Blood cancer UK

Guidance for Applicants

Introduction

Blood Cancer UK has a five-year organisational strategy focused on bringing forward the day when no one dies of blood cancer or its treatments.

This includes a commitment to significantly increase our research funding over the course of the strategy. In recognition of this increased research investment and ambition, we are currently refreshing our research strategy so that we can ensure we are making this increased investment in the areas where it can have the biggest impact for people affected by blood cancer.

We are excited to launch this new clinical trial funding scheme through which we will support large-scale clinical trials that have significant potential to improve the survival for those affected by the hardest to treat blood cancers.

Remit

This scheme is open to applications for innovative, large-scale clinical trials testing multiple interventions that are adaptable in design (for example, multi-arm, multi-stage trials). Applications must focus on the testing and development of at least one of the following:

- Novel treatments or treatment combinations;
- Improvements in treatment sequencing/scheduling;
- More personalised treatment approaches, for instance through use of/development of predictive or prognostic biomarkers.

All applications must also:

- Be inclusive by design and have an inclusive recruitment strategy in place to ensure patients recruited are representative of the disease group/subgroups under investigation.
- Have a clearly defined pathway to impact, aiming to achieve paradigm-shifting changes to current clinical practice or disease management for people living with the least survivable blood cancers.

Studies must be focused on patients with blood cancer who, with current clinical management, have a predicted 5-year survival of less than 50% at the point of diagnosis.

As an example, this could be acute myeloid leukaemia, myelodysplastic syndromes, myeloma or certain subtypes of lymphomas (based on the latest HMRN statistics). However, we recognise that certain blood cancers can also have poor survival, when considering demographic factors or disease subgroups. Applicants will therefore be asked to provide detail on how the study being proposed fits the remit, as well as provide justification for the patient and clinical need of this study. Whilst applications must focus on at least one blood cancer group with a 5-year survival of less than 50%, they may involve recruitment of additional disease groups, however these must also have a 5-year survival of less than 50% at the point of diagnosis.

We intend to support one study in each of the main disease areas: myeloma, leukaemia and lymphoma.

We would also encourage studies to include (where appropriate):

- Biomarker stratification;
- Translational research where this is aligned with and adds value to the clinical research questions. We would expect this to be no more than 20% of the overall budget but can consider smaller/larger requests if justified (please discuss with Blood Cancer UK staff prior to submission);
- Inclusion of Quality-of-Life endpoints;
- International collaboration and recruitment, if justified (for instance, in rare subtypes with small patient numbers);
- Industry collaboration;
- A plan for long-term follow up, where suitable, to facilitate Health Economics assessment/data analysis and enable longer-term adoption into clinical practice;
- Integration of real-world data sets (such as electronic health records/patient registry data) to monitor long-term outcomes or validate findings.

Grants will typically range from £4m to £8m, for up to seven years. The maximum that can be requested is £8m.

What we are not looking for:

- Single-arm studies testing one intervention or standard two-arm randomised control trials;
- Studies requesting funding for the master protocol only, with no arms yet planned or designed;
- Tool or technology development applications;
- Infrastructure funding requests.

Eligibility

We expect studies submitted to this scheme to be large collaborative programmes of work.

- The Study
  - Studies must be Investigator-led, interventional studies of blood cancer treatments.
  - Supported and/or developed by the relevant UK Blood Cancer Research Network group.
- The Institution:
  - This funding scheme is open to individuals based at UK universities, hospitals or other recognised research institutions who are able to sign up to Blood Cancer UK's Terms and Conditions.
  - Applications must be developed with the participation of a relevant UKCRC registered Clinical Trials Unit (CTU). The CTU must have experience delivering large complex clinical trials.
- The Applicants:
  - Lead Applicants must have experience in running complex, large-scale clinical trials and should be scientists, clinicians or healthcare professionals employed by a UK university, medical school, hospital, or other recognised academic research organisation. This scheme is not open to applicants employed by a commercial organisation.
  - A senior statistician must be involved as a Co-Applicant on the application to ensure appropriate statistical oversight.
  - Named Patient and Public Involvement (PPI) representative(s) must be involved as a Co-Applicant(s) on the grant (see the below PPI section for more information).
  - We would typically expect Lead and Co-Applicants to have salary support from their host institution for the duration of the award. However, we will consider case-by-case salary funding requests, for example, where clinician buy-out for research is required or

where an early-career researcher is spending the majority of their time on this grant and requires salary support.

