Find tehcnical File requirements

Project	Lu_Topol
Completed	open
Deadline	
Priority	High

MHRA Guidance on legislation Clinical investigations of medical devices 7/16 IRAS Form and supporting documentation required MHRA Devices submission checklist on IRAS

The Checklist tab on IRAS contains a list of all documents that should be included in the submission to MHRA:

Title	Column 1	Column 2
Item	**Document description**	**Staff**
Covering letter on headed paper	To be created	LC
Clinical investigation plan	TO be created	LC+TK
Investigator’s brochure	To be created	LC+TK
Participant consent form	To be create – need examples for this, maybe ask kitec	LC+TK
CVs for UK clinical investigators	CV’s for LU and TK	LC+TK
Device details	Short description - QMS Known Anomalies Use Cases User Settings Software requirements	LC

Aa Title	Column 1	Column 2
Essential requirements checklist / General Safety and Performance	System requirements specification + Software Requirements specification	LC
Participant information sheet	Information sheet	LC+TK
Requirements checklist	QMS Requirements SYstem requirement specification developed with clinician	
Risk analysis	Hazard Log + CRMF + CRMR Need a Clinical Safety officier with CRM training and certification. Risk assessment needs to inform the requirements specification. David Stell - risk assesssment for clinical devices - get certification.	LC +HS

Title	Column 1	Column 2
Instructions for use of a medical device	Instruction for use: 13.6.Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I[F1.] [F2If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;] (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	LC

Aa Title	Column 1	Column 2
Device labels	As per MDR 2002 – directive 93/42 EEC: the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;] (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;] (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (f) ~~[F1where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;]~~ (g) ~~if the device is custom-made, the words 'custom-made device';~~ (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization[F3;] (n) ~~[F4in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.]~~	LC
Summary of all bench testing and pre-clinical testing conducted	Bench testing: Verification and validation documents Preclinical testing: This study's results!!	LC
Summary of all clinical experience with the device to date	Local clinical investigations	LC

Aa Title	Column 1	Column 2
End of study reports for any concluded clinical investigations that involved the same medical device under investigation	None - gathering this evidence still	
List of standards met	Software we not built under QMS Need Hardware Validation form for Camera Need	
Sterilisation validation report (where relevant)	None	
Software information (where relevant)	Short description	
Biological safety assessments of patient contacting materials (where relevant)Information on animal tissues (where relevant) Information on any medicine or human blood derivative, or non-viable human tissues and cells incorporated into the device	None – no patient contact with materials	
Research ethics committee opinion (if available)	Local ethics approval	