The Broad Institute of MIT and Harvard

Request For Proposal

for

DISTRIBUTION PARTNER FOR CELL LINES AND DATA

Prepared October 26, 2015

Proprietary and confidential

REQUEST FOR PROPOSAL
INVITATION

BACKGROUND

The Broad Institute, Inc. (Hereafter “TBI”), is an independent 501(c)(3) research institution whose mission is to advance biomedicine, through research aimed at the understanding and treatment of disease and the dissemination of scientific knowledge to the scientific community and general public. It is a partnership of The Massachusetts Institute of Technology (MIT), Harvard University and Harvard-affiliated hospitals and involves research collaborations around the world.

SUMMARY

TBI Procurement is inviting proposals from potential Distribution Partners for Cell Lines and Data for the Broad Cell Line Factory Project.

TBI, together with collaborating hospital partners aims to identify a mission-driven distribution partner to ensure that the approximately 2500 cancer cell lines and associated genomic data that have or will be generated and collected over the next 7 years as part of the “Cell Line Factory” collaborative project are widely and rapidly distributed to the world’s scientific community.

Respondents may request qualification in one or more of the areas described in the “Scope of Required Services” section below. Such Respondents should clearly indicate the category or categories for which they wish to be considered for selection. TBI may choose, in the sole exercise of its discretion to select all, some or none of the Respondents.

Proposals are to be submitted, as per the “Key Dates” section detailed below.

CONTACT

Any questions regarding technical specifications, Scope of Required Services requirements, contractual terms and conditions, or proposal format must be directed in writing (email is acceptable) to:

<table>
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<tr>
<th>Name</th>
<th>Jesse S. Boehm, Ph.D.</th>
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<tr>
<td>Title</td>
<td>Associate Director, Broad Institute Cancer Program</td>
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<td>Phone</td>
<td>617.714.7494</td>
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<td>Email</td>
<td><a href="mailto:boehm@broadinstitute.org">boehm@broadinstitute.org</a></td>
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KEY DATES

All proposals are due at the close of business on November 23, 2015. Proposals and attachments should be submitted electronically to boehm@broadinstitute.org. Any proposal received after the required time and date specified for receipt shall be considered late and non-responsive.

SCHEDULE OF EVENTS

- **October 26, 2015**: RFP announcement (Phase I)
- **November 23, 2015**: Phase I proposals due to boehm@broadinstitute.org
- **December 7, 2015**: Broad to select distribution partner(s) with which to commence formal negotiations (Phase II).
- **January 15, 2016**: Broad and selected distribution partner(s) to jointly submit biorepository IRB protocol for approval
- **March 11, 2016**: End Phase II: Broad to make final selection for exclusive distribution partner based on contractual negotiations.
- **March 31, 2016**: Broad to ship initial set of cell line vials to distributor, make genomic data available (mechanism TBD).
- **May 2, 2016**: Distributor starts fulfilling requests.
- **December 1, 2016 (estimate)**: Broad to ship additional sets of vials corresponding to 100-200 cell lines, repeating annually.

PHASE I INSTRUCTIONS:

Please review the background and principles document entitled “Distribution Principles for Broad Cell Line Factory,” which describes the goals and philosophy of the Cell Line Factory project regarding distribution of cell lines and associated data.

We are looking for a mission-driven collaborator to join the Cell Line Factory project as its exclusive distributor for an initial period of 24 months. If all parties deem the initial period successful, the contract may be extended in 24 month intervals.

Please provide a written narrative that responds to the following questions, as well as any other information that might be helpful in assessing your organization’s motivation and capacity for making this project a success.

1. Briefly describe your organization’s motivation for collaborating on this project.
2. Briefly describe your organization’s principles, organizational structure and philosophy.
3. We expect this project to gain significant attention from cancer patients, advocacy groups and the media. Please describe your organization’s experience with interacting with such groups.
4. Who will be the primary contact person? What will be his/her responsibilities? Who will be responsible for working with the Broad to prepare repository-specific documentation for the IRB submission? How will your organization ensure that sufficient attention is devoted to this project overall?
5. Briefly describe the process that you recommend for sample transfer. How many initial vials would you require Broad to provide? What QC steps would be done upon receipt?

6. We expect that the majority of cultures will be 2D cultures in one of ~12 media types. Please describe how different growth conditions (e.g. different media types, 2D vs. 3D) will impact the ease of distribution. Please provide an example of draft web-pages (sample and collection) for the project. How will the contributions of specific PIs and organizations be recognized?

7. Ideally, the distribution of these samples would fully recover costs for the biorepository and after an initial supply of vials and QC data, the Broad would not financially support distribution. How best to establish pricing structures to achieve this goal? How will pricing for academia and industry be set? How could the Broad be helpful?

8. Ideally, Broad investigators and IRB protocol co-PIs would have access to the new cell lines at no cost. Do you foresee any issues with this?

9. Ideally, commercial entities would develop new drugs and diagnostic products using the new cell lines. In the rare cases, these might generate revenue that could off-set distribution costs at the biorepository, cell-line generation costs at the Broad, or both. The ideal solution would be one that is mutually-beneficial. How might this be established?

10. Please comment on possibilities and any foreseeable challenges associated with international distribution.

11. How is regulatory compliance managed, and do you foresee any changes based on the recent issuance (and likely adoption) of the new NPRM?

12. What will be the protocol for withdrawing samples upon the request of a patient?

13. What are possible formats to display and distribute genomic and clinical data that have worked for other projects? Where might such data be stored and how to ensure secure access? How might genomic data be displayed? What formats could be used? What tools are available for browsing data? Is it possible to link to dbGaP?

14. In the case of on-site data storage, how do you ensure data security? Is data storage cloud-based, or on premises?

15. How will the MTA process work? What safeguards ensure the process is expedited?

16. Ideally, derivative cell cultures that have been subjected to genomic modification (e.g. Cas9 or barcode insertion) would be deemed different entities than the parent cultures (allowing investigators to self-distribute). Would this pose a problem? Would there be interest in also distributing such derivative cultures?

17. What mechanism do you propose we establish together to evaluate the success of the distribution process?
GUIDELINES FOR PROPOSAL PREPARATION

PROPOSAL SUBMISSION
Contract award(s) resulting from this RFP will be based upon the most responsive Vendor(s) whose offer will be most advantageous to TBI in terms of expertise, service, cost and other factors as specified elsewhere in this RFP.

TBI reserves the right to:

• Reject any or all offers and discontinue this RFP process without obligation or liability to any potential Firm
• Accept other than the lowest priced offer
• Award a contract on the basis of initial offers received, without discussions or requests for best and final offers
• Award more than one contract

Respondent Vendor proposals shall be submitted in multiple parts as set forth below. Respondent Vendors should confine submission content to those matters sufficient to define its proposal and to provide an adequate basis for the TBI’s evaluation of the Firm’s proposal.

Thank you for your interest in collaborating on this project. We look forward to working together to accelerate the generation and dissemination of genomically characterized cell line models of cancer.

Sincerely,

Jesse Boehm, Associate Director, Broad Institute Cancer Program
Keith Ligon, Associate Professor, Pathology, Harvard Medical School
Katherine Janeway, Assistant Professor of Pediatrics, Harvard Medical School
Stacey Donnelly, Senior Director, Strategic Operations, Broad Institute