

**AEMPS**  
**Agencia Española de  
Medicamentos  
y Productos Sanitarios**

[www.aemps.gob.es](http://www.aemps.gob.es)

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**AGENCIA ESPAÑOLA DE  
MEDICAMENTOS Y  
PRODUCTOS SANITARIOS**

**THE SUPPORT OFFICE FOR  
INDEPENDENT CLINICAL  
RESEARCH**

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The screenshot shows the AEMPS website's navigation bar with links for the Government of Spain, Ministry of Health, Social Services and Equality, and the agency's logo. The main menu includes 'La AEMPS', 'Medicamentos de uso humano', 'Medicamentos veterinarios', 'Productos sanitarios', 'Cosméticos e higiene', and 'Industria'. The 'Investigación clínica con medicamentos' section is highlighted. Sub-links include 'Investigación clínica con medicamentos', 'Investigación clínica con productos sanitarios', 'Enlaces de interés', 'Terapias avanzadas', 'Ayudas a la Investigación', and 'Notas informativas'. A sidebar on the right shows a researcher in a lab coat. A large hand cursor is pointing at the 'Última actualización: 07/06/2011' link.



**La Oficina de Apoyo a la Investigación Clínica Independiente (The Support Office for Independent Clinical Research)** is the contact point in the AEMPS so that, whenever needed, **investigators and non-commercial sponsors** can receive advice regarding technical, regulatory or administrative aspects.

The **access point** to submit queries to the Support Office is via the query form, accessible on the following website:  
[http://www.aemps.gob.es/investigacionClinica/medicamentos/form\\_consInvClinica.htm](http://www.aemps.gob.es/investigacionClinica/medicamentos/form_consInvClinica.htm)



A screenshot of a website page titled 'Oficina de Apoyo a la Investigación Clínica Independiente'. The page includes a sidebar with links to 'Portada', 'Investigación clínica con medicamentos', 'Investigación clínica con productos sanitarios', 'Enlaces de interés', 'Terapias avanzadas', 'Ayudas a la Investigación', and 'Notas informativas'. The main content area contains a heading, several links (e.g., 'Formulario para efectuar su consulta', 'Formulario de asesoramiento sobre la consideración de si un producto es medicamento de terapia avanzada'), and a paragraph about the office's role in providing advice to investigators and promoters. At the bottom, there is a note about the regulation of clinical trials under Real Decreto 223/2004.

**Queries relating to** the following issues can be raised:

- **Categorisation** of whether a study is a **clinical trial with medicinal products** or not.
- **Administrative requirements** necessary to carry out a clinical trial with medicinal products.

- **Documentation** needed for the **request of authorisation of a clinical trial**.
- **Online submission** of clinical trial requests.
- **Notification of the serious unexpected adverse reactions** occurring during the trial.
- **Notifications of amendments** to the **protocol** once the trial has started.
- **Manufacturing or packaging** of an **investigational medicinal product**, including placebos (e.g. re-encapsulation), for the trial.
- Compliance with **Good Clinical Practice** guidelines.
- **Advice regarding** research and regulation of **advanced therapy medicinal products** (both for commercial and non-commercial sponsors).

The demand that the **Support Office** is experiencing confirms how useful this initiative is to promote independent research in Spain, and it is in accordance with the European policies to encourage non-commercial research.

