NWORTH CHARTER

Introduction

The North Wales Organisation for Randomised Trials in Health & Social Care, (NWORTH), has a reputation for quality and excellence in delivering randomised trials and evaluations of complex interventions. This reputation depends upon our outputs and collaborations. As a UKCRC registered Clinical Trials Unit, (CTU), we have established robust systems to ensure the conduct and delivery of clinical trials and other well-designed studies to the highest quality standards. All our work is underpinned by a quality management system and the CTU follows these rigorous auditable procedures for all aspects of its work, including study adoption.

We have developed this Charter to assist current and potential collaborators and research partners to understand the range and quality of service they can expect to receive when engaging with the Trials Unit. The Charter aims to make explicit the input that we expect from collaborators and our expectations in turn. We hope this Charter provides a useful roadmap for you and that it answers most of your questions regarding collaborating with NWORTH.

Our Services

NWORTH offers a range of expertise and services to cover the full life cycle of a study or trial from initial design, through to conduct, analysis and dissemination. Our services include:

- Design and Methodology
- Protocol Development (including advice on calculation of research costs)
- Project Management
- Development of Information Technology (IT) Systems including randomisation systems, electronic Case Report Forms (eCRFs) and electronic data capture systems (EDCS)

- Design of Case Report Forms (CRFs)
- Data Management
- Full Statistical input, analysis and reporting
- Advice on Quality Assurance and regulatory affairs

Approaching NWORTH

We are always interested in discussing new studies and collaborations which will complement and expand our portfolio. Potential collaborators wishing to engage with NWORTH are advised to contact us as early as possible. Ideally, this should be at least two to three months before an application deadline. This will enable us to provide adequate time to assess an application and judge whether the CTU has the capacity to collaborate. Unfortunately, proposals with very short deadlines are unlikely to be considered as we need sufficient time to review and make a meaningful contribution.

Triage

All requests for NWORTH collaboration are discussed at our weekly Core Operational Group (COG) meeting. To assist with these discussions, we request that potential collaborators complete a Collaboration Request Form: (https://nworth.bangor.ac.uk/forms/view.php?id=13472). The COG considers each study on its merits, but particular attention will be paid to studies that enhance the quality of our portfolio and use novel methodologies. Before determining whether NWORTH can engage with a request, we assess each request based on the following criteria:

1. Does the research address a focused research question which is of importance to patients and could result in a change of policy or practice?
2. Is there a clear gap in the evidence base?
3. Has an appropriate research team been assembled, (or is there the potential to bring a team of experts together with the appropriate skill mix?)

4. Is the study feasible? What is the likelihood of reaching recruitment targets and delivering the study within the proposed budget and timeframe?
5. Have the research team referred to appropriate guidelines and tools in the work-up of their protocol e.g. SPIRIT (http://www.spirit-statement.org), CONSORT (http://www.consort-statement.org) and COMET (http://www.comet-initiative.org)?
6. Is the proposed role and input of NWORTH clear?
7. What is the likelihood of the application securing funding?

NWORTH Expectations

Costs

We seek to cost grant applications pragmatically, making sure that the study can be delivered on time, within budget and in accordance with our Standard Operating Procedures. If these principles cannot be met, we do reserve the right to re-evaluate our collaboration with a Chief Investigator (CI).

Capacity

NWORTH is a busy CTU and has a finite capacity. As a result, one of the key considerations in the decision to collaborate with a CI is whether there is sufficient capacity to do so. Proposals that are methodologically rigorous and that have clear reporting structures and timelines are given priority.

NWORTH as co-applicants

For all grant applications, we expect NWORTH staff members to be costed and named as co-applicants, as appropriate.

Publications

NWORTH co-applicants will be co-authors on any relevant published output and that the publication strategy is discussed *a priori* with relevant members of the NWORTH team.

Data sharing and Individual Patient Data

NWORTH is working towards the Medical Research Council's "Good practice principles for sharing individual participant data from publicly funded clinical trials" guidance: (http://www.methodologyhubs.mrc.ac.uk/files/7114/3682/3831/Datasharingguidance2015.pdf). This is a set of standards that describes how Individual Patient Data (IPD) from trials should be made available for secondary research to minimise research waste. NWORTH will provide a data-pack after the formal end of the trial / study. Further statistical input or secondary analysis beyond the pre-defined Statistical Analysis Plan will require further resources to be agreed with the Unit.

Communication

Clear and timely communication throughout the lifecycle of the study is fundamental to its success. Our expectations regarding communication processes are further outlined in Table 1 below.

We expect CIs to communicate with NWORTH if an extension to the study period is expected. If any major aspect of the design changes substantially between the date of NWORTH's initial agreement to collaborate and the date of the submission of the grant, the CTU reserves the right to re-evaluate NWORTH's collaboration.

We will attempt to meet all required grant deadlines agreed at the time of the initial decision to collaborate. However, should this become unsustainable we will advise CIs accordingly as soon as this becomes clear.

