Overview Information	
Funding Opportunity Title	**Precision Medicine Initiative® Cohort Program Direct Volunteers Pilot Studies** http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151116-pmi-pilot-phase-studies-ota-sow.pdf
Funding Opportunity Number	OT-PM-16-001
Participating Organization	National Institutes of Health (NIH)
Components of Participating Organizations	This funding opportunity is developed as a part of the NIH Precision Medicine Initiative® through the NIH Common Fund. The funding opportunity will be administered by the National Center for Advancing Translational Sciences (NCATS) on behalf of the NIH.
Announcement Type	New
Related Notices	NOT-OD-15-159 Precision Medicine Initiative Cohort Program Recommendations Issued and Accepted OT-PM-16-002 Communication Support for the Precision Medicine Initiative® Research Programs at NIH RFA-PM-16-001 Precision Medicine Initiative® Cohort Program Coordinating Center (U2C) RFA-PM-16-002 Precision Medicine Initiative® Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3) RFA-PM-16-003 Precision Medicine Initiative® Cohort Program Participant Technologies Center (U24) RFA-PM-16-004 Precision Medicine Initiative® Cohort Program Biobank (U24)
Funding Opportunity Purpose	The purpose of this funding opportunity is to invite applications for a prototype set of technologies and experiments that will inform successful conduct of a national research cohort of one million or more volunteers for the Precision Medicine Initiative® Cohort Program. Awards made through this announcement will support the establishment of innovative methods and technologies for data collection and management, and participant engagement.
Funding Instrument	Other Transaction (OT) award: A mechanism that is not a grant, contract or cooperative agreement.
Funds Available	Actual amounts will depend on funds available.
Anticipated Number of Awards	NIH intends to fund one (1) award in FY2016.

Key Dates

Award Project Period	The total project period will be one (1) year.
Post Date	November 17, 2015
Application Due Date	December 22, 2015
Scientific/Technical Review Date	Review will be conducted immediately upon receipt of applications.
Award Timeline	Award will be made upon selection and award negotiation

Application Instructions

Required Application Instructions	Organizations may submit multiple applications. However, each application must address and integrate all task areas. Applications shall include sufficient detail to allow the Government to assess the applicant's capabilities to provide the requested services. Applications should include the following with the total application package not exceeding 25 pages: • Technical Approach: Not to exceed 15 pages • Past Performance (Corporate/Organizational experience as relate to the solicitation): Not to exceed 5 pages • Key Personnel (Applicants should provide brief bios of key personnel): Not to exceed 3 pages. Each application must identify a Program Director/Principal Investigator • Cost Proposal: Applicants should build a milestone driven, cost allocated plan for proposal. Cost models can be cost-sharing, fixed price, adjustable (cost reimbursable) or a hybrid approach: Not to exceed 2 pages. Applicants should familiarize themselves with the report of the PMI Working Group to the Advisory Committee to the Director entitled *The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine.*
Instructions for Application Submission	Applications should be submitted in an email attachment in PDF (Adobe) format to Ms. Irene Haas, PMI Cohort Program Agreements Officer, at PMICPFOAInquiries@mail.nih.gov. Applications must be submitted by an authorized organization representative. Paper applications will not be accepted.

Eligibility Information

Eligible Applicants	Higher Education Institutions • Public/State Controlled Institutions of Higher Education • Private Institutions of Higher Education The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

	○ Hispanic-serving Institutions ○ Historically Black Colleges and Universities (HBCUs) ○ Tribally Controlled Colleges and Universities (TCCUs) ○ Alaska Native and Native Hawaiian Serving Institutions ○ Asian American Native American Pacific Islander Serving Institutions (AANAPISIs) Nonprofits Other Than Institutions of Higher Education • Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education) • Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) For-Profit Organizations • Small Businesses • For-Profit Organizations (Other than Small Businesses)
Foreign Institutions	Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Application Review	
Review Process	Applications will be evaluated for scientific, programmatic, and technical merit by an appropriate review group convened by the NIH Office of the Director, and will include federal reviewers.
Evaluation Process	Reviewers will evaluate applications based on the following criteria. • Technical Approach • Past Performance • Key Personnel • Cost Proposal Applications will not receive a written summary.
Questions Regarding this Solicitation	Questions may be submitted via email to Irene Haas, Agreements Officer (NCATS) at PMICPFOAInquiries@mail.nih.gov.
PMI Cohort Program Agreements Officer Contact	Ms. Irene Haas National Center for Advancing Translational Sciences (NCATS) Telephone: 301-827-2562 Email: PMICPFOAInquiries@mail.nih.gov
Authority	Other Transaction awards will be made pursuant to current authorizing legislation.
PMI Cohort Program Other Transaction (OT) Policy Guide	Other Transaction awards are subject to the requirements of the *Other Transaction Award Policy Guide for the Precision Medicine Initiative® at NIH*. Applicants may review this policy guide, which will be available

