

All
of **Us**

Research
Priorities
Workshop
Report

July 2018

All of Us would like to thank the members of the [Trans-NIH Liaisons Coordinating Team](#), who played a critical role in the success of the Research Priorities Workshop.

Executive Summary

By enrolling one million or more volunteers, the National Institutes of Health (NIH) *All of Us* Research Program will have the scale and scope to enable research for a wide range of diseases, both common and rare, as well as increase our understanding of human health. To ensure that the cohort is collecting the right kind of information needed to enable this research, *All of Us* is using a process of requirements gathering to collect input from key stakeholders on the future design and content of the Program to meet the needs of participants, researchers, and the broader community. Using the crowdsourcing platform IdeaScale, the research community and the public submitted ideas for “use cases,” which described research questions that the Program could address and the data that would be needed to address those questions. Over 350 individuals across all sectors, from *All of Us* research participants to academic and industry researchers, participated in a workshop on March 21-23, 2018, in Bethesda, Maryland, to create additional research questions, refine data elements common across many use cases generated from these questions, and identify priorities for future versions of the *All of Us* protocol. In total, over 1100 use cases capturing nearly 3,500 unique data types were developed through IdeaScale and the workshop. After the workshop, the data were cleaned, standardized, compiled into a [searchable PDF](#), and made available to the public. The next steps will be to analyze the data for trends and gaps; combine this with other stakeholder input about requirements for the protocol; and develop and implement a process for making decisions about short, medium, and long-term protocol changes. The Research Priorities Workshop was just the first of many opportunities that the *All of Us* will use to gain input from its diverse stakeholders; *All of Us* plans to collect additional input throughout the lifespan of the Program.

About the *All of Us* Research Program and Workshop Planning

The [All of Us Research Program](#), led by the NIH, is an historic effort to gather data from one million or more people from all life stages living in the U.S. to accelerate research and improve health. Researchers will have access to these data to study differences in lifestyle, environment, and biology, to uncover paths toward delivering prevention strategies, treatment, and care tailored to each individual – known as precision medicine.

All of Us has many innovative aspects that makes it unique. It's one million or more participants will reflect the rich diversity of the United States, including volunteers of many races and ethnicities, age groups, geographic regions, sex, gender identities, sexual orientations, and health statuses. Diverse participants will fill gaps in our scientific knowledge and ensure no group is left behind in prevention strategies and treatments. The Program will combine surveys, information from electronic health records (EHRs), assays performed on blood and urine samples, physical measurements, and eventually wearable device data and other digital health technologies. Because *All of Us* is committed to open access, these data will be broadly accessible to researchers of all kinds, including citizen scientists, to support thousands of studies across a wide range of different health topics. Participants will have access to study information and data about themselves. Most importantly, *All of Us* participants will be true partners—not subjects—with ongoing opportunities to help shape the Program. The goal is to build a public resource that grows in capacity and value over time.

The timing is right for the scientific opportunities enabled by this unique cohort. Thanks to advances in technology, a human genome can be sequenced for under \$1,000 in less than one day. More than 90 percent of people living in the U.S. own a smartphone, compared to the less than 2 percent who owned one in 2004. More than 90 percent of health care providers now keep patient records electronically, in the form of EHRs, and they are being made available for research purposes. But most importantly, people are increasingly interested in their own health and taking part in research studies and want to be active partners in that research.

As a result of these factors, *All of Us* has the potential to help answer critical research questions that could improve the health and wellbeing of millions of Americans. For example, can better pain medicines be developed that aren't addictive by better understanding medication effectiveness across broad segments of the population? Can we identify subtypes of type 2 diabetes that could lead to better prevention strategies and treatments? How can we slow or even stop the development of different kinds of dementia based on what *All of Us* discovers about its early signs?

This is just a sampling of the questions *All of Us* could help address. *All of Us* plans to engage its stakeholders on a regular basis to gather input on the kinds of research questions that could be answered using this cohort and the type of data that should be collected to answer these questions. This information will help expand upon the initial [All of Us protocol](#), which will continue to evolve and improve as new tools, technologies, and scientific opportunities emerge, over many decades, creating a longitudinal glimpse of human health over the lifespan. To guide this process, *All of Us* is developing a protocol roadmap that lays out a plan for how we will update versions of the protocol.

