The University of Maryland Baltimore Life Science Discovery (UM-BILD) Pilot Project Grant Program

Cohort 3 Request for Application (RFA)

August 1st, 2025
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THE UM-BILD PILOT PROJECT GRANT PROGRAM –REQUEST FOR APPLICATIONS

Deadlines:	*Call for Letter of Intent:* August 1, 2025 *Letter of Intent Deadline:* September 12, 2025, 5:00 PM (EST) *Invitations for Full Applications:* October 2025 *Full application Deadline:* December 12, 2025, 5:00 PM (EST) *Cohort 3 Projects Begin:* May 2026 *Late submissions **will not be** accepted.*
Eligibility:	Faculty and Staff from the University of Maryland, Baltimore (UMB), University of Maryland, Baltimore County (UMBC), Morgan State University, University of Maryland, College Park (UMCP – a UMB partner is required) or Faculty at other Baltimore City public universities.
Budget:	Up to $75,000 in direct costs (indirect costs not allowed) for a 12-month term.
Grant period:	*Cohort 3 Notice of Awards Announced:* March 2026 *Cohort 3 Projects Begin:* May 2026 *Cohort 3 Projects End:* April 2027

The University of Maryland - Baltimore Life Science Discovery (UM-BILD) Accelerator is pleased to announce that we are accepting applications for the 3rd cohort of the UM-BILD Pilot Project Grant. Every year, UM-BILD Accelerator will provide approximately 12 proof-of-concept technology development grants to faculty innovators. These grants will be milestone-driven, development-focused programs that will serve to directly advance a life science technology to the next phase. The goal is to translate basic science research projects into commercial products that will advance patient care, whether it be through new company formation or via movement towards licensing to a development partner. All types of products in the human health space (e.g. therapeutic, preventive, diagnostic, device, method, tool, software) are eligible. The research must have a direct application to an important unmet clinical need and the proposed solution, when commercialized, must have a benefit to patients and to community health. Projects with the potential to address healthcare disparities or otherwise benefit the people of Baltimore are particularly welcome. Early-stage technologies typically include unproven innovations still undergoing laboratory testing, and prototype devices in the process of refinement and optimization.

Successful Pilot Project applications will explain how the intended product will address an unmet medical need, outline the product's market potential, and include a product validation workplan. Projects must be completed within 12 months, with the goal of attracting follow-on funding from TEDCO, from a federal SBIR/STTR grant, from other non-dilutive sources, or through equity investment into a spinoff company.

Research teams should not already have secured funding for the proposed Specific Aims and/or milestones (no 'double dipping.') The focus should be on gathering data that advances the core hypothesis and addresses key translational risks.

For questions regarding application guidelines, please email the UM-BILD Admin Core at UM-BILD@umaryland.edu.

UM-BILD PROGRAM OVERVIEW

The University of Maryland Baltimore Life Science Discovery (UM-BILD) is a funding and mentoring resource for academic researchers led by the University of Maryland, Baltimore (UMB) with the School of Medicine being one of the anchor partners, and with University of Maryland Baltimore County (UMBC), Morgan State University (MSU), University of Maryland College Park (UMCP), Blackbird Labs, and TEDCO's Maryland Innovational Initiative (MII) as partners. Funded by the NIH through their Research, Evaluation and Commercialization Hubs (REACH) program, UM-BILD offers funding and industry-grade advising and support that will help improve applicants' projects.

RESOURCES

UM-BILD will provide commercialization-related education and training. A formal didactic learning opportunity - "Life Science Entrepreneurship" - seminar course, tied with a formal mentoring apprenticeship program, will help project teams to assess clinical needs, conduct market analysis, and prepare for regulatory requirements. Research teams may also make use of a range of UM-BILD Incubator services.

Each Pilot Project team will be supported by the Project Management Team, members of UM-BILD's Administrative Core (Admin Core) staff. They will collaborate with the Lead Principal Investigator (Lead PI) throughout the duration of the project. The UM-BILD's Project Management team will track progress on milestones according to the proposed timeline, and they will receive updates on spending. The Lead PI (or his or her designee) is required to meet monthly with the Project Management Team.

In addition, each Pilot Project team (and UM-BILD MII Project team) will be matched with a Mentor. Each Mentor is a veteran of the biotechnology space, with experience in entrepreneurship and in private industry. Mentor activities can include topics such as product development, contract manufacturing, regulation, reimbursement strategies, and writing commercialization grants such as SBIRs, STTRs, and MIIs.

The UM-BILD Administrative Team will also grant each Lead PI and their project team access to the "Entrepreneurship in Life Science" course via a Dropbox link. This course contains a curated collection of asynchronous learning materials, organized into individual monthly folders. A course syllabus will be shared to guide participants through the available resources. The course is designed to build understanding of business planning for drugs, medical devices and digital

health. It emphasizes the opportunities and challenges of startups in the Mid-Atlantic region and highlights key concepts in early-stage commercialization. Prospective entrepreneurs are encouraged to learn about these topics as they consider whether to participate in the founding of a biotech startup based on the technology being explored in the UM-BILD Pilot Project grant. Content includes:

1) The makeup of a business plan
2) Managing long pre-revenue timelines
3) Licensing of I.P.
4) The nature of biotech drug and medical device risk, and of risks in other areas such as IT
5) Sources of funding, specifically early-stage financing which include STTR and SBIR grants, State level programs, grants from foundations, angel and venture-based equity financing, and partnership-based funding with established pharma and device companies
6) Brick-and-mortar and virtual approaches to planning a biotech company
7) Accessing and augmenting management
8) Exit strategies

The course is designed for graduate students (undergraduates are also welcome), post-doctoral trainees, and faculty. All team members of current and former UM-BILD Pilot Project grants and UM-BILD MII Projects are welcome to participate. This will provide a boost to the local entrepreneurial ecosystem by providing additional training for scientists working on projects with translational potential. The course will be offered both in-person and via virtual formats to maximize the reach to students.

