THE TRANSLATIONAL AWARD FULL APPLICATION

Guidance Notes for the Full Application Stage 2025

Contents

Introduction

The Translational Award is looking to fund key ex vivo/in vivo Proof of Concept studies, with up to £400,000 per project available over 12 - 18 months. The primary aim for the scheme is to either drive concepts nearer to the clinic or fail faster. You should have already received communication from The Charity inviting you to have a video call to discuss the reviewer feedback in greater detail - please contact The Charity ASAP if you are yet to be contacted about this meeting. The purpose of the call is to provide reviewer feedback and advice to strengthen your application. This feedback will assist with developing the optimal translational path, ensure the most suitable models are used and advise about how to move projects closer to clinical implementation.

Key Considerations

We are looking for projects with a clear pathway to patient benefit, involving any modality, for any primary brain tumour type.

Projects should have strong target validation, with strong preliminary data in clinically relevant models. Therapeutic applications should ideally show evidence of efficacy, indication of blood brain barrier (BBB) penetration and have a lead candidate identified. This scheme is intended to generate the robust data packages required to secure further funding to move into the clinic. We intend to work with applicants to develop the optimal translation path, ensure the most suitable models are used and provide ongoing support to move projects closer to the clinic. We acknowledge that drug delivery systems and some advanced therapies, such as CAR-T cells, deviate from more traditional translational drug development routes. Therefore, please contact The Charity to discuss how these may fit the scheme, as we are keen to drive all innovation closer to the clinic.

In addition to academic proposals, we will consider applications from biotechnology companies on a case-by-case basis. This scheme is also open to international researchers/companies

Assessment Criteria

- Scientific excellence
    - Is the proposed target expressed by tumour cells?
    - Is the proposed target/mechanism significantly validated?
    - Is the proposed therapeutic intervention feasible?
    - If successful, will the data package generated be sufficient to secure onward funding for subsequent first in human (FiH) studies?
- Credible onward plans for both further funding and route to FiH.
- Evidence the team have the necessary knowledge and support (e.g. Translational Research Office (TRO)/Technology Transfer Office (TTO)/Consultants) to run a truly translational programme.
- Is the study designed to maximise the chances of a definitive outcome of either progressing towards the clinic or failing faster?
- Have the team considered what this intervention will look like as a patient treatment?

The Brain Tumour Charity is a member of the Association of Medical Research Charities (AMRC) and adheres to its principles of peer review. All applications will be considered by our Translational Advisory Board.

Key points

- The whole translational journey, including FiH studies, needs to be considered in advance.
- Projects should ideally result in clear stop/go criteria.
- Applicants should be starting to build their Target Product Profile (TPP) before applying.
- Optimal choice of models and justification is fundamental for the underpinning of this award.

- Tightly managed, detailed project plans are required at full application stage.
- The Charity will adopt a regular, proactive and light-touch oversight/advisory role for the lifetime of the award, working with applicants to ensure the project continues to progress towards the clinic, post-award.
- Funding can cover regulatory advice, statisticians, external consultants (medicinal chemistry, study design etc.) and will cover work outsourced to Contract Research Organisations (CROs).

Beginning your full Application

The application is available for completion via the Grant Management Portal which is only visible to applicants who have been invited to submit following the outline stage. Please read the system guidance, available on the portal, and use these guidance notes to support completion of the application.

For academic applicants: Please allow sufficient time for your Head of Department and Administrative Authority to approve this application before the grant deadline. Once the application has been submitted by the Lead Applicant, it will not be received by The Charity, until these individuals have given their approval.

For Commercial Applicants: Please allow sufficient time for the Chief Executive Officer (CEO)/Chief Scientific Officer (CSO) and Chief Finance Officer (CFO) – or authorised signatories - to approve this application before the grant deadline. Once the application has been submitted by the Lead Applicant, it will not be received by the Charity, until these individuals have given their approval.