Part of this plan for stakeholder engagement includes engaging scientific leaders across NIH to ensure that the research priorities for each of the [NIH's Institutes, Centers, and Offices](#) are incorporated into the Program. *All of Us* collaborated with this [trans-NIH team](#) to plan the Program's inaugural effort to collect feedback from the broad research community and the public. The result was a groundbreaking workshop held on March 21 – 23, 2018, that brought together a variety of key stakeholders to “think big” and help set research priorities for the *All of Us* Research Program for the next 10 years.

To accomplish this, workshop attendees were asked to partake in a requirements-gathering process; a concept used frequently in the information technology industry, which focuses on the needs of a diverse set of users when building a product, service, or system. In this case, *All of Us* asked attendees to work together, using their collective expertise, to identify important data elements (requirements) that could be potentially incorporated into future versions of the protocol. Specifically, the goal of the workshop was to identify research questions (and the requirements to address them) in three timeframes:

1. *Near Term (0-2 yrs)*

What are the questions for which the scale of *All of Us* could help accelerate knowledge and breakthroughs in precision medicine with no or minor adjustments to the protocol?

2. *Mid-Term (2-5 yrs)*

What questions might this Program answer with more significant, but currently achievable, changes to the protocol?

3. *Long Term (5-10 yrs)*

What questions are ripe for a program of this size, but require fundamental science and technology to develop the instruments and methods to collect the data?

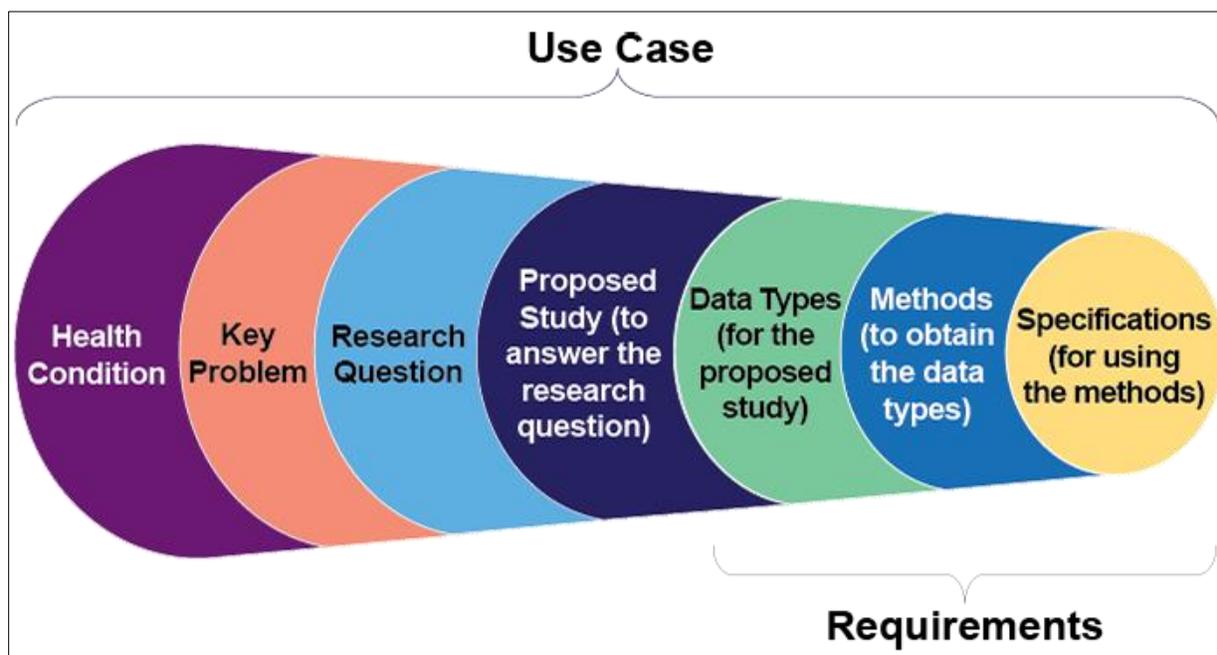
Gathering Input

To collect input to inform the future design and content of the Program, *All of Us* used a tool called a “**use case**,” a hypothetical study designed to answer an important research question. Use cases included a succinct sentence describing the key problem and research question proposed. A use case also contains the following information, or requirements, which collectively we refer to as potential protocol elements (PPE):

