Guidance on Clinical Evaluation of Medical Devices and Clinical Performance of *In Vitro* Diagnostic Medical Devices

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1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 Devices in Great Britain are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which requirements were derived from the EU directives listed below:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD);
- Directive 93/42/EEC on medical devices (EU MDD);
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD).

Please note: the EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) and EU *in vitro* Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) have come to force and implemented in the EU Member States and North Ireland from May 2021 and May 2022, respectively. For trials intending to have sites in EU Member States and North Ireland an EU Representative will be required (see MHRA guidance for Northern Ireland implementation of EU MDR and EU IVDR).

1.3 Other harmonised and international standards are also applicable to perform clinical investigations and manufacture Medical Devices:

- ISO 13485 Medical devices – Quality management systems: Requirements for regulatory purposes;
- ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice;
- ISO 14971 Medical devices – application of risk management to medical devices;
- ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice.

1.4 Several guidance documents are available to provide support on the application of the regulations by manufactures, investigators and notified bodies. These can range from the classification of devices to commercialisation and placement on the market:

- MEDDEV 2.4/1 Classification of medical devices;
- MEDDEV 2.7/1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC;
- MEDDEV 2.14/1 Guidance document - In Vitro Diagnostic Medical Devices - Borderline and Classification Issues. A Guide for Manufacturers and Notified Bodies.

1.5 According to the Regulations a medical device means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

1.6 According to the Regulations an *in vitro* diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood

and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

1.7 A clinical investigation is a clinical study that trials a device in or on a person. A study that validates an *in vitro* diagnostic for medical use is a performance evaluation (*see guidance* How to comply with the legal requirements in Great Britain).

1.8 Clinical evaluation of Medical Devices (CIMD) or Performance Evaluation of *in vitro* diagnostic devices conducted in Northern Ireland must meet the requirements of the EU MDR and be submitted to MHRA in accordance with those regulations (*see overview* MHRA legal compliance guidance).

1.9 In order to apply the UKCA/CE/CE UKNI marking (*see guidance* UKCA mark), it is necessary for the manufacturer of the device to provide clinical data to back up any clinical and performance claims made. Compliance with the essential requirements in Part II and Part III of UK MDR 2002, Annex I modified by Schedule 2A of UK MDR 2002 or Annex I of EU MDR is required. Thus, an evaluation will be required to:

- Verify that under normal conditions of use the performance characteristics of the device are those intended;
- Determine any undesirable side-effects and to assess whether these are acceptable risks when weighed against the intended performance of the device.

1.10 A clinical evaluation is defined in MEDDEV 2.7/1 as a 'methodologically sound ongoing procedure to collect, appraise and analyse clinical data pertaining to a medical device and to analyse whether there is sufficient clinical evidence to confirm compliance with

relevant essential requirements for safety and performance when using the device according to the manufacturer's instructions for use'.

1.11 There is no requirement to perform a clinical evaluation for *in vitro* diagnostic devices but instead conduct a performance evaluation of the device. According to the regulation of *In Vitro* Diagnostic Medical Devices in Great Britain (January 2021) a device for performance evaluation means a 'device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses, or in other appropriate environments outside their own premises. These are used alongside established methods of diagnosis to make sure the results provided by the test say with regards to sensitivity and specificity are appropriate in terms of clinical need'.

Please note: instruments, apparatus, appliances, materials or other articles which are intended to be used for research purposes without any medical objective are not regarded as devices for performance evaluation.

1.12 Devices for performance evaluation are not subject to the normal conformity assessment procedures, but manufacturers must draw up the statement of conformity (Part IV of the UK MDR 2002, Annex VIII [as modified by Part III of Schedule 2A to the UK MDR 2002]) and the devices must be registered with the MHRA (see *guidance* *In vitro* diagnostic medical devices: guidance on legislation).

Please note: a notification to the MHRA will not be required for medical devices that are UKCA/CE/CE UKNI marked for the purpose that is under investigation.

1.13 An application to the MHRA will need to be submitted at least 60 days before the evaluation is due to begin. It may only then proceed after MHRA no grounds for objection are raised (*see guidance* Notify MHRA about a clinical investigation for a medical device).

