Director’s Program Update for the *All of Us Research Program*

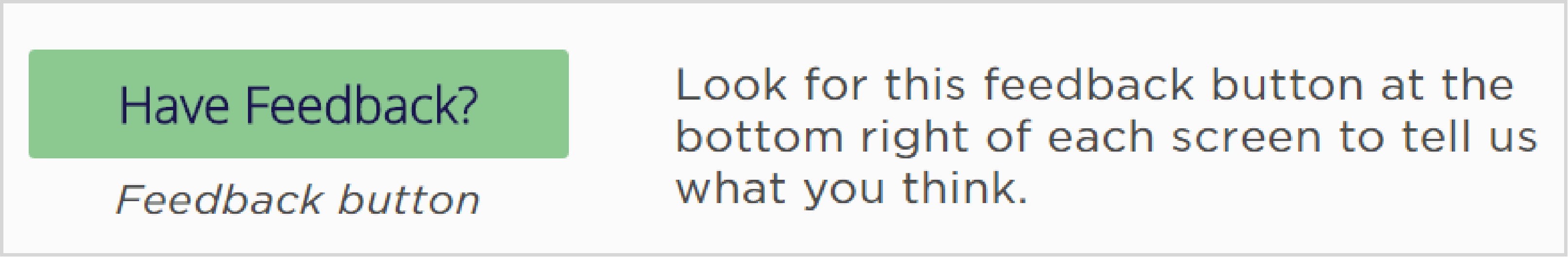
Advisory Panel Meeting
January 19, 2018
9:10 AM – 10:10 AM

National Institutes of Health

Eric Dishman
Entrepreneurial Patient, Advocate, Caregiver
Director, *All of Us* Research Program

Welcome to those in the room and those online

- **Welcome advisory panel members, ACD WG members, and especially any new participants tuning in!**
- **For presenters**
  - Use microphones, especially for discussion
  - Many are not familiar with the program
    - Explain acronyms
    - Quick definitions of key concepts/terms
- **For listeners online**
  - You are in listen only teleconference mode
  - Participants can give anonymous online feedback via your participant portal



Feedback button

Look for this feedback button at the bottom right of each screen to tell us what you think.

Link for NIH videocast is https://videocast.nih.gov/

It doesn’t seem so long ago that we were meeting as the ACD WG…

(But I am 35 pounds heavier and 4 pants sizes bigger—lots of comfort eating and little exercise!)

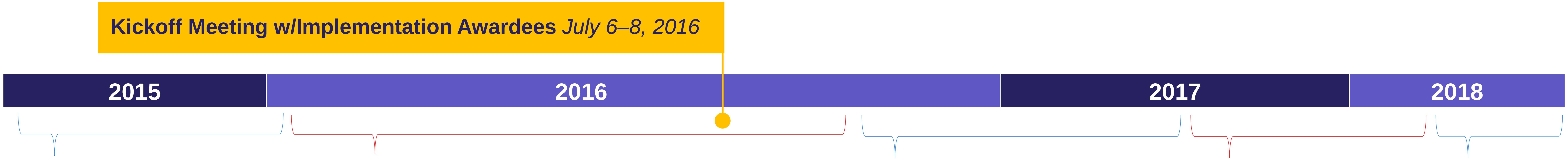
Or meeting for the first time as a consortium…

Consortium now > 1000 people; hard to capture all in one place or photo anymore!

Agenda: Many (New) Audiences Today

9:00 – 9:10 AM	Welcome and roll call – *Eric Dishman and Gwynne Jenkins*
9:10 – 10:15 AM	Program update – *Eric Dishman* Update on genomics plans – *Brad Ozenberger* Update on child enrollment plans – *Holly Garriock*
10:15 AM	*Meeting Closes*

