## Appendix 2: Trial Risk Based Monitoring Strategy

### CTIMP Studies

<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 |

*Note: Capacity for monitoring multi-centre centre studies will be ascertained on a case by case basis during sponsor review.*
### Non-CTIMP Studies

<table>
<thead>
<tr>
<th>Type of Non-CTIMP study</th>
<th>Risk Level *</th>
<th>Examples of Types of Non-CTIMP studies</th>
<th>Minimum Monitoring</th>
<th>Minimum SDV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional: Procedure</td>
<td>High</td>
<td>High e.g. Invasive procedure, high risk patient population</td>
<td>Aim to monitor 10% of interventional p.a. Different clinical areas to be equally monitored unless triggered monitoring deemed necessary</td>
<td>Assessed on case by case basis</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Medium e.g. Non-invasive procedure, diagnostic procedures</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Interventional: Tissue</td>
<td>Medium</td>
<td>Sample /Tissue collection studies</td>
<td>Aim to monitor 10% of interventional p.a. Different clinical areas to be equally monitored unless triggered monitoring deemed necessary</td>
<td>Assessed on case by case basis</td>
</tr>
<tr>
<td>Non-interventional</td>
<td>Low</td>
<td>Questionnaires Interviews Qualitative Data Collection</td>
<td>One study per quarter, with triggered monitoring as necessary.</td>
<td>Assessed on case by case basis</td>
</tr>
</tbody>
</table>

- *Ascertain during sponsor review*