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
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|  | 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
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|  | Confidentiality* Method of participant identification
* Identifying characteristics distributed beyond the site
* Data sent outside the EU
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|  | Burden* Self-administration
* Procedures/contact/risk exposure beyond standard of care
* Co-enrolment
* Invasive or experimental administration
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| **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
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|  | 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
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|  | 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
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|  | Enrolment* Randomization system
* Blinding
* Verifiable eligibility criteria
* Recruitment target feasible
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|  | Design* Multiple/crossover arms
* Dose escalation/modification/interruption
* Sample size
* Type of trial
* Potential for increase in number of sites; define maximum
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| **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
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|  | Trials unit (Project Management)* CRUK CTU
* GCTU
* TSC
* International requirements
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|  | 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)
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|  | Monitoring* NHS GGC monitoring team
* CRUK CTU
* International requirements
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|  | Pharmacovigilance* CRUK CTU
* Robertson’s Centre
* International requirements
* Access to and control and distribution of the IB/SmPC.
* DMC
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|  | QA* (CRUK) CTU
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|  | Non-compliance reporting* (CRUK) CTU
* NHS GGC Governance Manager
* International requirements
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|  | 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
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| **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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