



Request for Applications

IMPACT Funding Opportunity Number: RFA-IMPACT-21-P03B

Pilot Grants

Pilot pragmatic clinical trials for people living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their care partners

KEY DATES:

<i>Request for Applications – Released</i>	August 16, 2021
<i>Letter of Intent Application – Opens</i>	August 23, 2021
<i>Informational Webinar</i>	August 23, 2021 @ 2pm ET
<i>Letter of Intent Due – Required</i>	September 17, 2021 @ 5pm ET
<i>Letter of Intent – Notification</i>	October 22, 2021
<i>Full Proposals Due – By invitation only</i>	January 14, 2022 @ 5pm ET

2021

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Program Overview

The National Institute on Aging (NIA) Imbedded Pragmatic Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (U54AG063546) was established in 2019 to build the nation's capacity to conduct embedded [pragmatic clinical trials](#) (ePCTs) of non-pharmacological interventions within health care systems to improve the care of people living with AD/ADRD and their care partners. The NIA IMPACT Collaboratory funds several one-year pilot studies annually; these are meant to generate the preliminary data necessary to design and conduct a future full-scale Stage IV effectiveness ePCT (based on the [NIH Stage Model](#)) funded through other grant mechanisms (National Institutes of Health or other sources). The IMPACT Collaboratory encourages applications that address dementia care for people of all backgrounds and promote health equity.

The IMPACT Collaboratory provides guidance for investigators in the design, conduct, and dissemination of ePCTs through its 10 **Cores and Teams**. Learn more at <http://www.impactcollaboratory.org>.

Funding Opportunity Description

The IMPACT Collaboratory will consider applications for pilot ePCTs that test non-pharmacological interventions embedded in health care system(s) for people living with AD/ADRD and their care partners. All applications must make a convincing case that the pilot ePCT proposed can be scaled up to a full-scale [Stage IV effectiveness ePCT](#) as the next step. Required features of the study design are delineated under [General Requirements](#).

In this cycle, up to five 1-year, non-renewable pilot studies will be funded. No-cost extensions are generally not allowed, but will be considered only in exceptional circumstances, will require NIA approval, and are not guaranteed.

Priority Areas for RFA-IMPACT-21-P03B

All applications for pilot ePCTs that evaluate non-pharmacological interventions to improve the care of people living with AD/ADRD and their care partners **will be considered**. However, this grant cycle will **prioritize** applications for interventions in these populations that aim to:

- Improve care through behavioral economics "**nudge**" interventions;
- Reduce **inequities in health care**;
- Reduce potentially inappropriate medications through **de-prescribing**; or
- Improve care in **emergency departments**.

Informational Webinar

An optional informational webinar will be hosted to provide investigators with an overview of application details and an opportunity to ask questions. Pre-registration is required using the link below. The webinar will be recorded and posted online at <https://impactcollaboratory.org/pilot-grants-program/>.

- **Monday, August 23, 2021 at 2:00pm ET: [Register here for webinar](#).**

Frequently Asked Questions

A set of frequently asked questions (FAQ) regarding this award is available online at <https://impactcollaboratory.org/pilot-grant-faq/>.

Award Information

Awards are for one year, up to \$175,000 (direct costs), and are non-renewable. Indirect costs are budgeted at your institution's negotiated facilities and administrative rate. Only a single Principal Investigator (PI) is allowed, and only one application per individual PI is permitted in each funding cycle.

Extensive primary data collection (i.e., direct cost exceeding \$30,000) is not permissible. Researchers are encouraged to use administrative data sources, such as electronic health records; other nursing home, federal or state administrative data; and low- to no-cost smartphone or web-based interventions. It is expected that applicants will fully describe primary data collection costs in the budget justification, when applicable.

On occasion, during the review of LOIs or full applications, the IMPACT Principal Investigators, Pilot Core leaders, and NIA project officer and scientists may jointly decide that a promising project, while not ready for full funding, merits consideration of a smaller award (up to \$40,000 in direct costs) to address a focused critical feasibility gap in the research. This support is intended to enable the PI to gather additional feasibility data for an aspect of the ePCT design, such that if this gap were to be addressed, the project would be potentially competitive for a future full pilot study award.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made from this funding opportunity.