Application Summary

Please complete the details requested, including:

- Title of the programme
- Proposed start date (must be between 01 March and 01 August 2026)
- The project duration must not exceed 18 months
- Total requested – this section will automatically populate when you complete the 'Budget' section of the application. This must not exceed £300,000 (projects < 12 months) or £400,000 (projects > 12 months).

Applicant details

Please note:

- Lead Applicants must hold an employment contract with their institution/company that exceeds the duration of the proposed research.
- If the Lead Applicant is based outside the UK and if the research will include UK research institutes/companies, then a Co-Lead Applicant from the lead UK Institution/company will be required.
- Co-Applicants will have access to edit this application, whilst Collaborators, TRO and TTO contacts will have read only access.
- Applications can only be submitted by a Lead Applicant.

Lead Applicant

Some of your details will have been pulled through from your CV and any remaining fields should be completed. Please add/amend basic information details in the 'Manage My Details' section of the Grant Management Portal.

A biographical sketch (CV) is required for the Lead Applicant. Please download the template from the application form and attach the completed version using the 

button.

The Lead Applicant's institution will be the Host Institution.

Please note:

- All financial awards will be made in Pounds Sterling (£). It will be the responsibility of the Host Institution to make conversions to other currencies.
- All costings should be completed in whole pounds only.
- The Charity is not responsible for any fluctuations in exchange rate over the course of the programme. We recommend that the Host Institution establishes a corporate exchange rate agreement if conversion to other currencies is required.

Co-Lead Applicant

If the Host Institution is based outside the UK, and the research will be conducted across UK and non-UK institutes/companies, a UK-based Co-Lead Applicant is required.

Please use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

The Co-Lead Applicant will be required to accept their involvement in the application prior to submission. They also need to ensure all their details are populated correctly and use the 'Manage My Details' section of the Grant Management Portal to add/ amend their basic information.

A biographical sketch is required for the Co-Lead Applicant. Please download the template from the application form and attach the completed version using the 

button.

Co-applicants

Please add the details of the Co-applicants. Use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

The Co-applicants will be required to accept their involvement in the application prior to submission. They also need to ensure all their details are populated correctly and use the 'Manage My Details' section of the Grant Management Portal to add/amend their basic information.

Co-applicants are those individuals with responsibility for the day-to-day management and delivery of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery. Collaborators normally provide specific expertise on particular aspects of the project but who do not share in the responsibility for the delivery of the project.

A biographical sketch is required for each Co-applicant. Please download the template from the application form and attach the completed version using the 

button.

Collaborators

Please use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

Please upload a letter of collaboration for each Collaborator listed. Letters should be signed by the Collaborator named in the application and include a summary of what they will contribute toward the project.

TRO or TTO Contact (for academic applicants)
Please provide at least one TRO and/or TTO contact as part of your application.

Please use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. They will receive an email, prompting them to set up a Portal account.

Head of Department and Senior Administrative Authority (For academic applicants)
Please provide the details of the Head of Department (HoD) and Senior Administrative Authority (SAA) from your Host Institution. Please use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address.

The HoD and SAA will be sent emails by the system once assigned to the application.

These authorities have two tasks during the submission of the application. Firstly, they will be required to tick a check box indicating they have read and understood the terms of the proposal and accept the role (HoD or SAA) that they have been nominated for. Ticking this box constitutes an electronic signature for the application. Secondly, they will need to approve the final submission of the application. This occurs **AFTER** the Lead Applicant clicks 'Submit'.

Please note that the HoD and SAA must both electronically approve the application for it to be submitted successfully.

CEO/CSO and CFO (For commercial applicants)
Please provide the details of the CEO/CSO and CFO (or authorised signatory) from the host company. Please use the 'Add Contact' button to search for contacts within our database. If the person you searched for was not found, please add this person to our system by entering their full name and email address. If the Lead or Co-lead Applicant is either of these roles, then there is no need to complete this section.