Please note: under the UK MDR 2002 and EU MDR, a clinical investigation may not proceed if grounds for objection have been raised by the MHRA, even if approval has been granted by a Research Ethics Committee.

Please note: For all performance evaluation studies a Declaration for Performance Evaluation – to UK MDR 2002 Regulation 43 Statement, Annex VIII of Directive 98/79/EC, or Part A of Annex XIII of EU regulation 2017/746 is required. Furthermore,

these will be need to be registered for performance evaluation in the MHRA DORS portal (*see guidance* MHRA Registration).

Please note: Some changes to the clinical investigation plan might not be possible without submitting a new clinical investigation/performance application, as per provision 56(3) of UK MDR 2002:

- a change to the number of patients or devices forming the basis of the proposed trial;
- a change or extension in the indications for use of the device or to the purpose or objectives of the trial;
- a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible;
- a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.

1.14 Standalone software and apps that meet the definition of a medical device are still required to be UKCA marked in order to ensure they are regulated and acceptably safe to use and also perform in the way the manufacturer or developer intends them to (please see section 3.2 Software as Medical Device).

Please note: MHRA provided guidance on what a software application medical device is and how to comply with the legal requirements, Medical devices: software applications).

2 Scope

2.1 This guidance applies to Investigators designing and participating in studies sponsored by NHSL and/or UoE. This guidance also applies to ACCORD staff assisting researchers with the development of study-related documentation and monitoring completion of study documents.

3 Guideline

3.1 Study Set Up: Documents Required

3.1.1 Investigators planning to undertake a Clinical Investigation of a medical Device (CIMD) or Clinical Performance of an IVD should design their Clinical Investigation Plan (CIP) or Clinical Performance Study Protocol (CPSP) in accordance with ISO 14155 and ISO 20916, respectively. If an Investigator does not have access to ISO 14155 and/or ISO

20916, the Investigator should contact ACCORD to discuss access (enquiries@accord.scot).

3.1.2 The documents required for a clinical investigation/performance and its risk assessment are detailed in the checklist document GS002-WI01.

3.1.3 The study must be described in a clear and detailed plan according with the principles of GCP. It will describe the objective(s), design, methodology, statistical considerations and organisation of a study and be carefully designed to safeguard the health and safety of the participants, as well as answer specific research questions.

3.1.4 Investigators must create a study plan based on the CIP/CPSP template provided (CR007-T23 Medical Device Study Protocol Template) and removing or adding "N/A" to sections that are not applicable.

3.1.5 The plan and amendments will be signed by the Sponsor Representative(s) and the CI to denote agreement to conduct the study according to it. Furthermore, if there is a study statistician(s), the lead statistician, or designee, will sign the plan to verify that the statistical plan and statistical rationale for the study are correct. Similarly, the plan and amendments will be signed by PIs at Investigator Sites. A fully signed plan should be retained in the TMF and/or Sponsor File.

3.1.6 The study documents for the clinical investigation or performance should contain all the information required by MHRA (*see guidance* Clinical investigations of medical devices – compiling a submission to MHRA) and the minimum information should comprise:

3.1.7 Details of the nature of the study will be described to potential participants, in lay language, via a Participant Information Sheet (PIS). Informed consent from study participants will be captured in an informed consent form (CF).

3.1.7.1 Investigators must create the consent form and the Patient Information Sheet based on one of the templates provided (CR007-T03 to CR007-T05).

3.1.7.2 Investigators must create supporting documentation including classification (see section 3.2 and section 7 below; for IVD Borderline devices consult MEDDEV 2.14/1) and risk mitigation, e.g., Investigator Brochure, Risk Management, Labels and Instructions for Use (IFU).

3.1.8 The medical device Investigator Brochure (similar to an Investigator Brochure in a Clinical Trial of an Investigational Medicinal Product) will contain a general description, drawings and ingredients and/or components/accessories of the device and a summary of all bench testing and pre-clinical testing. It should detail the intended purpose and classification, manufacturer information and compliance with manufacturing standards (e.g., ISO 9001 and ISO 13485) as well as the storage/shelf-life and handling instructions (see template CR007-T24 Medical Device Study Investigator Brochure Template).

Please note: if required, a pre-qualification/facility audit will be conducted by ACCORD to ensure compliance of the Quality Management System as well as any other assessments requested during Combined Risk Assessment.

