**Appendix 2: Trial Risk Based Monitoring Strategy**

**CTIMP Studies**

| 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><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>(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><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><br>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**

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

- *Ascertained during sponsor review*