	by Wednesday, November 18, 2015, by accessing: http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151118-ot-award-policy-guide.pdf

Precision Medicine Initiative® Cohort Program
Direct Volunteers Pilot Studies

The National Institutes of Health invites proposals for pilot studies and the needed information technology support for the development of the Direct Volunteer component of the Precision Medicine Initiative® Cohort Program.

Background

In his State of the Union Address on January 20, 2015, President Obama announced his intention to launch the Precision Medicine Initiative® (PMI) "to bring us closer to curing diseases like cancer and diabetes, and to give all of us access to the personalized information we need to keep ourselves and our families healthier." In order to achieve the President's ambitious plan, the PMI Cohort Program will build a national research cohort of one million or more U.S. volunteers that will provide the platform for expanding knowledge of precision medicine approaches and that will benefit the nation for many years to come.

On September 17, 2015, the Precision Medicine Initiative Working Group of the Advisory Committee to the Director (ACD) presented a detailed framework for building the national research cohort in its report entitled *The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine* . Applicants to this solicitation are encouraged to familiarize themselves with the PMI Working Group report as well as the NIH request for applications (RFA) for cooperative agreements to fund the full implementation phase of the PMI Cohort Program: http://www.nih.gov/precision-medicine-initiative-cohort-program/funding-opportunities.

Enrollment of PMI Cohort Program participants will be through two distinct approaches: one leveraging the strengths of healthcare provider organizations (HPOs) with existing relationships with potential participants and the other opening enrollment directly to volunteers who are not part of a participating HPO. This solicitation is for the development, pilot testing and refinement, of the participant interface for the Direct Volunteers component of the PMI Cohort Program.

The PMI Cohort Program proposes a highly interactive participation model which is untested for a project of this scale. Participants will be the primary source of many research observations, providers of information about their health and experiences, consultants on proposed research studies, mediators of access to their healthcare data, contributors to overall data quality control, donators of data from mobile and wearable devices, and recipients of their own as well as aggregate data and analysis results, according to their preferences. The PMI Cohort Program will collect a diverse set of data types, beginning with a more limited set of self-reported observations to be acquired primarily at entry from all cohort participants, as well as a set of longitudinal variables.

This solicitation for Pilot Phase studies is motivated in part by the recognition that engagement of PMI Cohort Program volunteers will require a strong 'customer focus', and therefore its online information services and user interface will benefit from application of cutting edge methods used by commercial product developers for designing and delivering online content. The expectation is that evidence-based approaches will help refine the presentation and functionality of initial interactions with individuals, facilitating their participation in the cohort.

Evidence-based approaches will also be essential to develop the best strategies to maintain interest and active participation. The PMI Cohort program expects to build upon experience with participant provided health information in other large cohort studies, particularly the UK Biobank, the Veterans Administration Million Veteran Program, and the National Health Interview Survey. These studies provide tested question sets about health matters that have been shown to provide consistent and reliable information. The PMI Cohort Program would like to build on this experience and potentially collect many of the same data elements, but there is little experience on the optimum presentation of these questions on hand held devices, or on the impact of data return on participation.

The Direct Volunteer pilot will include the collection of participant biosamples. The pilot studies will be used to determine the best methods for approaching potential and enrolled participants for the provision of biosamples (e.g., saliva, urine, and blood).

Pilot phase goals

The pilot phase envisions an iterative process to meet the following four goals:

1. An informational website and potentially other materials which, through extensive experimentation and testing, will be used to help identify the best communications and approaches to encourage volunteers to become participants;
2. A participant interface which has, through extensive user testing, been optimized to keep participants engaged, maximize their interests and ongoing engagement, and returns to the participants information of value;
3. Data structures to implement 1 and 2, and ensure the secure collection and maintenance of data from the first set of volunteers; and
4. An engagement strategy and process, which encourages volunteers to provide biosamples needed for different types of PMI cohort program research.