We would also strongly encourage:

- Involvement and participation of Early-Career Researchers (ECRs), for example as Co-Applicants. Evidence of support and mentorship of ECRs involved in the application is essential.
- Embedding training opportunities for Research Nurses.

Additional Expectations

Patient and Public Involvement

We expect meaningful Patient and Public Involvement (PPI) to be embedded in all studies. As these are large complex trials, we would expect more than one PPI representative to be involved in both the design and delivery of the study. Applicants must also seek to involve a diverse group of PPI representatives.

Other PPI expectations include:

- Early engagement and involvement of PPI members during the development of the application, including at the EOI stage, to ensure alignment with the patient pathway and acceptability of the trial design.
- Involvement of named PPI representative(s) as Co-Applicant(s) on the grant that support with the design, delivery and dissemination of the study.
- PPI representatives involved in the Trial Steering Committee and Trial Management Group (see below for more information).
- You will be required to provide a draft Patient Information Sheet (PIS) as part of your application. We would strongly encourage people affected by blood cancer to support PIS development and/or review prior to submission.
- Please ensure adequate costings for Patient and Public Involvement. This includes reimbursement of expenses (including care support costs) and/or involvement payments you have, or will, offer to people involved in your research. For further guidance, refer to the UK Standards for Public Involvement.

Blood Cancer UK Staff can support you with PPI, so please read our PPI guidance and contact the team (research@bloodcancer.org.uk) if you would like any further support. Staff can support you with guidance on how to involve people

affected by blood cancer in the development, design and delivery of your study, share relevant PPI resources, as well as provide a matchmaking service with existing PPI representatives from its network.

If your application for funding is successful, you will be asked to submit annual progress reports to Blood Cancer UK including updates on PPI activities and ongoing involvement of people affected by blood cancer throughout the study.

Inclusive Recruitment Strategy

In line with our Blood Cancer Action Plan, we want studies supported by this scheme to be leading the way in transforming how clinical trials are designed and conducted.

Studies must have a strategy in place to reduce barriers that hinder trial participation (in particular for under-served groups), for example geographical, cultural, financial or communication barriers. Studies must also have a strategy in place to ensure engagement with diverse and underrepresented blood cancer communities with the aim of recruiting participants that are representative of the disease group/subgroups under investigation.

When developing your recruitment strategy, we would advise involving a diverse range of people affected by blood cancer.

See below some examples of what you may wish to consider:

- Have an adaptable study design with broad eligibility criteria, thereby giving as many patients as possible an option to participate in one or more arms.
- Careful consideration to avoid any restrictive eligibility criteria or unnecessary exclusion criteria and how this may hinder participation from diverse groups of potential participants.
- Increasing sample sizes where sub-group analysis is designed to draw conclusive evidence and where this adds value to the study.
- Use of decentralised trial processes, where appropriate.
- Improving clarity and accessibility of trial information, for instance by having high quality, up to date and accurate information about the trial and recruiting arms that is findable and easily accessed by potential participants. Where required this should also be available in other languages or formats.

