|  |  |  |
| --- | --- | --- |
| **Please complete the minimally required information below** | | |
| Chief Investigator or Primary Collaborator | Name: | |
| Position: | |
| Institution/Department: | |
| Email address: | |
| Individual submitting (if different from above) | Name: | |
| Email Address: | |
| Proposed research title (full) |  | |
| Proposed research title (short/acronym) |  | |
| Brief outline of research question and case of need | Or attach synopsis if available assuming no issues of confidentiality | |
| Protocol | Attach if available assuming no issues of confidentiality | |
| Proposed funder | Name: | |
| Call title: | |
| Deadline: | |
| URL: | |
| Outline/Expression of Interest  Full  Resubmission | |
| Proposed sponsor | Name: | |
| Has the proposal been discussed?  Yes  No | |
| If yes, outcome: | |
| Proposed project start date and duration |  | |
| CTU services of interest  (select all that apply) | Full service (all of below)  Trial design  Protocol development  Ethics and regulatory submissions  Trial management  Trial Master File maintenance  Pharmacovigilance  Monitoring  Quality assurance  Database development  Data management  Randomisation  IMP management  Pharmacy  Statistics  Clinical trial report production  Publication | |
| **Please complete sections below if known** | | |
| Type | Clinical Trial of Investigational Medicinal Product (CTIMP)\*  Medical device\*\*  Surgery  Qualitative  Access to existing datasets  Other specify: | |
| \*IMP | Name: | |
| Licensing status: | |
| Supplier: | |
| \*\*Device | Name: | |
| Licensing status: | |
| Supplier: | |
| Phase | I  II  III  IV  Pilot/feasibility | |
| Design | Parallel  Crossover  Adaptive  Other specify: | |
| Randomised | Yes  No | |
| If yes, number of arms: | Ratio: |
|  |  | |
| Control arm | Placebo  Standard of care  Other specify: | |
| Blinding | Open label  Single blind  Double blind  Assessor blind | |
| Primary outcome |  | |
| Secondary outcome(s) |  | |
| Follow-up period |  | |
| Location | UK  Multinational (EU only)  (Multinational (incl. non-EU) | |
| No. of sites |  | |
| No. of participants |  | |
| Participants | Healthy volunteers  Type I diabetes  Type II diabetes  Other specify: | |
| Feasibility/recruitment rate data |  | |
| Competing trials | Yes  No | |
| If yes, provide details: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­ | |
| Statistical design |  | |
| Genetics | Yes  No | |
| Biomarkers | Yes  No | |
| Health Economics | Yes  No | |
| Quality of Life or Patient Reported Outcome Measures | Yes  No | |
| Qualitative | Yes  No | |
| PPI plans |  | |
| Other collaborators |  | |
| Other information |  | |
| **Please return to dtu@dtu.ox.ac.uk** | | |
|  | | |
| **For office use only** | | |
| Date of receipt (dd/mmm/yyyy): | | |
| Receipt acknowledged by (print name): | | |
| Content Management System Reference Number: | | |
| Date of DTU Management Committee review (dd/mmm/yyyy): | | |
| Outcome of review: | | |
| Feedback: | | |
| Date outcome/feedback returned: | | |
| Feedback returned by (print name): | | |