

Application and Approval Pathways:

Clinical Trial Application (CTA):

- Sponsor submits the application dossier via the single Clinical Trials Information System (CTIS) which is an online portal for clinical trial applications
- **The dossier consists of two parts:**
 - **Part I:** Scientific, technical aspects (e.g. protocol, investigator brochure, Investigational Medicinal Product dossier)
 - **Part II:** National, ethical, site-specific aspects (e.g. informed consent, investigator suitability, insurance)The application is submitted once all the documents are uploaded via CTIS
- The initial assessment of a CTA typically takes around 45 days, with a further 30 days for potential additional information requests and responses
- National competent authorities within the EU Member States are responsible for the assessment and authorization of CTAs

Marketing Authorization Application (MAA):

- The MAA is submitted online to EMA using the e-Submission Gateway / Web Client in the eCTD (electronic Common Technical Document) format
- Before submission: Applicant must submit an eligibility request (to check if the product qualifies for the centralized procedure) and notify EMA of the intention to submit the MAA (often around 7 months in advance)
- Dossier includes quality, non-clinical and clinical data demonstrating the safety, efficacy, and quality of the medicinal product

Application and Approval Pathways:

Marketing Authorization Application (MAA):

- Scientific evaluation is conducted by the Committee for Medicinal Products for Human Use (CHMP)
- The standard timeline for assessment is 210 active days
- After EMA's scientific committee (e.g., CHMP) issues an opinion, the decision is made by the European Commission, which results in a marketing authorization valid across the EU

The working language of the European Medicines Agency (EMA) is English and all initial applications for Clinical Trial Authorisation (CTA) and Marketing Authorisation Application (MAA) must be submitted in English. However, translations into all official EU languages (plus Icelandic and Norwegian) are required at later stages of the MAA procedure

Inspection:

The purpose of EMA inspection is to ensure trials are ethical, safe, and scientifically sound. Inspections are conducted at Clinical trial sites, sponsors, CROs, and labs involved in EU-authorized trials. EMA coordinates inspections with national GCP inspectors across EU member states

When are inspections done?

- During review of a Marketing Authorisation Application (MAA)
- If concerns arise about data or trial conduct
- As part of routine checks or follow-up actions

Inspection:

What is checked?

Informed consent procedures, Data accuracy and integrity, Protocol compliance, Investigator qualifications, Record keeping and reporting

Findings are reported to EMA's Committee for Medicinal Products for Human Use (CHMP), which uses them to support regulatory decisions

For more information on EMA inspection procedures click here: [Good clinical practice \(GCP\) inspection procedures | European Medicines Agency \(EMA\)](#)