**Grant or Investigator Initiated Study with a medical device – Checklist**

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| **Applicant:** |  |
| **R&I Study reference**: |  |
| Study Title: |  |
| **Date of multi-functional Team Meeting:** |  |
| **Attendees at meeting:** |  |

**Section A: Types of device to be used within the study**

1. What types of medical device are to be used in the study? (Yes/No – delete as appropriate)
2. Standalone software Yes/No
3. General medical devices Yes/No
4. Implantable medical devices Yes/No
5. In vitro diagnostic devices Yes/No

If Y to a) alone complete Section B and D only

If Y to b), c) or d) complete Section C and D only

Where there are multiple categories, complete all relevant sections.

**Section B: Software defined as a medical device**

1. Details of any medical device standalone software and apps

*Complete one row per device*

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| --- | --- | --- | --- | --- |
| **Name of Device** | **Manufacturer** | **UKCA/CE marked?**  Y/N | **If yes – is it being used for intended purpose?** | **Device classification** (Class I, IIa, IIb, III) |
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1. Medical purpose of any software/apps

**Example medical purposes:**

Disease prevention; disease diagnosis; monitoring of disease, alerting patients that action is require. May include in vitro measurement of physiological or pathological state; safety; monitoring therapeutic measures

**Example non-medical purposes:**

Education; monitoring fitness/well-being without providing advice; storing or transmitting medical data without change; administrative for e.g. appointment booking; digitization of a paper service

*Complete one row per device*

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| **Device** | **Describe medical purpose** | **Describe non-medical purpose** |
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1. What impact does the software/ app have on patient care?

*Complete one row per device - Y/ N*

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| **Device** | **Does it impact on patient care?** | **Does a clinician make final decision?** | **Does output of device contribute to clinician’s decision?** |
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1. a. Does the Manufacturer intend to use the results for research purposes only? i.e. they DO NOT intend to market the product at this stage. This means that the manufacturer cannot use the data to support an application for UKCA/CE marking at any point in the future.

*Complete one row per device*

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| **Device** | **Manufacturer** | **Research use only (Y/N)** |
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b. If research only, will the model(s) be published on GitHub? Y/N

1. Is the manufacturer involved in the trial i.e. are they providing funding or medical devices for use in the study? Y/N

If Yes, describe their input below

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1. Is there to be a transfer of data between the manufacturer and the Sponsor/Data centre?

If Yes, describe the nature of the data transferred below

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1. Is a Clinical Investigation of Medical Device (CIMD) required?
   1. A UKCA/CE marked device used within its intended purpose does not require a CIMD
   2. A UKCA/CE marked device used off label **requires** a CIMD
   3. A non-UK/CE marked device used for a non-medical purpose does not require a CIMD
   4. A non-UKCA/CE marked device that has no impact on patient care (eg data used in silico; appraisal of existing clinical literature) does not require a CIMD
   5. A non-UKCA/CE marked device that surfaces existing data or information to support a clinician does not require a CIMD
   6. A non-UKCA/CE marked device that directly impacts on patient care **requires** a CIMD eg uses an algorithm to diagnose or predict prognosis or interpret raw data
   7. A non-UKCA/CE marked device that is not intended for market and is for research use only should not require a CIMD but advice from MHRA should be sought
   8. A non-UKCA/CE marked device that is not intended for market and is for research use may require a CIMD where the manufacturer is involved in the trial financially or where a transfer of data is taking place advice from MHRA should be sought  
      1. A device manufactured using the in house exemption does not require a CIMD if used within the Health Board manufacturing the device
      2. A device manufactured using the in house exemption **requires** a CIMD if tested within a different Health Board from that manufacturing the device

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| **Device** | **CIMD required?** Y/N | **Category (7.1 – 7.9) may be >1 category** |
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**Section C: General medical devices, implantable medical devices, and in vitro diagnostic devices only**

1. Details of any medical devices

There are 3 main categories of medical devices and these may also include software as an accessory i.e. software that controls a medical device.