Phased implementation is envisaged, beginning with design, development and implementation of the Pilot Phase Direct Volunteers informational website. The website will educate users about the program, and offer potential volunteers the opportunity to provide contact information and indicate 'expression of interest' and willingness to be re-contacted. Those in the 'interested' group will serve as a pool of potential volunteers for continued refinement of the informational website and subsequent pilot testing of the prototypes described below in the Task list.

In summer 2016, the NIH anticipates awarding cooperative agreements for the full implementation phase. One award will establish a Coordinating Center (alone or with subcontractors; see RFA-PM-16-001) that will assume final responsibility for implementation of the Direct Volunteer component of the program. The awardee for this Pilot Phase solicitation will be expected to collaborate closely with the CC awardee to complete pilot phase testing and ensure smooth transition of data structures and data acquired in the pilot phase. Another award will establish a Biobank (RFA-PM-16-004). The awardee for the Pilot Phase solicitation will be expected to work closely with Biobank awardee in implementation of Task 6 listed below.

Task Overview

Task 1. Create and optimize a prototype PMI Cohort Program Direct Volunteers informational website:

Task 2. Create a prototype PMI Cohort Program Direct Volunteers participant interface for consent and collection of basic enrollment information.

Task 3. Create a prototype PMI Cohort Program Direct Volunteers participant interface for collection of select modules of participant provided health information and return of aggregate data to participants.

Task 4. Design and implement pilot experiments to optimize the tools developed under Task 1 to 3.

- Prioritize questions to be answered in collaboration with NIH PMI Cohort Program staff
- Develop and conduct user-centered experiments to answer questions
- Use experimental results to iteratively refine prototypes

Task 5. Provide the services necessary to identify and enroll a diverse cadre of volunteers for pilot testing, including a toll free number and help desk to support volunteers during pilot testing.

Task 6. In collaboration with the Biobank awardee, test the impact of specimen collection (blood, urine or saliva) on participant engagement, and the optimum methods to obtain specimens.

Task 7. Create a secure data management environment to implement tasks listed above, to acquire, analyze and safeguard all user-submitted data, make it available for analysis, and ensure smooth transition of data and IT infrastructure to awardees funded for the full implementation phase.

Explanation of Tasks

Task 1. Informational website

The task set related to creating and optimizing a prototype PMI Cohort Program Direct Volunteers informational website has the following components:

a. Develop web content to educate about PMI and convey value of enrolling as a volunteer.
b. Develop user scenarios.
c. Develop web templates/stylesheets for overall look and feel for desktops and mobile web (smartphones and tablets).

The scenario of an individual considering participation in the PMI Cohort Program begins with their having been engaged by something they have seen, heard or read to connect via their web browser or mobile device to the PMI Cohort Program Pilot Phase website.

The site educational content needs to be able to quickly and entertainingly answer the following questions:

1. What is precision medicine? What is the Precision Medicine Initiative® (PMI)? What is the Precision Medicine Initiative® Cohort Program?
2. What is the program's Pilot Phase?
3. Why would I want to volunteer for the larger PMI Cohort Program (i.e., what are the benefits to me, my family, society and my country as a whole?) Why would I want to volunteer for the Pilot Phase?
4. What is expected of me if I do volunteer, and how long does my participation last?
5. What kinds of data will be collected from me and about me?
6. Is my personal information safe?
7. Can I quit later if I do not want to continue, and if so, how?
8. I have a special concern or question. How can I get it answered?
9. What do I do to join?

Content should accommodate desktop and mobile web clients, and be displayed wherever feasible as a very short synopsis with a "learn more" option to minimize the information users must get through

before moving to signing on (many will have already decided to sign up before ever accessing the site). Content is to be developed by the awardee in English and Spanish.

Task 2: Enrollment website

The awardee will design and optimize an enrollment interface. It is anticipated, that after completion of steps defined in the informational website described above, some individuals will decide that they do indeed wish to participate. The next step would be asking potential volunteers to provide contact information in the form of an e-mail address and/or cell phone number with SMS text capability. It is envisioned that the enrollment process will include some basic form of identity proofing, such as sending a one-time authentication code hyperlink, via a valid e-mail, or SMS text message to a cell phone number, to be entered by the user. Once verified, users will be presented with options for the types of information they would like to receive from the PMI Cohort Program, how they wish to be contacted and whether and how often they would be interested in participating in the experiments designed to answer Pilot Phase questions, as outlined above.