- The types of data (**datatype**) needed to answer the research question
- The **methods** to obtain the data types and to analyze the data
- The **specifications** for using the methods

Together, these three PPE requirements could be incorporated into future versions of the protocol. For example, measuring participants’ sleep patterns (datatype) using a smartwatch or activity tracker (method) on a daily basis (specification). Figure 1 outlines the components of a use case.

Figure 1.



These use cases were collected in two parts: (1) through the crowdsourcing platform IdeaScale prior to the March 2018 Research Priorities Workshop; and (2) over the course of the three-day Workshop.

Crowdsourcing

To ensure the Program meets the needs of participants, researchers, and the broader community, *All of Us* set out to build an information gathering process that would be accessible to as many people as possible. Using the crowdsourcing platform IdeaScale, *All of Us* launched a public [request for use cases](#) several months prior to the March 2018 workshop to gather input that would help guide and inform the discussion at the workshop and the requirements gathering process.

The public response was significant. Over 800 use cases were submitted in IdeaScale by researchers, advocacy groups, associations, citizen scientists, and the public on a broad range of topic areas, such as cancer, dementia and aging, mental health, environmental factors, child and maternal health, and cardiovascular disease.

Although IdeaScale is currently closed to new submissions, *All of Us* plans to periodically reopen it (or a similar information gathering platform) to continue to gather ideas throughout the life of the Program.