* general medical devices
* active implantable medical devices
* in vitro diagnostic medical devices (IVDs)

*Complete one row per device – NB some devices will have multiple components*

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| --- | --- | --- | --- | --- |
| **Type of Device**  (from categories above) | **Manufacturer** | **UKCA/CE marked?**  Y/N | **If yes – is it being used for intended purpose?** | **Device classification**  Class I, IIa, IIb, III  Class A, B, C or D for IVDs  General, self-test, List A or List B for IVDs |
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1. Medical purpose of the device

**Example medical purposes:**

Diagnosis, prevention, monitoring, treatment or alleviation of disease; Diagnosis, monitoring, treatment, alleviation of or compensation for an injury/ handicap; Investigation, replacement or modification of the anatomy or of a physiological process; Control of conception

**Example purposes not attributed to medical devices:**

Pharmacological, immunological or metabolic means although it can be assisted by these. Some devices may be combination of a device and a drug.

*Complete one row per device*

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| **Device** | **Describe medical purpose** | **Describe any additional purpose** |
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1. Is the device active?

An active medical device requires a source of energy

*Complete one row per device*

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| **Device** | **Does it require a source of energy? (Y/N)** |
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1. Does the Manufacturer NOT intend to market the product i.e. the results are for research use only? This means that the manufacturer cannot use the data to support an application for UKCA/CE marking at any point in the future.

*Complete one row per device*

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| --- | --- | --- |
| **Device** | **Manufacturer** | **Research use only (Y/N)** |
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1. Is the manufacturer involved in the trial i.e. are they providing funding or medical devices for use in the study? If Y, please describe their input into the trial in box below

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1. Is there to be a transfer of data between the manufacturer and the Sponsor/Data centre?

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1. For in vitro diagnostic devices only: Is the diagnostic test being used within a clinical trial within a validated diagnostic laboratory i.e. NHS lab? Y/N
2. Is a Clinical Investigation of Medical Device (CIMD) required?
   1. A UKCA/CE marked device used within its intended purpose does not require a CIMD
   2. A UKCA/CE marked device used off label **requires** a CIMD
   3. A non-UKCA/CE marked device that is not intended for market and is for research use only should not require a CIMD but advice from MHRA should be sought
   4. A non-UKCA/CE marked device that directly impacts on patient care **requires** a CIMD
   5. A non-UKCA/CE marked device that is not intended for market and is for research use may require a CIMD where the manufacturer is involved in the trial financially or where a transfer of date is taking place advice from MHRA should be sought
   6. A non-UKCA/CE marked in vitro diagnostic device, or a non-UKCA/CE marked IVD used outside its intended purpose, utilised as part of a clinical trial where that test is administered within a validated laboratory does not require a CIMD
      1. A device manufactured using the in house exemption does not require a CIMD if tested within the Health Board manufacturing the device
      2. A device manufactured using the in house exemption **requires** a CIMD if tested within a different Health Board from that manufacturing the device

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| **Device** | **CIMD required?** Y/N | **Category (8.1 – 8.7)** |
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**Section D: Required for all categories of medical device**

1. Will the study be considered a feasibility CIMD on IRAS? Y/N
2. Will the study be considered a pivotal CIMD on IRAS? Y/N
3. Is the CTU providing statistical support? Y/N
4. How is study data being collected? Please confirm Y/N in table below

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| **Study data collected by** | **Yes/No** |
| eCRF designed by CTU |  |
| CASTOR |  |
| RedCAP |  |
| Paper CRF and routinely collected data through SafeHaven |  |
| Other |  |

1. Summary of considerations for grant or project costing:-

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Once completed and agreed, this checklist will be saved in PDF and signatures added using adobe ‘fill and sign’.

**Signatures**

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| --- | --- | --- | --- |
| **Applicants full name** | **Job Title** | **Signed** | **Dated** |
|  |  |  |  |
| **Manufacturer’s Representative – full name** | **Job title** | **Signed** | **Dated** |
|  |  |  |  |
| **NHS GG&C Innovation Team member – full name** | **Job title** | **Signed** | **Dated** |
|  |  |  |  |