In the near future, we plan to launch a partnership with the Smith School of Business to offer a week-long in-person certificate program at their College Park campus. Scholarships to defray most of the tuition will be available to UM-BILD Pilot Project and UM-BILD MII Project team members.

PILOT PROJECT GRANT APPLICATION PROCESS

Each year, the UM-BILD Accelerator will encompass approximately 12 projects (8 Pilot Project Grants and 4 UM-BILD MII Projects), with one cohort each year.

An application for the **UM-BILD Pilot Project Grant** begins with the submission of a Letter of Intent (LOI). LOIs will be reviewed, and applicants with the highest-rated scores will be invited to submit a Full Application.

Summary of the Application Process

A. Writing and Submission of Letters of Intent.
B. Evaluation of LOIs by UM-BILD's Internal Advisory Committee (IAC).
C. Invitation of the top-ranked LOIs to proceed to Full Applications.
D. Writing and Submission of Full Applications.

E. Evaluation of Full Applications by the External Review Board (ERB).

F. Selection of top-ranked Full Applications to be submitted to the NIH's Technical Guidance Committee (TGC).

G. Final selection of Cohort Pilot Projects by the IAC.

H. Notification of awardees and distribution of ERB and TGC feedback to applicants.

In exceptional cases, an investigator who demonstrates outstanding success in achieving or exceeding all first-year milestones may be eligible to submit an LOI for a second year of funding to continue development of their awarded Pilot Project. The second-year LOI will compete on equal terms with all first-year LOIs in its cohort.

UM-BILD MII Project applications are not submitted directly to UM-BILD. Instead, these projects are selected by the UM-BILD IAC from among the active Technology Assessment MII projects that TEDCO has awarded via its usual processes, per the relevant RFA (link).

PILOT PROJECT GRANT LETTERS OF INTENT

A. Submission of a New Letter of Intent

All LOIs must be prepared according to the following guidelines and submitted via the UM-BILD REDCap portal, accessed via the "How to Apply" webpage (link). The September deadline for Cohort 3 will be announced at least four weeks in advance. Please check our website regularly for updates for the current Call for LOIs, which specifies the submission deadline. Late submissions will not be accepted.

UM-BILD strongly recommends that teams considering the submission of an LOI begin by emailing UM-BILD@umaryland.edu to request a pre-submission discussion. This will ensure the alignment of the project with the funding criteria and provide guidance on the pre-submission process.

The Specific Aims proposed in the LOI may overlap with those in an application to another funding source, if that source has not made a funding decision by the time that the LOI is submitted. However, if a project is funded by another source prior to the UM-BILD funding decision, the applicant is obliged to notify UM-BILD. As two sources of funding for a single specific aim is not permitted, acceptance of the UM-BILD award would require the applicant to either withdraw the other award or decline the UM-BILD award. If the UM-BILD award is declined, the applicant may revise the project with new Specific Aims and submit a new LOI in a subsequent UM-BILD funding round.

By the LOI submission deadline, technologies must be disclosed to the Technology Transfer Office at the investigator's university, and assigned to the university, or subject to university ownership. See the **UM-BILD Program Guidelines' Eligibility** section, below, for information on that important topic.

The LOI submission has two parts. First, the applicant must fill in the online form and provide information on a series of topics:

- The project title
- The names of the PI and of the Co-PI (if applicable; only one Co-PI is allowed)
- The type of technology (biologic drug, diagnostic assay, surgical device, etc.)
- The disease indication of interest
- The status of the underlying intellectual property (I.P.) and its disclosure to the applicant's university
- A Project Description (Abstract) limited to 3,500 characters and including the following information:
    - A description of the technology
    - An explanation of the healthcare problem that the technology could help to solve. What would the product or service be? Who would be its customers?
    - A sketch of the current status of the project. For example, is the biochemical pathway identified? Have in vivo proof-of-concept experiments been run? Have initial prototypes been built? Is there clinical validation?
    - A brief outline of the key milestones and an estimated budget for the proposed year-long project.
        - The investigator should budget $75,000 to be spent on the project (direct costs only; indirect costs are handled separately)

Second, the applicant uploads the LOI, as a formatted two-page document. A Word document template is provided in the Formatted Application Template section of the REDCap portal page, accessed from the "How to Apply" page of the UM-BILD website (link).