Timeline: Vision to Planning to Development to Beta to Enrollment Launch



Kickoff Meeting w/Implementation Awardees *July 6–8, 2016*

Vision
January–September 2015

- SOTU by President Obama (*Jan. 2015*)
- ACD (Advisory Committee to the (NIH) Director)
    - PMI Working Group formed (*Mar. 2015*)
    - Held 4 workshops to gather input from researchers, public on scientific opportunities, digital health data, participant engagement, and mobile technology (*May-July 2015*)
    - Published 2 RFIs – 221 respondents (*Apr. 2015*)
    - Report/recommendations (*Sept. 2015*)
- Public opinion survey conducted – 2601 responses (*May-June 2015*)

Planning & Prototype Piloting
Fall 2015–Fall 2016

NIH wrote implementation papers, began staffing up

Vanderbilt pilot project: Built prototype infrastructure & group of 5000+ for feedback on enrollment/engagement, consent, surveys, and return of results (*awarded Feb. 2016*)

Sync for Science pilot (*awarded Feb. 2016*)

Communications awardees began research, campaign planning, and content development (*awarded Mar. 2016*)

Director (Eric Dishman) started (*June 2016*)

Consortium partners met for the first time to building program (*July 6-8, 2016*)

Implementation & Development Phase
Fall 2016–Spring 2017

Built network of health care provider organizations (RMCS, FQHCs, VA) and direct volunteer partners to support enrollment & retention

Established Support Center for participants (toll-free number/email, etc.)

Built biobank building/robots & 24-hour shipping process

Protocol developed for Version 1 / approved by IRB

Developed website and participant portal—internet, iOS and Android app

Developed data warehouse with infrastructure to collect, clean, curate, de-identify, and eventually share the data

Developed software for providers/assistants to transmit data from participants' in-person visits

Conducted end-to-end security testing & usability testing

Congress passed H.R.34, 21st Century Cures Act, in Dec with bipartisan support. Provides funding, strengthens data sharing & privacy provisions

Beta Phase for Version 1 Platform & Protocol
Summer 2017–Spring 2018

Launched beta test with the real infrastructure, protocol, & participants

Established partnerships with community, provider, and advocacy organizations and the National Library of Medicine to help educate and engage diverse populations

Made three new health care provider organization awards to expand program's geographic reach

Fitbit pilot effort: to learn more about the use of wearables in sharing health data

Developing genomics plan, with input from the Genomics Working Group

Developing plans for the enrollment of children, with input from the Child Enrollment Scientific Vision Working Group

Collecting use cases for the Research Priorities Workshop, to obtain input from the stakeholder community about important research questions

National Launch
Spring 2018

If ready and right and all things worked well in beta phase

How does *All of Us* compare to other large cohort programs?

Differentiation	Investments We Are Making
• **Breadth:** 1m+ = large sample size	• Large network of Health Provider Organizations (HPOs) & Direct Volunteer (DV) partners • National engagement & communications campaign • Future: “franchise” paradigm for rare disease? Linkages & comparability across other large cohorts?
• **Diversity**: Recruit those who are “UBR” & those who are healthy	• Network of community partners; expansion of FQHC network • DV grand experiment—put research capacity where key communities are • Targeted marketing/analytics infrastructure • Inclusion of children and other special populations
• **Data depth**: Diverse data sets, longitudinally	• Samples, surveys, assays, etc. over lifespan • Rich clinical data: S4S and data aggregators; Specialty EHR, other sources like claims & meds • Rich genetic data: WGS • Rich environmental & behavioral: mobile device partnerships & infra; assays & GIS datasets • Massive data & biobank repositories
• **Participant Focus**: Design to Deployment	• Responsible Return of Information: genetic counseling capabilities; Provider Partners Initiative • Participant Advisory Groups across country & “Super Participant Group” • Citizen science workshops, training; future: credentialing platform for citizen scientists?
• **Accessible**: Expand who gets to do biomedical research	• Data platform open to all interested researchers; citizen science training • Data curation & cleaning • Open & open source tools, developer ecosystem

Update on Expanded Beta Phase

What is expanded beta phase?

