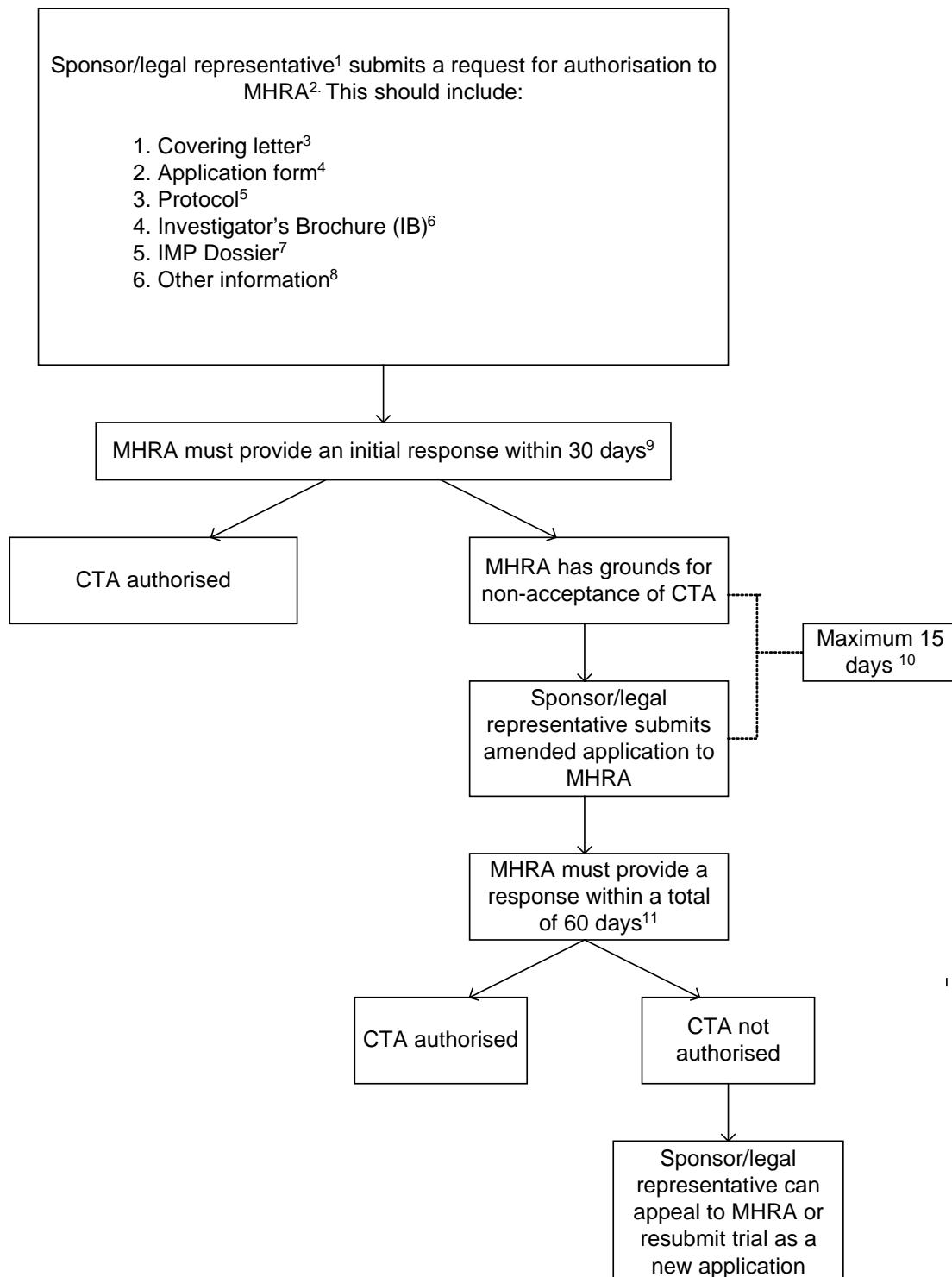


# Application to MHRA for Clinical Trial Authorisation (CTA)



## Footnotes for flow chart

### Footnote 1

- If the applicant is not the Sponsor<sup>1</sup>, a letter of authorisation enabling the applicant to act on behalf of the Sponsor

### Footnote 2

- For multi-state trials, an application to the competent authority in each Member State (MS) is required.
- Some MS require the application in the local language.\*

\* Emea will be providing local language documents in the next version of EudraCT

