

IMPACT

The Partnership for Accelerated Clinical Trials

IMPACT Transplant Centres Application Form Guidance:
Bid for Transplant Centre Grant and IMPACT Membership

Applications from interested Transplant Centres are invited to apply for IMPACT research nurse or other trial-related staff funding to assist in delivering a portfolio of prospective trials in stem cell transplantation and related cellular therapies

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. By reducing the time for set-up and creating new capacity, the IMPACT trials network has been a transformative development in accelerating trial delivery with the potential to improve patient outcomes.

Since the inception of the specialised clinical networks, the IMPACT and TAP networks have demonstrated their value by recruiting over 2000 patients to trials, informing clinical practice in the UK and internationally, and creating access to innovative therapies, many of which have been subsequently approved by NICE.

How IMPACT is structured

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

- *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 trial centres, the IMPACT network has created new resource permitting rapid patient recruitment and high-quality trial delivery
- *A central trial delivery vehicle* which oversees and facilitates the design, regulatory approval and delivery of a trial portfolio by the UK transplant community. Working with transplant clinicians, this provides a dedicated resource focussed on trial development, patient recruitment, data management, statistical analyses and publication. This function was previously provided by the CRCTU at the University of Birmingham. For future studies, the trial hub functions will be provided by Accelerating Clinical Trials Ltd (ACT).

Taken together, these components aim to overcome the recognised barriers to opening and recruiting to clinical trials, including attempting to meet the challenge of trial delivery by busy clinicians and ensuring dedicated resource is available for patient recruitment and data return.

Accelerating Clinical Trials Ltd (ACT) has been created as a not-for-profit clinical trial delivery vehicle specialising in blood cancers with the mission:

- *To accelerate haemato-oncology patient access to novel medicines, combinations and cellular therapies, and to improve outcomes for patients.*
- *To attract, support and deliver research trials in the UK for patients with blood cancer.*

ACT is delighted to support the IMPACT network by acting as the trial delivery vehicle for future IMPACT-portfolio studies. ACT will be providing funding to support the dedicated IMPACT research nurses or other trial-related staff.

ACT will deliver a mixed portfolio of investigator-initiated and industry-sponsored trials. Commercial trials will have per-patient funding as per the usual arrangements.

DIDACT Foundation is a charity set up to:

- Improve the outcome of patients with blood cancer through the delivery of clinical trials in the UK
- Provide education and training for clinicians, nurses and associated medical practitioners working in the field of blood cancer
- Publish the results of clinical trials and any associated research for the benefit of the public

Prioritising and approving clinical trials

The IMPACT Medical Leadership will make open, competitive calls for proposed trial concepts for investigator-initiated clinical trials. These proposals will be prioritised by the IMPACT medical leadership team, working together with other key stakeholders, such as the BSBMT-CT and the NCRI Haematology-Oncology Group.

The DIDACT Foundation and ACT will provide prospective investigators with assistance to develop the prioritised trial proposals, especially with regards to concept and protocol development, access to translational science, and a rapid feasibility and site selection process through the IMPACT network. Proposals will be developed as grant applications to increase likelihood of success in achieving funding. Successful proposals will be submitted for peer review, and progress through the eligibility process for adoption on to the NIHR CRN national portfolio. Proposals will then proceed to 'set-up' phase before submission for ethical and regulatory approval. Participating sites will confirm local capacity and the trial will open for recruitment. The 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.

Assessment criteria and selection process

ACT is providing £1.8 million grant funding to support UK transplant centres deliver clinical trials. The duration of these awards will be for 3 years, subject to centres meeting the following criteria: a commitment to open IMPACT portfolio trials, return of accurate feasibility surveys, recruitment to time and target, timely data submission, provision of translational research samples and regular participation in IMPACT meetings. The meeting of these criteria will be reviewed on an annual basis to confirm continuation of funding. Centres will receive funding towards the costs of a Band 6 (midpoint) research nurse with responsibility for patient recruitment, data reporting and the collection of samples to facilitate adjunctive scientific studies. As an alternative to a research nurse, there will be an option for centres to request equivalent support towards other non-medical trial staff (e.g. Trial Practitioner, Trial Pharmacist, Data manager). Depending on the availability of additional resources for the initiative, there is an aspiration to expand the number of centres receiving this funding in the future.

Transplant Centres who do not receive grant funding through this call, but who 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.

All UK Transplant Centres are eligible to apply for funding. Centres will be also expected to provide information to address how they would use funding for specified roles in the event they do not receive the full level of funding. IMPACT centres will be selected via an open, competitive peer-reviewed application process overseen and ratified by the IMPACT Medical Leadership team. To review applications for grant funding for both the IMPACT and TAP networks, the IMPACT and TAP Medical Leadership Teams will convene an Independent Expert Panel including representation from non-UK and UK specialists in stem cell transplant, cell therapy and clinical trials.

The panel will consist of:

1. Chair: non-UK International expert
2. Medical Director of IMPACT
3. Medical Director of TAP
4. Clinical trial delivery hub – Accelerating Clinical Trials operational representative
5. Clinical trial delivery hub – Accelerating Clinical Trials Board member representative
6. DIDACT Foundation representative
7. NCRI Haemato-Oncology chair
8. NCRI Lymphoma chair
9. Funder 1 – NHSBT representative
10. Funder 2 – Cure Leukaemia representative
11. Patient representative 1
12. Patient representative 2

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

Selection Criteria

These will include:

- Evidence of strong commitment from the host organisation and proposed IMPACT Lead Investigator to support future IMPACT portfolio studies
- A clear description of the process for trial prioritization and expected timelines for local trial set up
- A demonstrable track-record of successful clinical trial delivery of early and late haemato-oncology, transplant and cell therapy studies
- Numbers of patients recruited to clinical trials, adjusted to overall activity
- For centres currently funded through IMPACT, prior performance in opening and recruitment to the IMPACT portfolio clinical trials
- An adequate clinical trials infrastructure supported by their Local Clinical Research Network (LCRN)
- A commitment to training and career development of clinical trialists and trials-associated researchers.
- A robust programme of patient and public involvement and engagement

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
- Applicants will be informed in writing about the outcome
- By completing the application form the applicant confirms that the contents are accurate and correct

Application Timeline:

w/c Monday 31 st October 2022	Process communicated and applications invited
1700 Friday 2 nd December 2022	Application deadline
w/c 12 December 2022	Independent Panel reviews applications and makes recommendations
w/c 9 th January 2022	Funding decision communicated by ACT

CLOSING DATE:

Please ensure applications are submitted by email to info@act4patients.com by 1700 on Friday 2nd December 2022.