- The initial, closed beta phase was very successful, uncovering what is working well and where we need to strengthen our platform, the participant experience, and messaging.
- Based on what we learned, we decided to launch an expanded beta phase starting in November 2017.
- <u>Four main objectives for this expanded beta phase:</u>
  1. **Improve the participant experience.**
  2. **Expand and test our engagement capacity with diverse communities.**
  3. **Enhance infrastructure and tools for staff.**
  4. **Add scientific and data capabilities.**
- <u>Enrollment Goals</u>: ramp to 10-15k participants (ramp daily capacity of 200-300; surge test 600 per day) by the end of expanded beta phase; then launch nationally in spring

The Dish | Expanded Beta Phase

Examples of additional capabilities coming during expanded beta phase

- **Improve the participant experience.**
  - Improved enrollment site (joinallofus.org) – with better design, simpler path, major new content
  - Participants able to self-schedule visit in the Participant Portal based on their affiliation
  - Accessibility improvements (ex. Spanish language, make complex language even simpler)
- **Expand and test our engagement capacity with diverse communities.**
  - Bring on more DV & HPO locations around country (alpha phase, beta phase, scale up)
  - Develop clearer UBR definition & metrics (white paper coming before launch)
  - Onboard more participant voices in governance structure (underway now)
- **Enhance infrastructure and tools for staff.**
  - Mission Control tool to provide local sites with better comms, scheduling, & capacity mgmt tools
  - Expanded digital capabilities drives additional security testing (and an additional ATO process)
- **Add scientific and data capabilities.**
  - Additional PPI survey modules developed and tested (underway)
  - Develop pilot plan for first “BYOD” wearable device (Fitbit announcement)
  - Clinical and omics assays selected; genomics plan publicized (genomics consent in place)
  - Complete working group report on enrolling children (any day now)

These are just a few examples of the capabilities we are building and testing in expanded beta.

So, how is it going so far?

- **Participant Feedback**
  - Straightforward to go through whole protocol
  - Need to know what we're signing up for out of the gate
  - Language & concepts in some areas (consent, what's in my EHR) need further simplification
  - Want my family to be able to sign up, too! / when do you get rid of the special code requirement?

- **HPO & DV network**
  - Launched 70+ clinics around the country
  - Anticipate new HPO partners to begin launching soon
  - Will have some coverage in 25 states by national launch
  - Ramp up DV capacity as we see where people cluster

- **Community partners**
  - All 18 partners have begun awareness & engagement
  - Making progress on bringing onboard additional partners
  - Working with NLM on education and training materials
  - Developed toolkit for community & provider organizations who want to support our program

- **Biobank**
  - As of 1/3/18, storing 10,670 participant's samples or 333,900 frozen vials
  - Current capacity is 600 participant samples/day; plan to ramp to 1,200 later this year with additional technology