3.1.9 The Essential Requirements/General Safety and Performance Requirements Checklist should detail how the requirements established in Annex I (EU MDD or IVDD) have been addressed, including references to designated or harmonised standards as appropriate.

3.1.9.1 It should also include evidence of how applicable standards have been met and any referenced supporting documents.

3.1.10 Investigators must consider the following principles when implementing the Risk Management listed below (preferably to ISO 14971):

- Eliminate or reduce risks as far as possible (inherently safe design and construction);
- Where appropriate, take adequate protection measures in relation to risks that cannot be eliminated;
- Inform users of the residual risks due to any shortcomings of the protection measures adopted.

3.1.11 The Label(s) must contain the following information listed below:

- Name or trade name and address of the manufacturer;
- Name of device and the contents of the packaging;
- The word 'STERILE' (or symbol) and method of sterilization, if applicable;
- The batch code, preceded by the word 'LOT' (or symbol);
- The expiry date, expressed as the YYYY-MM-DD;
- The words 'for clinical performance only' (IVD) or 'exclusively for clinical investigation' (MD);
- Statement or symbol indicating the in vitro use of the device, if applicable;
- Any storage conditions and shelf-life and/or handling conditions;
- If intended for self-testing, that fact must be clearly stated.

Please note: devices intended for clinical investigation should not bear the UKCA/CE/CE UKNI marking in the labelling (e.g., outer packaging, device label or Instructions for Use).

3.1.12 The Instruction for Use (IFU) is required to describe and contain any essential information on setup of the device/equipment for use with a participant including any required pre-use checks. It must contain the following information listed below:

- Name or trade name and address of the manufacturer;
- Name of device and the contents of the packaging;
- The word 'STERILE' (or symbol), if applicable;
- The words 'for clinical performance only' (IVD) or 'exclusively for clinical investigation' (MD);
- Statement or symbol indicating the in vitro use of the device, if applicable;
- Any storage conditions and shelf-life and/or handling conditions;
- Any appropriate warnings and/or precautions to take;
- Date of issue or latest revision of the IFU;
- Detailed list of symbols used in device labelling;
- If intended for self-testing, that fact must be clearly stated *note;
- Indication of any special equipment required including information necessary for the identification of that special equipment for proper use;
- Type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;
- Detailed description of the procedure to be followed in using the device;
- Any information on the principle of the method, specific analytical performance characteristics, limitations of the method and information about the use of

available reference measurement procedures and materials by the user and the indication whether any particular training is required;

- Measures to be taken in the event of changes in the analytical performance of the device;
- If device used in combination with or 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 and proper combination;
- 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 device operates properly and safely; information about safe waste disposal;
- Instructions in the event of damage to the protective packaging and details of appropriate methods of re-sterilisation or decontamination, if applicable;
- If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and re-sterilisation or decontamination, and any restriction on the number of reuses;
- Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources;
- Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature.

*Note: further requirements described in paragraph B 8.7(t) (Annex I of Directive 98/79/EC on *in vitro* diagnostic medical devices).

3.1.13 The investigator team and/or an external manufacturer should provide a technical file for UKCA/CE/CE UKNI devices that should contain all the information available about the device, e.g., Instructions for Use, preclinical testing, sterilisation, biological safety, manufacturing processes, packaging validation, risk management and regulatory compliance, among others.

Please note: NHS Lothian Medical Physics and other applicable supporting departments, e.g., Infection Control, should be contacted at early stages to ensure appropriate oversight and timely approval of the technical documentation and device(s) before investigation start.

3.1.14 The MHRA will need to be notified when the evaluation ends as per Regulations 16(11) and 29(10) of the UK MDR 2002 (Article 77 of EU MDR). A copy of the final clinical investigation/performance report will be sent to MHRA within 1 year of the end of the evaluation.

Please note: MHRA will need to be notified if early termination occurs. Justification and a copy of the final written report of the evaluation will need to be provided.