The CEO/CSO and CFO (or authorised signatory) will be sent emails by the system once assigned to the application.

These authorities have two tasks during the submission of the application. Firstly, they will be required to tick a check box indicating they have read and understood the terms of the proposal and accept the role (CEO/CSO or CFO) they have been nominated for. Ticking this box constitutes an electronic signature for the application. Secondly, they will need to approve the final submission of the application. This occurs **AFTER** the Lead Applicant clicks 'Submit'.

Please note that the CEO/CSO and CFO – or authorised signatory – must both electronically approve the application for it to be submitted successfully.

Required attachments for this section:

- Biosketches for the Lead Applicant, Co-Lead Applicant (if applicable) and Co-applicants.
- Letters of collaboration from all named Collaborators.

Lay Section:

Lay Summary
This section of the application form must be completed in plain English, using non-technical language. The information should be comprehensible to people with no scientific background and abbreviations and acronyms should be avoided. Any unavoidable scientific terminology should be clearly explained.

This section of the application form will be reviewed by the Lay Advisory Board members as part of the assessment process. Do not include any confidential or sensitive information in this section as this section may be used to publicise the project if the application is successful.

Please note, the lay section will be returned to you to be rewritten if it is not easily comprehensible and not written in plain English. You may also find it helpful to refer to the AMRC's Guidance for Researchers - Writing Lay Summaries.

The Brain Tumour Charity has established an Involvement Network (IN) which is a resource applicants can use to check readability of the lay section of the application. If you would like to learn more about Patient and Public Involvement or the IN and the help they can offer, please see https://www.thebraintumourcharity.org/get-involved/volunteering/use-your-experience/using-involvement-in-your-research/

Please allow sufficient time for the IN to respond to your request, the typical turnaround time is 4 weeks.

Lay Summary (500 words)

- Tumour type(s) that the intervention is targeting, as well as a clear indication of who would benefit/be eligible if successful.
- Brief description of the modality/mechanism of action.
- What would the intervention look like from a patient perspective?
- Outline the timeline for the next steps and the likelihood/sources of further funding to progress the project closer to patient care.
- ESSENTIAL: Please use this section to highlight the Patient and Public Involvement and Engagement (PPIE) that you have used to develop the proposal, as well as how you plan to disseminate key findings from your research to patients and the general public.

Graphical Abstract
Please upload a graphical abstract to illustrate the project concept and vision. The graphical abstract should be suitable for a lay audience and fit on one page

Categorisation
Please select which grade of primary brain tumour that the project will be targeting, as well as whether it is specific to either paediatric or adult tumours. Please note, it is possible to select multiple options; for example, the technology could be relevant to both paediatric and adult tumours.

There are text boxes included, with 100-word limits, to briefly describe the target name and target type.

Please tick the boxes that best represent the technology type. The categories are 'therapeutic', 'delivery' and 'device', and each one has subcategories for a more-specific description. If the technology type is not covered, please select other, and then further elaborate in the textbox titled 'If other is selected, please specify'.

Background

Background and Validation Data
Please upload a PDF document containing the most relevant background information and validation data, suitable for a scientifically qualified assessor. Please note this summary will not be published and may contain confidential information.

The maximum number of pages for this section is 3. Please use a minimum of size 10 font and single spacing.

Some examples of what could be included for different therapies/modalities are:

Small molecules:

- Target validation
- Details of prevalence of target (over-expression/mutation/methylation etc.)
- Biomarkers (both for patient selection and pharmacodynamics if available)
- Preliminary data / indication PK/PD specifically BBB penetration and solubility/route of administration
- Any preliminary ex vivo/in vivo efficacy and/or safety data

Delivery Systems:

- Preliminary data
- Indication of PK/PD and specifically BBB penetration and targeting potential
- Pertinent non-brain tumour data for the same delivery system
- If proposing delivery system with active payload then we require target validation and details of prevalence of target (over-expression/mutation/methylation etc.)
- Any preliminary ex vivo/in vivo efficacy and/or safety data

Diagnostics and Medical Devices:

- Evidence/rationale for the approach. What is the problem and how will the community benefit?
- For devices/software, please provide any prototype/early validation data
- For diagnostics, we require preliminary data and evidence for the proposed approach.