Eligibility

Institution

- Eligible institutions include: colleges, universities, medical or nursing schools, health care systems or settings, or other fiscally responsible organizations within the United States. No research may be performed outside of the United States.

Principal Investigator

- Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their organization to develop an application.
- Applicants must hold a faculty or research scientist position at an eligible institution by the start date of the award or be otherwise eligible to serve as a Principal Investigator as determined by their organization.
- Applicants must be citizens or permanent residents of the United States.

Applicants from under-represented racial and ethnic groups as well as individuals with disabilities are strongly encouraged to apply for funding.

How to Apply

Interested applicants are required to submit a Letter of Intent (LOI) through the Brown University U Funds system at: <https://ufunds.brown.edu/>. LOIs may be submitted on a rolling basis but no later than September 17, 2021 at 5:00PM ET. LOI decisions will be provided on or before October 22, 2021.

*How to Apply
continued*

Access to UFunds: UFunds can be accessed either with a Brown University email address or with a Gmail address that has been granted rights to the system. The PI may request Gmail access, or someone else may request permission to submit on behalf of a PI. UFunds is not a multi-user environment. If the PI needs more than one person to work on the application in UFunds, contact Faye_Dvorchak@brown.edu to discuss a possible workaround prior to requesting access to UFunds.

The same account must be used to submit materials for the LOI and, if invited, the full proposal application. If you were granted access to UFunds previously, your credentials are still active. New users to UFunds must first request access using a Gmail address here: <https://tinyurl.com/UFundsAccess>. You will receive an invitation at your Gmail address once access to the UFunds system has been granted. *Please note that the registration process can take up to 2 business days, so applicants are strongly encouraged to request access as early as possible.*

There is a competitive two-step application process:

STEP 1: LETTER OF INTENT

The LOI application includes the following main elements (access templates [here](#)):

- [Pilot Study description](#) not exceeding 2-pages (single spaced, 11 Arial font, 0.5" margins) including: A. Background/Rationale, B. Specific Aims, C. Design Overview, D. Setting (types and names of health care systems), E. Participants and Participant Identification Strategy, F. Intervention Structure and Implementation Strategy, and G. Outcome Definitions and Collection Methods. (PDF upload)
- Bibliography and References Cited (no more than 1-page; not included in the 2-page limit above) (PDF upload)
- Attestation in UFunds that Principal Investigator has read and/or viewed the following materials:
 - Viewed the video "[Pragmatic Clinical Trials: How Do I Start?](#)"
 - Read the [RAPT Model](#) paper **OR** viewed the IMPACT Collaboratory Grand Rounds on "[Are you ready for a pragmatic trial? The RAPT Model and implementation considerations](#)"
 - Read the [PRECIS-2](#) paper
- Completion of the [LOI Pilot Study Pragmatic Design Worksheet](#) (not included in 2-page limit above) (PDF upload)
- Anticipated total direct costs (maximum of \$175,000) and whether subawards are anticipated. Subawards are allowed (cannot exceed 2). Whenever feasible, purchase of services and consulting agreements are strongly preferred to subawards.
- PI's [NIH Biosketch](#) (PDF upload)

General Requirements

Guidance for the Pilot Grant Program including information on how to develop the Specific Aims for a pilot study for an ePCT can be found in [Appendix 1](#). The following study design features are required of full applications and should be briefly addressed to the extent possible in the LOI application.

