

8th December 2022

ECTU Portfolio Prioritisation Strategy and Implementation V1.0

Background

Clinical trials have been significantly impacted by the COVID-19 pandemic and by the post-COVID-19 recovery efforts. Most clinical trials in ECTU's portfolio experienced substantial delays during COVID-19, leading to a significant number of extension requests by research teams (18/53 [34%], 14 already awarded by the funder). The delivery of these extended studies means that existing ECTU resources continue to be committed for longer than planned, reducing the unit's ability to start new, funded research.

In the summer of 2020, the Department of Health and Social Care (DHSC), NHS England, NHS R&D Departments, the NIHR Clinical Research Network and delivery partners across the sector began working to restore the UK's diverse clinical research portfolio. The Managed Recovery process was implemented in Spring 2021 and had success with the studies it included. However, this initiative did not clear the path for other studies paused or delayed in the early stages of the pandemic to return to the levels of recruitment that would normally be expected. Therefore, in the Spring of 2022, the Research Recovery and Reset Programme (RRRP) was developed with the aim of giving as many studies as possible the chance of completing and yielding meaningful results. A necessary part of this was that studies not viable in the current context would be amended or closed.

In response to these national initiatives, the ECTU Senior Management Team undertook a portfolio review based on the RRRP programme guidelines and identified 10 studies as being at high risk of early closure. Based on this information ECTU continued with a conservative approach to recruiting new staff in the first half of 2022 to minimise the risk of redundancies due to any RRRP-led study closures. However, the RRRP has not resulted in the closure of any at-risk studies so far. To date, the RRRP has flagged only four ACCORD-sponsored studies within ECTU's portfolio for review: three due to slow recruitment, and one due to a delay in opening sites for recruitment. At the time of writing, the RRRP has not flagged any Edinburgh-led studies within ECTU's portfolio for closure. On the other hand, funders have already extended 14 studies, and another three applications for extension are under consideration.

In the meantime, 33 clinical trials that are in the scope of ECTU's clinical trials strategy have been funded with a start date between 2020 and 2022, along with a further 36 clinical research projects (e.g., methodological research, observational studies, etc). This represents a 19% increase in new studies compared to the previous 3 years (2017-2019). We are delighted with these successful collaborations between chief investigators and ECTU, but they add to the demands on ECTU's capacity. Furthermore, between 2020 and 2022, ECTU lost 12 experienced members of staff (8% annual turnover rate).

To continue to appropriately resource the growing current and future portfolio in these extraordinary circumstances, ECTU is actively working towards increasing the unit's capacity. However, due to sector-wide shortage of qualified staff, recruitment to certain posts, including trial management, has been very challenging. Our resource capacity is now over-extended by the existing portfolio (in large

part due to study extensions), and, as a result of the challenges in recruiting new staff, we are finding it difficult to accommodate the new, funded studies due to start in 2023.

To address these challenges, the ECTU Senior Management Team undertook a second portfolio review. The aim was to prioritise and focus ECTU's activities to those that support the University of Edinburgh Clinical Trials Strategy 2020 (Box 1), and the ECTU Business Objectives 2022 (Box 2), and to free-up capacity to undertake new, funded studies.

Box 1. University of Edinburgh Clinical Trials Strategy 2020

- Clinical trials led by chief investigators in Edinburgh.
- Clinical trials that will make an impact on human health challenges, at least locally, and preferably globally, involving any type of intervention (e.g., drug, device, and complex).
- Clinical trials that are informed by sufficient expertise and experience.
- Clinical trials that address the University of Edinburgh's strategic priorities (especially data-driven innovation, digital transformation, global health, and partnership with industry).
- Clinical trials that synergise with other research strengths of the University of Edinburgh, including experimental/translational medicine, imaging, and data science.
- Funding applications for clinical trials that converge with these scientific priorities, maximise the chances of success (e.g., commissioned research calls), and benefit the business plan (e.g., funders that support the infrastructure of the host institution, such as NIHR/MRC/Wellcome Trust).
- Observational (non-randomised) studies in ECTU only when the immediate next step will be a clinical trial (e.g., feasibility studies).
- Methodological research into the design, conduct and analysis of clinical trials.

Box 2. ECTU Business Objectives 2022

- ECTU maintains a culture and working environment that focuses on security, health & wellbeing, growth & development, equality, diversity & inclusion and collaboration.
- Provide sufficient capacity and expertise for timely, efficient and sustainable development, design and delivery of world-class clinical trials with a focus on University of Edinburgh strategic priorities, human health challenges, excellence of execution, adaption to contemporary trends and innovative trial design & methodology.
- Embed the necessary governance for unit sustainability, continuity, growth and success.
- Provide the organisational infrastructure and staff to deliver a growing project portfolio and teaching commitments to a high standard.
- Employ procedures and practices to ensure the unit is inspection-ready and achieves high levels of regulatory compliance.
- Establish the infrastructure, staffing, and procedures for a Trusted Research Environment platform to enable ECTU to conduct digitally enabled clinical trials.

