User Feasibility Study – Invitation to submit proposals

1. Introduction

Members of the User Steering Committee are invited to submit proposals to test or demonstrate research techniques (experimental methods, decisional tools, analytical techniques, approach, etc.) generated by the Hub in a company or user context. The studies should assess the user benefits and impact of the technology/approach and review the requirements for successful adoption. Successful projects are expected to generate tangible outputs which could include one or more of the following:

a) Preliminary data that is then used to apply for further funding to accelerate the route to adoption or application.
b) Publication that demonstrates Hub results in a User context.

User Feasibility Studies will address the following:

1. How does the Hub technology/approach perform in a user environment or on user materials?
2. What are the potential benefits for individual users?
3. What is the potential scale of the impact for users and the wider healthcare system if the technology/approach is adopted widely?
4. What is the route to commercialisation after the end of the feasibility study and what is required to enable this to happen (including funding)?

The Hub will redirect Post-Doctoral Researcher time to undertake these projects. All the studies must involve at least one Hub User (partnering company/organisation) and one Hub Researcher. Up to 3 months of Full Time Equivalent (FTE) Hub Researcher time will be awarded, which can be distributed over one calendar year, and up to 30 September 2023 at the very latest. Users are expected to provide industry supervision to the project and provide access to the necessary materials, equipment or data.

2. Results from Feasibility Studies

On conclusion, the study team will provide a high-level report outlining the potential of the technology/approach that has been investigated. The report should be submitted within one month of the project end date, and by 31 October 2023 at the very latest. The Hub Directors will use this for reporting to sponsor (UKRI-EPSRC) and to aid wider dissemination to the Hub consortium. The User organisations will facilitate the publication of the results in academic journals providing that commercially confidential information has been protected in accordance with the Hub Collaboration Agreement. The high-level report should address each of the items 1-4 in the list above.

3. Confidentiality

All projects that are taken forward will be carried out under the terms of the Hub Collaboration Agreement, in compliance with the clauses around Intellectual Property, Confidentiality and Publication (Sections 7-9). In cases where separate CDAs and MTAs are required, over and above the clauses in the Hub Collaboration Agreement, the Hub/Spoke University partner will provide templates.

4. Application Process

User Feasibility Studies are awarded competitively. Applications will be via a 1-stage process to facilitate a fast turnaround with submission of a detailed work plan for the study with milestones and deliverables (see proposal form).

Applications should be developed by the User organisation(s) in collaboration with the Hub Researcher(s).

5. Process

Allocation of resource to these feasibility studies based on their potential impact will be decided by a committee of users and academics, the Translation and Impact Committee, chaired by one of the Catapult representatives. Proposals will be assessed against the following

Eligibility questions *(yes or no)*
Is the Hub research sufficiently advanced for the proposed feasibility study, and is the need clearly stated? Prompt: Is there sufficient data to support moving this into a feasibility study
Is the technology/approach part of a pathway to affordable personalised / individualised medicine? Prompt: Is there a user statement describing the benefit for personalised or stratified medicine scenario
Ratings criteria *(scores given for each of the questions below)*
Does the proposed study have a realistic plan with clear assessable deliverables and endpoints? Prompts: scope, activities, milestones and endpoint clearly described? Can success or failure be assessed?
Is there a clear commitment from the user partner? Prompts: Are there named contacts/supervisor(s) at user, with involvement stated? Are there resource commitments? for example access to data is regarded as a tangible benefit
Is there a clear plan to take the technology/approach forward afterwards, including seeking additional funding?

Prompts: is the pathway to adoption and application set out? Does it have sensible milestones and timelines? Have potential funding routes been considered?
If successful, does this technology/approach have the potential to deliver real benefits to users? Prompts: Potential breadth of application, scale of impact for users and for healthcare system

6. Key Dates

Activity	**Date**
Submission deadline for proposals	5 October 2022 17:00 UK time
Review by Translation & Impact Committee	Early November 2022
Review of decisions by Advisory Board	Early November 2022
Announcement of successful proposals	Late November 2022
Earliest project start date	December 2022
Latest project end date	30 September 2023
Deadline for reporting	31 October 2023

Examples of User Feasibility Studies

- Historical batch analysis and trajectory optimisation for T-cell expansion process control.
- Development of supply chain optimization models for autologous CAR-T cells.
- Comparing freeze-thaw performance of vials vs bags for the cryopreservation of T cells.
- Formulating recombinant human albumin as a nanoparticle-scaffold and assessing the potential for drug delivery.
- Economic analysis to investigate the consequences of switching to scalable GMP processes for viral vectors on drug development lifecycle costs.
- Mechanistic modelling for immunotherapy manufacture.
- Testing and developing established cell-free synthesis protocols for 3 classes of product.
- Techno-economic evaluation of a cell-free synthesis system for the expression of recombinant toxins.
- Real-time process analysis and control of continuous chromatography.