*How to Apply
continued*

- Non-pharmacological intervention that utilizes an embedded [pragmatic trial design](#) to target people living with AD/ADRD and/or their care partners.
- Intervention has a reasonable evidence-base demonstrating its efficacy as described in the [RAPT Model](#) paper. *All interventions must have a reasonable evidence-base demonstrating their efficacy.*
- Evaluate an intervention that can be implemented with a high level of fidelity.
 - Pilot ePCTs evaluating relatively simple interventions (e.g., nudges) that have a greater likelihood of being implemented with fidelity are encouraged.
 - More complex, multicomponent interventions must have well-developed, transportable training and implementation protocols with ‘a priori’ evidence (e.g., from a stage II or III study) demonstrating the training programs work and the intervention can be delivered with fidelity.
 - It could be appropriate to use this pilot funding to better assess intervention fidelity when the intervention is scaled up for implementation within a health care system.
- Setting includes two or more health care systems or sites within health care systems (e.g., nursing homes, hospitals, health care provider practices).
- The number of sites and subjects should be maximized to provide a convincing foundation to support the feasibility, generalizability, and scalability to a full-scale ePCT as the next research step. Randomization is NOT required.
- Be no more than minimal risk to human subjects in accordance with [Federal regulation 45 CFR §46.102\(j\)](#).
- When possible and if appropriate, be designed to qualify for a waiver or alteration of informed consent in accordance with [Federal regulation 45 CFR §46.116\(f\)\(3\)\(i.-v.\)](#). Informed consent may be needed to address targeted research questions (e.g., collect gold-standard primary data to validate pragmatic measures).
- Have a feasible approach to participant identification/enrollment using existing electronic health care system data sources or infrastructures (e.g., electronic health record).
- Have a single, primary clinical outcome that can be collected pragmatically (i.e., from electronic health records, billing claims, or widely used electronic surveys such as Consumer Assessment of Healthcare Providers and Systems (CAHPS)). The main purpose of delineating a primary outcome is to demonstrate the feasibility of collecting it pragmatically. The pilot study is NOT expected to be powered to demonstrate an effect of the intervention.
- Have secondary feasibility endpoints evaluating implementation fidelity, usability, acceptability, or additional target metrics (e.g., > 80% adherence) when appropriate.
- Have high alignment with stakeholder priorities. Stakeholders include, but are not limited to: people living with dementia, care partners, frontline providers, health care systems, and/or payers.
- Addresses biologic variable of sex as it relates to populations and outcomes.

*How to Apply
continued*

STEP 2: FULL PROPOSALS BY INVITATION ONLY

Applications selected for further consideration will be invited to submit a full proposal that will be due no later than January 14, 2022 at 5:00PM ET.

Full proposal applications must be submitted online through Brown University's UFUNDS system: <https://ufunds.brown.edu>.

Applicants invited to apply for full proposals will be provided with an Application Guide containing detailed guidance on the required elements. An overview of the general format of the full proposal application can be found in [Appendix 2](#).

Applications that do not demonstrate a substantially pragmatic trial design will be administratively triaged prior to review. Pilot studies for efficacy trials (e.g., Stage III on [NIH Stage Model](#)) will NOT be considered. Applicants must submit the Pragmatic Pilot Study Worksheet (version for full proposals) based on the [RAPT Model](#) and [PRECIS-2 framework](#) and consider the elements of these frameworks in their research design and methods.

Consultation from IMPACT

All applicants selected for further consideration will have two meetings, each for one hour, with an IMPACT Consultation Team assembled specifically for each proposal to help guide the development of the strongest application. The team will be comprised of experts from IMPACT's Cores and Teams. The applicant and their biostatistician must attend both meetings. Prior to the first meeting, the Consultation Team lead will provide the applicant with an initial structured feedback form based on the LOI. This document will be discussed at the first consultation meeting with an opportunity for the applicant to provide clarifications, ask questions, and receive guidance. The applicant must submit a draft of the Specific Aims one week prior to second consultation meeting. The draft aims will be discussed at the second meeting, providing another opportunity for feedback and guidance. Applicants may also request individual meetings with specific cores and teams throughout the proposal development process.

Principal Considerations

Applications should convey the degree to which the proposed intervention is ready for an ePCT based on the [RAPT Model](#) and the design of the pilot study represents a pragmatic approach based on the [PRECIS-2 framework](#).

Applications must also address the degree to which health equity considerations are addressed in preparation for the full-scale ePCT. [Learn more](#) about achieving health equity in the design of ePCTs. A description of how the pilot project considers issues related to health equity must be integrated into the Research Plan and discussed in a separate 1-page section of the application (not included in page limits).