- Key aspects of the LOI's formatted document:
    - Two pages, with margins set at 0.5 inches all around
    - 11-point type, single spacing
    - A single image or figure can be included, with the font size of the figure legend set to 10 points or larger
    - Uploaded to the portal as a .PDF
- Page 1 contents:
    - The project title
    - The PI's name, university, and contact information
    - A copy of the Project Description (Abstract), containing exactly the same information reported in the online form (limit 3500 characters)
    - A Figure with a legend (optional; legend with ≤ 300 characters).
- Page 2 contents:
    - List of Team members. For each key Team Member, provide their role (e.g. Co-PI, Co--I, consultant, etc.) and a one-paragraph biography.
    - A list of up to five References (optional).
    - ONLY for resubmissions: a Response to Reviewers (max 1,000 characters; ~150 words).

B. Resubmission of a Letter of Intent

- The resubmitted LOI must include a "Response to Reviewers" section, which is to be placed on page 2 of the Formatted LOI PDF document. In this section (1,000 characters or ~150 words), applicants should summarize the reviewers' key concerns and explain how these have been addressed. Feedback is intended to guide teams in revising their proposals to improve competitiveness for future submissions. The resubmitted LOI should be revised to address the weaknesses noted by reviewers.
- Projects at the LOI stage that were not invited to submit a Full Application will have received written feedback summarizing the project's strengths and weaknesses, as identified by UM-BILD's IAC.
- Projects that were invited to submit a Full Application will have received written feedback summarizing the project's strengths and weaknesses, as identified by the External Review Board (ERB) and, in some cases, the NIH's Technical Guidance Committee (TGC). In this case, only a single resubmission is allowed.

C. Triage of LOIs

The LOIs will be reviewed by the UM-BILD's Internal Advisory Committee (IAC) to consider the potential of the proposed projects, and how well they fit with UM-BILD's mission. The IAC includes reviewers with scientific, clinical, and entrepreneurship expertise, as well as reviewers with expertise in I.P. protection, technology transfer, and commercialization.

All applicants who submit a LOI will be notified of the outcome. They will receive feedback from the UM-BILD IAC.

PILOT PROJECT GRANT FULL APPLICATIONS

A. Submission of a Full Application

Selected teams will be invited to complete Full Applications, which are based on the REACH Common Application (UM-BILD REDCap portal). About 9 weeks will separate the invitation date and the Full Application deadline. ***The Full Application Submission Deadline is December 12, 2025, 5:00 PM (EST).*** The Full Application submission has two parts:

i. Online form

As a first step, the applicant must submit the online form, which covers five main points:

1. The technology under consideration.
2. The clinical problem that is being solved.
3. The competitive positioning of the proposed application considering competing inventions, along with discussions of the invention's market, assessments of key risks, and reimbursement strategy (where applicable).
4. The potential for follow-on funding, both private and public.
5. The key experiments that are proposed, and how they fit into the path towards a regulatory milestone.

ii. Formatted Full Application

At the bottom of the REDCap portal page, provision is made for uploading the Full Application as a formatted document. Applicants can use the Word .docx template provided in that section of the REDCap portal page.

The Formatted Full Application must include an Appendix containing the applicable sections below. Where appropriate, a sample template for each section is available for download from the UM-BILD website's "How To Apply" page (link). These files are:

1) GANTT Chart (Specific Aims) (link).
2) Budget Worksheet (link).
3) Compliance Form (link).
4) Institutional Approval Letter (link).
5) Vertebrate Animal Research (where appropriate; link).
6) Human Subjects and Clinical Trials (where appropriate; link)
7) A Dual-PI Leadership Plan (where appropriate).
8) NIH-Formatted Biosketches for each key team member; format outlined here.
9) Any quote for fee-for-service work that is proposed as part of the application. In accordance with the State of Maryland Procurement rules governing contracts, for each contract exceeding $25,000, three quotes must be submitted. See section D for "Expenses".

A Dual-PI application must have a sole Lead PI and a single Co-PI. In such cases, a brief (~ 150 word) Dual-PI Leadership Plan that describes their respective roles must be included in the Appendix of the Full Application. (See point C-3 of this NIH FAQ). In these cases, the Lead PI will serve as the point of contact for communications.

The Formatted Full Application is uploaded to the REDCap portal as a single PDF file.

B. UM-BILD Administrative Coaching Support

The UM-BILD Administrative Team will be available to provide support to each principal investigator submitting a UM-BILD Full Application. The Admin Team will schedule a meeting to inform investigators of program requirements. For Cohort 3, this presentation is scheduled for **Friday, October 10, 2025.** Guidance will be provided for the following areas:

1. Sketching a product development plan
2. Setting project milestones
3. Proposing a project budget
4. Assisting with compliance and eligibility questions
5. Submission of the REDCap Full Application

(Re-submissions will receive limited support on formatting of the Formatted Full Application.) Teams will have about 9 weeks to draft, edit, and submit their Full Application. Investigators are encouraged to engage with UM-BILD support staff early in the development process to ensure alignment with funding guidelines before submission.

C. Review of Full Applications

Full Applications will undergo review by the UM-BILD External Review Board (ERB), comprising industry and technology experts who are not employees of UMB or a UM-BILD partner university. These reviewers will evaluate proposals for feasibility and for commercial potential. Following the advice of the ERB, the IAC will select the highest scored proposals for submission to the NIH's Technology Guidance Committee (TGC).