### Footnote 3

- A covering letter should be submitted by the Sponsor<sup>1</sup> or someone acting on behalf of the Sponsor<sup>1</sup> with the following:
  - EudraCT number (in the heading)
  - Trial protocol number (in the heading)
  - Title of trial (in the heading)
  - Details of any special issues, such as special trial populations, unusual IMPs, unusual trial designs

### Footnote 4

- The application form is available on the [EudraCT database](#). From this web site, Create New Clinical Trial Application. The information added on the EudraCT database will populate the CTA form where appropriate.
- Detailed guidance on the European clinical trials database and the CTA application can be found on the [EMEA web site](#).
- The application form should be printed, signed and dated by the Sponsor<sup>1</sup> or someone acting on behalf of the Sponsor<sup>1</sup>
- [Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use](#) is available.

### Footnote 5

- Each trial requires a protocol **LINK TO INFORMATION REQUIRED IN TRIAL PROTOCOL – DOCUMENT 2**
- MHRA will not review the protocol and make comments, and only require the protocol for their records

### Footnote 6

- An Investigator's Brochure should only be included if one is available for the trial. It is not necessary to develop one specifically for the CTA submission. Link to CPMP/ICH/135/95, for content of IB. (see <http://www.emea.eu.int/pdfs/human/ich/013595en.pdf> section 7 for further details)

**Footnote 7**

- Applicant can cross-refer to IB for pre-clinical and clinical parts of the IMPD, if available.
- What type of IMPD should be submitted?

**Full IMPD**

- for IMPs without a marketing authorisation in any Member State, or
- for IMPs where the MHRA has not granted a CTA previously, or
- for IMPs where relevant information from another Sponsor’s application for the same product cannot be cross-referred

**Simplified IMPD**

- for IMPs that have been assessed previously as part of a marketing authorisation in any Member State or as a CTA to the MHRA
- guidance on the types of previous assessment is provided in the table below
- may require a letter of authorisation to cross-refer to the data submitted by another applicant

**Summary of Product Characteristics**

- for marketed products, the current version of the SmPC can be submitted instead of the simplified IMPD

- What information should be provided?

Full IMPD - present data in tabular form: summaries of information related to the quality, manufacture and control of the IMP, non-clinical and clinical data

Simplified IMPD - guidance on the categories of information required is provided in the table below

	QUALITY DATA	NON CLINICAL DATA	CLINICAL DATA
The IMP has a MA in any EU Member State and is used in the trial:			
- Within the conditions of the SmPC	SmPC	SmPC	SmPC
- Outside the conditions of the SmPC	SmPC	YES (if appropriate)	YES (if appropriate)
o With a change to the drug substance manufacture or manufacturer	S+P+A	SmPC*	SmPC
o After it has been blinded	P+A	SmPC	SmPC
Another pharmaceutical form or strength of the IMP has a MA in any EU Member State and:	P+A	YES	YES
- the IMP is supplied by the MAH			
The IMP has no MA in any EU Member State but drug substance is authorised in a MS and:			

- is supplied from the same manufacturer	P+A	YES	YES
- is supplied from another manufacturer	S+P+A	YES	YES
The IMP has a previous CTA in the Member State(s) concerned#:			
- no new data available since CTA	NO	NO	NO
- new data available since CTA	NEW DATA	NEW DATA	NEW DATA

S: Drug substance data; P: Drug product data; A: appendices of the IMPD; SmPC: summary of product characteristics; MAH: Marketing Authorisation Holder

\* Where the change to drug substance manufacture produces a new potentially toxic substance such as a new impurity or degradation product or introduces a new material in the production of a biological product, additional non-clinical information may be required.

# This may require a letter of authorisation to cross-refer to the data submitted by another

**Footnote 8**

- Other information required = list of competent authorities to which the same application has been submitted, with details of their decisions and a copy of the opinion of the ethics committee concerned when available.
- Examples of labels for trial supplies must be submitted to the MHRA.

**Footnote 9**

- The 30 day period starts at the date of the receipt of the application by MHRA.

**Footnote 10**

- The 15 days is from the date of the receipt of MHRA's grounds for not accepting the CTA.

**Footnote 11**

- MHRA must provide a response within a total of 60 days from the receipt of the original application.
- Note that the timeframe is 90 days for trials involving medicinal products for gene therapy and somatic cell therapy, including xenogeneic cell therapy, or medicinal products containing genetically modified organisms.