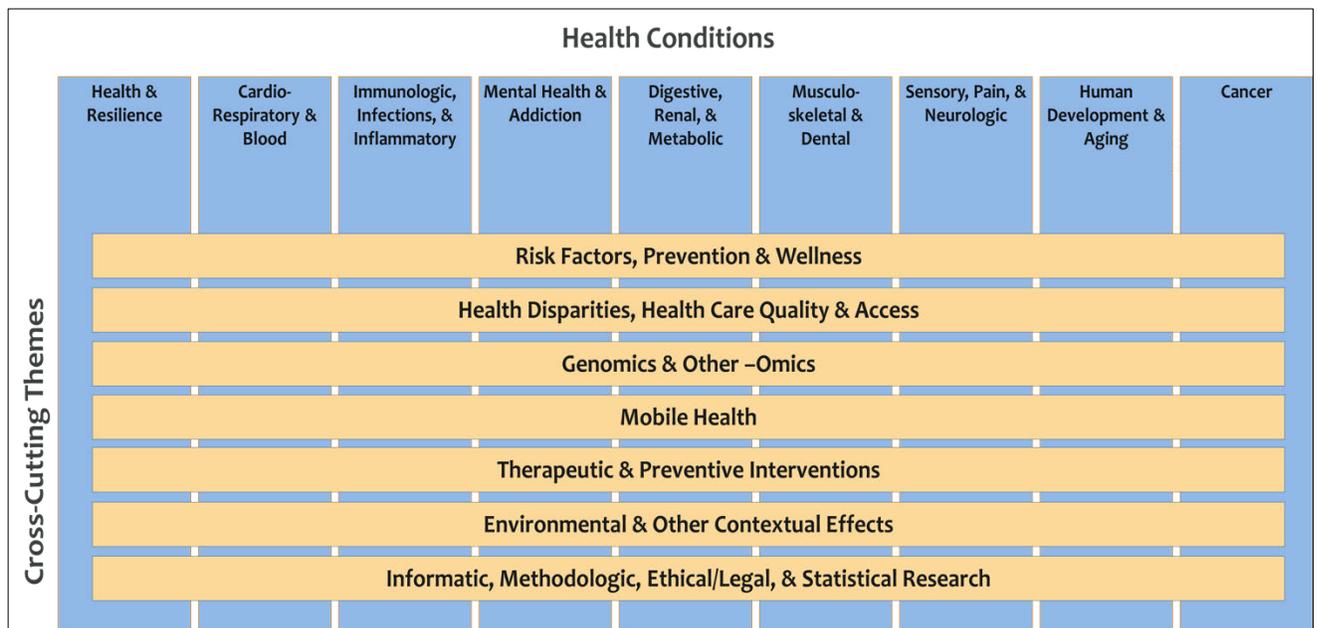
Research Priorities Workshop

The March 2018 *All of Us* Research Priorities Workshop was held in Bethesda, Maryland, with over 350 attendees. Stakeholders included *All of Us* research participants; academic researchers; disease advocacy organizations; professional associations; industry researchers; technology companies; NIH leadership; and other government agencies. A detailed summary of the workshop's plenary sessions can be found [here](#).

Attendees were asked to bring their own ideas, build on ideas developed during the workshop, and work collaboratively with other attendees to generate ideas across disciplines. Attendees also had access to the previously submitted use cases. A critical component of this workshop was to enable stakeholders, who wouldn't otherwise have the opportunity to collaborate, to brainstorm outside-of-the-box ideas in a way that capitalizes on their collective expertise. The goal of the requirements gathering process was to generate hundreds of new use cases and PPEs that would cover a wide range of scientific areas, diseases, and conditions with specific details about the data needed to make breakthroughs in our understanding of health. Attendees were also asked to identify use cases they deemed "most important" to advancing precision medicine, as well as identify "game changing" PPEs that could have a significant impact on advancing precision medicine. These exercises were done in separate processes across the breakout sessions and at different points in the workshop.

To help categorize and organize use cases to identify common data types needed to address research questions that cover multiple health conditions, *All of Us* worked with the trans-NIH group described above to develop a framework to guide the discussions (see Figure 2 below). The framework was organized into nine Health Conditions (vertical bars) and seven Cross-cutting Themes (horizontal bars). Over the course of the workshop, attendees gathered in breakout groups assigned by health condition or cross cutting theme to develop use cases and PPEs in those areas.

Figure 2.



Working together in teams, workshop attendees developed over 500 additional use cases, 87 of which were deemed "most important," and identified 75 game-changing PPEs across the cross-cutting themes. Because the game changing PPEs were identified separately on day three of the workshop, there was very little overlap between the game changing PPEs and use cases.

Analyses

Following the Research Priorities Workshop, *All of Us* staff compiled and cleaned the use cases (i.e., removed duplicates and standardized the terminology) that came out of the workshop and combined them with those submitted through the crowdsourcing effort. They then created a master list of all the use cases in a [searchable PDF](#). In total, 1110 use cases (after removing duplicate use cases) and 3482 unique PPEs were collected.

The number of use cases and PPEs were relatively evenly distributed among the health conditions. Health and Resilience generated the most use cases, with 162; (see Figure 3). Cardio, Respiratory, and Blood generated the greatest number of PPEs, with 840 (see Figure 4).

Figure 3.