The enrollment interface will need to lead potential enrollees through a series of questions to verify eligibility, using enrollment criteria proposed in the PMI Working Group report. Also to be incorporated into the enrollment module will be all needed steps to provide appropriate informed consent. The requirements for informed consent will be developed in cooperation with the PMI Cohort Program staff.

Task 3: Participant provided information

This task focuses on the participant interface for collection of select modules of participant provided health information and for return of aggregate data to participants.

The PMI Cohort Program will include an ongoing focus on how to best present and acquire data on self-report measures that will increase in number and scope over time, as well as to return that self-report data in aggregate form back to volunteers (e.g., to show them how their responses compare to others already submitted). It is anticipated that questions will largely be derived from other large cohort and survey projects such as the UK Biobank, the Veterans Administration Million Veteran Program, and the National Health Interview Survey. For the start of pilot testing an initial set of questions that have the highest value in characterizing launch cohort participants will be developed by the awardee in consultation with the Steering Committee. The Awardee will be asked to optimize the interface for acquiring this core set of information. Questions should be grouped to provide the optimum number to be answered during a single session; principles and methods for doing this comprise an important social and behavioral science activity of the PMI Cohort Program Pilot Phase.

Further information collection will continue to be modular and driven by pilot testing on the impact on participant engagement. Domains of interest include health behaviors, a health condition survey, and medication use.

It is expected that all data acquired from the test users will be archived and carried forward into the full implementation phase.

Task 4. Design and implement pilot experiments to optimize the tools developed under Task 1 to 3.

The task of designing and implementing pilot experiments to optimize the tools developed under Task 1 to 3 has the following components:

- Prioritize questions to be answered in collaboration with NIH PMI Cohort Program staff
- Develop and conduct user-centered experiments to answer questions
- Use experimental results to iteratively refine prototypes

The applicant is invited to propose a prioritized set of questions for achieving the goals indicated above, and a quantitative approach to develop and conduct user-centered experiments to answer them. Potential questions include:

- What do different groups /different communities want to hear/learn about PMI Cohort Program?
- What educational content and delivery enhance willingness to proceed to initial sign up? In this context, what are the effects of:
    a. Health status
    b. Language (English vs. Spanish, monolingual vs. bilingual)
    c. Age
    d. Sex/gender
    e. Race
    f. Ethnicity
    g. Socioeconomic status
    h. Technology use preferences: desktop; smartphone; tablet; no Internet
    i. Willingness to provide biosamples: donation of saliva vs. blood as biosample(s)
- What is the rate for major demographics for each transition on the progression of visitor, to interested in knowing more, to volunteer, to volunteer providing self-report data, to volunteer providing biospecimens, to fully enrolled participant that will stay engaged with the cohort?
- How do different ways of presenting information and requests effect retention/attrition?
- What are the key variables that predict retention/attrition at each step?
- What are effective methods to increase successful transitions at each step noted above?
- What is the optimal time spacing between activities (average, minimum, maximum) to maintain engagement?
- What prompting schedules and prompting content increase the likelihood of positive and negative responses?
- How often and in what ways do Direct Volunteers choose to engage with PMI Cohort Program: seeking education, information; providing differing types of self-reporting data; etc.?
- What value does availability of aggregate data have for participants?
- How does the form and timing of availability of information affect subsequent engagement
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Task 5. Provide the services necessary to identify and enroll a diverse cadre of volunteers for pilot testing, including a toll free number and help desk to support volunteers during pilot testing.

The pilot study will require a dedicated and customer focused support team to provide sign-on, live chat and other basic end-user support tools to ensure a seamless end user experience. Support staff will be required to assist users who dial in via the toll free number requiring enrollment or IT assistance and will require staff to maintain a current knowledge and understanding of the content within the pilot phase website.

It is expected that the awardee will provide support staff seven days per week from 8AM to 8PM across all continental time zones. It is expected that English and Spanish-speaking staff will be available at all times. Use of an incident management tracking system is required.

Task 6. In collaboration with the Biobank awardee, test the impact of specimen collection (blood or saliva) on participant engagement, and the optimum methods to obtain specimens by mail.

