CLINICAL TRIAL AND RESEARCH PATHWAY IN EDINBURGH:

Summary of external review recommendation and actions taken

The external review

In 2019, the University of Edinburgh and NHSL Lothian commissioned an external review of current clinical trial pathways and research development, approval, and delivery arrangements. The external reviewers were:

Christine McGrath, (Chair). Director of Research and Development, University Hospital Southampton NHS Trust and Chair of UKRD.

Professor Danny McAuley, Professor of Intensive Care Medicine at the Wellcome-Wolfson Institute for Experimental Medicine, Queen's University of Belfast, and Consultant in Intensive Care Medicine, Royal Victoria Hospital, Belfast. Director of the NIHR Efficacy and Mechanism Evaluation (EME) Programme.

Professor Jacob George, Professor of Cardiovascular Medicine and Therapeutics, Hon. Consultant Physician & Clinical Pharmacologist, Ninewells Hospital, Dundee, Director of R&D, NHS Tayside, Tayside Medical Sciences Centre.

Within the University of Edinburgh/NHS Lothian, a steering group was formed to oversee the review and was tasked with developing an action plan based on findings and recommendations. This group comprised: Prof Charles Ffrench-Constant (Dean of Research, UoE); Dr Catherine Elliott (College Registrar, UoE); Prof Tim Walsh (Director of Research & Innovation); Fiona McArdle (Deputy R&D Director, NHSL); Prof John Norrie (Director, Edinburgh Clinical Trials Unit); Prof David Newby (Director Clinical Research Facility & Clinical Research Imaging Centre); Prof Aziz Sheik (Head, Usher Institute); Prof Hilary Critchley (Head, Deanery of Clinical Sciences); Prof Kev Dhaliwal; Prof Rustam Salman.

Aims of the external review

The agreed main aims of the review were:

1) To look at the five stages of the trials pathway and how processes function within the pathway, namely: (1) pre-award; (2) start-up; (3) delivery; (4) close-out and (5) post-trial activity. Identify and define the blocks and things that are done well.

2) Categorise the blocks into those that can and cannot be changed.

3) Consider the overall culture and shared understanding

4) Recommend solutions

5) Comment on how Edinburgh compares with other institutions?

Activities during the external review

The review took place on 29th-30th January 2020.

During the review, external reviewers met individually with the Dean of Research, College Registrar, Director of Research & Innovation, Director of ECTU, and the Head of College. The reviewers met with specific teams involved in the clinical trial pathway, including senior members of the ACCORD team (both UoE and NHSL), the Edinburgh Clinical Trials Unit, and the legal/contracts team within the UoE. The reviewers also met with a wide range of researchers individually, including senior clinical trialists, new investigators/PIs, and researchers focussing on delivering hosted research. These researchers included both UoE and NHS employed individuals.

Actions since the external review

The steering group has met regularly during 2020 to address the recommendations. In addition, ACCORD and ECTU provided detailed reflection on the review, and suggested actions to address the recommendations.

Summary of key recommendations and actions taken

1. **Establish a joint NHS Lothian and UoE College of Medicine Oversight Board.**

The external review recommended developing a clearer joint strategy between NHSL and the UoE in relation to research capacity, resource, and strategic direction. This included a clearer oversight and advisory structure, especially in relation to monitoring performance and the matching of capacity within the system to demand. The joint NHS Lothian and UoE College of Medicine Oversight Board will have senior representation from both organisations, will meet 2-3 times annually, and will oversee the development of a joint strategy. The Board will monitor delivery of the strategy, policy, culture, performance and finance issues for the clinical trials and broader research pathway. Terms of Reference and the composition of the Oversight Board will be agreed and the Board established in early 2021.