The TGC is composed of NIH Program Officers, Entrepreneurs-in-Residence, and I.P. specialists. Representatives from the FDA and CMS will weigh in on regulatory and reimbursement issues, where this is relevant to a project's commercialization pathway. Feedback from the TGC takes a narrative form. A key function of the TGC is to evaluate each proposal for its relevance to the core missions of the NIH's constituent Institutes and Centers. In rare cases, TGC reviewers may judge that no Institution or Center would be likely to endorse a proposed project. Such projects cannot be funded by UM-BILD or undertaken under its auspices.

The ERB's reviews and the TGC's comments will be the basis for the UM-BILD Internal Advisory Committee's final determination on which projects will be accepted into the UM-BILD Cohort.

Full Applications that are not selected for funding may submit an LOI in a future cohort. Note that in this case, only a single resubmission is allowed.

- Projects at the Full Application stage that were not selected for funding will receive extensive feedback from ERB reviewers (and in some cases, from TGC reviewers), highlighting key strengths and noting areas for improvement.
- The resubmitted LOI must include a "Response to Reviewers" section, which is to be placed on page 2 of the formatted LOI PDF document. In this section (1,000 characters or ~150 words), applicants should summarize the reviewers' key concerns and explain how these have been addressed.

PILOT PROJECT GRANT ADMINISTRATION INFORMATION

Successful applicants will receive a letter that outlines the steps that must be taken prior to the initiation of the project. These will include:

- **Notice of Award (NOA):** Return the signed notice of award, along with responses to the reviewers' comments and any other documents required by the UM-BILD Admin Core, by the requested deadline.
- **PHS398 Form:** Complete and return Page 1 and Page 2 of the PHS398 form.
- **Reviewers' Comments from ERB and TGC:** Lead PIs will have the opportunity to respond to the reviewer's questions/concerns to address the comments from the ERB and TGC reviewers and if necessary, make the required changes to their project. However, **it is not required** to submit responses to questions or comments addressing the reviewers' feedback ***(unless requested in writing by the UM-BILD Administrative Team)***.

- **Departmental and Institutional Grants/Research Administrators:** Provide the name and contact information of the Lead PI's departmental level Grants Manager.
- **Human Subjects (HSCT) and Vertebrate Animals Section:** Review of the proposed use of Vertebrate Animals and of any potential Human Subjects Research. The UM-BILD Admin Core must be provided with the required documents, as highlighted in the **Institutional Regulatory Requirements/Approvals** section of the **UM-BILD PROGRAM GUIDELINES**, below.
- **IACUC and IRB Approval Letters:** Lead PIs are responsible for submitting Institutional Regulatory Requirement Approval Letters—such as IACUC, IRB, or both, as applicable—to the UM-BILD Administrative Team for their respective pilot projects.
- **Kick-off Meeting:** Schedule a kick-off meeting between the UM-BILD Project Management Team and the Awarded Lead-PI to discuss the award process and to review expectations on progress, spending, mentorship, and reporting.
- **UM-BILD Mentorship:** A Mentor will be matched with each Pilot Project team. He or she is required to meet monthly with the team (the Lead PI or designee) to share insights on aligning team initiatives with commercialization priorities. The Lead PI (or his or her designee) is responsible for setting up a monthly meeting schedule with the Mentor. For convenience, Project Manager meetings and Mentor meetings can be scheduled together.

Certain steps must be taken following the initiation of the project. These will include:

- **Monthly Project Update Meetings:** Lead PIs are required to meet monthly with the UM-BILD Project Management team and the matched mentor throughout the duration of the UM-BILD Pilot Grant. During each meeting, the Lead or Co-PI will provide a progress update on project milestones. Examples of update topics:
    - Completion status of current milestones
    - Challenges encountered and mitigation strategies
    - Adjustments to timelines or deliverables
    - Budget updates or anticipated changes
    - Plans for upcoming activities or next steps
- **Midterm Project Presentations:** At the six-month point, the monthly meeting will take the form of the required Midterm Meeting. Both Project Manager and Mentor will attend. See **GUIDELINES FOR THE UM-BILD PILOT PROJECT MIDTERM MEETING**, below, for more detailed information**.**

UM-BILD MII PROJECTS

Although UM-BILD and TEDCO's MII program are separately administered and have different sources of funding, there is close alignment on objectives.

TEDCO accepts applications for Technology Assessment MII grants four times a year, on January 15, April 15, July 15, and October 15. These grants fund nine months of work.

Each year, UM-BILD will review the about-to-begin and ongoing MII Technology Assessment grants with PIs from UM-BILD partner universities. Up to four of these projects' teams will be

invited to join the hub as *UM-BILD MII Projects*. While this status is not accompanied by a cash award, teams will be invited to participate in UM-BILD activities, including assignment of an industry mentor, participation in educational events, and attendance at seminars.

