Appendix 2: Trial Risk Based Monitoring Guidelines for CTIMP Studies

Risk Level	Examples of Types of Clinical Trials	Minimum Monitoring	Maximum SDV
Type A: No higher than that of standard medical care	Trials involving medicinal products /devices 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 Class I medical devices	• 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 / devices 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	• 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*

	(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) Class IIa/IIb medical devices		
Type C: Markedly higher than that of standard medical care	Trials involving a medicinal product / devices 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 Class III medical devices	• 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. *% may be revised following reviewed of risk profile &/or monitoring findings*

Trial Risk Based Monitoring Strategy for non-CTIMP / CE Marked Devices Studies

Type of Non-CTIMP study	Risk Level	Examples of Types of Non-CTIMP studies	Minimum Monitoring
Interventional : Procedure	High Medium	High e.g. Invasive procedure, high risk patient population, high risk protocol Medium e.g. Non-invasive procedure, diagnostic procedures	Audits / monitoring will be conducted according to the risk profile of research activity. 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.
Interventional: **Tissue**	Medium	Sample /Tissue collection studies	Aim to monitor 10% of interventional p.a. 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.