UNIVERSITY OF LEICESTER

# Monitoring Strategy Table

## 1. CTIMP Trials

| Risk Level^ | Examples of Types of Clinical Trials | Minimum Monitoring[$] | Minimum SDV |
|---|---|---|---|
| **Type A:**<br>No higher than that of standard medical care | Trials involving medicinal products licenced in the EU member state if:<br>• They relate to the licensed range of indications dosage and form<br><br>Or they involve off-label use (such as in paediatrics and in oncology etc.) if this off label use is established practice and supported by sufficient published evidence and/or guidelines.<br><br>e.g. Phase 4 studies | • SIV<br>• Trial specific Interim Monitoring visits after first 3 patients recruited<br>• Close Out | 100% consent<br>100% SAE reporting<br>20% eligibility*<br>20% SDV on primary endpoints* |
| **Type B:**<br>Somewhat higher than that of standard medical care | Trials involving medicinal products licensed in any EU member state if:<br>• Such products are used for a new indication (different patient population/disease group) or<br>• substantial dosage modifications are made for the licence indication or<br>• If they are used in combinations for which interactions are suspected<br>Trials involving medicinal products not licensed in any EU member state if:<br>• The active substance is part of a medicinal product licensed in the EU<br><br>A grading of Type A may be justified if there is extensive clinical experience with the product and no reason to suspect a different safety profile in the trial population.<br><br>e.g. Phase 3, Phase 2b studies (may include some Phase 1/2a studies of licensed products in new indications) | • SIV<br>• Trial specific Interim Monitoring visits after first 1-2 patients recruited<br>• QC of dose escalation data<br>• Close Out | 100% consent<br>100% SAE reporting<br>50% eligibility*<br>50% SDV on primary & secondary endpoints* |
| **Type C:**<br>Markedly higher than that of standard medical care | Trials involving a medicinal product not licensed in any EU Member State.<br><br>A grading other than Type C may be justified if there is extensive class data or pre-clinical and clinical evidence.<br><br>e.g. Phase 1, phase 2a studies | • SIV<br>• Trial specific Interim monitoring visits after 1st patient recruited<br>• QC of dose escalation data<br>• Close Out | 100% consent<br>100% SAE reporting<br>100% eligibility*<br>Trial specific SDV on primary & secondary endpoints* |

*^Ascertained during sponsor review.*

*[$]Capacity for monitoring multi-centre centre studies will be ascertained on a case by case basis during sponsor review.*

**% is subject to increases or decreases based on monitoring visit findings, review of risk profile and in accordance with a risk-based (adaptive) approach to monitoring.*

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## 2. Non-CE Marked Medical Device Studies

| Risk Level^ | Examples of Types of Clinical Trials | Minimum Monitoring[$] | Minimum SDV |
|---|---|---|---|
| **Type A:**<br>No higher than that of standard medical care | Class I medical devices<br>e.g. Wheelchairs, Stethoscopes, Spectacles<br><br>Class D In-Vitro Diagnostic medical devices<br>e.g. Clinical chemistry analysers, Specimen receptacles, prepared selective culture media | • SIV<br>• Trial specific Interim Monitoring visits after first 3 patients recruited<br>• Close Out | 100% consent<br>100% SAE reporting<br>20% eligibility*<br>20% SDV on primary endpoints* |
| **Type B:**<br>Somewhat higher than that of standard medical care | Class IIa and IIb medical devices<br>e.g. Dental fillings, Surgical Clamps, Tracheotomy tubes (Class IIa)/Condoms, Lung ventilators, Bone fixation plats (Class IIb)<br><br>Class B and Class C In-Vitro Diagnostic medical devices<br>e.g. Pregnancy self-testing, Urine test strips, Cholesterol self-testing (Class B)/Blood glucose self-testing, PSA screening, HLA typing (Class C) | • SIV<br>• Trial specific Interim Monitoring visits after first 1-2 patients recruited<br>• QC of dose escalation data<br>• Close Out | 100% consent<br>100% SAE reporting<br>50% eligibility*<br>50% SDV on primary & secondary endpoints* |
| **Type C:**<br>Markedly higher than that of standard medical care | Class III medical devices<br>e.g. Pacemakers, heart valves, Implanted cerebral simulators<br><br>Class D In-Vitro Diagnostic medical devices<br>e.g. Hepatitis B blood-donor screening, HIV blood diagnostic test, ABO blood grouping | • SIV<br>• Trial specific Interim monitoring visits after 1st patient recruited<br>• QC of dose escalation data<br>• Close Out | 100% consent<br>100% SAE reporting<br>100% eligibility*<br>Trial specific SDV on primary & secondary endpoints* |

*^Ascertained during sponsor review.*

*[$]Capacity for monitoring multi-centre centre studies will be ascertained on a case by case basis during sponsor review.*

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## 3. Non-CTIMP and CE Marked Medical Device Studies

| Type of Non-CTIMP study | Risk Level^ | Examples of Types of Non-CTIMP studies | Minimum Monitoring[$] | Minimum SDV |
|---|---|---|---|---|
| **Interventional Procedure** | High<br><br>Medium | Invasive procedure, high risk patient population<br><br>Non-invasive procedure, diagnostic procedures | • Monitoring will be conducted according to the risk profile of research activity.<br>• Different clinical areas to be equally monitored unless triggered monitoring deemed necessary<br>• High risk studies should be monitored within first 6 months of sponsor green light.<br>• SIV if deemed necessary for high risk studies or new investigators only. | Assessed on case by case basis and as determined by a Risk Assessment |
| **Interventional Tissue** | Medium | Sample/Tissue collection studies | • Monitoring will be conducted according to the risk profile of research activity.<br>• Aim to monitor 10% of studies annually.<br>• Different clinical areas to be equally monitored unless triggered monitoring deemed necessary | |
| **Non-interventional** | Low | Questionnaires<br>Interviews<br>Qualitative<br>Data Collection | • One study per quarter, with triggered monitoring as necessary. | |

*^Ascertained during sponsor review.*

*[$]Capacity for monitoring multi-centre centre studies will be ascertained on a case by case basis during sponsor review.*

**% is subject to increases or decreases based on monitoring visit findings, review of risk profile and in accordance with a risk-based (adaptive) approach to monitoring.*