UM-BILD PROGRAM GUIDLINES

A. Eligibility

- Any Faculty or Staff member from one of the member universities of UM-BILD is eligible to apply as a Lead PI or Co-PI on a UM-BILD Pilot Grant. These institutions are the University of Maryland, Baltimore (UMB), the University of Maryland, Baltimore County (UMBC), and Morgan State University (MSU). Faculty/staff at other Baltimore City public universities are also eligible. Finally, faculty/staff from the University of Maryland, College Park (UMCP) may apply, so long as the project is based on I.P. that is owned or co-owned by UMB, and the subject of an Inter-Institutional Agreement designating UMB as the Lead Party.
- An application must have a sole Lead PI. A single Co-PI is also permitted. In such cases, a brief (~ 150 word) Dual-PI Leadership Plan that describes their respective roles must be included with the full application. (See point C-2 of this NIH FAQ). In these cases, the Lead PI will serve as the point of contact for communications.
- The Faculty or Staff appointment for a Lead PI or Co-PI must be for a 0.51 FTE or greater position.
- Other team roles do not share the eligibility limitations and responsibilities of the Lead PI and Co-PI. Their duties and titles (e.g. Co-Investigator, advisor, collaborator) will vary from application to application. Per NIH guidelines, a Co-Investigator (Co-I) is involved with the Lead PI in the scientific development or execution of the project. Co-Is typically devote a specified percentage of time to the project. Co-PIs and Co-Is are considered 'senior/key personnel.'
- An investigator may serve as a Lead-PI ***or*** as a Co-PI on a maximum of one Pilot Project application per cohort. However, he or she may serve in other roles on any number of applications and ongoing projects.
- Lead PIs and Co-PIs are limited to one active UM-BILD application at a time.
- Lead PIs and Co-PIs with a previously funded UM-BILD project may apply as a Lead-PI or Co-PI for a new project only when the previous project is completed and there is no scientific overlap.
- In a limited number of cases, Lead PIs and Co-PIs with a current or previously funded UM-BILD Pilot Project may be invited to submit an LOI for a second year of UM-BILD Pilot Project funding, contingent upon satisfactory completion of the first year and the availability of funds. In these cases, the Specific Aims for the proposed second year of funding should build on the progress of the project's initial year.

- The Lead PI or Co-PI of an MII/UM-BILD joint project awarded in a previous cohort is welcome to submit an LOI for the next UM-BILD Pilot Program cohort. The Specific Aims for the proposed project should build on the progress of the MII/UM-BILD joint project.
- A Pilot Project Grant cannot be transferred to another institution. The Lead PI and Co-PI must remain at the same institution for the entire duration of the award. If the Lead PI or Co-PI changes institutions, funding will end.
- Collaborative proposals are encouraged, but this is not a requirement.
- At the time the LOI is submitted, the I.P. described in the proposal must be disclosed to the Technology Transfer Office at the PI's or Co-PI's university. Inventors must assign the I.P. to the university. I.P., that is owned or co-owned by another party, cannot form the basis of a UM-BILD Pilot Project. At the university's Technology Transfer Office's discretion, I.P., that is co-owned by another party but whose co-owners have executed an Inter-Institutional Agreement specifying that it will be wholly managed by the Office may be deemed eligible for UM-BILD Pilot Projects.
- Applicants may have created a company to pursue translation of their innovative technology, but there is no expectation that they would have done so. UM-BILD encourages applications at an early stage, prior to a decision to form such a company.
- On the day that the Pilot Project grant is awarded, a company may be *in negotiations* with the UM-BILD member university for the technology underlying the project, or it may have signed an *option* in this regard. However, technology that has been licensed is not a suitable basis for starting a Pilot Project grant. If a technology license is signed *during* the Pilot Project, that project may continue to completion.
- There is no limit to the number of applications that may be submitted from each university.
- A UM-BILD Pilot Project grant application does not need to be routed through the UM-BILD partner university's grants or external funding division. Instead, it is submitted directly to the UM-BILD web portal by the Lead PI (or his or her designee).
- Conditions that make a project ***ineligible*** for a UM-BILD Pilot Project Grant:
    - Undergraduates and graduate students are not eligible to lead a project as a Lead PI, Co-PI or Investigator. They are welcome as team members and may have other roles in the proposal. Students who are also inventors must assign their I.P. rights to the UM-BILD member university as a condition of participation.
    - Applications based on I.P., that is 1) encumbered by a third-party agreement at the start of the award (e.g. a sponsored research agreement, licensed to a third party or existing startup company) or 2) co-owned with a commercial third party are not eligible for UM-BILD Pilot Grant funding.
    - Applications based on I.P. where the UM-BILD member university has decided against pursuing a patent application (or another form of protection) are not eligible for UM-BILD funding.
    - NIH regulations do not permit UM-BILD or the other REACH Hubs to include institutions located outside of the United States in Pilot Projects, even if no funding is

allocated for the work. Specific Aims or milestones may not depend on the work of collaborators at foreign universities or other institutions, or on any fee-for-service activities (such as those performed by CROs or CDMOs).

- A Lead PI or Co-PI with a UM-BILD Pilot Project Grant that is still underway on the deadline for Letter of Intent (LOI) submission is not eligible to submit a LOI for this funding cycle.

