

# Protocol Amendments: MHRA Submission

- MHRA must provide authorisation for amendments to documents that they received in the CTA application and originally authorised.
- MHRA only need to be informed of amendments to documents that they are not required to authorise.
- A covering letter should be submitted by 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)
  - Amendment number (in the heading)
  - Reasons for the amendment, in one or two sentences
  - Brief description of the change(s) included in the amendment
  - Name of the documents that are modified
  - Reason for qualification as 'substantial'
  - Draw attention to any special issues related to the amendment and indicate where the relevant information or text is in the original application
- A CT Amendment Form should be submitted. The form is available at  
Emea: <https://eudract.emea.eu.int/eudract/index.do>,  
COREC: <http://www.corec.org.uk/applicants/apply/amendments.htm>  
R&D: <http://www.rdforum.nhs.uk/workgroups/ethics/Flowcharts%20230404.pdf>
- An extract of the modified documents, where applicable, showing the previous and new wording, where applicable should be included.
- The new version of modified documents, where applicable, identified with an updated number of the version and date should be included.
- Supporting information including:
  - Summaries of data, if applicable
  - An updated overall risk benefit assessment, where applicable
  - Possible consequences for subjects already included in the trial
  - Possible consequences for the evaluation of the results.