

A Template for Class III Active Implantable Device Research in the UK

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Supplemental Q&A Box – a parent’s perspective of device trials for children

1. **What was your motivation for choosing for your child to take part in a medical device trial? (a little background about your child, as well as clinical need)**

My child was diagnosed with epilepsy in March 2014 with multiple seizure types, often hundreds a day and without a seizure free day since. We tried all available medication and ketogenic diet but none reduced seizures. Due to seizures becoming life threatening, new options needed to be explored and this led us to the CADET study

2. **Did you have any concerns or worries about your child receiving a new medical device?**

Being the first to have the device was always going to be a learning experience, and as a parent any operation on your child is concerning, however we were very much part of the whole team and decision making process. At no time did we feel lacking in knowledge or information and were always very much involved at every stage allowing any concerns to be acknowledged and resolved quickly.

3. **What advice do you have for clinicians, scientists, engineers and all those developing new medical devices for children?**

My advice to the whole team, would be to keep the transparency and communication open and honest. Listen to the parents, they really are the experts on their child, and can often give you insight into potential difficulties you may not have considered, only improving overall success.

4. **What advice do you have for parents/carers who are considering taking part in a device trial for their children?**

To other parents considering a device trial, "no question is a silly question ". Ask everything you need to know and ask again if you need to. Trust your team! They really are there with you and want this to be a success as much as you do. Talk to them, communicate with them. And, lastly, be brave!

Document / Requirement	US – IDE (FDA)	UK – MHRA Clinical Investigation (UK MDR 2002)
Device Description	Required – description, system diagrams, and functions per IDE investigational plan.	Required – device description including components, diagrams, and intended function per UK MDR 2002. For NI, EU MDR applies.
Risk Management File	Required – risk analysis & mitigations per ANSI/AAMI/ISO 14971:2019 (FDA-recognized).	Required – risk management per EN ISO 14971:2012 (UK Designated Standard), mapped to the UK MDR 2002 Essential Requirements (Annex I as modified by Schedule 2A), or ISO 14971:2019 (NI under EU MDR).
Design History File (DHF)	Required internally — 21 CFR 820.30 design controls; summarize key outputs in IDE.	Internal requirement; key outputs submitted (e.g. design dossier); QMS evidence per EN ISO 13485:2016 and EN ISO 13485:2016/AC:2016 (UK Designated Standards).
Bench/Preclinical Testing Summary	Required – mechanical, electrical, software, AIMD and MRI safety, and biocompatibility (see rows below).	Required – mechanical, electrical, software and biocompatibility evidence aligned to UK Designated Standards (examples for AIMD/DBS systems: EN 60601-1:2006 + AC:2010 + A1:2013; EN 60601-2-10:2000 + A1:2001 (nerve & muscle stimulators) where applicable; EN 62304:2006 + AC:2008 (software); EN ISO 10993 series (biocompatibility)).
Software Documentation (if applicable)	Required – per FDA 2023 final guidance; Documentation Level = Basic/Enhanced (no longer LoC). Software lifecycle per AAMI/IEC 62304:2006 + A1:2015/2016 (FDA-recognized).	Required – per EN 62304:2006 and EN 62304:2006/AC:2008 (UK Designated Standards); includes classification, architecture, verification.
Sterilization & Packaging Validation	Required – e.g., EO: ISO 11135:2014/A1:2018; Radiation: ISO 11137-1:2006+A1:2013+A2:2018, 11137-2:2013+Amd1:2022, 11137-3:2017; Packaging: ISO 11607-1:2019, -2:2019 (FDA-recognized).	Required – validated processes aligned to UK Designated Standards, e.g., EN ISO 11135-1:2007 (EtO), EN ISO 11137-1:2015 + A2:2019 and -2:2015 (radiation), and EN ISO 11607-1:2009 / -2:2006 (sterile barrier systems and process validation).
Electrical Safety/EMC Testing	Required – typically IEC 60601-1 Ed 3.2 (2020) and IEC 60601-1-2 Ed 4.1 (2020) (FDA-recognized).	Required – per applicable UK Designated Standards: EN 60601-1:2006 + AC:2010 + A1:2013; relevant particular standards (e.g., EN 60601-2-10 for nerve/muscle stimulators) as appropriate.
Biocompatibility Testing	Required – per ISO 10993-1:2018 with chemical characterization 10993-18:2020, sample prep 10993-12:2021, irritation 10993-23:2021, etc. (FDA-recognized).	Required – per EN ISO 10993 series (e.g., EN ISO 10993-1:2009 + AC:2010; other parts as applicable to materials and duration).

Document / Requirement	US – IDE (FDA)	UK – MHRA Clinical Investigation (UK MDR 2002)
Clinical Evaluation/Justification	Required – scientific rationale, prior investigations, and risk analysis within the investigational plan.	Required – clinical evaluation supporting the CIP under UK MDR 2002 (derived from Annex X of the pre-MDR directives, as modified by Schedule 2A). CIP design is expected to follow ISO 14155:2020 (good practice), while the designated GB edition is EN ISO 14155:2011.
Informed Consent & Subject Materials	Required – per 21 CFR 50 & 56.	Required – REC/HRA aligned consent and subject materials; ethics and methodology rules per UK MDR 2002 and UK GCP.
Labeling / Instructions for Use (IFU)	Required – draft labeling for investigators/subjects; include §812.5 ‘CAUTION—Investigational device...’ statement.	Required – draft IFU and patient materials. Investigational devices must be labelled “exclusively for clinical investigation”; no UKCA/CE/CE-UKNI marks on investigational devices.
Manufacturing Process Description	Required – summary of key manufacturing steps and quality controls under 21 CFR 820 (moving to QMSR in 2026).	Required – general manufacturing overview per UK MDR 2002 Annex II; demonstrate QMS control (EN ISO 13485:2016).
**Essential Requirements Checklist / GSPRs	Not applicable — FDA does not use ER or GSPR checklists	Mandatory – Essential Requirements (ER) checklist aligned with Annex I of UK MDR 2002 (as amended by Schedule 2A); GSPRs not applicable.
Declaration of Conformity	Not required at IDE stage.	Not applicable for investigational devices — instead, sponsor statement provided.
UDI / Traceability Plan	Not required for IDE — investigational devices are exempted from UDI under 21 CFR 801.30(a)(6) (investigational status labeling per §812.5 still applies).	UDI is not mandatory in GB (as of 2025). For NI, EU MDR applies; however, UDI does not apply to investigational devices—maintain a robust traceability plan instead.

Table 1: comparison of the requirements for a US-based Investigational Trial Exemption and a UK-based Clinical Investigation for a class 3 active implantable device.