists various 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
- XML File Identifier**: oUx868FX9Lo/mBGRPEmW Vy#Mr/U=

The 'CTA Sections' section 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 arrow points from a red-bordered box containing the text 'Identificación del ensayo' to the 'CTA Information' section in the sidebar.



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, there 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 'XML File Identifier' is highlighted in a red box, and a red arrow points to it from a larger red box containing the text 'Identificador del XML'. The XML File Identifier is: oUx868FX9Lo/mBGRPEmW Vy#Mr/U=

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

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 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 'CTA Information' section with details such as EudraCT Number (2004-000001-22), Sponsor's Protocol Code Number (ELA-1), NCA (Spain - AEMPS), and XML File Identifier. Below this is a 'CTA Sections' menu with a list of sections from A to H. A red box highlights the 'Clinical Trial Application Menu' and the 'CTA Sections' menu. A red arrow points from the text box below to the 'Clinical Trial Application Menu' box, and another red arrow points from the text box to the 'CTA Sections' 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

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 the text 'European Clinical'. A secondary navigation bar contains several function buttons: 'Validate', 'Compare', 'Save as XML', 'Switch XML', and 'Save PDF'. These buttons are highlighted with a red rectangular box. Below the navigation bar is the 'Clinical Trial Application Menu', which lists various 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. An orange arrow points from a red-bordered box labeled 'Botones de función' to the 'Switch XML' button. On the left side of the interface, there is a sidebar with sections for 'Login', 'CTA Information', and 'CTA Sections'. The 'CTA Information' section displays details such as 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 a hierarchy of sections from A to H.



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



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 and 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.

IMP Details	
IMP	No IMP name was specified

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	<input type="text"/>	<input type="text"/>
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"/>

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	Add active substance

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		
Related IMP(s)	CETROHEMADEXMOS/CTM2010/Powder for oral solution	
Pharmaceutical form	Oral powder	
Route of administration	Ocular use	
Related IMP(s)	HormonPlus(R)/Hormona crecimiento humano/Concentrate for solution for injection	
Pharmaceutical form	Solution for injection/infusion	
Route of administration	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:CETROHEMADEXMOS/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

Return



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



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CTA Information

EudraCT Number

2004-000001-22

Sponsor's Protocol Code Number

ELA-1

NCA

Spain - AEMPS

[update XML identifier](#)

CTA Sections

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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
	CETROHEMADEXMOS	CTM2010

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

FIELD	RULE ID	DESCRIPTION
D2.1 IMP has MA	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.
D2.1 IMP has MA	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
HormonPlus(R)	Hormona crecimiento humano	

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

FIELD	RULE ID	DESCRIPTION
D2.1 IMP has MA	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
PL1

D.8 Information on the Placebo

FIELD	RULE ID	DESCRIPTION
D.8 Trial has placebo	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

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- 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

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

English

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



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A. Trial identification

A.1 National Competent Authority • ?

A.2 EudraCT Number • ?

A.3 Full title of the trial •

<input type="text" value="A PHASE I/II CLINICAL TRIAL ON THE USE OF BONE MARROW'S AUTOLOGOUS STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS"/>	<input type="text" value="English"/> +
<input type="text" value="ENSAYO CLÍNICO EN FASE I/II DE UTILIZACIÓN DE LAS CÉLULAS TRANCALES DE MÉDULA ÓSEA AUTÓLOGAS EN PACIENTES CON ESCLEROSIS LATERAL AMIOTRÓFICA"/>	<input type="text" value="Spanish"/> ✖
<input type="text" value="CLINICAL TRIAL ON THE USE OF BONE MARROW OWN-PATIENT'S STEM CELLS IN PATIENTS WITH AMYOTROPHIC LATERAL SCLEROSIS"/>	<input type="text" value="English"/> +

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

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



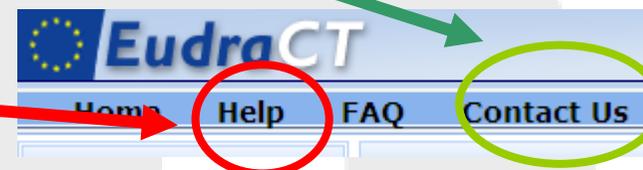
Contacto

- Incidencias y ayuda EudraCT



eudract@ema.europa.eu / Menú “Contact Us”

⇒ Ayuda: Menú “Help”



Incidencias técnicas y sugerencias portal ECM:



⇒ 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
- Solicitudes al CEIC: CEIC de referencia