Common errors seen at validation

Failure to supply an XML file of the completed clinical trial application form:
The XML file of the completed clinical trial application form information is required to enable us to enter the details of the trial into the EudraCT website, as we are obliged to do by the Clinical Trials Directive 2001/20/EC.

Failure to complete section C1 of the clinical trial application form or section D1 of the notification of amendment form
Section C1 of the clinical trial application form and D1 of the notification of amendment form provide information on the person authorised by the sponsor to correspond with the MHRA on behalf of the sponsor. We need this information in order to be able to communicate with you.

Failure to provide PDF documents for the protocol, investigator's brochure, investigational medicinal product dossier (IMPD) and summary of product characteristics (SPC) (where appropriate) that have undergone optical character recognition (OCR)
PDF documents of the protocol, investigator's brochure, IMPD and SPC (where appropriate) should be created directly from Word or undergo Adobe Acrobat optical character recognition (OCR) at the time of creation. PDF document scanned images should not be provided as it is not possible to cut-and-paste data in this format. The OCR layer also supports text searching within the document and across the entire MHRA document store. For further information on OCR files and how to make them, please see Guidance on Text Searchable Documents for MHRA Submission (19Kb)

Failure to provide proof of payment
Applicants are required to pay for the assessment of their clinical trial application prior to submission. Proof of payment should be provided with the application.

Failure to provide the correct product name in section D.3.1 of the application form
The product name provided in section D.3.1 of the application form should be the trade name for the product or the name routinely used by the sponsor to identify the IMP in the clinical trial documentation (protocol, IB….). It is not the mechanism of action or class of the product.

Password protection on disks
We ask that you do not password protect documents or discs as we may not have the software to access your data even if you supply the password. We need this information in order to be able to process and assess your application.