- Ensure that the trial is registered on a recognised trial registry (see below for more information), as well Blood Cancer UK's Clinical Trials Support Service.
- You may also want to use services such as NIHR Be Part of Research to reach additional participants.
- Removing geographical barriers to participation for instance, by having broad geographical representation of sites/centres, as well as having a strategy in place to enable patient recruitment from District General Hospitals.
- Removing cultural and communication barriers to participation, for example by having a strategy in place for engaging with diverse and underrepresented groups or including costings for the translation of Patient Information Sheets.
- Having a person-centred approach to enrolment, as well as allowing sufficient time for informed consent processes ensuring this is reasonable for those who may need longer than 24 hours.
- Removing financial barriers to involvement, for instance by including costs for patient travel and accommodation at sites.
- Development of community engagement resources that are tailored suitably to each community/target audience, co-created with those from under-served communities.
- Providing training to Healthcare Practitioners (HCPs) to increase awareness of trials and opportunities for participation in arms of the study.
- Incorporating sub-studies within your application, that investigate barriers to trial inclusion and/or non-participation, as well as analysis of any tested interventions.

Also, note that successful applicants will be asked to submit annual reports outlining progress against this strategy and provide (where appropriate) any diversity data on the participants recruited and how this compares with the disease under investigation.

Other Useful Resources:

- Dr Andrew Smart's report funded by Blood Cancer UK which examines some of the potential barriers and solutions for addressing underrepresentation of patients from minority ethnic groups in UK clinical trials.
- NIHR INCLUDE guidance
- Trial Forge INCLUDE Ethnicity Framework

- The Centre for Ethnic Health Research which has various resources on increasing the diversity of research participants, PPI representatives, as well as cultural adaptation and trial design.
- Equality Impact Assessment (EqIA) Form Guidance Notes
- HRA resources for public involvement in research

Trial Conduct

- Data and samples:
  - For studies involving sample collection and banking, ensure appropriate patient consent is obtained to enable samples and data to be used for future analyses.
  - Datasets and samples must be annotated with high-quality metadata (including demographic data) to enable future analysis and disaggregation of results.
  - Datasets must be made available to other researchers and have a process in place to manage data access requests, in line with FAIR principles.
- Registration:
  - The study must be registered on a recognised trials registry such as the ISRCTN registry or the ClinicalTrials.gov registry before the first participant is recruited and no later than six weeks after. A lay/Plain English summary must be provided either on the registry itself or via a link.
  - Details on the registry must be kept up to date throughout the lifetime of the trial. Details of how to access the trial protocol and analysis plan must be provided on the registry and on the trial website, if one exists. Any approved changes to the protocol must be updated on the registry as soon as possible.
  - You will also be required to provide the up-to-date trial information and documentation to Blood Cancer UK's Clinical Trials Support Service when requested.
- Reporting of results:
  - Results from completed arms should be disseminated in a timely manner, whilst ensuring the integrity of other comparisons is not compromised.
  - Summary results must be made available within 12 months of the end of the study (where suitable and clinically acceptable).
  - Results must be published in a peer-reviewed journal, per Blood Cancer UK's terms and conditions.

- Study findings must be reported back to participants in a timely manner, in line with HRA guidance.

Trial Governance

Governance arrangements must be agreed with Blood Cancer UK at the full application stage.

Trial Management Group (TMG): For all trials, a Trial Management Group (TMG) should be established to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself. For large studies, the TMG may involve sub-groups responsible for monitoring individual components and a communication plan must be in place to ensure streamlined decision making.

Trial Steering Committee (TSC) and Independent Data Monitoring Committees (IDMC): these should be established as required. The membership of the TSC should include: an independent chair; a statistician; a clinician(s); at least one individual who is able to contribute a patient and/or wider public perspective; any additional relevant observers; any others with expertise relevant to the project. Independent members must make up a minimum of two thirds of the TSC membership. Members of the IDMC should be independent of the study team and the TSC.

Other governance expectations:

- PPI representatives must be involved in both the TSC and TMG, and more than one should be involved for larger more complex studies with multiple groups/committees.
- Blood Cancer UK reserves the right to attend TSC meetings as an observer.
- Copies of all TSC and all open IDMC minutes should be provided to Blood Cancer UK upon request.

Costs

As a member of the Association of Medical Research Charities, Blood Cancer UK will only fund directly incurred costs and not the full economic costs of the research. We will not fund directly allocated costs or indirect costs.

