Developing Clinical Research in Trauma & Orthopaedic Surgery in the UK

SUMMARY

The British Orthopaedic Association (BOA) is working with partners, notably the Royal College of Surgeons of England (RCS) and Arthritis Research UK (ARUK) to develop research infrastructure in Trauma & Orthopaedic Surgery (T&O) in the UK. The strategic aim is to develop and expand the T&O clinical trials portfolio over the next five years. The first step is to establish centrally funded methodological support embedded within an existing UKCRC-registered Clinical Trials Unit (CTU).

We are calling for grant proposals from CTUs to host and support a Senior Research Fellow / Trial Methodologist experienced in the design and conduct of surgical trials. The CTU will be expected to provide essential multi-disciplinary support for development of trial protocols and grant applications. Any CTU interested in applying for this grant, will ideally have a candidate in mind for the role, or a track record of recruiting similar candidates to provide an assurance that they could recruit/retain a suitable individual.

The Senior Research Fellow / Trial Methodologist will be required to work closely with the Chairman of the BOA Research Committee and relevant individuals and organisations (such as Arthritis Research UK) to identify trial ideas, facilitate their development and support the preparation of funding applications to relevant grant-giving bodies. They will be supported by Chairman of the BOA Research Committee and facilitated by dedicated surgical subspecialty leads (including leads appointed by RCS), who will have the responsibility to ensure that trials are relevant to specialty development and the patients being treated. These surgical leads will develop clinical networks required to run the trials, will help train the surgical investigators and thus facilitate delivery of clinical trials in a timely fashion.

The key deliverables for the post will be development of at least two new grant applications per year and to establish two new multi-centre trials in the first two years. This is also intended to help the RCS clinical research initiative, which aims to engage and train 50 new surgical investigators, and recruit 600 patients nationally to surgical trials in the first four years.

The funding available would be used for costs of employment and expenses. It is anticipated that the CTU involved would have the opportunity to run and manage any trials developed through this initiative that result in successful funding awards.

BACKGROUND

Musculoskeletal disorder affects over 6.5 million individuals of working age in the UK. Currently, 1.6 million T&O surgical procedures are carried out annually in the UK, with the rate of surgical intervention increasing but still lower than comparable countries. The New
BOA Research Strategy outlines the challenges faced by the specialty, including the need to conduct high quality surgical research in order to inform clinical treatment decisions.

The importance of multicentre, clinical research in maintaining and developing a high quality service has been recognised by the NHS, which has ring-fenced £1 billion per annum (1% of the total health budget) for this purpose, protected through to 2015. T&O currently attracts a very small proportion (of around 1.5% attracted by all surgical specialties) of this funding. Two key factors that have led to lack of trials in surgical disciplines are the complexity of surgical trials and the potentially hazardous and invasive nature of interventions.

We intend to address these challenges by boosting our trials infrastructure in conjunction with the RCS clinical research initiative and by influencing change in the research culture in our specialty. This is already showing progress, with a number of T&O multi-centre trials now registered on the national portfolio. We now intend to support development of trials in T&O further by securing sufficient methodological expertise and support.

This strategy aligns with that of RCS, where solutions are being sought by the RCS and key funding partners, including the National Institute for Health Research, the National Cancer Research Network and Cancer Research UK. It is clear that huge patient benefits will be gained from a rapid expansion in surgical trials, and delivery of such a programme is now seen as a priority for the NHS.

**REQUIREMENTS FOR HOST CTU**

The Host CTU will need to have and demonstrate:

- Senior-level commitment to support this initiative;
- Experience of developing and successful delivery of multi-centre clinical trials in surgery, ideally trauma and orthopaedic surgery;
- A track record in securing funding for clinical trials in collaboration with relevant parties;
- That it has appropriate employment and HR policies in place to appoint and manage the post-holder on a day-to-day basis.

The Host CTU will be expected to:

- Recruit or designate an individual to take up this role;
- Collaborate with the BOA, other trials units, specialist societies and other relevant bodies to contribute to the successful implementation of the BOA’s strategy;
- Collaborate with the BOA in promoting this initiative;
- Provide day-to-day line management and employment support to the postholder;
- Provide multi-disciplinary support for development of trial protocols and grant applications;
- Undertake financial oversight of the grant, including budgeting, tracking and reporting costs;
- Agree on a workplan with the BOA at the start of the grant and liaise with the Research Board during the course of the grant if any deviation is expected or needed;
- Be held accountable for the progress on the grant; this shall include reporting developments and progress achieved through the grant to the BOA Research Board twice a year, and provide senior representation for these meetings as requested (with due notice given by the BOA). These reports may be circulated more widely within the BOA, and used for publicity purposes as required.
- Be part of a Host Institution that accepts and abides by the BOA’s standard terms and conditions of grant award. (These are available online alongside the present document.)
It is assumed that the host CTU will not levy a service charge, other post holder support costs or any indirect costs associated with this grant. The CTU may appoint the individual as an employee or a contractor at their discretion.

**REQUIREMENTS OF SENIOR RESEARCH FELLOW (SRF) / TRIAL METHODOLOGIST**

The Senior Research Fellow (SRF) / Trial Methodologist will act as a key link between a CTU / Surgical Trials Unit (STU) and the BOA Research Board or Committee nominated surgical specialty lead to develop multicentre clinical trials within T&O.

