

NCI Moonshot Initiative: Research to Develop Evidence-Based Approaches to Patient Engagement

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on behalf of the Moonshot Network for Direct Patient Engagement Implementation Team

Recommendation A: Establish a Network for Direct Patient Engagement

Key Components

- Direct patient engagement
- Tumor sequencing
- Engage patients to contribute their comprehensive tumor profile data to inform and advance precision medicine
- Patients are eager to provide data
- Data sharing
- Pre-registration of patients to network
- Need to reach minority and underserved populations

Critical Need for Researchers to Engage Directly with Patients

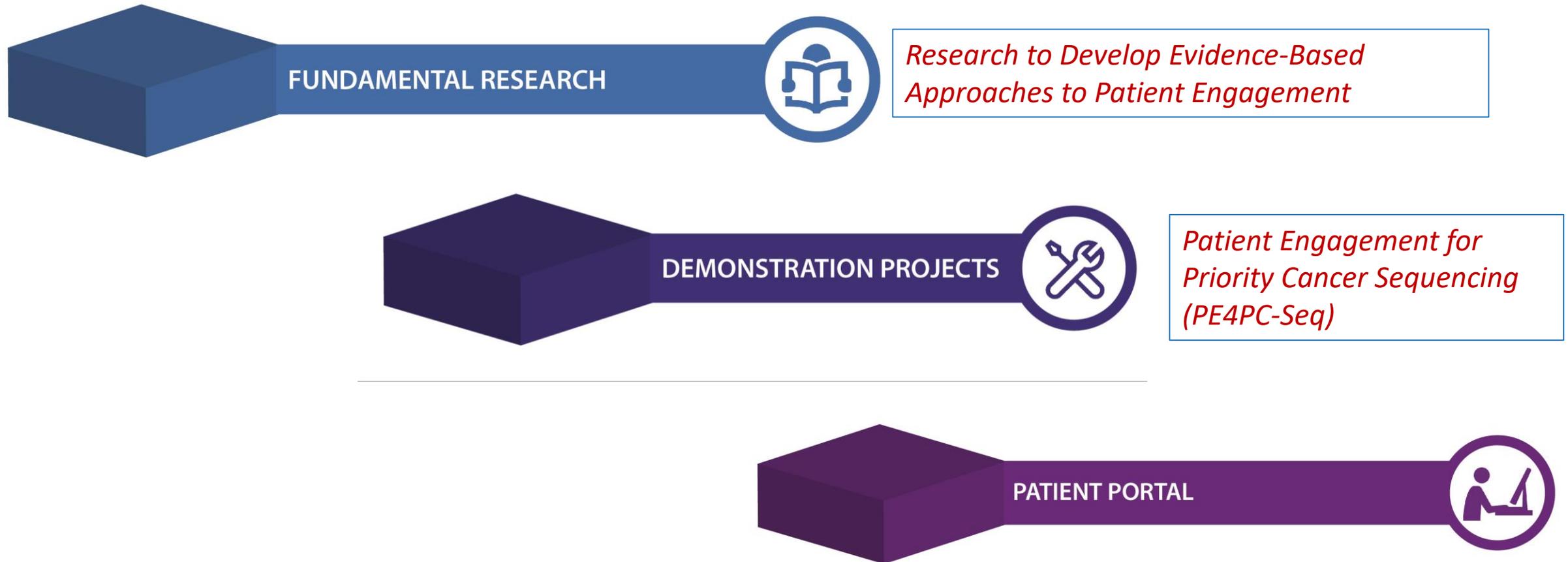


Patient engagement is an ongoing, bi-directional and mutually beneficial interaction between patients and researchers, where patients are included as an integral part of the research process and by extension, across the research continuum from basic research to pragmatic trials (*Fergusson et al 2018*).

