Initial MHRA Submission Guidance

MHRA Submission for CTIMP's

The MHRA submission can only be made once:

- The CTO, the R&D Research Governance Manager and the relevant pharmacy department have reviewed all submission documentation and have confirmed they are satisfied with the content (and that all changes have been made where required)
- The CTO authorises the CTA for signature by the CI by email or telephone

Before making the submission the CI or delegate should read the guidance provided by the MHRA by following this link: http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/Whattosend/index.htm

The MHRA Submission is made by the CTO via an online portal called CESP (Common European Submission Portal) for which each sponsor is provided with a single login.

When preparing the documents for the MHRA submission the CI or delegate should ensure:

- A detailed signed covering letter is submitted with all other documentation. This must include:
  - Trial details including the EudraCT number and trial title
  - A list of all submission documentation with versions and dates
  - A list of files included in the submission for documents which are not relevant to the application
  - Contact details of the person submitting the application
  - Identification of the reference safety information as described in SOP061.
- The covering letter must also identify any additional information about the trial which could be important to the MHRA submission. The following may also have to be included, if applicable to the trial:
  - Any information regarding drug manufacture or supply where this is not standard should be detailed. For eg. unmatched placebos or IMP coming through a 3rd country for shipment purposes
  - Whether the trial involves vulnerable populations
  - Who is responsible for producing and submitting the DSUR and when the submission will be made if it has been agreed that this is not the responsibility of the Trust and/or University as Sponsor
  - If scientific advice has been sought from the EMA or competent authority

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  - For TYPE A TRIALS details of the risk adaptations that have been made within the trial and protocol.
- A PDF file is provided for all submission documentation listed on the MHRA website. This should include files for documents listed by the MHRA which might not be applicable for a trial. These files should include a brief explanation why the document has not been supplied, for example 'The IMPD/Simplified IMPD is not required for this submission for *Insert Trial Title* (*Insert EudraCT No.*)'
- All submission documents are saved as individual PDF files in the same folder to avoid sending an incomplete application
- All files are given a simple, relevant title. Guidance is provided on the MHRA website
- The folder should be then zipped in order to make the submission via CESP
- The CTO will print a copy of all submission documentation and file it in the Sponsor File. Both CESP e-mails should also be printed off and filed in the same folder as the submission, they are responding to.
- The CTO should also e-mail a copy of the MHRA submission and the CESP e-mails to the CTC/Point of Contact for filing in the TMF

MHRA Validation

- The CTA will be validated on receipt and an acknowledgement letter will be sent to the CI and the CCTU
- If the application is valid then the initial assessment period of 30 days will begin. This starts from the date of receipt of a valid application
- If the application is not valid then the person named in C1 of the application will be emailed a letter from the MHRA confirming the reasons for this