NWORTH will provide a data-pack after the formal end of the trial / study. Further statistical input or secondary analysis beyond the pre-defined Statistical Analysis Plan will require further resources to be agreed with the Unit.

Procedure

The procedure for the adoption of studies onto the NWORTH portfolio is provided in Figure 1. Following review and discussion at the COG, a representative from NWORTH will contact the CI to inform them whether NWORTH is in a position to collaborate or not. In some instances, further information may be requested to aid this decision.

Please note: this does diminish the time the Unit has to input to a grant application and therefore we do kindly request that as much information as possible is provided in the initial request using the Collaboration Request Form: (https://nworth.bangor.ac.uk/forms/view.php?id=13472).

If NWORTH decides that it is unable to collaborate at this time, feedback will be provided. We are always happy to discuss this decision with prospective CIs and provide details on how the decision was reached and offer advice and constructive feedback, as appropriate. However, the COG's decision is final. Should NWORTH proceed with collaboration, we will contact the CI to clarify roles, expectations and proceed with developing an estimate of costs.

If you wish to talk through any aspects highlighted in this Charter or are unclear regarding the process, please contact:

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Table 1: Expectations at different stages of the study process

GENERAL PRINCIPLES	PRIOR TO STUDY START	DURING THE STUDY	AFTER THE STUDY
Expectation:	***Expectation:***	***Expectation:***	***Expectation:***
NWORTH staff members costed and named as co-applicants, as appropriate. To receive a final copy of the grant application that is submitted with sufficient time to allow final input and comment from NWORTH. To receive a final copy of responses to referees before submission and with sufficient time to allow final input and comment from NWORTH. CI to be in regular communication with members of the research team and NWORTH staff during all relevant aspects of study design and delivery. CIs to follow the relevant guidelines and tools available e.g. SPIRIT (http://www.spirit-statement.org),CONSORT (http://www.consort-statement.org) and COMET (http://www.comet-initiative.org).	CIs to register their study with an appropriate trial registry (e.g. http://www.isrctn.com/login). Timely initiation meetings between the CI and NWORTH. Timely feedback regarding progress on all applications for regulatory approvals. Timely instigation of the contracting process to enable smooth study set-up and prevent delays to staff appointments. The CI to meet with NWORTH trials managers (TM) (when NWORTH are providing this service) to discuss / determine risk, logistics and operational issues. Sign-off of the Statistical Analysis Plan*. The Trial Team to collaborate with NWORTH to support the specification and user testing of NWORTH provided trial IT systems:	Timely meetings throughout the duration of the study. Regular meetings with NWORTH Trial Managers (when NWORTH are providing this service). Trial statisticians to be invited to all Trial Steering Groups and Data Management Committees, as appropriate. CIs to ensure all monitoring reports are completed and copies sent to NWORTH. CIs to review all Serious Adverse Events reported in the study or delegate an appropriate person to do so. CIs comply with all regulatory issues relating to CTIMPs (where appropriate). CIs to ensure that appropriate data cleaning or data manipulation has been undertaken	NWORTH co-applicants will be co-authors on any relevant published output and that the publication strategy is discussed *a priori* with relevant members of the NWORTH team. Appropriately costed time for study wind-down and completion of necessary governance arrangements. NWORTH will provide a data-pack after the formal end of the trial / study. Further statistical input or secondary analysis beyond the pre-defined Statistical Analysis Plan will require further resources to be agreed with the Unit.

	1. An appropriate trial team member (e.g. the Trial Manager or a Research Officer) to assist in the specification of NWORTH supplied IT systems For Electronic Data Capture Systems (e.g. via MACRO) this will include the provision of final CRFs, contributing to and reviewing EDCS question definitions (categories, scoring, warnings, skip logic, visit schedule based question visibility etc) and the subsequent review and sign off of the NWORTH generated User Requirements Specification (URS) 2. Once the IT systems have been built by NWORTH to meet their URSs, trial team members (nominated by the PI, CI or Trial Manager) are to perform user testing as specified within NWORTH provided test and qualification documents. 3. Nominated trial representatives are to attend face to face or virtual training sessions covering the NWORTH developed IT systems	prior to sending information to NWORTH unless this has been delegated to NWORTH statistical team (when we are involved with statistical analyses). CIs to take full responsibility for the study finances (although day-to-day monitoring may be delegated to NWORTH, as appropriate). Early notification of expected changes or delays in study timelines which will impact upon NWORTH's input. Should an extension be required, NWORTH will be required to determine the additional costs and seek recovery from the CI over a mutually agreeable timeframe.	

	Note a MACRO based EDCS development for a new trial typically takes up to 3 months from the URS sign off to being live for data capture. Agree appropriate data management support. It is NOT the task of NWORTH trial statisticians to undertake extensive data cleaning/manipulation.		

***if substantial changes are made in the process of set-up, NWORTH reserve the right to make an additional charge for the additional time for staff**

Figure 1: Overview of NWORTH portfolio adoption process