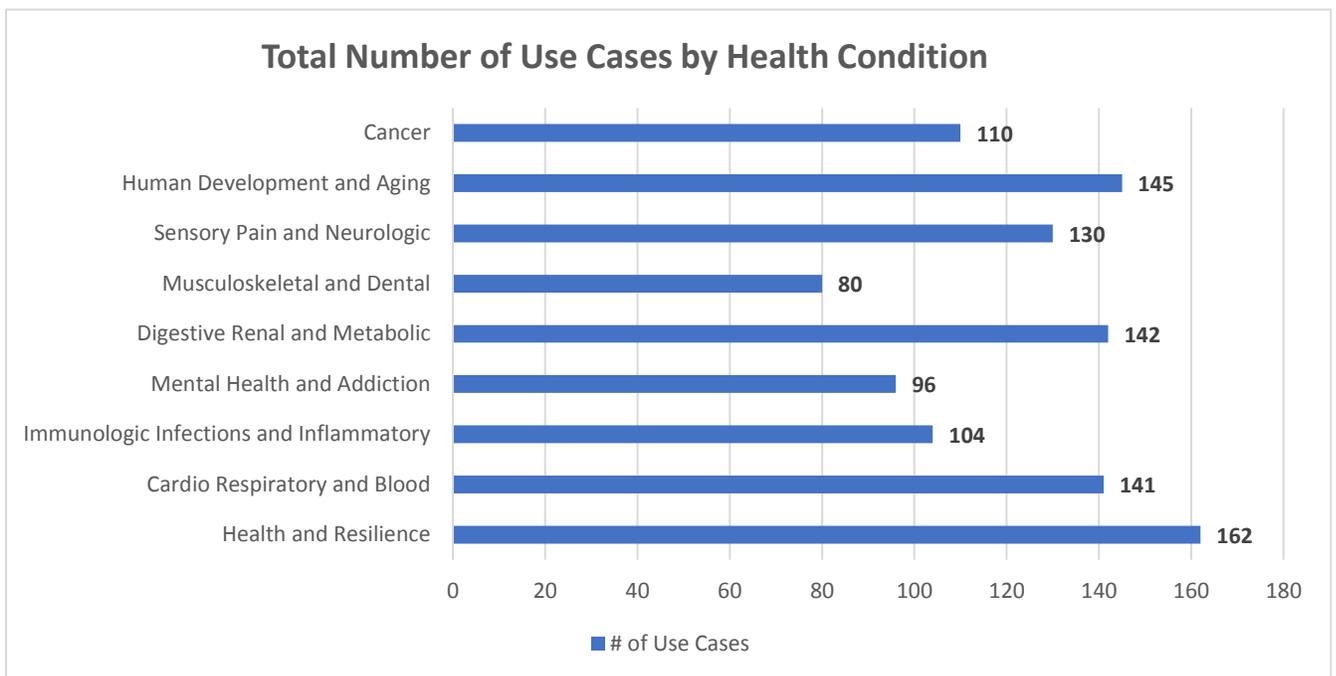
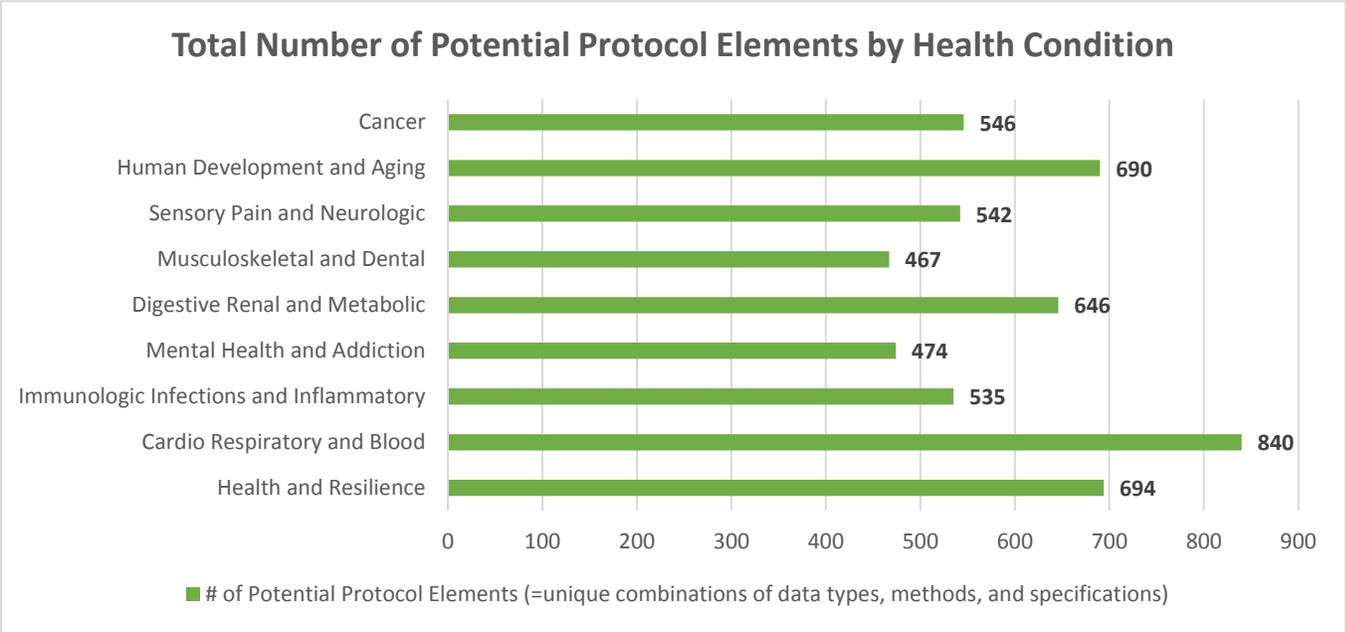