Please note the following additional cost guidance for this scheme:

- You must ensure the study is suitably resourced to enable timely and efficient trial set up. For example, please ensure NHS research costs are attributed correctly and that there is sufficient resource in place during the

set up to facilitate efficient regulatory and contract approvals to take place.
- Ensure suitable phasing of staff costs depending on the trial design. For large complex studies, more adaptive resource may be needed, as well as suitable project management support.
- You may request Research Nurse salaries as part of this scheme to ensure appropriate support for trial delivery at sites.
- For large and more complex protocols, ensure that the necessary data management, programmer and statistical support is in place to develop and maintain databases.
- You may request costs to facilitate recruitment of a representative and diverse group of patients to the study (see the inclusive recruitment strategy section for more guidance).
- Blood Cancer UK can only provide funding to eligible UK institutions. However, we are open to considering requests for international collaboration and recruitment, where suitably justified. Please outline this in your EOI so this can be discussed with Blood Cancer UK staff.

Industry Support and Involvement

Where the study involves support from industry, you will be asked to provide letters of support as part of your application. These letters of support should outline and provide assurance of what support will be provided (e.g. provision of free drug). You must ensure that the contract terms do not hinder the longevity of complex trials especially where there may be multiple arms supported through different sources. Please inform Blood Cancer UK staff if any challenges arise with obtaining Industry Support.

Before submitting your application, ensure you seek input and review from relevant groups

When developing your application, be aware that the following is expected from all applications prior to submission:

- Proposals should be discussed and endorsed by the relevant UK Blood Cancer Research Network disease specific study group prior to submission of your full application. Letters of support must be provided alongside the full application. To attend a meeting and discuss your proposal, please contact the Chairs of the relevant groups. Please let Blood Cancer UK know if you require further guidance on this.
- Ensure you have discussed all aspects of your trial design with regulators (HRA) prior to submitting your full application to Blood Cancer UK.

- In partnership with your local R&D office, we encourage you to involve the NIHR Research Delivery Network (RDN) in discussions as early as possible when planning your study to fully benefit from NIHR RDN support.

Review Process and Timelines

1. Submit your Expression of Interest (EOI) to Blood Cancer UK via email at research@bloodcancer.org.uk by 26th June 2025.
    - EOI submissions are open on a rolling basis, but we strongly advise submitting by the deadline to ensure staff can provide necessary guidance and support ahead of full application development and submission. Staff will check eligibility, remit and strategic fit, as well as provide you with guidance to assist with developing and submitting your application for funding review. It is only after your EOI is approved that you will be able to start a full application, and more guidance on the full application will be provided.

2. Submit your full application by 3pm on 1st October 2025.
    - Depending on the volume of applications submitted, the Strategic Funding Committee may triage the applications invited for interview.

3. Invitations to Interview sent in November 2025.
    - You will be given your approximate interview date, and we will also share some guidance about preparing for the interview at this stage.

4. Written comments from peer reviewers shared: ~January 2026.
    - These comments are intended to help you prepare for the interview. You may choose to respond to these comments in writing before your interview or respond to these as part of your interview.

5. Interviews with an Expert Interview Panel: ~Feb 2026.
    - The Interview Panel will comprise UK and international experts in the field relevant to your application, as well as people affected by blood cancer. Members of the Strategic Funding Committee will also be present observing your interview and may also ask questions.
    - We will share the Interview Panel membership with you as soon as this is confirmed.
    - You may be asked to provide clarification on any outstanding questions after the interview. Blood Cancer UK staff will be in touch if this is required.

6. Strategic Funding Committee Review: ~Feb/March 2026
    - This Committee will make the final recommendations, taking into consideration the scores and discussions from the Interview Panel, as well

as the strategic fit of the application.

7. Notification of outcome: ~March 2026

Questions

If you have any questions about this scheme, or if you would like to discuss your EOI prior to submission, please contact the Research Team.