Introduction

The National Institutes of Health (NIH) All of Us Research Program (All of Us) is an ambitious effort to gather health data from one million or more people living in the United States to accelerate research that may improve health. All of Us is committed to creating a cohort that reflects the diversity of the US, with individuals who have traditionally been underrepresented in biomedical research (UBR). All of Us includes the following populations: UBR racial and ethnicity minority groups; children and seniors; sexual and gender minorities; people living with disabilities; people with barriers in access to care; people who have low income or low educational attainment; and rural residents. A key success metric of the program is to be of value to its constituents: participants, health care providers, and researchers.

Establishing authentic engagement with participants and providing value for them is important to long-term retention and continued recruitment of participants from diverse populations. One opportunity to provide both value and authentic engagement is returning personalized genetic results to participants. In November 2020, the program launched the Genomics Engagement Module (GEM) on the Genomics Platform, to begin returning genetic results to participants. These include genetic ancestry and four non-clinical trait results (bitter taste perception, clairension preference, eye type and lactose intolerance). Here we describe the return of results process as well as participant engagement and feedback.

Methods

Result Generation and Participant Experience

All of Us participants enrolled in opt-in samples for the program through a variety of methods including in-person at Healthcare Provider Organizations and mobile clinics or online. Participants subsequently complete a consent for genomic return of results (gROR), including genetic ancestry and non-clinical trait results. Samples are stored and extracted at the Biobank (Mayo Clinics) and processed utilizing Illumina Global Diversity Array (GDA) at one of three Genome Centers (Baylor College of Medicine, Broad Institute of MIT and Harvard, University of Washington). Data is analyzed and results are generated by the Geromics Platform (Color). Participants are then notified either by email or SMS by the Participant Technology System Center (PTSC, Vibrent Health) that they are eligible to receive results. Participants complete an informing loop, or a series of screens with information on the benefits and risks, about receiving genetic ancestry and trait results. At the end of informing loops participants select ‘yes’, ‘no’, or ‘Maybe later’ to receive results. Participants who selected ‘yes’ are then able to immediately view their genetic ancestry and trait results (Figure 2).

Figure 1. All of Us result generation process.

Figure 2. All of Us genetic ancestry and trait result screenshots.

Survey Analysis

Once a participant has viewed their results, they can complete a brief set of survey questions within the Geromics Platform to share their experience, ask additional questions and provide feedback. These survey questions include Likert scale based questions, yes/no questions, and open ended, free text questions. We analyzed a random subset of 10,000 free-text surveys from January 2022 to October 2022. Participant responses were extracted and coded utilizing Illumina Global Diversity Array (GDA) at one of three Genome Centers (Baylor College of Medicine, Broad Institute of MIT and Harvard, University of Washington). Data is analyzed and results are generated by the Geromics Platform (Color). Participants are then notified either by email or SMS by the Participant Technology System Center (PTSC, Vibrent Health) that they are eligible to receive results. Participants complete an informing loop, or a series of screens with information on the benefits and risks, about receiving genetic ancestry and trait results. At the end of informing loops participants select ‘yes’, ‘no’, or ‘Maybe later’ to receive results. Participants who selected ‘yes’ are then able to immediately view their genetic ancestry and trait results (Figure 2).

Table 1. Free text responses from participants about their genetic ancestry results.

Table 2. Free text responses from participants about their genetic ancestry results.

Figure 3. Demographic information of participants who viewed their genetic ancestry results.

Figure 4. Uptake by participants who determined to be underrepresented in biomedical research (UBR).

Figure 5. Participant understanding of their trait results.

Results

Participants were asked, “What questions do you still have about your [trait] results?” and “Is there any other feedback you want to share?”. Participants had specific questions about certain traits but a common theme across traits was not understanding the specific nucleotide results.

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Conclusions

• Returning ethnic ancestry and trait results to All of Us participants is highly effective at engaging research participants. On average 70% of participants clicked to view results when notified.

• Participants who viewed genetic ancestry results were from all races, ethnicities, and age brackets.

• Participants were satisfied with their genetic results, on average responding 4.3 out of a 5-point satisfaction scale. The majority (90%) of participants responded they were either a little satisfied or very satisfied with their genetic ancestry results.

• Participants on average found their genetic results easy to understand (4.4 out of 5), but some have more questions, including about what they can receive health-related information. Participants will be eligible to receive health-related results beginning in late 2022.