



mail@bsbmt.org

# IMPACT

## The Partnership for Accelerated Trials

Transplant Centre Bid 2017-01-26

### Application Form Guidance

Applications from interested Transplant Centres are invited to join IMPACT to deliver a portfolio of randomised prospective trials in stem cell transplantation and related cellular therapies.

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## Background

### IMPACT Aims

The overarching aim of IMPACT is to accelerate and facilitate the delivery of a portfolio of randomised phase 2 and 3 trials by UK transplant centres. It is anticipated that 9-12 trials will be delivered over the four-year pilot, with approximately 400-500 patients participating.

By reducing set-up and creating new capacity, the IMPACT trials network represents a potentially transformative development within the UK transplant community with the potential to accelerate trial delivery and improve patient outcomes.

In addition, the platform offers the opportunity, through the provision of high-quality biological samples with matching clinical data, to drive basic scientific research in areas such as predictive biomarkers, genomic mechanisms of resistance to therapy and drug discovery. Discussions with the MRC have confirmed the substantial contribution that the initiative can make to the UK's scientific infrastructure in areas such as stem cell biology and regenerative medicine. To ensure this scientific focus is firmly embedded in the platform's governance structure, a Scientific Advisory Group, Chaired by Professor Paresh Vyas, is being established.

### How IMPACT is structured

The model reflects the experience of successful trials networks already in place, which demonstrate the value of a 'hub and spoke' approach comprising:

- A central *Management Hub* overseeing and facilitating the design, regulatory approval and delivery of a trials portfolio by the UK transplant community. Working with transplant clinicians the Hub will provide a dedicated resource focussed on trial development patient recruitment data management, statistical analysis and publication. To ensure trials are supported by a hub that is integrated within the strategic, management and operational structures of an academic clinical trials unit with experience in both accelerated trials delivery and a proven track record of transplant and haemato-oncology trial

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delivery, it is located within the Cancer Research UK Clinical Trials Unit (CRCTU) at the University of Birmingham.

- An *integrated network of Transplant Centres* collaborating to open studies, recruit patients and share data. By funding full time research nurses working at research active BMT Units the IMPACT network will create new resource permitting rapid patient recruitment and high quality trial delivery

Taken together, these components will help to overcome the recognised barriers

to accelerated clinical trial design and delivery, including the challenge of trial delivery by busy clinicians and ensuring dedicated resource is available for patient recruitment and data return

### **Prioritising and approving clinical trials**

The BSBMT Clinical Trials Committee (CTC) will make an open, competitive call for proposed trial concepts to all Transplant Centres biannually, and prospective investigators will be assisted by the Management Hub in the development of their proposals. These will be considered by a subcommittee of the BSBMT CTC, which will include representatives from the Management Hub who will take into account the relevance and scientific originality of proposed clinical questions, including anticipated benefits to patients and the ability to recruit rapidly within 24-30 months.

If a trial proposal meets the criteria for adoption, feasibility assessments will be undertaken by each participating Transplant Centre. Proposals will be worked-up as a grant application by the IMPACT Management Hub and submitted for peer review. Successful proposals will progress through the eligibility process for adoption on to the NIHR CRN national portfolio.

Proposals will then proceed to 'set-up' phase, and will be submitted for ethical and regulatory approval. Participating sites will confirm local capacity and the trial will open for recruitment. The hub and participating sites will work closely with the NIHR CRN during set-up, liaising with Local Clinical Research Networks and R&D offices to ensure sites receive the maximum support to establish and deliver studies.

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## Assessment criteria and selection process

### Participating UK Transplant Centres

Initially, ten Centres will receive funding for a dedicated research nurse with responsibility for patient recruitment, data reporting and the collection of samples to facilitate adjunctive scientific studies. Depending on the availability of additional resources for the initiative, there is an aspiration to expand the number of Centres receiving this funding. The duration of the award will cover the four year term of the IMPACT pilot, subject to standard criteria concerning recruitment to time and target, data submission and participation in IMPACT meetings reviewed on an annual basis to confirm continuation of funding. The funding will provide for one whole time equivalent mid-point Band 6 Research Nurse.

All UK Transplant Centres are eligible to apply for funding, and decisions will be made through a rigorous process of external peer review and approved by the IMPACT Oversight Committee.

Transplant Centres who do not receive a grant to fund a research nurse but can demonstrate the required capacity and capability to deliver clinical trials will also be encouraged to join the network as a full participating member. Accrual to trials and data submission will be monitored for these centres.

IMPACT centres will be selected via an open, competitive peer-reviewed application process overseen and ratified by the IMPACT Oversight Committee.

To review applications IMPACT will convene an expert panel including representation from stem cell transplant specialists and clinical trialists, Chaired by a non-UK expert in stem cell transplantation. The panel will consist of:

Chair: Professor Nicolaus Kroeger  
Professor David Marks IMPACT - Medical Director  
Professor Charlie Craddock - IMPACT Clinical Hub Lead  
Representatives from the NIHR  
Shamyla Siddique – Acting IMPACT Hub Team Leader  
Dr Sue Bailey – Bristol-Myers Squibb and Association of the British Pharmaceutical Industry

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This panel will assess the applications against the criteria below and the application form then provide a recommendation to the IMPACT Oversight Committee on the Transplant Centres to be selected. Feedback on the outcome will be provided on request.

### Selection Criteria

These will include:

- A demonstrable track-record of successful clinical trial delivery of NIHR CRN portfolio early and late haemato-oncology and transplant studies.
- Numbers of patients recruited to transplant studies
- An adequate clinical trials infrastructure supported by their Local Clinical Research Network (LCRN).
- The academic track-record of the Centre's transplant team.

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## General Information

- All information pertaining to the application process will be treated as confidential
- Applications that do not contain all the information requested may not be considered
- All applications will be peer reviewed by an expert panel with the necessary skills and experience to make an informed decision
- All participating IMPACT centres will be encouraged to submit trial proposals to the BSBMT CTC
- Submission of a trial proposal in the open, competitive call for clinical studies is independent of the Transplant Centre selection process
- Applicants will be informed in writing about the outcome
- By completing the application form the applicant confirms that the contents are accurate and correct

## Timelines

09/02/2017	Application process communicated via BSBMT
09/02/2017	Application process opens
10/03/2017	Application process closes at 12pm
Early March	Applications reviewed by independent panel
20/03/17	Panel meet
Late March	Centres notified of outcome

### CLOSING DATE:

Please ensure applications are sent to

[Alexandra.ross@nhsbt.nhs.uk](mailto:Alexandra.ross@nhsbt.nhs.uk) by 12pm on 10/03/2017

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