The SRF is expected to act as the main CTU contact for interested clinicians and to provide a forum for discussion and development of proposals that can be processed through appropriate funding bodies. Support from the CTU / STU where the post holder is based will be provided to work up proposals, prepare protocols, and develop trial material. Once a project is in the latter stages of preparation, the trials unit will also help prepare an Integrated Research Application Service (IRAS) application and oversee the acquisition of funding.

The SRF would likely have experience in multi-centre clinical trials and a track record of working effectively with clinicians. They would also be expected to co-chair a clinical research group to help develop new trials in their field. Such a group would usually be within a specialist society. The BOA Research Committee, specialist societies of the BOA and specialty leads will further develop surgical research networks, encompassing both consultants and trainees where appropriate in order to help deliver commissioned trials.

**SUPPORT**

The BOA Research Board and Research Committee will provide a broad base of support for the SRF, for example in with prioritisation and choice of research questions to be developed into grant proposals. Expert guidance in topic selection and developing multi-centre/multidisciplinary teams will be provided. It is envisaged that the SRF, along with surgical leads, will work, where feasible, as a *clinical study group* using the NCRI model, to help develop ideas and disseminate best practice. Other models for research priority setting, notably in partnership with the James Lind Alliance are under way and should help identify key research questions in T&O subspecialist areas.

It is also expected that the CTU that hosts the post holder will provide full multi-disciplinary support for development of new research grant proposals for multi-centre surgical trials in T&O. It is also anticipated that the CTU that has helped develop the proposal and grant application will be given the opportunity to run and manage the trial if commissioned.

The Local Clinical Research Networks (LCRNs) will provide research infrastructure support for the individual units participating in these portfolio trials.

The NIHR surgical specialty group will provide an infrastructure to ensure wide publicity for national participation in these portfolio studies.

**PERSON SPECIFICATION FOR THE POST**

It is envisaged that the Host CTU would produce a job description and personal specification for the postholder, which should be submitted for review by the BOA as part of the process of applying for funds.

We would envisage that the person specification would cover the following:
The successful candidate would be expected to be post-doctoral senior research fellow with a track record of running multi-centre clinical studies, including randomised controlled trials. A track record of publication of multi centre studies would be beneficial.

Experience of developing multi centre clinical trials, writing protocols, submitting applications to IRAS and applying for external funding would be expected.

The candidate would be expected to have experience of working with multi disciplinary teams, developing and leading committees, along with evidence of project development and timely delivery.

Key qualities/experience
1. Academic track record in clinical research
2. Experience of submitting grant applications to NIHR, research councils, and / or charities
3. Working knowledge of clinical trials and experience of working with trials units
4. Creative and energetic team player
5. Effective interpersonal and time management skills
6. Evidence of delivering projects or activities to set time frames and budgets

MILESTONES AND DELIVERABLES

Year 1
• Develop working partnership with the base CTU / surgical trials unit
• Establish (multidisciplinary) working group for study development
• Engage with identified surgical leads to help with study development and delivery
• Work up two potential multicentre studies, with one being taken forward for portfolio status and funding

Year 2
• Open first multi-centre study for recruitment
• Start recruitment from at least 10 centres

Year 3
• Open 2\textsuperscript{nd} multi-centre trial and establish one new surgical CI
• Open (total) 20 participating centres and at least 20 surgical PIs

It is expected that dedicated trial managers will be needed for the new trials arising from this grant, and that this role will not be overseen under this initiative, in order to allow the focus here to be development of further new grant proposals.

FUNDING AVAILABLE

The funding available is a maximum of £60,000 per annum, including salary and associated costs and the postholder’s expenses incurred directly with the role. The BOA will not support institution indirect costs (in line with Association of Medical Research Charities guidance).

Funding is available initially for three years, with the second and third years of funding renewable annually, based on satisfactory assessment of performance.

Potential applicants may be interested to know that the BOA is also committing an additional £4,000 in 2014 for partnership with specialist societies and the James Lind Alliance for research priority setting and identification of key research questions. The CTU and postholder would be likely to be involved in this but would not receive additional funding.
HOW TO APPLY

Interested CTUs must apply by **Thursday 30th January 2014**, providing the following information:

- A letter outlining the suitability and commitment of the CTU for working on the initiative (up to 2 pages)
- Confirmation from an appropriate administrative authority at the host institution confirming the institution’s acceptance of the terms and conditions of grant award if successful. (These are available online alongside this document.)
- A financial statement indicating the total grant request and proposed 3 year budgetary breakdown of grant (maximum of £60K per annum)
- A copy of the CV of the proposed postholder outlining his/her suitability (if an individual has been identified) or information on the proposed recruitment plan if there is no proposed postholder
- A proposed job description and personal specification for the role

Applications will be reviewed and shortlisted by members of the Research Board with representation from the BOA Exec (but excluding any members with a conflict of interest - i.e. those members formally affiliated to applying institutions). Interviews will be held on **Wednesday 26th February 2014** for the shortlisted applications, which we will expect a representative of the CTU and the proposed postholder (if applicable) to attend. Further details of the interview process will be provided to shortlisted applicants.

To apply, please send all relevant documents to **l.rich@boa.ac.uk**.