



Developing Clinical Research in Trauma & Orthopaedic Surgery in the UK: Funding Call for BOA sponsored units for T&O trials in the UK

SUMMARY

The British Orthopaedic Association (BOA) has been working with partners, notably the Royal College of Surgeons of England (RCS) and Versus Arthritis, to develop clinical research infrastructure in Trauma & Orthopaedic Surgery (T&O) in the UK. After five successful years working with the British Orthopaedic Surgical Research Centre in York, the BOA is keen to extend this project. The strategic aim is to further develop the T&O clinical trials portfolio over the next five years.

We are seeking applications to establish centrally funded methodological support embedded within one or more existing UKCRC-registered Clinical Trials Units (CTUs). We are calling for proposals from CTUs experienced in delivering surgical trials. The CTU will be expected to provide essential multi-disciplinary support to develop study protocols and grant applications in the field of Trauma and Orthopaedics.

The CTU will work closely with the BOA Research Committee, who will have the responsibility to ensure that trials are relevant to specialty development and the patients being treated.

The key deliverables for the award are outlined below.

The funding available may 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. Priority will be given to CTUs that can demonstrate how the funding will increase their capacity for surgical trials beyond their current level.

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 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. T&O currently attracts a disproportionately small proportion of this funding compared to the massive burden of musculoskeletal conditions on

NHS expenditure. 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 are addressing these challenges by further boosting our trials infrastructure. 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.

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 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 (or otherwise can demonstrate a significant interest in expanding their portfolio in T&O and how this could be achieved);
- A track record in securing funding for clinical trials in collaboration with relevant parties;
- That it is fully UKCRC-registered.

The Host CTU will be expected to:

- 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, other trials units, specialist societies and other relevant bodies to disseminate the outcomes of the host CTU's work and to raise awareness of the successes, to the BOA membership and more broadly. This may involve presentations at BOA Congress and associated meetings, and articles in the Journal of Trauma and Orthopaedics and other relevant media;
- Provide multi-disciplinary support for development of trial protocols and grant applications;
- Identify an individual to be held accountable for the progress on the award; this shall include reporting developments and progress achieved through the grant to the BOA Research Committee 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);
- Proactively provide support to PIs and CIs nationally, in line with the BOA being a national organisation, and particularly support first-time PIs and CIs in order to build capacity and capabilities.

SUPPORT

The BOA Research Committee will provide a broad base of support for the award, for example with research prioritisation exercises and advice regarding the choice of research questions to be developed into grant proposals. Expert guidance in developing multi-centre/multidisciplinary teams will be available.



EXPECTED OBJECTIVES in addition to milestones

Year 1

- Development of a working partnership between the base CTU / surgical trials unit and the BOA Research Committee and BOA members.
- Review existing and ongoing research priority-setting exercises supported by the BOA.

Year 2

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

Year 3

- Open 2nd multi-centre trial
- Establish one new trainee co-applicant
- Open a minimum of 20 participating centres and at least 20 surgical PIs and Associate PIs

MILESTONES AND DELIVERABLES

Year 1

- Establish (multidisciplinary) working group for T&O study development
- Develop patient and public involvement groups relevant to trials in trauma and orthopaedic surgery
- Develop associate PI schemes to enhance recruitment into trials
- Submit two applications for potential multicentre studies in T&O
- Establish one new surgical CI

Year 2

- Submit two applications for potential multicentre studies in T&O
- Establish one new surgical CI

Year 3

- Establish one new surgical CI
- Submit two applications for potential multicentre studies in T&O

FUNDING AVAILABLE

The funding available is a maximum of £40,000 per annum. 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. While we are, in principle, interested in funding the full grant of £120,000 over three years, we are in the first instance awarding the funding for the first year of £40,000, as per our usual grant-award practice. Confirmation of future years' funding is subject to satisfactory progress.

We will require regular progress reports from you. Payment will be quarterly in arrears, on receipt of the Host Institution's appropriately itemised invoices, in line with the funding structure set out in your initial application. The future years' funding will be assessed based on the performance report received at the nine month time point. Failure to provide a



report by the deadline may delay a decision about continued funding of the project, and may jeopardise future funding. In addition, payments may be withheld if reports are not received. Payment of the invoice on the final quarter of the grant will be subject to receipt of a satisfactory final report.

The BOA is not specifying how the funds should be spent, but is looking for the applicants to outline the intended use of the funds in order to meet the aims and objectives of the programme.

RELATED FUNDING

The BOA is also committing £4,000+ annually for partnership with T&O specialist societies and the James Lind Alliance for research priority setting and identification of key research questions. We would like to encourage the BOA-sponsored CTUs to support trials in priority areas identified by previous JLA projects (such projects have been undertaken in various T&O areas over the past 5 years).

HOW TO APPLY

There are two deadlines that interested CTUs must meet in order to apply.

- 1) An initial expression of interest will be due by **Wednesday 8th January 2020**. This should include the name of the CTU and institution, the names of the principal applicant, the names of any co-applicants and a single paragraph of support. Please send your expression of interest to [insert email].

This information will be used to help us in our planning but does not form part of the assessment process. All those submitting an expression of interest should submit a full application as per the below.

- 2) Interested CTUs must submit their full application by **Tuesday 28th January 2020**, providing the following information:
 - A letter (up to 2 pages) outlining:
 - the suitability and commitment of the CTU for working on the initiative
 - what the BOA funding would be used for and how this would deliver the objectives outlined above
 - 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 £40K per annum)

Applications will be reviewed and shortlisted by members of the Research Committee with representation from the BOA Executive Group (but excluding any members with a conflict of interest - i.e. those members formally affiliated to applying institutions). Interviews will be held in late March 2020 for the shortlisted applications, which we will expect a senior representative of the CTU to attend. Further details of the interview process will be provided to shortlisted applicants.

To apply, please send all relevant documents to policy@boa.ac.uk.