Adoptive Cell Therapies:

- Validation of cell surface targets
- Manufacturing processes – current state/stage
- Autologous versus allogenic
- Route of delivery/dosing (mRNA multi-dosing)
- Any preliminary in vivo efficacy data

Background and Validation Data
To avoid applicants from being penalised for using several references as part of the background and validation data PDF upload, a separate text box has been included for applicants to include all the in-text references present in the document.

Is this a re-submission of a Full Stage Proposal?

If the application is a re-submission, then please detail how you have taken reviewer comments onboard and have modified your proposal accordingly. Please also detail any further changes that have been made to your proposal since the previous submission.

This section should only be completed by those who have completed a 'Full Application Stage' proposal for the Translational Award in the past. Those who have submitted outline applications but were not invited to the full application stage do not need to complete this section.

Competitor Analysis

Provide a thorough analysis of potential competitor solutions/technologies, highlighting both their strengths and weaknesses. Please clarify the unique selling proposition (USP) of your research, how timelines to clinical implementation compare and differentiate yourself from ongoing, or past, similar solutions.

Supplementary figures

This section is optional. Please upload any further supplementary data to support your application (maximum of two pages).

Plan and Milestones

Project Plan (1,000 words)

The funding for this scheme is generous and comes with the expectation of an industry-like approach to the translational development, we wish to maximise the chances of success or fail faster. Grant extensions are unlikely to be given, so please resource and plan accordingly. Please provide the experimental plan and timeline of the project broken down into tasks/milestones.

Please include:

- Rationale
- Aims and objectives
- Experimental plan
- Project timelines for each aim and experiment
- All milestones, including the required 'Stop/Go' milestone (please use the SMART format: Specific, Measurable, Achievable, Relevant and Time-framed). See the following link for more guidance on how to write SMART milestones.

Gantt Chart

Attach a detailed Gantt chart for the proposed research project, including timelines and interdependencies for critical aspects of the above project plan including; key experiments, milestones (and sub-tasks), location of the task (in-house/CRO/Collaborator) and timings of regulatory advice. This should be the definitive document for both the project team and The Charity to drive and monitor progress.

Stop/Go Milestone

For projects greater than 12 months in length, we require a Stop/Go milestone. Please detail your key Stop/Go milestone for your research proposal to ensure a 'Fail Faster' approach. There should be measurable and definitive values against which progress through the Stop/Go milestone can be judged.

Please use the SMART milestones format: **S**pecific, **M**easurable, **A**chievable, **R**elevant and **T**ime-framed. The following link can provide more information about how to effectively write and use SMART milestones. You will be asked to provide any unacceptable outcomes, as well as the minimum desired outcome that would allow the proposal to progress further. You will be asked which month of the project the STOP/GO milestone occurs (must be within the first 12 months), as well as the cost to reach the STOP/GO milestone

Additional Questions (400 words)

- Depending on the modality, have you identified the final: lead candidate, biomarker or technological mechanism of action? If not, please indicate what steps remain.
- If applicable, briefly describe earlier identification rounds and how the hit candidate(s)/final product/technology/delivery system were identified?
- If applicable, indicate the cost/feasibility of manufacturing your lead compound/delivery system/diagnostic/medical device in a Good Manufacturing Practice (GMP) process.

