**Appendix 2
FEASIBILITY ASSESSMENT FORM**

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| **Background information** | **Feasibility Meeting information** |
| Study title: |  | Date of meeting: |  |
| Protocol reviewed: | Version:Date: | Meeting held: | Face to faceOnline/via email |
| EDGE number: |  | Meeting conducted by: |  |
| IRAS number: |  | Meeting attendees: |  |
| University reference number (if applicable): |  |
| NIHR portfolio study? | Yes No | **Key Study Dates** |
| * If YES, CRN Speciality:
 |  | Proposed study open to recruitment date: |  |
| Commercial or non-commercial? |  | Proposed site open to recruitment date: |  |
| Observational or Interventional? |  | Proposed study end of recruitment date: |  |
| Phase: |  | Recruitment period duration (locally): |  |
| CTIMP, non-CTIMP, ATMP or device? |  | Study treatment duration: |  |
| Sponsor: |  | Study follow up duration: |  |
| Chief Investigator: |  | Expected last patient last visit date: |  |

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| **Funding** | **Key Contacts** |
| Funder: |  | R&I |  |
| Funding/budget details: |  | Contracts |  |
| * Are patient expenses included/ considered?
 |  | Pharmacy |  |
| * Are screen failures funded (if so, is there a cap)?
 |  | Lab |  |
| * Is CRF fee included/ required?
 |  | Imaging |  |
| * Is Chief Investigator fee included/ required?
 |  | Other support departments (if applicable) |  |
| * Is Site Initiation Visit fee included/ required?
 |  | Study Monitor/ CRA/ Trial Manager |  |
| * Have monitoring costs been considered (if applicable)?
 |  | Recruitment Point Of Contact |  |

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| **Questions to discuss with the CI/ PI/ Study Team** |
| **Staffing** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| Principal Investigator: |  |  |  |
| Co-Investigators: |  |  |  |
| What staff/support is needed to deliver the study? |  |  |  |
| * Is there capacity to support this with appropriately trained/ knowledgeable staff?
 |  |  |  |
| Is any reception/admin support required? |  |  |  |

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| **Patient Population and Targets** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| What patient population is required? |  |  |  |
| Do any cohorts need to be considered? |  |  |  |
| How many patients are seen per week/ month/ year with the condition? |  |  |  |
| How many patients are seen per week/ month/ year who fit the inclusion/exclusion criteria? |  |  |  |
| Is the inclusion/exclusion criteria appropriate for the population/participants? |  |  |  |
| What is the patient’s view of the study (medication, study visits, post-study access to IMP, etc.)? |  |  |  |
| What is the overall study recruitment target (per week/month/year?) |  |  |  |
| * What is the local recruitment target?
 |  |  |  |
| * Can this be achieved?
 |  |  |  |

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| **Patient Identification, Approach, Consent and Visits** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| How and where will participants be **identified**, and who will do this?  |  |  |  |
| How and when will participants be given **information**? |  |  |  |
| Who will receive **informed consent** (ensure they are appropriately qualified/ trained)? |  |  |  |
| How does the protocol pathway compare to the standard of care pathway? |  |  |  |
| * Are participants likely to be available to attend study visits (if additional to standard care)?
 |  |  |  |
| * Are participants likely to be available to attend support services procedures e.g. imaging?
 |  |  |  |
| Where will study visits take place?  |  |  |  |
| * If within clinics, which day(s) are they held?
 |  |  |  |
| * If outside of clinic, what is the room availability like?
 |  |  |  |
| * Is an application or approval required to use the room?
 |  |  |  |
| Are any overnight stays or out of hours visits/samples required? |  |  |  |
| * Are beds/staff/facilities available for this?
 |  |  |  |
| Who will book patients onto CRF Manager? |  |  |  |
| Are there any transport arrangements required for study visits? |  |  |  |

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| **Study Procedures, Treatment, and Equipment** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| Who will undertake the procedures at each study visit (list as required)? |  | **Procedure** | **Undertaken by?** | **Standard or Study?** |  |
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| Who will administer the study treatment/ intervention? |  |  |  |
| What consumables are required? |  |  |  |
| Is any specialist equipment required? |  |  |  |
| * What calibration and accreditation is needed for them?
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| **Support Services** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| Which support services are required? |  |  |  |
| CTIMP studies- have pharmacy been notified? |  |  |  |
| * Who funds/ supplies the IMP?
 |  |  |  |
| * Where will the study treatment be stored?
 |  |  |  |
| * Are pharmacy available for dispensing (including satellite units and out of hours)?
 |  |  |  |
| * Is there any post-study access to the IMP?
 |  |  |  |
| Is there in-house lab availability (consider processing, storage, shipment, and costs)? |  |  |  |
| Are research samples being stored for future use (home grown-studies?) If YES, discuss arrangements. |  |  |  |

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| **Administration** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| Who will set up the Case Report Form (for home-grown studies)? |  |  |  |
| Who is going to design and maintain the database (for home-grown studies)? |  |  |  |
| * Is funding available for this?
 |  |  |  |
| Who will complete CPMS (if applicable) |  |  |  |
| Who will complete the CRFs? |  |  |  |
| Who will enter the data and answer data queries? |  |  |  |
| Who will complete EDGE? |  |  |  |
| Who will maintain the Site file/ Trial Master file? |  |  |  |
| Who will meet with study monitors? |  |  |  |
| * Have monitoring costs been considered (for home-grown or commercial studies)?
 |  |  |  |
| What are the archiving arrangements (including funding)? |  |  |  |
| Who will report AEs/ SAEs/SUSARs? |  |  |  |
| * What is the likelihood of SAEs/AEs?
 |  |  |  |
| Who will review SUSAR line listings? |  |  |  |

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| **Governance** | **Page no.** | **Responses** | **If further information/ action is required or the response can be mitigated, document in this column** |
| Has study received funding/ sponsor/ MHRA/REC/ HRA approval? |  |  |  |
| Who is going to set up the study? |  |  |  |
| Is NIPAG approval required (for new non-drug interventions)? |  |  |  |
| Who is going to organise the Site Initiation Visit? |  |  |  |
| Will there be an Investigator Meeting? |  |  |  |
| * If YES, who will attend?
 |  |  |  |
| Have all GDPR considerations for data storage and transfer been considered? |  |  |  |
| Which internal speciality does the study come under? |  |  |  |
| * Does the study fit within the speciality’s strategy?
 |  |  |  |
| Are there any competing/conflicting studies? |  |  |  |
| * If YES, how will this affect recruitment?
 |  |  |  |
| Are up to date CVs, GCPs, consent certificates, LoAs/RPs available for all key study staff? |  |  |  |
| Is the study feasible?  |  | YesNoFurther clarification needed |  |

Signature: ……………………………………………

Name: …………………………………………………

Date: …………………………………………………..