Portfolio Prioritisation Strategy

The first outcome of the portfolio review undertaken between August and October 2022 was the development of the criteria for prioritising studies (Box 3). This was informed by an assessment of the resources required to deliver these studies. The second outcome will be an implementation plan, which will focus on phasing-out studies that do not align with the Strategy (Box 1) or Business case (Box 2), and focusing on studies which do support these. Together, these outcomes will enable ECTU to prioritise the allocation of its resources to deliver clinical trials to target, and free-up capacity to undertake new, funded clinical trials that support the Clinical Trials Strategy and fulfil ECTU's business objectives.

Box 3. ECTU Portfolio Prioritisation

Focus 1: Current portfolio

- 1a. Full collaboration RCT led by Edinburgh CI
- 1b. Full collaboration non-RCT led by Edinburgh CI
- 2a. Partial collaboration RCT led by Edinburgh CI
- 2b. Partial collaboration non-RCT led by Edinburgh CI
3. Observational or methodological research led by Edinburgh CI
4. RCT led by External (i.e., non-Edinburgh) CI
5. Non-RCT or observational study led by External CI
6. Other study types led by Edinburgh CI
7. Other study types led by External CI

Focus 2: Future portfolio

- 8a. Full collaboration RCT led by Edinburgh CI*
- 8b. Full collaboration non-RCT led by Edinburgh CI*
- 9a. Partial collaboration RCT led by Edinburgh CI*
- 9b. Partial collaboration non-RCT led by Edinburgh CI*
10. RCT led by External CI
11. Non-RCT, observational or methodological research led by Edinburgh CI
12. Other study types led by Edinburgh CI (considered on a case-by-case basis)
13. Other study types led by External CI (considered on a case-by-case basis)

NB: Non-clinical trial work will generally only be taken on if it directly leads to an RCT, or if it involves methodology development for RCTs.

* Studies in these categories that are funded by eligible funders according to [NHS Research Scotland](#) will be considered as priority

Abbreviations: CI = chief investigator, RCT = randomised controlled trial, non-RCT = non-randomised clinical trial

Definitions: Full collaboration: ECTU undertakes trial management, methodology and statistics, and data management and programming (and health economics, as required).

Partial collaboration: ECTU undertakes at least one (but not all) of trial management, methodology and statistics, data management and programming, and health economics.

Portfolio Prioritisation Implementation

The first priority for ECTU is to deliver our portfolio of ongoing funded studies. A review of the current portfolio identified 104 studies in categories 1-7 (Box 3). The review also identified 13 studies that have continued to use ECTU resources beyond the contracted period, or beyond available funding; the studies in this latter category have been flagged for exit by ECTU. The processes around communicating this information to chief investigators and other stakeholders, as well as the processes around developing the exit plans are currently being established. In addition to our active recruitment of new staff, these activities will enable ECTU to free-up further capacity to undertake new, funded, high priority clinical trials.

The second priority for ECTU is to ensure that appropriate resources are available for starting new funded studies. New studies will be prioritised based on categories 8-13 and ECTU's Business Objectives (Box 2), and resources will be allocated accordingly. There are several funded studies in these categories that are awaiting resource allocation, as well as a large number of studies awaiting decisions from funding agencies. Because of the situation that we have described, we are not yet able to communicate precisely the timelines for starting new studies that have start dates beyond February 2023. Outcomes from the ongoing activities around exiting unfunded work, and staff recruitment are required to enable us to plan the timings of new study start dates accurately. Recently, we have experienced reassuring levels of understanding from some funding agencies in our conversations with them about delaying the start dates of some funded studies.

Over the next 3-6 months, ECTU will be actively working to implement the outcomes of the portfolio prioritisation strategy. We understand that these changes in our ways of working may bring temporary challenges for ECTU itself, Chief Investigators and other key stakeholders. However, these changes are essential to provide sufficient capacity and expertise for timely, efficient and sustainable development, design and delivery of world-class clinical trials according to the clinical trials strategy.

The ECTU Senior Management team will continue to re-assess the Unit's capacity and portfolio commitments weekly at the Portfolio Management Meetings with reference to the Clinical Trials Strategy (Box 1), ECTU's Business Objectives (Box 2), and ECTU's Portfolio Prioritisation (Box 3). We will also continue to ensure that Chief Investigators and other stakeholders are kept up to date with our progress through regular communications and reports to the Clinical Trials Oversight Group (CTOG). We understand that Chief investigators may require further information and reassurance in addition to this explanation of the current situation, and we will do our very best to communicate when required whilst we implement these urgent prioritisation measures.

ECTU Prioritisation Strategy



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ECTU Consultation: 25th October 2022 – 3rd November 2022

CTOG Consultation: 14th November 2022 – 21st November 2022

Edinburgh Chief Investigators Consultation: 21st November 2022 – 25th November 2022

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Final Remarks: We would like to extend our sincere thanks to colleagues in ECTU and ACCORD, as well as Edinburgh Chief Investigators for their engagement with our consultation process, and the comments/feedback we received on the draft ECTU Portfolio Prioritisation Strategy.

The comments and feedback received influenced the final drafting of this strategy (v 1.0).

Additionally, we will pass along pertinent comments we received as part of our consultation of this prioritisation strategy to help inform a future update to the Edinburgh Clinical Trials Strategy.