Does this project involve drug repurposing? (400 words)

If the answer is yes, you will need to provide information on the following:

- Is there evidence that the target is shared across tumour types?
- Is there evidence of BBB penetrance and real likelihood of achieving an active dose level at the tumour site?
- Is the plan for the proposed repurposed compound to be co-administered alongside other drugs and/or standard of care (SOC) for clinical efficacy? How could this translate to a brain tumour clinical setting?
- Would the route of administration/dosing/formulation/combination therapy likely to be significantly different in brain tumour setting and require further regulatory safety studies?

You might find it useful to review LifeArc's **Repurposing Medical Toolkit**, which was developed in consultation with scientific, industrial and regulatory experts, and consolidates the complexities of repurposing treatments and navigating potential roadblocks, as well as finding ways to overcome them. The aim of the toolkit is to maximise the chances of getting potentially life-changing medicines to the people who need them.

Model and Statistics

Use of models

Please include information on the models (including cell models) you will be using in the research. There should be a separate entry per model being used in the research. Also, to align with guidance from the AMRC and the recent publication of the UK Government commissioned Sullivan report, The Brain Tumour Charity will require both sexes to be used as part of robust experimental design plans in grant applications involving animals (including humans), human tissues and cells (except for immortalised cell lines), unless there is a strong justification for not doing so. If applicable, please provide further details on the representation of both sexes as part of your experimental design.

Statistics

Please detail any statistics or power calculations that have been used in the experimental design of your proposal, as well as a planned ongoing statistical approach across the project. A key aim of this funding is to generate a robust data package to attract significant follow-on funding to progress the intervention closer to clinical utility, therefore, all studies must be suitably powered. Note, that biostatistician time is an applicable cost that can be justified in the budget section of this application form.

Personnel

How will the assembled team provide the best chance of success for the project? (500 words)

Please highlight the skills, expertise and knowledge of all team members and how they complement each other to maximise the chance of success. Highlight here, if a project manager will be used to drive the project forward. Include details of how staff, that will be appointed using the grant's money, will contribute to the team. If applicable, please also include how any CRO's and/or consultants will contribute to form part of one focused team.

Route to Clinical Implementation

What are the next steps for the project? (500 words)

The amount of funding through this award will only be able to cover part of the translational pathway and, if successful, we would anticipate all applicants to actively seek further funding and continue progressing the intervention towards the clinic. Please detail below what the next steps will be, and likely sources of funding following completion of this grant. Whilst The Brain Tumour Charity may not be able to fund the next steps directly, we will pro-actively work with you to try and facilitate sources of further funding. Commercial applicants should use this section to outline how you would fund/support the next steps to clinical implementation, including other sources of investment.

Regulatory Product Pathway (500 words):

Include details of the key regulatory steps; outline your regulatory strategy and include details of any meetings, to date, with regulators (if applicable). For medical devices, please indicate the classification and the proposed regulatory route. For further information, please consult the MHRA's website guidance and RegMetrics.

Figures of support

Some examples of what you can upload are:

- For drug development/diagnostics we would expect you to upload the in-progress TPP. Please see appendix A in this document for an example of a TPP. Your TRO/TTO contact may also be able to help you with this.
- A diagram/roadmap to clinic to demonstrate the estimated timelines for each required stage to get your intervention into the clinic. Please note, this is separate to your Gantt chart provided earlier, which is specific to just this proposal.

Please keep all text on figure legends/uploaded documents to a minimum.

IP and Freedom to Operate

IP and Freedom to Operate (500 words)

Generation of novel IP/commercial potential is not a prerequisite for this call; however, you must be able to demonstrate a clear pathway for how your proposal could reach the market/be accessed by patients. Please include:

- Any relevant background IP.
- Potential and likely ownership of any novel IP generated.
- If applicable, your IP protection strategy.
- Indication that there are no pre-existing patent restrictions which could impede progress of your proposal and route to market (freedom to operate). This must relate to any of the technologies, materials or interventions that form part of your proposal.
- Reference to any other relevant third-party agreements which may impact the pathway to clinical implementation.
- Details, including links, to all relevant competitor patents or patent applications.