B. Institutional Regulatory Requirements/Approvals

i. General

- All required institutional registrations/approvals (e.g., Data Use Agreements, Biosafety registrations, Clinical Engineering clearance of devices, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required. To avoid delays in the launch of the Pilot Project, applicants are strongly encouraged to submit the necessary documents to the UM-BILD Administrative Team **at least two months before** the anticipated start date.
- **Delays by the Investigators in submitting regulatory documents to the UM-BILD Admin Core can cause the initiation of a Pilot Project to be postponed. A postponement of 3 months or more from the stated start date would imperil UM-BILD funding for the project.**
- Once all required documents are submitted to the UM-BILD Administrative team, they may be forwarded to NIGMS for review and approval to commence the project. Upon approval, account setup and fund allocation will follow.
    - Before submission, investigators must meet all regulatory compliance requirements related to vertebrate animals and human subjects.
    - Investigators should be aware that IACUC Animal Use Plans and Institutional Review Board (IRB) submissions (both proposals and exemptions) take weeks or even months to be reviewed and approved. An early start to the process is necessary to avoid delays to the start of the Pilot Grant Project. The Lead PI may seek the advice of UM-BILD staff in this area.

ii. Human Subjects Research (HSR)

- The one-page Pilot Project Compliance Form (link) is incorporated into the Appendix of the Formatted Full Application. It includes questions about the HSR status of the proposed Pilot Project.
- It can be difficult to anticipate which activities are considered HSR by the NIH. Thus, teams must use the NIH decision tree to determine if the NIH will consider their project to include Human Subjects Research. If so, the team must complete the Human Subjects and Clinical Trials Information Form.
- An IRB Letter of Determination/Approval (or an analogous document) is not required at the time of the Pilot Project application submission. However, the IRB submission time-burden is likely to be significant, therefore, applicants are strongly encouraged to begin the Human Subjects Research (IRB) process as early as possible. All required

regulatory approvals, and their supporting documents are required to be in place prior to the release of funds and the start of project activities.

- For UMB: Review the UMB IRB website for required training of UMB and non-UMB team members engaged in research. MSU, UMBC and the other USM schools have comparable training requirements. Applicants from other institutions should contact their respective IRBs for information on other training requirements for research conducted at their institution.
- If research activities are split across sites, consider the need for an IRB Reliance Agreement.
- If the HSR activity is a clinical trial, teams must register the trial's protocol at ClinicalTrials.gov.
  - IRB Documentation Requirements During the Review Period
    - The Lead Principal Investigator (PI) must provide the following:
      - The IRB determination letter
      - The IRB-approved protocol
      - A Letter of Exemption, if applicable
    - For projects involving human subjects research (HSR) conducted:
      - At collaborating institutions outside the UM-BILD hub, or
      - Through a Contract Research Organization (CRO)
        - The IRB protocol must be submitted from the institution where the research will be conducted.
    - The submitted IRB protocol must remain valid for the entire duration of the Pilot Project.
- Information on HSR activities will be forwarded to the NIH office responsible for the REACH hubs. Their approval (on completion of review) is needed before the Pilot Project can begin.

iii. Vertebrate Animal Studies

- The one-page Pilot Project Compliance Form (link) is incorporated into the Appendix of the Formatted Full Application. It includes questions about the Vertebrate Animal studies included in the proposed Pilot Project.
- Final IACUC approval and other supporting documents are not required at the time of the Pilot Project grant application submission. However, applicants are strongly encouraged to begin the submission process early. ALL required regulatory approvals and other supporting documents are required to be in place prior to the start of funding.
- During the review period, the Lead PI will be asked to provide updates about the status of the Animal Care and Use Protocol (ACUP) by the IACUC under which the animal work is to be undertaken. This will typically be the UM-BILD partner university's IACUC. Projects involving animal work conducted at collaborating institutions outside the UM-BILD hub or through a CRO must submit the ACUP approved by the institution where the work is performed. This must be accompanied by a description of the procedures involving animals, using the NIH's template (link). The ACUP should be valid by the

start of the Pilot Project. However, the ACUP may be reviewed or amended. Analogous to HSR work (discussed above), information on animal studies will be forwarded to NIH's office, two months before the initiation date of the project. Their approval (on completion of review) is needed before the Pilot Project can begin. 2 months before the initiation date of the project.

C. Funding Policies

- UM-BILD Pilot Project budgets must total no more than $75,000 in direct costs (indirect costs are not allowed).
- Funding for UM-BILD projects will be for one year, with May 2026 as the starting date for Cohort 3, and March 2027 as the starting date for the final cohort (Cohort 4).
- Required regulatory approvals and agreements, as well as other supporting documents, must be obtained prior to disbursement of funds. **Applicants are strongly encouraged to begin the submission process early**. Delays in submission of regulatory documents that delay the start of the project greater than 3 months from the stated funding period might result in loss of funding.
- Funds will be distributed in two disbursements: 50% at the start of the project period following the fulfillment of regulatory requirements, with the second 50% disbursement contingent upon satisfactory progress at the time of the 6-month meeting.
- Projects that do not meet predetermined milestones may be suspended or terminated upon the recommendation of UM-BILD's IAC.
- The Full Application must include a Budget, in the form of an Excel worksheet (link).
- In the event the Lead PI leaves his or her faculty position or is unable to continue leading the UM-BILD Pilot Project, responsibility and funding may be transferred to the Co-PI, if one is serving. Responsibility and funding may also be transferred to a qualified successor Lead PI at the UM-BILD member university. Funding cannot be transferred to another institution.
- Budget Revisions: During a UM-BILD Pilot Project, changes to the budget may become advisable. When such cases arise, the Lead P.I. should notify the UM-BILD Admin Core of this request and then prepare a revised budget. The revised budget must adhere to the policies outlined in this RFA. If feasible, budget revisions will be approved promptly by UM-BILD.
    - Changes to the budget that are within a major category (e.g. Personnel, Equipment, Supplies) are not considered "significant" and do not require prior approval from UM-BILD, or notification.
    - All "significant" proposed budget revisions – those that re-allocate funds among major categories – must be submitted in writing. If changes to milestones or to timing are involved, the new versions of these must also be submitted in writing.
    - The UM-BILD determination on whether budget changes are allowed will also be communicated in writing.

