Checklist for submitting Clinical Investigation notification

Before submitting your notification, you must make sure you have included all information listed below.

We will only accept notifications that:

- include all of the relevant documents listed below
- are submitted on CD, with all documents labelled as separate attachments
- have attachments labelled on the CD in a way that reflects their content
    - e.g. clinical investigation plan, essential requirements checklist, instructions for use
- have all attachments in English
    - any other language must be translated and included with the original version as a separate document
- include only attachments that are searchable
    - do not include pdfs of scanned documents

Documents to include

Cover Letter As a minimum, your cover letter should include the following information.	
an explanation of the purpose of the clinical investigation	
confirmation of whether the same device has been the subject of previous notifications to MHRA	
MHRA reference numbers for any previous notifications	
confirmation of whether any subsequent modifications have been made to the device or whether the device remains unchanged from the previous notifications	

Notification Forms Please print, sign and scan these forms and include them on the CDs. We recommend you also send an additional version of the PCA forms with no signature (i.e. a pdf version that has not been scanned).	
PCA1 form	
PCA2 form	
Sterilisation annex	
Supporting documents	
details of who to invoice • full company name, address and registered tax/VAT number	
clinical investigation plan	
investigator's brochure	
patient information	
patient Consent	
CVs for UK clinical investigators	
detailed information on the device and its accessories (if any) • intended purpose, drawings etc.	
essential requirements checklist	
risk analysis	
instructions for use	
device labels	
summary of all bench testing and pre-clinical testing conducted	
summary of all clinical experience with the device to date	

end of study reports for any concluded clinical investigations that involved the same medical device under investigation	
list of standards met	
sterilisation validation report (where relevant)	
software information (where relevant) • pg 26-27 guidance for manufacturers	
biological safety assessments of patient contacting materials (where relevant) • biological safety assessment guidance	
information on animal tissues (where relevant) • Appendix 2 guidance for manufacturers	
Information on any medicine or human blood derivative incorporated into the device • Appendix 5 guidance for manufacturers	
research ethics committee opinion (if available)	