Budget

Please note that only directly incurred costs can be requested. Please refer to our **Finance Guidelines** before completing this section.

All amounts must be provided in Pound Sterling (£) and **rounded to the nearest whole pound**.

If no costs have been requested for a specific budget category, please input 'N/A' in the justification section.

Please note, The Charity is not responsible for any fluctuations in exchange rate over the course of the project. If the lead institution/company is not based in the UK, we advise that they establish a corporate exchange rate agreement, if conversion to other currencies is required.

Salaries

For each staff member, please include:

- Staff name (if known)
- Role
- Period on grant (months)
- % of full time
- Total salary costs per year
- Materials and consumables
- For each item, please include total costs per year

Animals

For each item please include:

- Species and number of animals to be used
- Cost category (purchase cost or maintenance cost)
- Total costs per year

Miscellaneous

For each item, please include total costs per year.

Consultancy or Subcontracting costs

For each item, please include total costs per year. Indicate where competitive quotes were sought and justification for choice of quote. Failure to justify costs can lead to an application being rejected.

Upload Quote

We require a signed quote from any company with whom you plan to use for consultancy or subcontracting work for your proposal. We require an itemised breakdown, including an indication of timelines for the quote. We appreciate that prices can fluctuate, therefore, this is just an approximation. Please note, quotes are only compulsory for outsourcing costs greater than £10,000(GBP)

UK/Non-UK Budget Breakdown

If the research will be conducted across UK and non-UK institutes/companies, please provide the separate UK and non-UK budgets by completing the Budget Breakdown Template. This can be downloaded in the application form, and the completed form should be uploaded.

If the Lead Institution/company is not UK-based, but UK institutions will be involved, two financial awards will be made – to a designated UK and a designated non-UK institute/company. The UK lead and non-UK lead will then be responsible for finance administration for the remaining institutes.

Please note that all financial awards will be made in Pounds Sterling. It will be the responsibility of the Lead Institution to make conversions to other currencies.

The Charity is not responsible for any fluctuation in exchange rate over the course of the programme. We advise that the Lead Institution establishes a corporate exchange rate agreement if conversion to other currencies is required.

Leveraged Funds and Indirect Costs of Research

As an AMRC member, The Brain Tumour Charity monitors the indirect cost of the research we support. Unlike some other funding bodies, such as the research councils, AMRC member charities will not fund the indirect costs of research, or a proportion of these. The figures provided should include the standard indexation rate used by the institution to calculate indirect costs.

The Charity will only cover the direct costs included in the budget breakdown above. Acceptance of a grant, if awarded, will imply that the institution is prepared to meet the full economic costs from its own sources of funding.

Please refer to our **Finance Guidelines** for advice on what are considered eligible costs that The Charity will pay for.

Total Indirect Costs (For academic applicants)

Please provide an estimate of the total indirect costs for this research. This should include the applicant's salary, estate costs and other indirect costs of research, such as administration costs, library expenses and utility charges.

Indirect Cost Breakdown (For academic applicants)

Please describe how these costs have been calculated and summarise what has been included in the Total Indirect Cost above.

Leveraged funding or resources value (For academic applicants)

Please provide the monetary value of any leveraged fund in or resources that have been received or will be made available for the project.

Leveraged funding or resources justification (For academic applicants)

Please provide a breakdown of any funding, facilities or resources in kind that have been received or will be made available for the project. Where funding or support has been given to cover parts of the research proposal, please explain how this will complement The Brain Tumour Charity award.

Current Funding

For academic applicants:

Please list existing and pending research funding for the Lead Applicant, Co-Lead Applicant (if applicable) and Co-applicants including:

- Status
- Team member – will default to the Lead Applicant
- Funding source
- Title of project
- Funding start date
- Funding end date
- Total amount – please include the currency

Please note, funding of industry is a new direction for The Charity and, even if an award is deemed fundable, The Charity reserves the right to not provide funding on a case-by-case basis. Awards will be made to both academia and industry based on our standard grant conditions, subject to specific negotiations. Therefore, please complete this section clearly.