Pilot studies to aid in establishing the most effective strategies for mail-in biospecimen collection are an important aspect of the pilot phase. We anticipate these studies will be performed after the award in summer of 2016 of the cooperative agreement for the Biobank (RFA-PM-16-004), and will require close

partnership between the Biobank awardee and the awardee for this solicitation. Questions of interest include the following:

- What is the rate of return of mailed tubes for saliva or blood specimen collection?
- How often are the samples adequate?
- Blood samples are generally preferred. Should both be requested at one time or will higher rates of return be achieved if a blood specimen is requested first and saliva sample only presented an option for those participants unable to provide a blood specimen?
- What is the impact of specimen collection on participant engagement?
- Does this differ for major demographic groups?
- If urine specimens are requested in addition, does this impact on the return rate?

Task Set 7: Data Management

The tasks related to creating a secure data management environment include:

- Define hardware and software environments;
- Create and implement a systems security plan. Optimized data security is a high priority;
- Create data models and common data elements for the initial PMI scientific data to be acquired during pilot testing;
- Design and implement secure web services for tasks listed above;
- Develop and implement query and analysis tools; and
- Archive data for carrying forward to PMI Cohort Program full implementation phase.

The PMI Cohort Program Direct Volunteers pilot phase requires a flexible, robust, secure data management and communications capability. This will include both a technical infrastructure and staffing to support design and implementation of a data management system and associated methods to assure data quality and completeness. The data management system is expected to form the foundation of the fully operational data infrastructure for future phases of the project.

The Data Management component will develop the technical specifications for the initial centralized "core" data set and associated database architecture that will be the foundation of future enhancements. NIH intends to acquire and represent PMI Cohort Program data in formats and with coded values that promote meta-analysis and interoperability with existing national and international research data resources. Appropriate expertise will inform the selection and/or adaptation of common data models (CDMs) and common data elements (CDEs) for the PMI Cohort Program data capabilities that use, wherever feasible, existing CDMs and CDEs. Where new data standards are needed, the awardee will collaborate with national and international standards organizations to extend and enhance existing resources.

Simple query and analysis tools (e.g., descriptive statistics, cross-tabulations) are envisioned for the pilot phase, as a first step toward a digital enclave that enables researchers as authorized users to access both PMI Cohort Program data and a wide variety of analytical tools in a secure environment. Dynamic management 'dashboards' that present a real time view of the current state of participant enrollment and engagement, and usage of PMI Cohort Program informational and scientific data resources will be needed. A specific set of reporting capabilities will also be required.

7a. Technical Infrastructure

The basic mode of client-server interaction for the PMI Cohort Program pilot phase needs to anticipate synchronous availability of content via a Section 508-compliant web server interface that has both

standard browser and a mobile device-optimized version of the same or similar content, in English and Spanish. The project will involve participant surveys, the form and content of which will be dynamically developed as a collaboration among PMI Cohort Program staff, the participants themselves, and awardee staff. For this reason, the data infrastructure proposed should include, wherever feasible, authoring systems and software tools that do not require computer programming expertise and a modular architecture that favors customization of the user interface to different target audiences. Open source software tools and methods are preferred but not required for the PMI Cohort Program Direct Volunteers pilot phase.

The database design should include methods to assign a Research Unique Identifier (RUI) to each user registering with the system that will become the referential integrity key for the server's data tables relating to each participant. The server receiving participant self-report data will need to maintain state for each session, including progress through the questions, so that dropped and interrupted sessions can be restarted wherever progress stopped. Session timeout logic will be needed that prompts users to re-login after an appropriate period of inactivity.

7b. Surge Capability

For the proposed launch of the direct participant enrollment pilot phase it may be anticipated that there will be substantial PMI Cohort Program-related press coverage. Although the volume is unknown, there is the possibility of an intense early spike of interest and enrollment activity. The server and telecommunications infrastructure should be prudently sized to anticipate transaction rates (HTTP page GET equivalents) in the thousands per second, and an aggregate number of interested potential participants in the first month of up to 1.0 million. Applicants are invited to propose alternative models of expected site traffic and numbers of individuals needed for pilot experiments based on their organizational experience.

