**Blavatnik Therapeutics Challenge Awards**

**Full proposal template**

**Full proposal submission deadline: March 16, 2020 at 5:00 PM ET**

BTCA scientific program staff will be available to work with PI’s on the development of full proposals, particularly with respect to describing the impact, establishing milestones, and determining the potential for commercialization of the project.

**Full proposals may be submitted by invitation and should not exceed 12 pages for questions 1–14.** All text material must be in a readable font (at least Arial 11 point), and margins must be at least 0.5 inches. The application form should not be altered.

**Cover Page (not included in page limit)**

1. PI name, academic rank, department, and institution
2. Project title
3. Total budget request
4. Executive summary (200 word maximum)

**Questions 1 through 14 are included in the page limit.**

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| 1. **Background: Describe the scope and nature of the problem the therapeutic will be designed to address. Include disease burden, expected users, and market space in which the product would operate, and a brief description of the solution provided by the proposed therapeutic.** |
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| 1. **Unmet Need: What is the unmet need to be addressed by the therapeutic? Be sure to provide evidence to support the need from multiple stakeholder perspectives (e.g., patient, clinician, payer). Compare your solution to the current and predicted future standard of care.** |
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| 1. **Proposed Product/Solution: Describe the proposed solution, the setting in which it will be utilized (e.g., ICU, in-patient, out-patient, primary care physician) and the primary patient population/indication for use. Characterize the expected benefit from the therapeutic and how it will enhance current or predicted future standard of care or replace it. Provide evidence to support the expected benefit.** |
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| 1. **Preliminary Data: Provide a synopsis of your preliminary data, including key figures and tables where relevant.** |
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| 1. **Market Size: Define the addressable market size for the targeted patient population or indication, and provide supporting data for the US and the rest of the world. Using appropriate comparisons within the current landscape, if any, describe what the market and patient population trends and projections are expected to be.** |
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| 1. **Competitive Landscape: Provide a summary of the competition for the therapeutic (companies, products, and substitutes), and list the strengths and weaknesses of each competing approach. Include other therapeutics in development as well as marketed products. How is the landscape shifting or projected to shift?** |
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| 1. **Differentiation: Explain how the proposed therapeutic is better than current options. Provide data to support this, and what further data would be needed to support the differentiation.** |
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| 1. **Development Path: Provide a brief description of the proposed therapeutic development path from the completion of the BTCA studies through clinical proof of concept (i.e., preliminary demonstration of efficacy in a clinical trial). Highlight any approaches, such as biomarkers, that could help de-risk further development of the therapeutic. Are any challenges, such as patient recruitment, foreseen in early clinical development? Also highlight any challenges foreseen in early manufacturing of the therapeutic or any unusual non-clinical development considerations.** |
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| 1. **Regulatory Path: Describe the expected regulatory path for the therapeutic. Which FDA division do you believe will regulate the therapeutic, or will development be started outside the US? Describe foreseeable regulatory risks or opportunities that could impact the therapeutic development.** |
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| 1. **Project Plan: Provide a description of the proposed project plan, including key milestones, timelines, and how success will be measured using quantifiable metrics. What is the final goal to be achieved at the completion of the project? Identify go/no-go decision points and potential pivot points within the plan. Explain how this project plan fits into the overall development plan for the product.** |
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| 1. **Funding Requirements:** **Briefly summarize the projected data package that would be available at the completion of the project plan to support a potential commercial transaction for the asset. Are there weaknesses in the data package that could be addressed by further funding? What magnitude of funding would be needed to get the asset to a viable “exit” or inflection point for commercial investment, and over what time period? What key milestones would need to be achieved?** |
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| 1. **Potential Risks and Mitigations: Define the potential risks (scientific, technical, personnel, market, and commercialization) that exist for the proposed development of the product, and how the team may be able to mitigate them.** |
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| 1. **Personnel: Provide the institutional affiliation, role, and relevant background and expertise of the individuals on the team, including the PI and all other team members.** | | | |
| Name | Institution and Dept | Role | Background/Expertise Relevant  to Project |
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| 1. **Intellectual Property: Please fill out the table below and describe the extent of your interactions with your technology transfer office. The table should include a list of all the IP filed or granted to protect your solution, including the identification number, title, assignee, date filed, status, and types of claims covered (e.g., method of use, composition of matter). Below the table, describe how this portfolio of IP protects the therapeutic and its uses in the intended indication. Please also note the types of IP you expect to generate at the completion of the proposed studies.** | | | | | |
| ID Number (application, serial, or patent) | Title | Assignee | Date Filed | Status | Type of claims |
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**Questions 15 and beyond are not included in the page limit**

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| 1. **References** |
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| 1. **Compliance and the Use of Human Subjects and/or Vertebrate Animals:**   *This information is not subject to page restrictions but please be succinct.* If the use of human subjects is proposed, describe the subject population and enrollment plans. If your data will be de-identified, explain who has the key. If the work is not expected to be exempt under 45 CFR Part 46, please describe: 1) the risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects, 4) importance of the knowledge to be gained, and 5) data and safety monitoring if a trial is involved.  Further information about the information that is needed for the use of human subjects is available at  <http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4_1_protection_of_human_subject>  If animals are to be used, describe the model and rationale, or your materials source if applicable. |
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| 1. **Milestones and Tranche Schematic Attachment** |
| Full proposals must include a “Milestone and Tranche Schematic” developed with the assistance of BTCA scientific program staff. The schematic provides a summary representation of your objectives mapped to the budget. The schematic should be included as the final page of the application. |

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| 1. **Budget and Budget Justification** |
| Full proposals must include a Budget, using the attached Budget template, and an NIH-style Budget Justification. |

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| 1. **Biosketches** |
| Full proposals must include an NIH Biosketch for the PI and all team members. |

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| 1. **Institution Official Signature**   Institution Official Signature approval for proposal. Please also sign the Institution Official Signature line on the “Summary” page of the budget template. |
| Signature:  Name:  Title:  Date: |

**Full proposal submission:** Pre-proposals must be received by 5:00 PM ET on **March 16, 2020,** as a single PDF file. Applications should be submitted via the Harvard Medical School online submission system. The submission URL will be posted on the Blavatnik Therapeutics Challenge Awards website (<https://btca.hms.harvard.edu>) by March 1, 2020.