For Industrial/Commercial Applicants:

You will be required to justify the following questions (500 words):

- Why is charity money required to progress a project within a commercial setting?
- Are there any additional resources and funding that the company is committing to the project?
- Is there evidence that the company has a cash runway for the duration of the project? (Soft commitments/conditional funding does not count).
- Detail how the company would rapidly progress the asset at the end of this award. Are the funds in place to take through to FiH/how would this be funded?
- The charity is unlikely to seek an equity stake in return for funding but will potentially seek some form of future royalty/revenue share to reflect the key role our funding played in progressing the asset. Please indicate here that you would be open to such negotiations?

Ethical and Legal Requirements

Does your Proposal Involve Human Subjects?

If you answer yes to the question, we will require details of the Ethics Committee/MHRA approval or expected date of approval.

Does your Proposal Involve Vertebrate Animals?

If the proposal involves vertebrate animals, details of ethical approval or expected date of approval are required. To ensure the proposal adheres to NC3Rs guidance, additional information will be needed including:

- Is the vertebrate animal a specially protected Species (SPS)? These include dogs, cats, horses, pigs and non-human primates. If the answer is yes, you will be required to provide additional information to justify why the research is essential in a SPS.

- Please note, if your research proposal uses an SPS, we will carry out a further peer review by the NC3Rs to ensure the justification for using the SPS is appropriate, and that you have strong animal housing, care and welfare. You can find further information using the following link.
- If your research is on non-primates, on the application form, you should be able to download a document containing additional questions, ahead of NC3Rs peer review. Please upload these completed questions to the application form using the **Attach** button. Before answering the questions, please read the NC3Rs guidance on 'Non-human primate accommodation, care and use' and 'Responsibility in the Use of Animals in Bioscience Research', which set out the expectations of major UK funders.

- If your research proposal uses vertebrate animals that are not SPS, we require details of the animal species being used, why this species/model is the most appropriate organism and whether there are any alternative approaches that could be used instead.
- Whether any of the animals being used are genetically modified.
- Justification for the number of animals to be used per experiment, including details of sample size calculations and statistical advice sought.
- Indicate the severity of the procedures being used – mild, moderate or severe.
- If any animal research will be performed outside the UK, you will be required to complete a checklist, to ensure that animal welfare and care is up to, or exceeding, the UK's standards. You can find further information using the following **link** and the checklists via the following **link**.

Please upload the checklists using the using the **Attach** button.

Licenses/Approval

Evidence of ethics approval, personal and project licences should be uploaded using the 'Add' button at the bottom of this section.

Additional Information

Reviewer Suggestions

Please use the 'Add a Reviewer' button to add the names of people that you would recommend as a reviewer and those who you would prefer we didn't contact for a review. Please include a justification for your choice to help us understand the nature of your relationship with the individual and why you think they would or wouldn't be a suitable reviewer for this application. You are required to provide a minimum of two recommended reviewers.

Letters of Support

Please use the **Attach** button to upload any letters of support you have received for this application.

Required Attachments

Please make sure you have attached all of the following documents to the application:

- Lead Applicant, Co-Lead Applicant (if applicable) and Co-Applicant Biographical sketches (CV's)
- Letters of collaboration for all named collaborators
- Graphical abstract
- Background and preliminary data PDF upload
- Further supplementary data (optional)
- Gantt chart

- Next Steps Figures
- Subcontracting approximation of costs (if applicable)
- UK/Non-UK budget breakdown template (if applicable)
- Non-human primate additional questions (if applicable)
- Non-UK animal research checklists (if applicable)
- Ethics approval, personal and project licences (if applicable)
- Letters of support (if applicable). For example, confirmation by clinical department to confirm protected academic time

You will see a list of the currently uploaded documents in your application to refer to. If anything is missing, please return to the relevant section of the application and upload the necessary document.