3.1.15 All serious adverse events occurring in all participating centres of the evaluation will need to be recorded and reported to the MHRA (*please consult* MEDDEV 2.7/3). A 'serious adverse event' is one which:

a) led to death;
b) led to serious deterioration in the health of the subject, that either resulted in;
   1) a life-threatening illness or injury, or;
   2) a permanent impairment of a body structure or a body function, or
   3) in-patient or prolonged hospitalization, or;
   4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
c) led to fetal distress, fetal death or a congenital abnormality or birth defect.

Please note: If hospitalisation was planned for a pre-existing condition, or a procedure required by the plan, without serious deterioration in health, is not considered a serious adverse event.

3.2 Software as Medical Device (SaMD)

3.2.1 Software as medical device is defined as software intended to be used for one or more medical purposes that perform those purposes without being part of a hardware medical device (*for classification and qualification of standalone software please consult* MEDDEV 2.1/6).

3.2.2 There are different medical software types:

- Part of a medical device or in vitro diagnostics device;
- Accessories 1;
- Standalone software 2;
- Not a medical device.

Please note: [1] Accessory means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device falling under that device regulations. [2] Standalone software means software which is not incorporated in a medical device at the time of its placing on the market or making it available.

3.2.3 Standalone software must have a medical purpose to be a medical device (*please consult Appendix 1 and* MHRA guidance on crafting an intended purpose for Software as a Medical Device).

3.2.4 Standalone software can qualify as medical device when directly controls an apparatus (e.g., radiotherapy treatment), can provide immediate decision triggering information (e.g., blood glucose meters), or can provide support for healthcare professionals (e.g., ECG interpretation). Additionally, MHRA has released guidance on qualification and classification of digital mental health technology, i.e. software products and related hardware that aim to support mental health and wellbeing. These devices can be considered SaMD depending on the intended purpose and functionality. To assess this please review the guidance document available here.

Please note: If the software does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression (i.e., using a compression procedure that allows the exact reconstruction of the original data), or does not benefit individual patients (e.g., aggregate population data, medical atlases or software for epidemiologic studies or registers) it is not a medical device.

Please note: Altering the representation of data for embellishment purposes does not make the software a medical device. However, where the software alters the representation of data for a medical purpose, it could be a medical device.
Similarly, software which is intended to create or modify medical information might be qualified as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals when reviewing medical information, (e.g., when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy) the software could be a medical device.

3.2.5 Standalone software can qualify as *in vitro* medical device when intended to be used for the purpose of providing information derived from *in vitro* examination of a specimen derived from the human body.

Please note: If the standalone software is intended specifically by its manufacturer to be used together with an IVD medical device to enable that device to be used in accordance with its intended purpose, the standalone software shall be treated as an IVD device in its own right, e.g., analysis and interpretation of the optical density delivered by an ELISA reader, line or spot pattern of a blot.

Please note: If the information provided by the software is based on data obtained from medical devices only, the software would be a medical device. However, standalone software that only collects results obtained from one or several IVD devices (directly and/or manually), and transmits without modification this information to a centralised database (e.g., Laboratory Information Management System, LIMS) or to healthcare providers is not an IVD medical device.

Please note: Standalone software (e.g., LIMS) managing the feedback to an IVD (e.g., retesting of samples) based on collected IVD results is not an IVD medical device. Software intended to modify the representation of available IVD, e.g., basic operations of arithmetic (e.g., mean, conversion of units) and/or plotting of results in function of time, and/or a comparison of the result to the limits of acceptance set by the user results is not considered as an IVD medical device.

3.2.6 In line with these, MHRA has provided guidance documents on what a software application medical device is and how to comply with the legal requirements (*please consult* Medical devices: software applications).

3.3 AI

3.3.1 Artificial Intelligence (AI) is the use of digital technology to create systems capable of performing tasks commonly thought to require human intelligence.