7c. Data Volume

The initial Pilot Phase data is unlikely to exceed 1 MB per participant, for purposes of estimating total initial data store capacity. The initial data to be acquired will be structured (name-value pair) alphanumeric data amenable to standard relational table data modeling and a SQL-based RDBMS environment that employs multi-level role based access control, particularly because many health related observations will have repeated measures whose maximum number of repeats cannot be specified a priori. However other database alternatives may also be proposed that accommodate the characteristics of the data. Streaming sensor data is anticipated in the future, along with other linked data types such as genome sequence and molecular variant data; these unstructured and semi-structured data will be voluminous and require elastic computing capabilities for their analysis, but are not anticipated in the pilot phase of the project. Similarly, acquisition of cell phone sensor data (activity, geolocation) will not be a component of the pilot phase but should be anticipated in the design of the data infrastructure. In the permanent phase of the project, high throughput laboratory data such as genomic data will be stored in a LIMS (Laboratory Information Management System) external to the main PMI Cohort Program server and use the participant RUID as the primary foreign key; the data model should accommodate this form of external data linkage.

7d. Data Security Requirements

In view of the high profile nature of the project and the personal data acquired, the server configuration will need to anticipate intense random and coordinated cyberattacks, including denial of service attacks, port scanning, malicious uploads, and fraudulent login attempts. The proposal should include a detailed

Systems Security Plan that addresses physical, technical and policy elements of maintaining overall security; applicants may wish to consult the NIST Security and Privacy Controls for Federal Information Systems and Organizations at http://csrc.nist.gov/publications/drafts/800-53-rev4/sp800-53-rev4-ipd.pdf for details. NIH anticipates that the research data acquired from the PMI Cohort Program project will be subject to Federal Information System Management Act (FISMA) "Moderate" security requirements (or their functional equivalents) as outlined at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table3.aspx. A FEDRAMP (Federal Risk and Authorization Management Program) compliant cloud-architecture, with protections equivalent to FISMA Moderate, is envisioned as an appropriate environment for data acquisition, storage and analysis but offerors may propose other data management approaches that provide equivalent or better security functionality.

Among the data security requirements that should be addressed are data encrypted at rest and in transit, and a server environment instrumented to detect intrusion attempts and misuse/alteration of access privileges. Safeguards will need to be in place for personally identifying data including names, email and home addresses, phone numbers, and similarly sensitive data. All server communications that request data from users should employ secure HTTP at an acceptable encryption level, with a server side digital certificate, but not require client certificates. Access control for privileged users should employ two-factor or better authentication.

The proposal for data and communications infrastructure should also include a business continuity plan to transition the responsibility for maintenance of computing and communications infrastructure if the awardee is a different organization than the Coordinating Center (or sub thereof) which undertakes long term responsibility for the national PMI cohort.
The proposal should provide a staffing plan that includes systems support, data architecture and database design services, database creation and update, backup and disaster recovery, as well as applications programming expertise for implementing the system design and user interface functionality envisioned for the project. Data management staff who have prior experience with and understanding of the semantics of the classes of research data to be acquired, particularly health-related observations, will add strength to the application.

All interface functionality, design, and navigation will need to be tested and iterated using usability testing procedures selected by the awardee. The system architecture should allow for configurability for specific groups of users, rapid future improvements and recurring A-B testing of various features and functions to optimize the site and mobile functionality. The development and deployment sequence of pilot phase information services and data capture is expected to be determined by an ongoing dialogue among awardee and the Steering Committee.

NIH Priorities

During the pilot phase the NIH wishes to ensure the development and evaluation of innovative methods for intensive involvement by participants in the evolution of PMI Cohort Program participant-facing resources, study design and execution. A rapid iterative design-build-test cycle will be needed for this activity, since it will break new ground with respect to research participant involvement in a highly scientifically complex research program.

Overall Timeline and Milestones

The accelerated design-build-test-deploy sequence envisioned for the components of the PMI Cohort Program Direct Volunteers Pilot phase suggests that components may have to be developed concurrently that normally would be sequential. Thus, applicants are at liberty to construct a set of milestones and timelines that they believe are fitted to their capabilities and workflow, and have a high likelihood of being able to deliver an operational "information and expression of interest" website as early as practicable in 2016. The shortest reasonable timeline achievable should be submitted; PMI Cohort Program will not launch a system with known significant flaws simply to meet a deadline. Timelines should include a phase of program review of the database design chosen, data dictionary, and overall data security plan; NIH will accomplish these reviews as quickly as practicable in order to avoid unnecessary delays.