D. Expenses

i. Allowable Expenses

- Research supplies, recruitment and compensation of clinical study participants are allowed.
- Salary and fringe support for faculty-level team members are allowed. Note that the Pilot Grant is designed to support research activities and is not intended to provide substantial salary support for faculty members.
- Salary and fringe support, including insurance, for technicians, research associates, graduate students, and coordinators are allowed. However, tuition fees are not permitted.
- Equipment costs (purchase or lease) are allowed, but these expenses are generally anticipated to account for under one-quarter of the budget.
- No set minimum effort (hours/week or % FTE) is required for this award. Team members' time commitments should align with the needs of the proposed project.
- Special consultative services from individuals may be budgeted.
- An outside organization may be compensated for providing a necessary service. Examples could include an academic core facility, CRO, or CMO. Such services can only be provided by a domestic (cf. foreign) entity.
    - To streamline the contracting process, the UM-BILD Administrative Team strongly recommends that PIs review the Policies and Procedure requirements under the University of Maryland, Baltimore (UMB), University of Maryland, Baltimore County (UMBC), and Morgan State University (MSU). It may be advisable to keep individual contract amounts below $25,000.
    - If a contract exceeding $25,000 is expected, the Principal Investigator (PI) must follow the applicable USM policies. Competitive bidding is favored. Such contracts will fall in the "Competitive Simplified Procurement Range." This is specified in the "Procurement Dollar Thresholds and Limits Guide" PDF; the UMB version is available at this web page (as the University System of Maryland sets these policies, UMBC and MSU have equivalent procedures). PIs should be aware that both the bidding process and the alternative procedure for single-source contracting can be time-consuming and effort-intensive. Here is UMB's "Sole Source Justification FAQ," and here is a link to UMB's 3-page PDF for justifying sole source contracts.
    - The PI must obtain quotes for all fee-for-service work from U.S. providers proposed in the UM-BILD Pilot Project and include them as Appendices in the formatted Full Applications. For contracts exceeding $25,000, the PI should submit three provider quotes – one from the favored provider, and two from competitors. Adherence to this policy is required to avoid delays in project approval and initiation.

ii. Unallowable Expenses:

- UM-BILD universities have agreed to pay for indirect costs. Thus, indirect costs should not be included in these budgets.
- A sub-award to an outside partnering organization is not allowed.
- None of the following categories of expenses are allowed: administrative support, alterations/renovations of laboratory space, purchases of furniture, purchases of periodicals/books, tuition, refreshments, phone services, professional society membership dues, editorial services, publication fees, or travel expenses.

E. Reporting Requirements

i. Failure to attend required meetings in a timely and regular manner risks termination of funding.

ii. Monthly Project Update Meetings

- The Lead PI, Co-PI of a funded project or their designees are expected to schedule a 15- to 30-minute monthly meeting with the UM-BILD Project Manager on an ongoing basis.
- Similarly, the Lead PI and/or Co-PI must schedule a 1 hour long monthly meeting with their UM-BILD Mentor.
- These meetings may be scheduled together for convenience.

iii. Midterm Meeting

- The 6-month meeting (counting from the official starting date) will focus on progress towards milestones and on budget expenditures. It will take the form of a 45-minute meeting, where investigators will present slides reviewing the Gantt Chart that was part of the original application (Aims, Milestones, and Timelines). Work to date, spending, and estimates of future progress will be discussed. See **"Guidelines for the UM-BILD Pilot Project Midterm Meeting**" section below.
- UM-BILD Admin Core approval of the Midterm Meeting is a prerequisite for the release of the second 50% tranche of Pilot Project funds. If satisfactory progress is not demonstrated at the 6-month mark, the release of the second disbursement will be withheld until acceptable progress is achieved. This progress will need to be demonstrated in one of the upcoming monthly meetings with the Project Manager.

iv. Final Report

- A five-page Final Report is due within **30 days** of the end of the Pilot Project award period. The Final Report will include:
  - An overview of all the activities undertaken during the funded UM-BILD Pilot Project period.
  - A description of the results of the project and the success in achieving the milestones listed in the UM-BILD Full Application
  - The impact of the technical milestone results on progress toward commercialization.
  - A final expenditure report from the Lead PI's Grant Administrator of all Project expenditures incurred. The final accounting budget must match the

approved project budget, including subcategories, within 10% of approved totals.

v. **Semi-Annual Follow-up Notifications**

- After completion of the project, teams agree to provide for the successive four years following completion of the project award. This is a brief semi-annual notification with questions relating to success resulting from the award that supports UM-BILD obligations for NIH REACH program evaluation to the federal government. Such notifications will track grant applications/awards, publications, and technological/ I.P. development/licensing. Notifications will also describe startup company formation resulting from the project, and any third-party funding events such as an equity raise. These Follow-up Notifications may take the form of emails to UM-BILD@umaryland.edu.

