

AEMPS
Agencia Española de
Medicamentos
y Productos Sanitarios

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AGENCIA ESPAÑOLA DE
MEDICAMENTOS Y
PRODUCTOS SANITARIOS

THE SUPPORT OFFICE FOR
INDEPENDENT CLINICAL
RESEARCH

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MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

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



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.