Rationale should be provided about how the design elements address health equity, including:

- Selection of health care system(s)
- Target study population demographics
- Tailoring of the intervention to different backgrounds, languages, cultures
- Monitoring differential implementation, adherence, attrition/retention
- Assessing outcomes

Principal Considerations continued

While it is not possible to address all these issues within the limited scope of a pilot study, at minimum, the proposal should address how the pilot project experience will inform the design of the future larger, Stage IV effectiveness ePCT in terms of its relevance to people with AD/DRD from diverse backgrounds and/or their care partners.

Scientific Merit Review

Full proposals will be reviewed by at least two non-conflicted scientific reviewers. Scientific merit ratings will consider input from the stakeholder review. More details on the review criteria can be found [Appendix 3](#).

Stakeholder Review

Full proposals must include a structured General Audience Summary (max 500 words) that will be reviewed by members of the stakeholder community who may have little to no formal research or clinical training. Stakeholders may include people living with dementia, care partners, or other health care system stakeholders. Details will be provided in the Application Guide.

Just-in-Time

After the scientific review committee meeting, you may be asked to submit Just-in-Time (JIT) materials needed to finalize your application. This request does not guarantee anything about the ultimate funding status of your application. Just-in-Time materials are generally due within 2 weeks of the request. *The IMPACT Collaboratory Administration Core will assist the PI with the Just-in-Time materials.*

Pilot Grant Recipient Award Requirements

Award recipients of the IMPACT Collaboratory Pilot Grants Program are expected to adhere to the following requirements:

1. Adhere to [sIRB](#), [Data and Safety Monitoring](#), and [Data and Resource Sharing](#) policies. The IMPACT Collaboratory will provide a specific Data and Resource Sharing Plan approved by NIA for IMPACT pilot studies and can provide further guidance. Human subjects research cannot commence without approval by the IMPACT Collaboratory's overseeing single Institutional Review Board (sIRB) and Data and Safety Monitoring Board (DSMB).
2. Adhere to [NIH policy and guidelines regarding inclusion of women and minorities](#) and [inclusion across the life span](#) in the design and conduct of the study as mandated by [Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2](#). The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.
3. Complete Financial Conflict of Interest (FCOI) assurance and training as detailed under their respective organization's policy and in accordance with PHS ([42 CFR Part §50.604](#)) FCOI regulations.
4. Register with [ClinicalTrials.gov](#) in accordance with NIA guidelines. Maintain the protocol registration system (PRS) record and complete all reporting requirements, including uploading results.
5. The PI will meet with an assigned Pilot Study Core Executive Committee member for one hour every month throughout the lifecycle of the pilot. The assigned Executive Committee member will be available to help strategize and navigate challenges. To help ensure successful progress, the IMPACT Collaboratory's Investigator Navigation Team will link PIs and their research team members with the IMPACT Collaboratory Cores and Teams, according to their pilot study's needs.

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Requirements
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6. Engage in the IMPACT Collaboratory's scientific community, including:
 - a. Participating in the academic activities of the Core and Teams (e.g., writing methods articles, developing guidance documents).
 - b. Attending and presenting at the in-person IMPACT Collaboratory Scientific Meeting in Bethesda, MD.
 - c. Attending webinar-based IMPACT Collaboratory Grand Rounds.
7. The National Institute on Aging (NIA) supports a central resource to NIA staff and extramural investigators to facilitate/support the conduct and management of clinical research. This resource, the Clinical Research Operations Management System (CROMS), is a comprehensive data management system to support the business functions, management, and oversight responsibilities of NIA grants that support the conduct of clinical research with human subjects. It is the expectation by NIA that all successful applicants will interface, integrate, or adapt their information system(s) and processes to interact with existing and future components of the CROMS as necessary.
8. Submit required reports for study tracking and standardized data elements as well as a final report at the end of the pilot study year.
9. Follow IMPACT Collaboratory invoicing guidelines.
10. Provide budget reports upon request and at the end of the pilot study year.
11. Adhere to the IMPACT Collaboratory publication policy and acknowledge sponsorship in all presentations, publications, and subsequent grants stemming from this pilot study. This information is required for reporting to NIA.
12. Respond to IMPACT Collaboratory queries for information after project ends.

Questions?

For eligibility and research-related questions, please contact: Kathleen Unroe, MD, MHA, Associate Core Leader, Pilot Studies Core at IMPACTcollaboratory@hsl.harvard.edu.

