Feasibility Checklist

If the answer to these questions is 'no' the study is not feasible:

	Yes	No
1. According to the inclusion and exclusion criteria, do you have adequate patient population to enroll?	☐	☐
2. Does UK own all equipment to perform the required testing and scans?	☐	☐
a. If not, will the sponsor cover the cost to purchase the equipment?	☐	☐
3. If needed, do you have access to a certified and calibrated freezer for samples?	☐	☐
a. If not, will the sponsor purchase one?	☐	☐
4. Is there a storage and record keeping plan for any investigational drugs or is IDS being utilized?	☐	☐
5. Is there storage and a record keeping plan for any investigational devices?	☐	☐
6. Is there adequate staffing to support the clinical trial?	☐	☐
a. Clinical research coordinator support?	☐	☐
b. Financial management support?	☐	☐
c. Regulatory management support?	☐	☐
d. Data management and entry support?	☐	☐
e. Radiology?	☐	☐

Additional work may be needed to ensure study is feasible depending on the answers to the below questions:

	Yes	No
1. Is UK currently running, or planning to run, other trials for the same disease?	☐	☐
a. If yes, how many? (If this is a high number, study may not have sufficient population to be considered feasible)		
2. Are the staff experienced in collection, processing and shipment of required samples?	☐	☐
a. If applicable, is staff IATA trained to managed the shipping of biological specimens? (If the answer is no, staff will need training to make the study feasible)	☐	☐
3. Can the UK lab process all the local labs required per the protocol? (If 'no', can the samples be processed at a third party lab like Quest? If 'no' then not feasible)	☐	☐
4. Is there an IND or IDE application? If so, is there staff knowledge to support?	☐	☐
5. Does the study budget fully cover all costs? If not, is the budget negotiable?	☐	☐
a. Is there staff knowledge and time to support development and negotiation of a budget?	☐	☐
b. If a study cannot cover costs, is there significant scientific or reputational value to ask for department support?	☐	☐
6. Is there a recruitment and retention plan? (If one does not exist, it will need to be developed)	☐	☐
7. Does the required start up time fall within the average UK start up timeline of 110-190 days? (If a very short start up time is required to meet enrollment deadlines, study most likely isn't feasible)	☐	☐
8. Does the study require ICF translations into languages other than English? (If so, added time and expense for translation will exist)	☐	☐
9. Does the study have a waiting or observation period after an injection or infusion? If so, can the rooms in the clinic can be used for the research visits. If not, the PI may need to contract with the CCTS for outpatient clinic space.	☐	☐
10. Does the study have a tight enrollment window? If 'yes', is there staffing to cover evening, weekend or holiday enrollments they may have to decline the study	☐	☐

11. How long is the study? (A very long study has greater risk and will need more staff and resources) ☐ ☐
12. Will our patient population benefit from the study? ☐ ☐
13. Is this study desirable to do from a scientific standpoint? ☐ ☐