Overview:

Direct Patient Engagement for Discovery Science Research Program

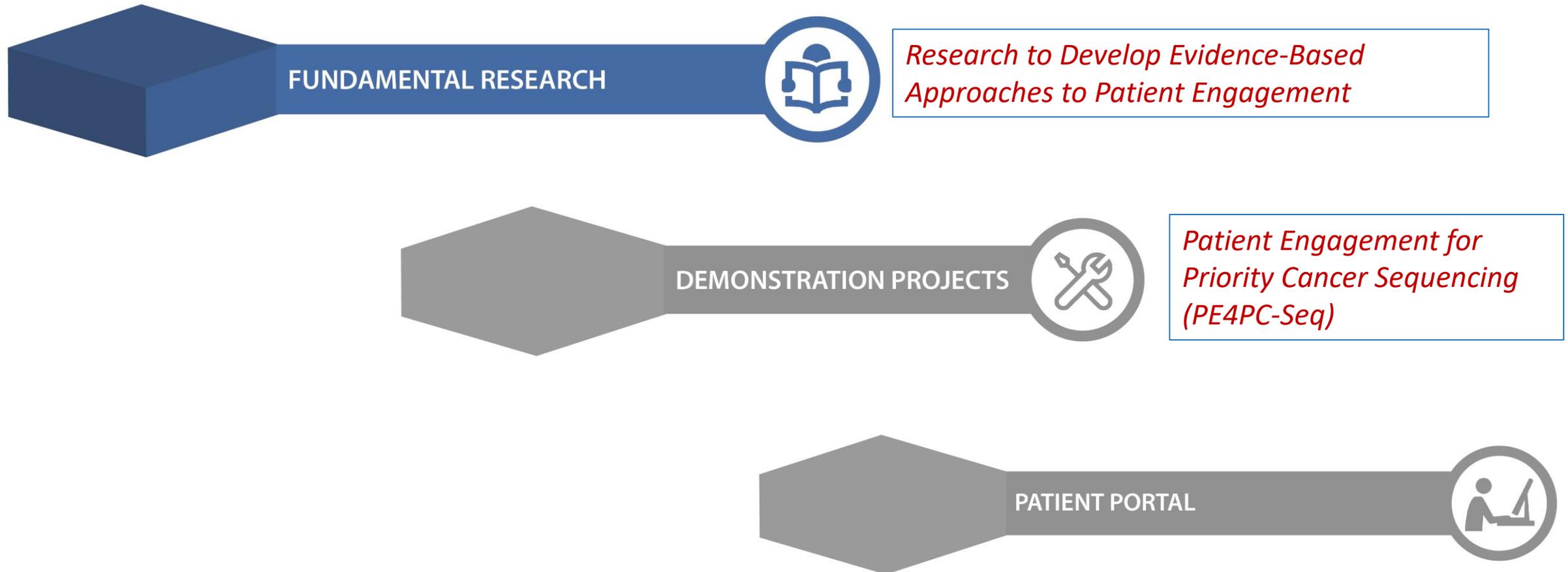
June 2018 BSA Presentations



Overview:

Direct Patient Engagement for Discovery Science Research Program

June 2018 BSA Presentations



Purpose of *Research to Develop Evidence-Based Approaches to Patient Engagement*

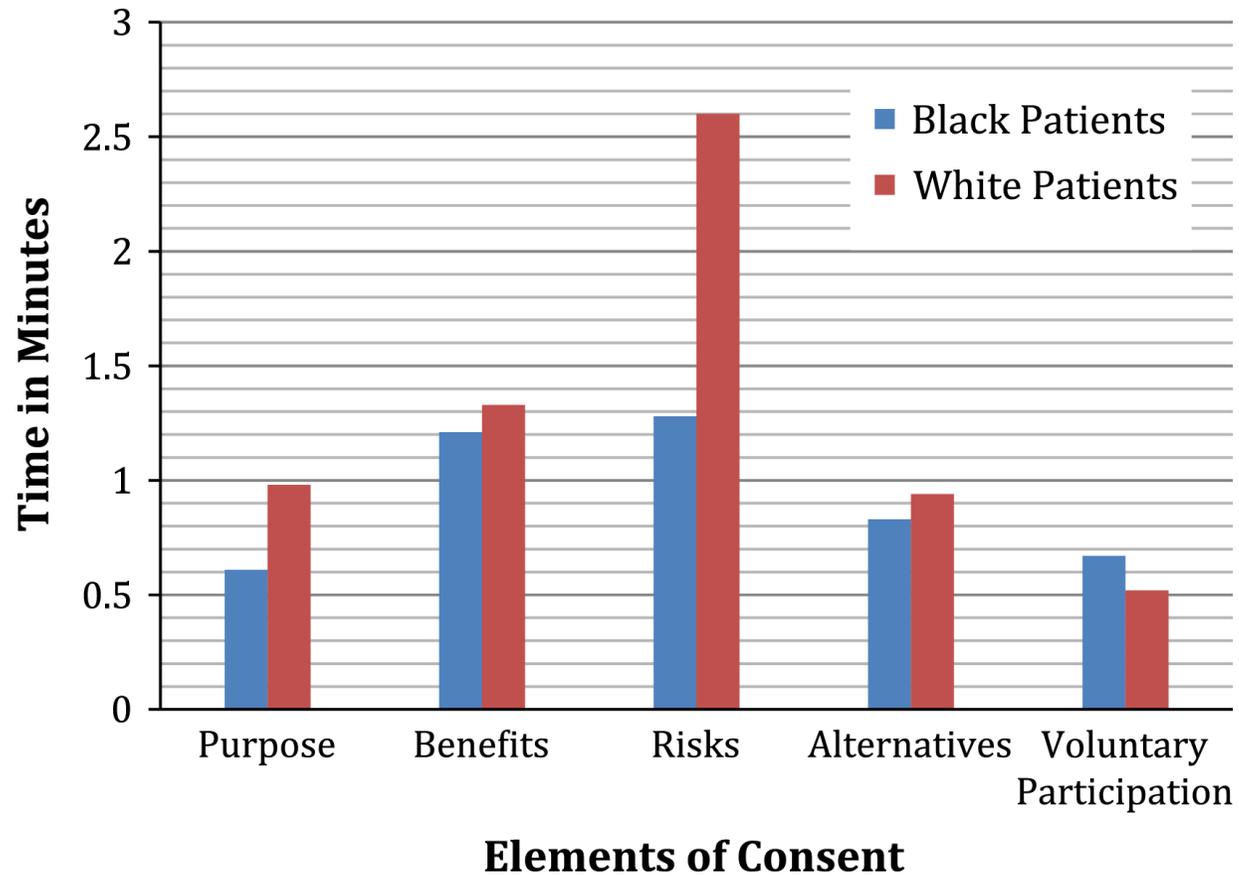
- Build scientific knowledge
- About using direct patient engagement to improve patient experiences related to participation in cancer research studies and foster study participant recruitment and retention
- For biobanking and natural history of diseases, epidemiology, cancer prevention and treatment, and survivorship studies and trials
- That could be broadly applied in future cancer research studies
- And with a priority on participation in cancer research studies by minority and underserved populations

Engaging patients as participants in research studies is influenced by complex barriers and facilitators

- Cognitive: Awareness, health literacy, educational, and language barriers
- Opportunity: Being offered an opportunity to participate in the research, protocol characteristics, transportation to research site, patient cost to participate
- Sociodemographic: age, gender, race and ethnicity
- Motivational: trust in the research enterprise, return of value from participation
- Ecological: Family, community, health care provider and system

A disparity of words: racial differences in oncologist–patient communication about clinical trials

Susan Eggly PhD,* Ellen Barton PhD,‡ Andrew Winckles PhD,§ Louis A. Penner PhD† and Terrance L. Albrecht PhD†



Hypothetical randomized intervention trial to address racial disparity in oncologist-patient communication about clinical trials

Intervention Arm

- **Patient**
 - Provided with a question prompt list
 - Asked to read a brochure about patients and physicians having equal, important roles and the need to work together for best care of patient
- **Physician**
 - Training on unconscious racial bias and communication skills

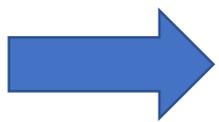


Outcomes

- **Primary**
 - Improved rates of patients' decisions to enroll in a clinical trial
- **Secondary**
 - Physicians' perceptions about their ability to communicate with diverse patients
 - Patients' understanding of the trial being offered
 - Patients' completion of enrollment process

