Medical Devices - UNITED KINGDOM

Competent authority

Contact Details	**Contact Name 1** Medicines and Healthcare products Regulatory Agency MHRA **Phone** +44 (0) 20 3080 6000 **Fax** +44 (0)020 3118 9803 **Email General** info@mhra.gsi.gov.uk **Address** 151 Buckingham Palace Road, Victoria **ZIP/City** London SW1W 9SZ **Country** United Kingdom (UK) **Web address** https://www.gov.uk/topic/medicines-medical-devices-blood/clinical-trials-investigations
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) **CA - Submission for authorisation mandatory for** MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA (MHRA) **CE-marked MD used within label are exempted from any notification obligation to CA** Yes **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** – **Entitled to study submission** –

	Prerequisites for submission –
Submission Format	**Format option(s)** Online portal **Preferred format** – **Online portal** Integrated research application system (IRAS)
Language of Submission	**Language(s) of application** English **Preferred language of application** – **English accepted** – **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** The fee depends on the class of your device. The figure in brackets is the fee for re-notification in the event of an objection: - Class I, IIa, or IIb other than implantable or long-term invasive: £3,820 (£2,920) - Class IIb implantable or long-term invasive, Class III, and active implantable: £5,040 (£3,570) - Device which incorporates a known medicinal substance from a source previously used in medicinal products or in medical devices where the MHRA has previously been consulted: £4,136 - Device which incorporates a known medicinal substance from a new source: £9,640 - Device incorporating a new active substance: £42,296 **Official guidance on required fees** The "Statutory guidance: Current MHRA fees" is available on the MHRA website
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit **Timespan counted from** Date of receipt of valid application

Ethics committee

Ethical Review – General	**Submission for Ethical review mandatory for** All clinical investigations of MD (falling within the scope of the Medical Devices Directive) **Submission to CA and EC to be performed in the following order** – **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s)

National legislation

Investigations on Medical Devices	**Applicable national regulations** Transposition of EU Directives on MD **Act on Medical Devices (or comparable national legal framework)** 1. The Medical Devices Regulations 2002 2. The Medical Devices (Amendment) Regulations 2012 have been published and came into force on 1 July 2012. These Regulations have the principal purpose of amending the Medical Devices Regulations 2002 to implement Directive 2011/100/EU such that variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation are added to List A of Annex II of Directive 98/79/EC on in-vitro diagnostic medical devices. The Regulations also make some other minor changes to the Medical Devices Regulations 2002, but these do not have any practical effect. **Additional Information** In addition to the UK regulations, internationally accepted documents and guidelines e.g. the Declaration of Helsinki and ISO 1415:2011 should be adhered to in order to guarantee a high standard of quality. (please note: Version 1996 of Decl.of Helsinki is most in line with UK regulations) ISO 14155 is a European standard which regulates the organisation, documentation etc. of clinical trials for medical devices. This document is available for a fee via the ISO-website (ISO 14155:2011).