Form 51.004A – Risk Assessment Tool

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| Project Identification (short title, R&D number, EudraCT number and phase): |  |
| Chief Investigator: |  |
| Sponsor(s): |  |
| Date Risk Assessment Performed: |  |
| Risk Assessment Coordinator: |  |
| Protocol version number reviewed for risk assessment |  |
| Additional documents reviewed for risk assessment  (include document title and version number) |  |

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| Investigational Medicinal Product(s) Risk; Select Type A/B/C: | Justification for category selection: | Summary of areas where risk adaption can be applied (CTA submission/IMP/PV/Documentation) according to MHRA Risk Adaption Paper (2011): |
| Risk Categories, in Relation to MHRA Risk Adaption Paper (2011)  **Type A** = Comparable to the risk of standard medical care  **Type B** = Somewhat higher than the risk of standard medical care  **Type C** = Markedly higher than the risk of standard medical care |

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| **Participants** | | | | |
| Identification of Hazard(s) and description of risk(s) | Factors to Consider (guidance only) | | Likelihood of Hazard /Risk Manifestation  (unlikely/possible/likely) | Risk Mitigation Strategy |
|  | Inform Consent Process   * AWI/emergency/Minors * Language provision * Capacity of researchers * GCP compliance * Tissue collection and storage * Emergency or intensive care consent | |  |  |
|  | Intervention   * Phase of trial * Novel or unlicensed IMP/NIMP * In-patient medical supervision * Anticipated reactions and other AEs * Potential for unexpected reactions * Device effects and deficiencies * Safety reporting process * Device or intervention in addition to IMP * Access to unlicensed intervention beyond trial participation * Reporting test/scan results and incidental findings | |  |  |
|  | Confidentiality   * Method of participant identification * Identifying characteristics distributed beyond the site * Data sent outside the EU | |  |  |
|  | Burden   * Self-administration * Procedures/contact/risk exposure beyond standard of care * Co-enrolment * Invasive or experimental administration | |  |  |
| **Scientific Integrity** | | | | |
| Identification of Hazard(s) and description of risk(s) | | Factors to Consider (guidance only) | Likelihood of Hazard /Risk Manifestation | Risk Mitigation Strategy |
|  | | Statistical justification/powering   * Statistician involved |  |  |
|  | | Objectively measurable endpoints   * Independent assessment of data * Consistent method for data interpretation * Potential for bias * Safety data as a primary or secondary endpoint * Experimental or non-standard investigation * Study specific equipment |  |  |
|  | | Data Capture, Storage and Analysis Plans   * Potential for data verification * Nature of source data * Control and medium of CRFs * Database regulatory compliance * Data analysis plan * Dissemination of results |  |  |
|  | | Enrolment   * Randomization system * Blinding * Verifiable eligibility criteria * Recruitment target feasible |  |  |
|  | | Design   * Multiple/crossover arms * Dose escalation/modification/interruption * Sample size * Type of trial * Potential for increase in number of sites; define maximum |  |  |
| **Management** | | | | |
| Identification of Hazard(s) and description of risk(s) | | Factors to Consider (guidance only) | Likelihood of Hazard /Risk Manifestation | Risk Mitigation Strategy |
|  | | Research team(s)   * Relevant experience compliance record of local Investigator * Number of sites & feasibility assessments * Relevant experience of external site Investigators and trial team * Training for protocol and non-standard procedures and minimum GCP training standards * International requirements * Capacity for archiving |  |  |
|  | | Trials unit (Project Management)   * CRUK CTU * GCTU * TSC * International requirements |  |  |
|  | | Vendors/labs/Collaborators   * Non-routine tests * Tests affected 1⁰/2⁰ endpoint(s) * UKAS Accreditation/G(C)LP standards * Non-routine, non-standard sample analysis (cat 3) |  |  |
|  | | Monitoring   * NHS GGC monitoring team * CRUK CTU * International requirements |  |  |
|  | | Pharmacovigilance   * CRUK CTU * Robertson’s Centre * International requirements * Access to and control and distribution of the IB/SmPC. * DMC |  |  |
|  | | QA   * (CRUK) CTU |  |  |
|  | | Non-compliance reporting   * (CRUK) CTU * NHS GGC Governance Manager * International requirements |  |  |
|  | | Sponsor Pharmacy   * Product interactions * Dosing procedure * Arrangements for manufacture * Arrangements for distribution * Experience of external Pharmacy * Accountable comparators * International and Non EU state pharmacy set up |  |  |
| **Other** | | | | |
| Identification of Hazard(s) and description of risk(s) | | Factors to Consider (guidance only) | Likelihood of Hazard /Risk Manifestation | Risk Mitigation Strategy |
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**Contributors to the Risk Assessment**

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| **Name** | **Job title** |
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**Sponsor representative confirmation of completion of risk assessment and mitigation strategies have been initiated**

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|  | **Signature** | **Date** |
| Sponsor(s) Representative: |  |  |

**Chief Investigator acknowledgement of the risk assessment and agreement to implement mitigation strategies**

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|  | **Signature** | **Date** |
| Chief Investigator: |  |  |

**Amendment to Risk Assessment**

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| Date of Risk Assessment Amendment |  |
| Reason for Assessment Amendment |  |
| Protocol version number |  |
| Risk Assessment Amendment reviewer |  |
| Risk Assessment Amendment contributors |  |

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| Identification of Hazard(s) and description of risk(s) | Factors to Consider (guidance only) | Likelihood of Hazard /Risk Manifestation | Risk Mitigation Strategy | Research Coordinator Initials and date | Chief Investigator Initials and date |
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