Gaps and challenges in research on patient engagement in cancer research studies

- Some engagement research studies have methodologic limitations
- Insufficient progress in addressing disparities in participation in research studies
- Patient perspectives not fully incorporated and not part of metrics of success of patient engagement approaches
- New technological and innovative approaches for engagement not well studied
- Interventions that we know work do not get broadly applied and implemented



Patient engagement research could lead to improved patient participation in cancer research studies

Objectives of research supported by this funding opportunity

- Fill knowledge gaps
 - To better understand how patient, family, community and provider factors jointly influence patient engagement in cancer research studies
- Develop and test efficacy of interventions to improve patient engagement in cancer research studies, especially among populations under-represented in cancer research studies
- Explore strategies to overcome barriers to adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions
- Applicants may address more than one of these goals

Key characteristics of responsive applications

- Should focus on engagement approaches, patient-centered outcomes (required) and, if appropriate, enrollment and retention in cancer research studies
- Should address the joint influence of multiple factors on engagement and multilevel contributors to engagement
- Interventions could involve patients, health care providers, and health care practices
- Types of cancer research studies could include biobanking and natural history of diseases, epidemiology, cancer prevention and treatment, and survivorship studies and trials
- Must include strong component on minorities and underserved populations
- Must demonstrate access to multiple ongoing studies for which the patient engagement approach could be integrated and tested.
- Must allow 10% set-aside in budget for cross-awardee collaborative and pilot studies

Examples of potential scientific research questions

- What motivates patients to participate in cancer research studies and why?
- What are patients' preferences regarding methods of being engaged in cancer research? How can we ensure the ways of engaging patients are consistently aligned with their values and goals?
- What motivates patients to provide serial biospecimens over time in studies when return of individual results is not feasible?
- Are there unique patient engagement strategies needed for cancer sequencing projects when return of individual results is not feasible?
- What approaches will optimally engage minority and underserved patient populations and reduce cancer health disparities?
- What is the best model for collaborations among cancer researchers, clinicians, caregivers and patients in ensuring patients remain engaged throughout the research process?

Portfolio analysis

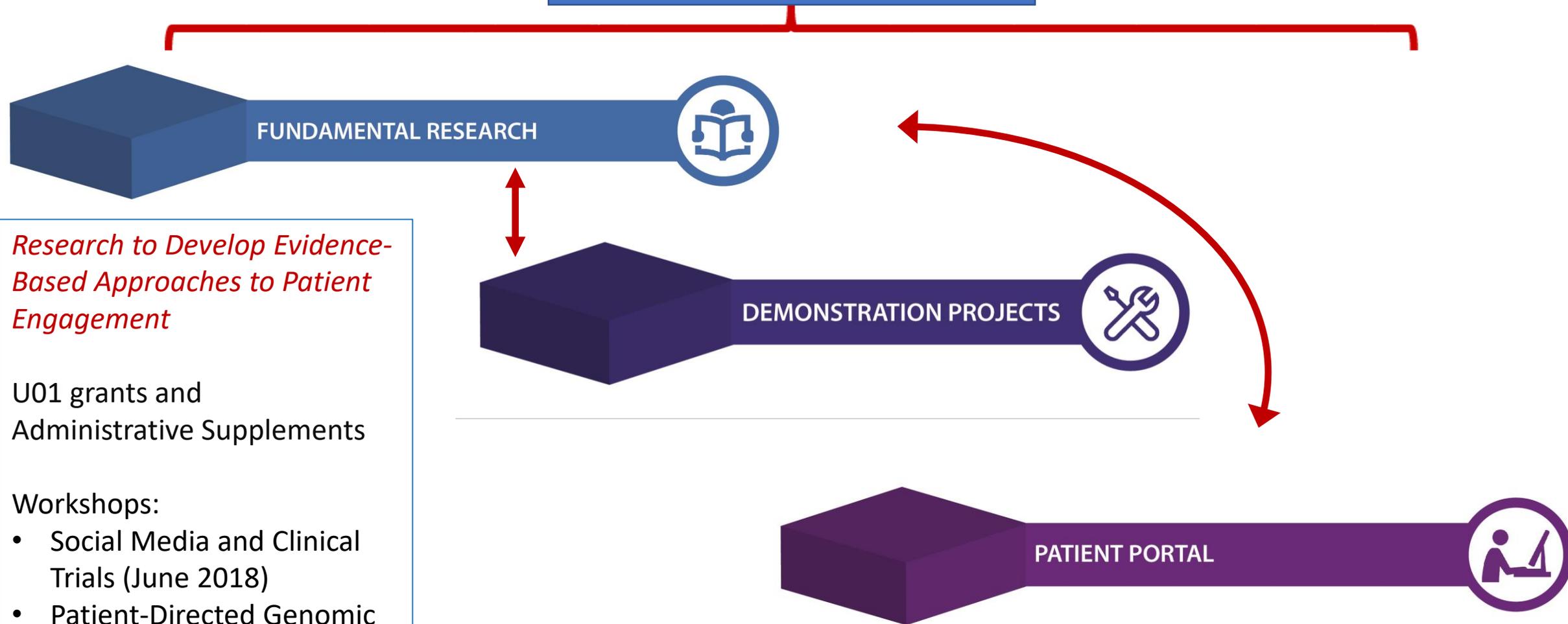
- 24 grants use patient engagement strategies in the context of health care decision-making or health outcomes
- Of the 24, only one project (PI: Eggly R01CA200718: *A multilevel intervention to increase the participation of African Americans in prostate cancer clinical trials*) addresses patient engagement related to participation in cancer research studies
- NCI support for activities to address issues in specific studies (e.g., Community outreach, educational programs)
 - Not intended as generalizable scientific findings
- Portfolio analysis has identified many investigators who could apply to FOA