For questions related to access or use of the UFunds system please contact Faye Dvorchak at Faye_Dvorchak@brown.edu.

Appendix 1

Guidance for Pilot Grant Program

The intent of the IMPACT pilot grants program is to ready projects for launching as a full ePCT as an immediate next step upon completion of the pilot study. All aspects of the proposal should be viewed through this lens. The pilot study should be leveraged to optimize and demonstrate the feasibility of all aspects of the full ePCT design, adhering to the features of a pragmatic trial rubric with focus on: 1) Demonstrating the feasibility of intervention implementation embedded in at least two health care systems/sites, and 2) Demonstrating the feasibility and validity of subject identification and outcome assessment in these health care systems using pragmatic methods.

The sites/participants do not need to be randomized unless there are key aspects of randomization that require pilot testing. If a control group is included, the pilot study is not expected to be “powered” to show a significant effect between arms. If there is no control arm, the pilot study should still be designed with one in mind, such that in the full ePCT, participant identification and outcome ascertainment must be done in a pragmatic fashion in both the intervention and control arms. Regardless of design the NIA requires a reasonably robust sample of people living with dementia and/or their care partners to be included in the pilot study.

The Specific Aims should reflect the aforementioned foci. An *EXAMPLE* of how to organize your aims (not necessarily in this order):

- Specific Aim 1: Demonstrate the feasibility of the intervention implementation using pragmatic design methods. Specifications of quantitative feasibility endpoints metrics that would indicate ‘success’ to move on to full ePCT should be provided. Qualitative interviews with key stakeholders about barriers, etc. are also permissible.
- Specific Aim 2: Demonstrate the feasibility of the following areas using pragmatic design methods: 1) Subject identification, 2) Primary clinical outcome ascertainment, and 3) Secondary outcome ascertainment. This Aim must specify a single primary clinical outcome that would be used in the full ePCT.

Other aims: You are free to include other important aims that will lay the foundation for the full ePCT. For example, validation of pragmatically obtained outcomes measures or subject identification from an electronic health record against primary data collection (a limit of \$30,000 is allowed for primary data collection).

Appendix 2

General Format of Full Proposals

Applications for full proposals will include applicable [PHS 398 Forms](#) specified in the Application Guide. Full proposals will follow the general format of an NIH R21 with IMPACT Collaboratory-specific additions, including but not limited to:

- **General Audience Summary** (max 500 words)
- **Specific Aims (1 page)**
- **Research Plan (6 pages)**
 - Background and Significance
 - Preliminary Studies (if applicable)
 - Research Design and Methods: Include the following: 1) Study population, 2) Setting (sites/health care systems), 3) Randomization scheme and masking when appropriate (not expected for all pilot studies), 4) Intervention structure, implementation protocol, and fidelity/adherence monitoring plan, 5) Data sources, elements, and collection protocol, and 6) Analytic plan. **Health equity considerations must be integrated in the research design and methods as described in RFA.**
 - Milestones: Specify milestones that are specific, measurable, and achievable by which your progress can be reviewed.
 - Future Directions and Next Steps: Specify how the pilot study will directly inform the development of a full-scale, Stage IV effectiveness ePCT (on the [NIH Stage Model](#)) application to the NIH or other funding sources and the anticipated timeline to apply for such funding.
- **Bibliography and References Cited**
- **Integration of Health Equity into Study Design (1 page)**: Describe how health equity is addressed in the proposed study and will be considered in the future ePCT. Rationale should be provided about how aspects of the design address the needs of people from diverse backgrounds as described in [General Requirements](#) of the RFA. If a project does not meet this expectation, provide a compelling rationale for why the design does not address issues of health equity and how the results of the proposed pilot study might support a subsequent ePCT that does address health equity issues.
- [PHS Human Subjects and Clinical Trial Information](#) – Form (Version F) IMPACT-specific instructions will be provided. All required attachments must be included.
- **Clinical Trial Milestones Plan** (Form will be provided)
- **Pilot Study Pragmatic Design Worksheet** (Form will be provided)
- [NIH Biosketches](#) for the PI and Key Personnel including the biostatistician. *Note: The research team must include a qualified biostatistician as co-investigator or consultant.*
- **Letters of Support**. Applicants must submit letter(s) of support from each participating health care system/site clearly stipulating that the proposal has high alignment with: 1) Priorities of the health care system in caring for people living with dementia and/or their care partners, and 2) Strong likelihood the intervention could be feasibly integrated and adopted into the clinical flow by frontline providers.
- **Acknowledgment Letter from IRB/HRPP Official**. Applicants must submit a letter of acknowledgment from their institution's IRB/HRPP official stating that, should the study be funded, they agree to cede IRB oversight to Advarra, the central [single Institutional Review Board \(sIRB\)](#) chosen by the IMPACT Collaboratory. An acknowledgment letter is also required from any collaborating institution that will also be engaged in human subjects' research activities. A template will be provided.