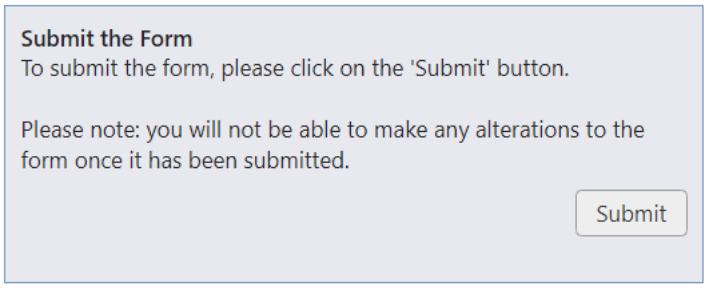
Confirmation

On the confirmation page you should be able to see The Charity's data protection statement, as well as a link to the webpage containing more information about the privacy and data protection policy of the charity. You must confirm that you agree with the following statements to submit your application:

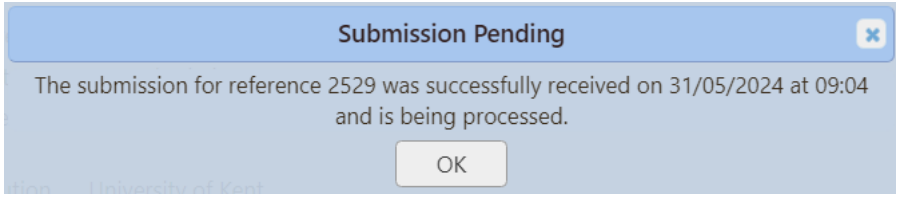
- I confirm that I (and all those providing personal information in the application) have read and understood The Brain Tumour Charity's Data Protection Statement.
- I have read and approve the completed application form. If granted, the work will be accommodated and administered in the department/institution in accordance with the grant conditions. I also confirm that there are no existing matters which would be a breach of any conditions which have not been brought to your attention in writing.
- I understand that the provision of any false or inaccurate information in this application would be considered very seriously and may result in disqualification of the application. To the best of my knowledge, the information provided in this application is accurate and complete.

Validation and Submission

This section will highlight any incomplete sections that require completion in order to submit the application. If all sections are complete, then the following message will be displayed *'The application now meets the minimum submission requirements'*. Press save and close to return to the main menu of the portal. When you are ready to submit your application, press the submit button, which is on the right-hand side of the page (please see below) and then press 'yes' to the follow up message.



If the application has been successfully submitted, then you should receive the following message:



Appendix

A. Example of a Target Product Profile

Attribute	Desired	Acceptable
Mechanism of Action	Multitarget	Unique target (but not uptake via P2-transporter only)
	Cidal	
Efficacy & product benefit	Effective against stage 1 and 2	Effective against stage 2
	Broad Spectrum (*gambiense* and *rhodesiense*)	Efficacy against *gambiense* only
	Clinical efficacy > 95% at 18 months follow up	Clinical efficacy no worse than current treatments
	Effective in melarsoprol refractory patients	
Safety & tolerability	<0.1% drug related mortality	1% drug related mortality
	Safe during pregnancy and for lactating women	
	No monitoring for AEs	Weekly simple lab testing (field testing)
Dosing / administration / regimen	Formulation adapted to adults and children	
	< 7 days p.o. once daily (DOT)	< 20 days p.o. (DOT)
	< 7 days i.m. once daily	< 20 days i.m.
		< 5 days i.v. if no toxicity
Delivery system / product presentation / market configuration	Stability in Zone 4 for > 3 years	Stability in Zone 4 for > 12 months
Pricing / cost of goods (COGs)	< 30 € / course (only drug cost)	< 100 € / course < 200 € / course ok if very good on other criteria