Budget by Fiscal Year and Mechanism (in \$1000s)

Mechanism	# Awards	FY19	FY20	FY21	FY22	FY23	Total
RFA for U01 (Cooperative Agreement) Grants	5	\$2500	\$2500	\$2500	\$2500	\$2500	\$12,500

Integration: Direct Patient Engagement for Discovery Science Research Program

NDPE Coordinating Center



Research to Develop Evidence-Based Approaches to Patient Engagement

U01 grants and
Administrative Supplements

Workshops:

- Social Media and Clinical Trials (June 2018)
- Patient-Directed Genomic Data Sharing (2019)

Criteria for evaluation success of the RFA: Strong evidence...

- Of barriers and facilitators that influence patient engagement in research studies that can provide fundamental insights into the behavior and motivations of patients, providers, and health care organizations and inform future interventions
- About the basis for disparities in participation in research across population subgroups and potential patient engagement interventions to reduce them
- For the efficacy of interventions to improve engagement of patients in cancer research studies that
 - Enable patients to be more able, empowered, and motivated to participate in cancer research and more confident in making decisions about their participation in the research
 - Are ready for broad implementation
- For potential for interventions to be effectively implemented widely and sustainably

Extras

Direct Patient Engagement for Discovery Science Research Program Coordination



- Coordinating Center will serve all three Patient Engagement Projects
- Coordinate activities across the three projects (as well as relevant Moonshot and Network for Direct Patient Engagement initiatives) to maximize synergy of efforts
- Serve as a clearing house for Patient Engagement best practices
- Plan and host conferences and webinars for investigator teams and patients
- Coordinate External Scientific Panel (which includes patients)
- Develop plans for sustainability of the Network for Direct Patient Engagement

BRP Recommendation A: Network for Direct Patient Engagement: Verbatim Text

- Enlist direct patient engagement through a federated network where patients will be offered comprehensive tumor profiling.
- Many patients are eager to provide their data, and gathering this information in a linked network of databases would enable more precise knowledge about what works, in whom, and in which types of cancer.
- Providing their data would also “preregister” patients for clinical trials, enabling them or their physician to be contacted if their tumor’s molecular characteristics made them eligible for new clinical trials.
- By enabling patients to enroll directly, the network would reach a broader and more diverse patient population; efforts to reach minority and underserved populations will be a high priority.