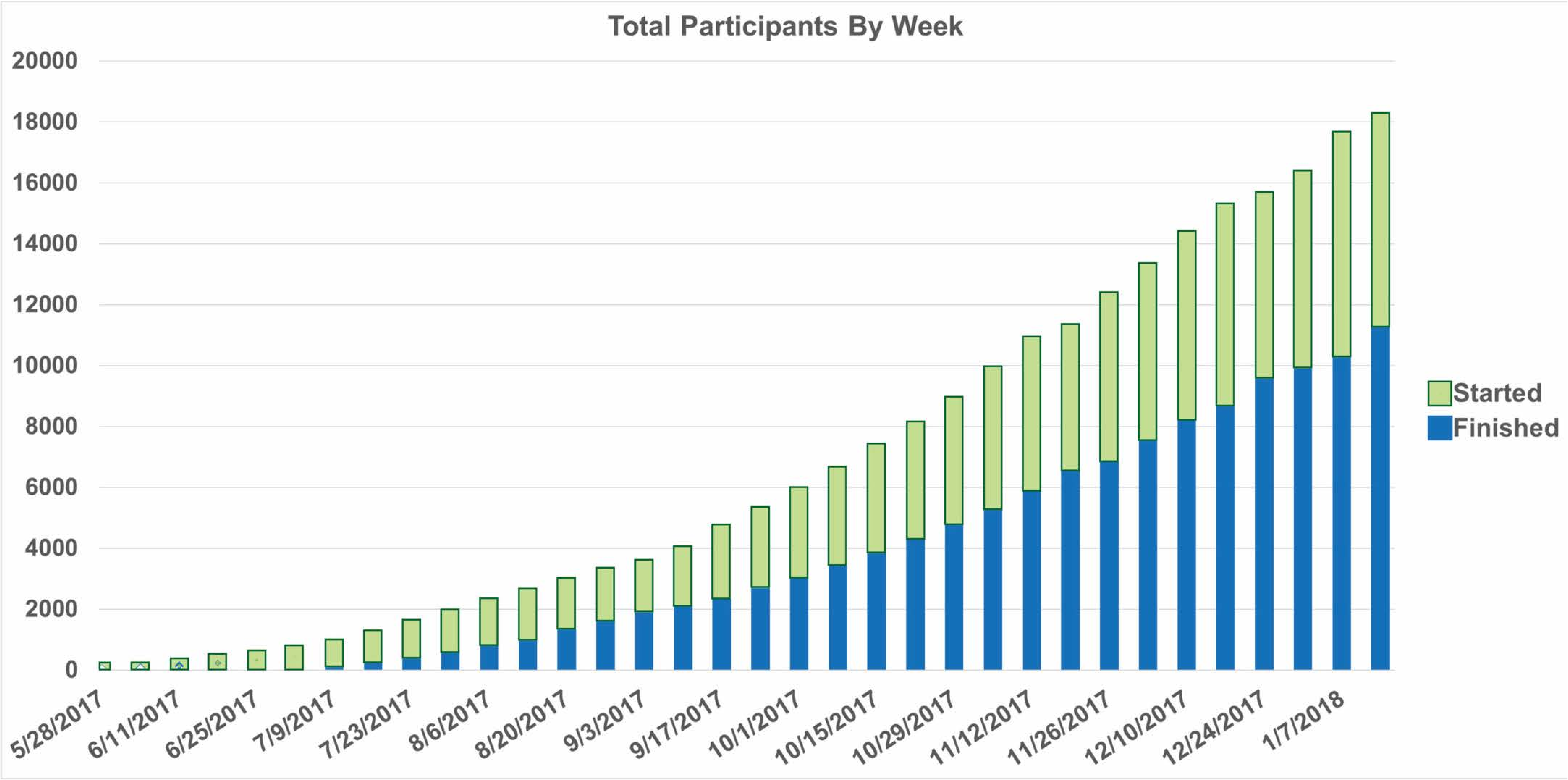
- **DRC**
  - 32 ISAs completed (security agreements for all sites)
  - Started receiving EHR records – cleaning & curation
  - Significant progress with development of researcher portal & workbench (end to end early demo last week!)

- **Participant Portal**
  - Updated dashboard based on participant input
  - Now available in Spanish
  - Working on v2 updates w/ new features (scheduling, etc.)

- **Support Center**
  - Operating bilingual (English/Spanish) call centers at two locations
  - Survived a hurricane – and helped us test & improve preparedness & recovery plans!
  - Current capacity is 625 contacts/day; plan to ramp up to 1,250 contacts/day by national launch

- **Website (joinallofus.org)**
  - Now available in Spanish
  - Working on v2 updates based on participant feedback & user testing (navigator, simpler path through, etc.)
  - 1,000 hits/day; 26,000 visitors/month

Beta phase enrollment status (as of 1/17/18)



We have >18,000 participants at some stage of the process, of whom >11,500 have completed the full protocol. After national launch, we will only report # of participants who have completed all available protocol modules

Other Recent Announcements

- Established partnerships with **14 national community groups and health care provider organizations** as well as the **National Library of Medicine** to help raise awareness about he program
- Developed new **pilot effort with Fitbit** to learn more about collecting wearables data
- Making progress with plans for **Research Priorities Workshop** in March – currently soliciting use cases for requirements gathering!
- Genomics WG released report; development genomics consent & implementation plan now
- Child Enrollment WG released report yesterday; implementation planning now underway

https://allofus.nih.gov/news-events-and-media