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

GERMANY (April 2021)

OVERVIEW OF NATIONAL REQUIREMENTS

Summary:
Clinical trials with medicinal products for human use containing or consisting of GMOs are regulated under the deliberate release framework- Part B of Directive 2001/18.

A single submission procedure applies to seek authorization under the clinical trials framework and under the GMO framework (submission to PEI).

Additional information can be found at:
https://www.pei.de/EN/regulation/clinical-trials/gmo/clinical-trial-gmo-node.html

APPLICATION FORMS TO SEEK AUTHORISATION FOR THE GMO ASPECTS

Application forms can be found at:
https://www.pei.de/EN/regulation/clinical-trials/gmo/clinical-trial-gmo-node.html

Language requirements:
Applications can be submitted in English.

PUBLIC CONSULTATION

Publication on the JRC website after the clinical trial has been authorised.

NATIONAL AUTHORITIES INVOLVED

Authorization of clinical trials:

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- **Paul-Ehrlich-Institut**[1] ("PEI"). PEI is responsible for the assessment and approval of the Clinical Trial Applications; a release permission is included in the authorisation of the clinical trial.

  Contact details: Clinical trial section, Paul-Ehrlich-Str. 51-59, D-63225 Langen.
  Email: ct@pei.de
  www.pei.de

Authorisation of GMO aspects:

- **Federal Office of Consumer Protection and Food Safety** (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) (BVL). BVL is involved in an internal process without involvement of the applicant.

  Contact details: Mauerstraße 39-42, 10117 Berlin
  www.bvl.bund.de

[1] In some cases the BfArM might be the responsible Competent Authority – the procedures and relevant requirements remain unchanged. Contact information: ct@bfarm.de