2. **Address gaps in capacity within the Edinburgh Clinical trials Unit (ECTU) and the ACCORD joint research governance office.**

The external review identified a range of capacity issues within the ECTU and ACCORD that required additional investment in key posts and functions. Following these recommendations, detailed reviews have been undertaken within both units to identify where key posts are needed, and these have been discussed at the steering group. A business plan has been developed for ECTU, and specific roles and infrastructure within ACCORD agreed. Actions have been taken including the appointment of new staff members. The steering group agreed that a plan to progressively address ongoing capacity issues was needed and that action should be taken, acknowledging the current financial constraints resulting from the impact of the COVID19 pandemic. This will require a phased approach and will be kept under review.

3. **Develop a strategy to guide the development and focus of the Edinburgh Clinical trials Unit.**

The external reviewers noted that the ECTU had evolved and grown 'organically' since its creation. They noted that the portfolio had grown substantially in recent years**,** which has created challenges in relation to capacity and leadership. The reviewers recommended considering the addition of a

senior clinician to the leadership team, and reviewing activities and focus within the ECTU. In response to these recommendations:

- A Clinical co-director for ECTU has been appointed (Prof Rustam Salman)
- An internal review of capacity and resource requirements has been undertaken and a business case developed
- A scoping exercise has been undertaken, and a strategy developed which has been reviewed and supported by the steering group, the college of MVM, and NHS R&D

4. **Establish a UoE college of MVM clinical research sub-committee**.

The external review noted that the volume and range of clinical research co-sponsored by NHSL/UoE via ACCORD was substantial, reflecting the academic strength within Edinburgh. It was recommended that clear oversight for this portfolio be established that monitors progress against strategy, and specifically tracks issues of demand versus capacity to support clinical research within the ECTU, ACCORD, and wider research support services and facilities. It was agreed that a clinical research oversight committee should be established to undertake this function, which should report to the College Dean of Research. This will be established in early 2021.

5. **Establish specific governance functions for global health studies.**

Although the external review focussed on NHS-based research, supporting global health research was identified as a challenge especially within ACCORD. The volume and complexity of global health studies has increased substantially as a result of increased grant income and several large University of Edinburgh programmes. It has been agreed that support for global health research requires dedicated ACCORD support, which has been put in place. In addition, it is agreed that R&D leadership for global health requires an individual with appropriate expertise separate from NHS R&D.

6. **Co-locate the ECTU and ACCORD teams and improve joint working**.

Although the joint University of Edinburgh and NHS Lothian governance teams that comprise ACCORD work closely, and interact regularly with ECTU teams, it was thought that benefits could be achieved from further developing joint working. After internal reviews within teams and discussion at the steering group several actions have been initiated:

- Regular meetings between ACCORD and ECTU leadership teams
- Honorary contracts for senior ACCORD UoE and NHS teams in the partner organisation to enable greater sharing of information, streamlined processes, and access to systems
- Re-design of some ACCORD functions, specifically for the UoE governance team to lead on all sponsor review, while the NHS team lead on all monitoring and QA as well as managing hosted research.
- The creation of a dedicated pharmacovigilance team and new database within the UoE governance team.
- Plans for the ACCORD office to move to the new Usher Institute building where it will be co-located with ECTU.

7. **Establish clearer guidance for and implementation of grant preparation and costing timelines.**

It was noted that Edinburgh generates a large number of grant applications, and that trends in recent years show a progressive increase. There has also been an increase in complex projects, such as phase 1 trials, international trials, and complex regulated trials. This has placed substantial pressures on those facilities providing support for grant preparation, including the UoE research office, ACCORD research facilitators, ECTU teams, and both UoE and NHS finance teams. Recent increased requirement for detailed costings at submission has had a substantial impact on finance/costing teams. It was noted that tight deadlines and lack of adherence to realistic timescales was detrimental to the working culture, and required improved processes. It was agreed that clear timelines for preparation of research proposals, including costings, would be produced and implemented across both organisations. These timelines would be adhered to in order to manage researcher expectations, support staff, and improve working cultures and behaviours.

8. **Establish a separate college of MVM ethics committee.**

The reviewers noted the need for a separate college of MVM ethics committee to review and approve studies not involving the NHS. In response to this recommendation a college ethics committee has been established.