National procedures that must be followed for the conduct of clinical trials with medicinal products that contain or consist of GMOs

# FRANCE (February 2023)

## OVERVIEW OF NATIONAL REQUIREMENTS

**Summary:**
The GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs can be regulated under the contained use and/or the deliberate release frameworks. A decision is taken case-by-case.

The Promotor of the clinical trial should submit the dossier to the ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé) for the classification and the conditions of contained use of the GMO. The ANSM gives an opinion on the type of contained use regarding administration and it also states whether this research presents a risk of deliberate release of GMO into the environment. If the ANSM has any doubts about the level of containment required or about the existence of a risk of deliberate release, the ANSM can request an opinion from the GMO contained use expert Committee (CEUCO) under the remit of the Ministry of Research (Ministère de l'Enseignement supérieur et de la Recherche - MESR).

When a risk of deliberate release is identified by the ANSM, the Promotor should submit the dossier to the Ministry of Environment (Ministère de la Transition Ecologique - MTE) for the deliberate release assessment.

The applications to seek authorization under the clinical trials framework and under the GMO framework are not linked; both applications can be submitted in parallel.

The Manufacturer of the medicinal product should submit the dossier to the Ministry of Research (Ministère de l'Enseignement supérieur et de la Recherche - MESR) for the agreement/authorization of the manufacturing site.

**Additional information can be found at:**
https://ansm.sante.fr/vos-demarches/industriel/demander-une-autorisation-pour-un-essai-clinique-pour-des-medicaments-categorie-1

https://www.enseignementsup-recherche.gouv.fr/fr/les-utilisations-confinees-d-ogm-86419

## APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:

For the administration sites:
https://ansm.sante.fr/vos-demarches/industriel/medicaments-composes-dogm-declarations-dutilisation-confinee-ou-demande-dautorisation-de-dissemination-volontaire

For the manufacturing site:
https://duo.adc.education.fr/duo/connexion.jsp

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**Language requirements:**
Applications can be submitted in English.

## PUBLIC CONSULTATION

There is a public consultation on GMO aspects prior to granting deliberate release authorization for a period of 15 to 30 days.

## NATIONAL AUTHORITIES INVOLVED

**Authorisation of clinical trials:**

- **Agence Nationale de Sécurité du Médicament et des produits de Santé (ANSM)**

  Contact details: 143/147 bld Anatole France 93285 Saint Denis CEDEX
  http://www.ansm.sante.fr
  https://euclinicaltrials.eu/home

**Authorisation of GMO aspects:**

- **Agence Nationale de Sécurité du Médicament et des produits de Santé (ANSM)**
  Competent authority under the contained use framework for administration sites

  Contact details: Email: innovation@ansm.sante.fr
  http://www.ansm.sante.fr

- **Ministère de l'Enseignement supérieur et de la Recherche (MESR):**
  Competent authority under the contained use framework for manufacturing sites

  Contact details: Email: ogm.confine@recherche.gouv.fr
  http://www.enseignementsup-recherche.gouv.fr/

- **Ministère de la Transition Ecologique (MTE):** Competent authority under the deliberate release framework.

  Contact details: Email: biotech@developpement-durable.gouv.fr
  https://www.ecologique-solidaire.gouv.fr/