3.3.2 ACCORD has an outline document with the applicable regulations and other information on the use of AI for healthcare settings, available on the ACCORD website here

4 References and Related Documents

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD);
- Directive 93/42/EEC on medical devices (EU MDD);
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD);
- EU Medical Devices Regulation (Regulation 2017/745) (EU MDR);
- EU in vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR);
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended);
- MEDDEV 2.1/6 Guidelines on the Qualification and Classification of Stand-Alone Software used in Healthcare within the Regulatory Framework of Medical Devices;
- MEDDEV 2.7/1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC;
- MEDDEV 2.14/1 Guidance document - In Vitro Diagnostic Medical Devices - Borderline and Classification Issues. A Guide for Manufacturers and Notified Bodies;
- ISO 9001:2015 Quality management systems — Requirements;
- ISO 13485 Medical devices – Quality management systems: Requirements for regulatory purposes;
- ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice;
- ISO 14971 Medical devices – application of risk management to medical devices;
- ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice;
- CR007-T23 Medical Device Study Protocol Template;
- CR007-T24 Medical Device Study Investigator Brochure Template;
- CR007-T03 PIS & CF Template;
- CR007-T04 PIS & CF AWI Template;
- CR007-T05 PIS & CF Recovered Capacity Template;
- GS002-WI01 Essential Document Checklist

5 Further Guidance Documents

- MEDDEV 2.4/1 Classification of Medical Devices
- Borderlines between medical devices and medicinal products in Great Britain
- Summary of requirements for Class 1 Medical Devices
- MHRA's clinical investigations of medical devices – guidance for investigators
- MHRA's clinical investigations of medical devices – guidance for manufacturers
- Borderline products: how to tell if your product is a medical device and which risk class applies
- Clinical investigations of medical devices – biological safety assessment
- Clinical investigations of medical devices – statistical considerations

6 Document History

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7 Approvals

Sign	Date
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8 APPENDIX 1: Software as Medical Device flow chart

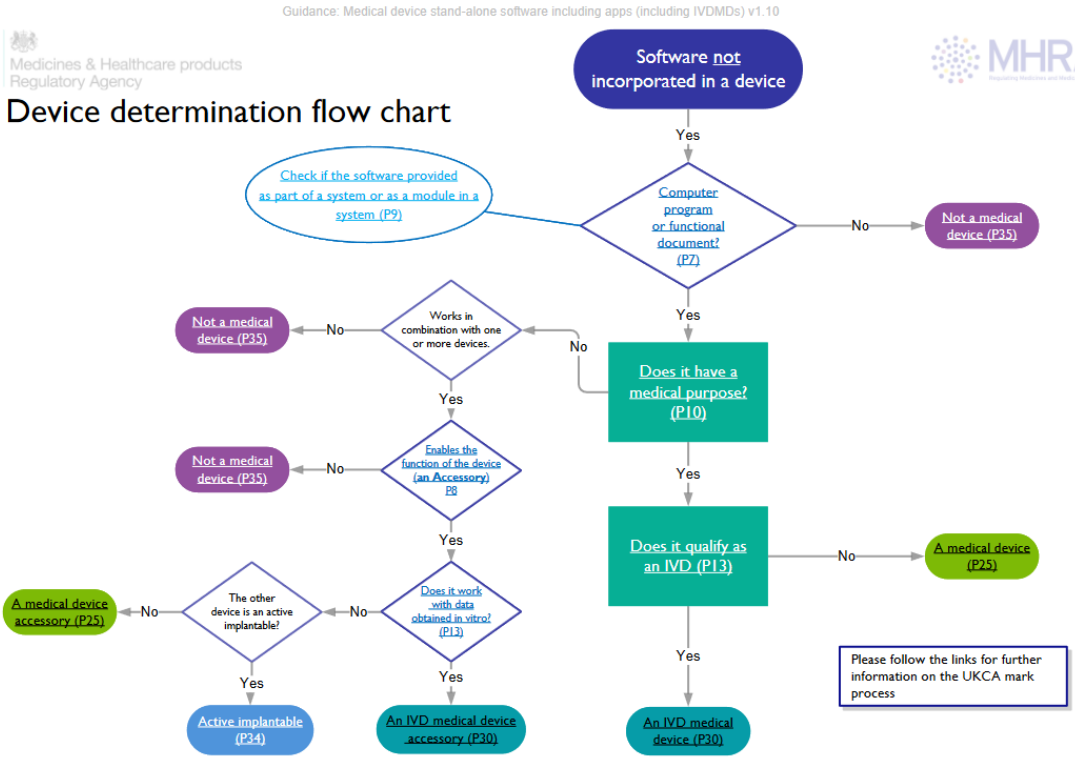

Figure 1. Interactive SaMD decision flow chart can be consulted here.

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