Figure 4.



Among the cross-cutting themes, Risk Factors, Prevention, and Wellness generated the greatest number of use cases and PPEs by a significant margin, with 393 and 2031, respectively (see Figure 5 and Figure 6).

Figure 5.

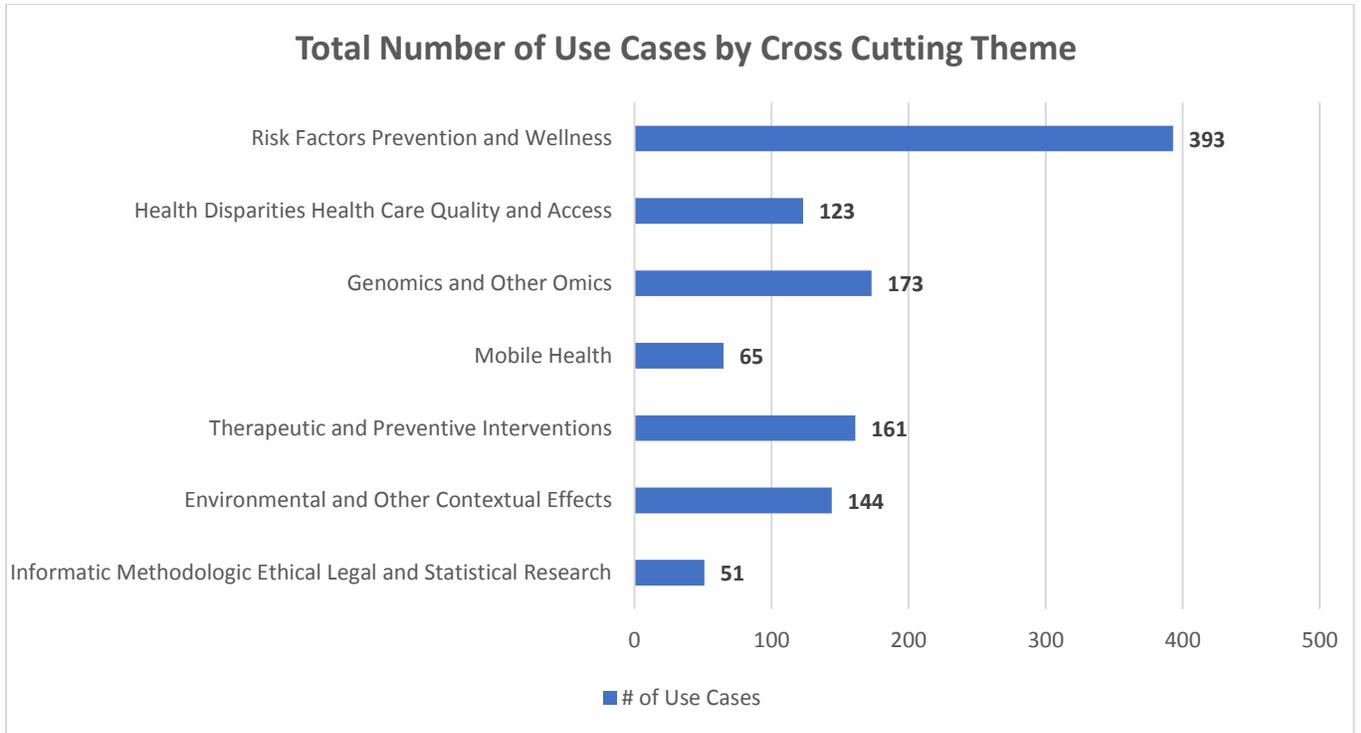
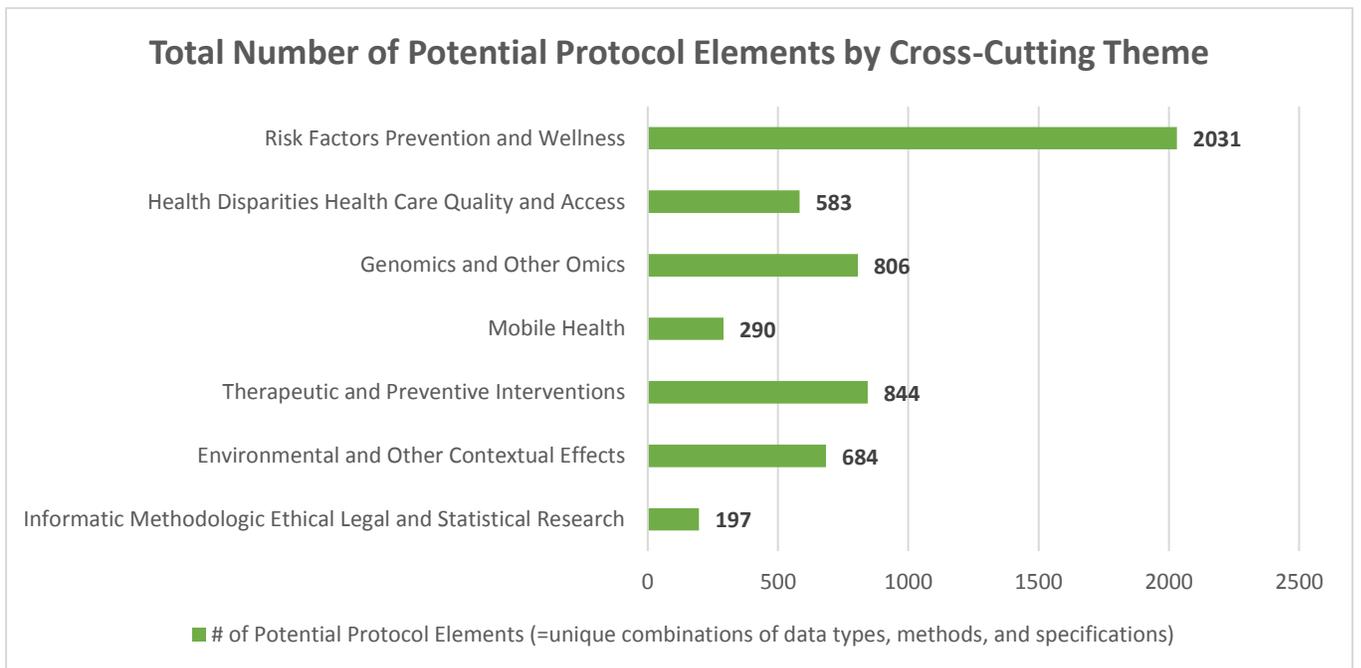


Figure 6.



Next Steps

Over the next several months, *All of Us* will analyze the use case and PPE data to help inform the development of the next major version of the protocol, a process that will be repeated over the life of the Program to ensure that the Program is evolving in line with scientific opportunities and taking advantage of technological advances. *All of Us* will also develop a core protocol roadmap that lays out a plan to (1) continually monitor scientific discoveries, technological advances, needs, and opportunities; (2) elicit input on the Program from *All of Us* participants and key stakeholders throughout the lifespan of the cohort; (3) develop and implement a process for making short, medium, and long-term core protocol changes; and (4) make decisions around proposed ancillary studies to catalyze research beyond *All of Us*.

Summary

The Research Priorities Workshop was just the first of many opportunities that the *All of Us* Research Program will use to gain input from its diverse stakeholders. Over the next decade, *All of Us* will seek feedback on the content and scope of the Program through many venues to ensure it maximizes its potential to advance precision medicine and improve health.