F. Conflicts of Interest

- It is the responsibility of the awardee and all members of the study team to report all financial or fiduciary interests that present or might appear to present a conflict of interest (COI). This holds true at the time that the Full Application is submitted, during the review process, and throughout the project period. COIs and potential COIs must be reported to the UM-BILD Admin Core, and to the Conflict-of-Interest Officer of the Research Integrity Office of the member university (UMB, UMBC, or MSU).
- The presence of a COI does not automatically disqualify investigators from receiving a UM-BILD Pilot Project Grant. Its presence will trigger the review and management of this conflict by the COI Officer.
- The failure of a member of the study team to disclose all outside interests could result in a Pilot Project Grant's termination and the disallowance of all study costs.
- UMB's COI Policy information, including examples of what constitutes an outside interest, may be found here.
- UMBC's COI Policy information may be found here.
- Morgan State's COI Policy information may be found here.

PUBLICATIONS AND ACKNOWLEDGEMENT OF UM-BILD

Publications resulting from UM-BILD funded work must adhere to the NIH Public Access Policy. A NIH Manuscript Submission System ID can serve as provisional evidence of compliance for three months after a paper is published. Beyond that, a PMCID (PubMed Central Reference Number) is necessary. (UMB teams can consider the Health Sciences and Human Services Library's open-access publishing fund, which is available to junior faculty.)

All publications, abstracts, poster presentations, grant/funding applications, intellectual/technological developments and licensing resulting from research supported by the UM-BILD Accelerator Program should cite UM-BILD as a contributing source of support. Please include the following citation:

"We acknowledge the support of The University of Maryland Baltimore Life Science Discovery (UM-BILD) Accelerator and the Research, Evaluation and Commercialization (REACH) Hub Award 1U01GM152511-01."

GUIDELINES FOR THE UM-BILD PILOT PROJECT MIDTERM MEETINGS

At the six-month mark, the monthly meeting with the UM-BILD Project Manager will take the form of a Midterm Meeting. The Lead PI, Co-PI (if applicable), and Mentor will attend; other team members are also welcome. The meeting may take place in person or via Zoom. If the Lead PI has completed project milestones ahead of schedule, as indicated on the Gantt Chart, and determines that an earlier midterm presentation is warranted, they may submit a request to the UM-BILD Administrative Team to hold the presentation prior to the six-month mark.

The most important thing is to explain the progress to date on the milestones stated in the Full Application, as laid out in the Gantt Chart. Based on this information, the Admin Core will decide whether to release the second 50% of funding. If progress has been delayed or certain goals have not been met, the team should use the Midterm Meeting as an opportunity to explain the circumstances and set forth a revised plan for the remainder of the project.

The Presentation:

The project team should prepare a 20-minute presentation, leaving the remaining time for discussion. The presentation should cover the content outlined below in 10 to 15 numbered PowerPoint slides (maximum of 15). Be sure to share the draft deck with your Mentor as you develop it. The UM-BILD Admin team (likely Alastair Mackay and Anthony Alexander) will be on the call. Do not go beyond the 'Required' and 'Optional' material; do not include additional content beyond these sections.

The slide deck must be emailed one week in advance of the meeting date to UM-BILD@umaryland.edu.

Required Slides:

- Open the PowerPoint file, "Midterm Progress Report Presentation_TEMPLATE.pptx"
- Overview of the project (1 or 2 slides). The UM-BILD team is already familiar with this, so these are reminders, *not* a comprehensive summary of the science.
- Gantt Chart pages from your original application (1 or 2 slides). These constitute a list of the milestones as they were proposed, along with their projected timing.
- Include one slide for each milestone (Aim).
    - For each milestone:
        - What has been accomplished?
        - What is yet to be accomplished?
        - Have any changes been made?
        - Are there any unexpected issues or challenges?
            - Provide reasons for delay
            - Provide impact assessment

        - Mitigation strategy
- An Update on the Budget (at least 1 slide)
    - On one table (e.g. a screenshot of the relevant cells of a simple Excel worksheet), show the overall proposed budget from the original application, and spending-to-date by category.
    - Ask your Grant Administrator for a printout of spending-to-date.
    - In one table (this can be a screenshot of the Budget worksheet), show the overall proposed budget from your original application, and spending-to-date by category.
    - Are there any unexpected spending issues, budget change requests, or looming challenges?
    - Open the Excel file, "UM-BILD Midterm Budget.xlsx" (see next page).
        - Note that the cells in dark blue are formula calls – do not change those.
        - Fill out "Originally Requested" to reflect what is in the Budget Table from your original UM-BILD application. If you have already received approval for a Budget Change Request, use those revised numbers instead.
        - Fill out the "Spent to Date" and "Remaining" then the "Project Expenditures" and "Total Cost "columns.
    - Copy the Excel table into PowerPoint. This will likely be your only budget slide
- Updates on I.P., licensing and publications (1 or 2 slides).

Optional Slides:

- The Big Picture (1 slide). Your current views on the Product Concept, Customer Needs, Regulatory and Development Challenges, and the Market.
- Your relationship with your mentor
- Results (progress towards project goals at the midterm point)
    - Figures
    - Tables

Once the Admin Core has found that you have satisfied the Midterm meeting requirement, the second (50%) tranche of the grant's funding will be released.