Appendix 3

Scientific Merit Review Criteria

The review process will consider each of the following criteria:

Fit within the Mission of the IMPACT Collaboratory

- Does the intervention target people living with AD/ADRD and/or their care partners?
- Is the proposed pilot study at the proper stage in the [NIH Stage Model](#) for Behavioral Intervention Development? In other words, is this a pilot study in preparation for a full-scale, Stage IV effectiveness ePCT?

Significance

- Are the magnitude and prevalence of the problem clearly defined and important to address?
- Is it likely that the intervention has face validity and could affect said problem?

Alignment with Stakeholder Priorities

- How clear is the case that the problem and outcome measures are aligned with stakeholder priorities? Stakeholders may include health systems/organizations, frontline providers, PLWD, and/or care partners.

Intervention Readiness for a Pilot ePCT based on [RAPT Model](#)

- Does the intervention have a reasonable evidence-base demonstrating efficacy?
- For complex interventions, has the intervention been successfully tested and shown to be deliverable with fidelity by the individuals who will be delivering it?
- Does a protocol accompany the intervention and is it clearly actionable?
- Could the intervention be performed in a pragmatic fashion without extensive support of research staff (other than implementation support or technical assistance)?
- Does the intervention present a strategy that may be cost-effective?
- Can the intervention be implemented by real world staff and organizations?
- Can this study be completed in the allotted time?

Design (Pragmatism and Scientific Validity) based on the [PRECIS-2 Framework](#)

- Can the primary clinical outcome measure be pragmatically collected?
- Are the strengths/limitations of outcome measures aligned with the goals of the study and the intervention?
- Are feasibility endpoints (e.g., adherence, dose, quality of delivery, acceptability to participants) collected, and are thresholds for success specified?
- Can subjects can be identified pragmatically using existing data/infrastructure, or if not, through modest augmentation of existing systems?
- Are subject inclusion and exclusion criteria broad and pragmatic in nature (e.g., looks like a usual care population)?
- Are the study site(s) suited for obtaining generalizable information to inform a larger pragmatic trial (vs. highly specialized and unique)?
- Is the intervention flexible in delivery and adherence, or must it be rigidly implemented and/or followed?
- Is the design feasible, rigorous, reproducible, and scientifically justified?

Appendix 3 continued

Integration of Health Equity into the Research Plan

- Are health equity considerations integrated into the design elements of research plan?
- Does the study consider health equity in its selection of health care settings and target population demographics?
- Does the study address an area where inequities currently occur (and is this addressed in the application)?
- Does the study include a plan for monitoring differential implementation, adherence, and attrition/retention across diverse groups?
- Does the study seek to enhance health equity?
- Does the study address the biologic variable of sex as it relates to populations and outcomes?

Investigative Team Qualifications

- Does the team's prior work support the likelihood that they can complete this study?
- Does the team include a biostatistician collaborator?
- Could this team competitively apply for a large-scale R01 or equivalent level grant?

Human Subjects

- Is this study minimal risk in nature?
- Is it likely to qualify for a waiver or partial waiver of informed consent and authorization? *Note: Pilot studies may require consent for collecting gold-standard data to validate pragmatic measure.*

Milestones

- Are the milestones specific, measurable, and achievable?
- Are the milestones aligned with the project at hand?

Future Directions

- Through this award, if successful, does this pilot project have the potential to lead to external funding (i.e., an R01 or equivalent) for a full-scale ePCT?