## Monitoring Strategy Table

### 1. CTIMP Trials

<table>
<thead>
<tr>
<th>Risk Level^</th>
<th>Examples of Types of Clinical Trials</th>
<th>Minimum Monitoring$</th>
<th>Minimum SDV</th>
</tr>
</thead>
</table>
| **Type A:** No higher than that of standard medical care | Trials involving medicinal products licenced in the EU member state if:  
- They relate to the licensed range of indications dosage and form  
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.  
e.g. Phase 4 studies | • SIV  
• Trial specific Interim Monitoring visits after first 3 patients recruited  
• Close Out | 100% consent  
100% SAE reporting  
20% eligibility*  
20% SDV on primary endpoints* |
| **Type B:** Somewhat higher than that of standard medical care | Trials involving medicinal products licensed in any EU member state if:  
- Such products are used for a new indication (different patient population/disease group) or  
- substantial dosage modifications are made for the licence indication or  
- If they are used in combinations for which interactions are suspected  
Trials involving medicinal products not licensed in any EU member state if:  
- The active substance is part of a medicinal product licensed in the EU  
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.  
e.g. Phase 3, Phase 2b studies (may include some Phase 1/2a studies of licensed products in new indications) | • SIV  
• Trial specific Interim Monitoring visits after first 1-2 patients recruited  
• QC of dose escalation data  
• Close Out | 100% consent  
100% SAE reporting  
50% eligibility*  
50% SDV on primary & secondary endpoints* |
| **Type C:** Markedly higher than that of standard medical care | Trials involving a medicinal product not licensed in any EU Member State.  
A grading other than Type C may be justified if there is extensive class data or pre-clinical and clinical evidence.  
e.g. Phase 1, phase 2a studies | • SIV  
• Trial specific Interim monitoring visits after 1st patient recruited  
• QC of dose escalation data  
• Close Out | 100% consent  
100% SAE reporting  
100% eligibility*  
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.
# Non-CE Marked Medical Device Studies

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

\(^a\)Ascertained during sponsor review.

\(^b\)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.
3. Non-CTIMP and CE Marked Medical Device Studies

<table>
<thead>
<tr>
<th>Type of Non-CTIMP study</th>
<th>Risk Level(^a)</th>
<th>Examples of Types of Non-CTIMP studies</th>
<th>Minimum Monitoring(^b)</th>
<th>Minimum SDV</th>
</tr>
</thead>
</table>
| Interventional Procedure| High            | Invasive procedure, high risk patient population | • Monitoring will be conducted according to the risk profile of research activity.  
• Different clinical areas to be equally monitored unless triggered monitoring deemed necessary  
• High risk studies should be monitored within first 6 months of sponsor green light.  
• 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 |
|                         | Medium          | Non-invasive procedure, diagnostic procedures |                          |             |
| Interventional Tissue    | Medium          | Sample/Tissue collection studies          | • Monitoring will be conducted according to the risk profile of research activity.  
• Aim to monitor 10% of studies annually.  
• Different clinical areas to be equally monitored unless triggered monitoring deemed necessary |             |
| Non-interventional       | Low             | Questionnaires  
Interviews  
Qualitative Data Collection | • One study per quarter, with triggered monitoring as necessary. |             |

\(^a\) Ascertained during sponsor review.

\(^b\) 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.