All of Us Research Program

21st Century Cures Act 10-Year Draft Plan for Precision Medicine Funding





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Precision Medicine Initiative Working Group of the ACD

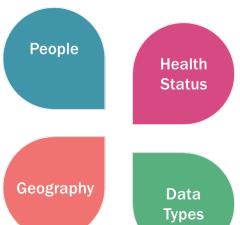
- Formed March 2015; report presented and accepted September 2015
- Provides framework for creating and managing an unprecedented research cohort
- Recommendations include:
 - Two overarching enrollment methods (health care provider orgs and direct volunteers)
 - One million + volunteers of all health statuses and all ages
 - Reflect broad diversity of the United States
 - Longitudinal cohort with continuing interactions & data capture
 - Highly interactive and proactive participant model
 - Rich data: surveys, biospecimens, physical measurements, EHR, omics, mHealth

Overview: All of Us Research Program

- Mission: To accelerate scientific discovery & medical breakthroughs in precision medicine
- How: Deliver a national resource of deep clinical, environmental, lifestyle, & genetic data from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)
- Priority: Reflect the **broad diversity** of the U.S.—all ages, races/ ethnicities, gender, SES, geo, & health status—by over-recruiting those underrepresented in biomedical research
- Priority: Build the tools & capabilities that make it easy for researchers from citizen scientists to premier university labs to make discoveries using the data & biosamples and through ancillary studies w/ the cohort

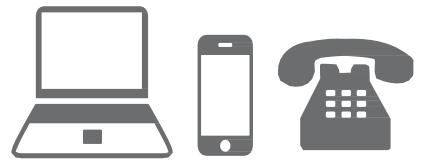








Direct Volunteers



Health Care Provider Organizations







1. Enroll & Consent



2. Surveys, Journals



3. Baseline Measurements



4. Bio-Samples (Blood/Urine)



5. Apps, Phones & Wearables

Current Status of All of Us

- Built robust <u>network</u> of 50+ academic, provider, technology, & community partners
- Have plans/methods to recruit as <u>underrepresented in biomed</u>
 <u>research</u> as a major part of 1M participants
- Pilot test completed on language, concepts, interfaces
- Version 1 <u>protocol submitted to IRB</u> (consent, EHR authorization, 5 initial surveys, blood & urine collection, physical measures)
- Biobank capacity ready for alpha/beta launch, on schedule for national launch (35M+ vials)
- Enrollment website, 1-800#, smartphone apps, and data center developed with early testing & training begun
- Final end-to-end security testing, user testing, workflow testing, & training start in April

DATA AND RESEARCH CENTER (DRC)

Big data capture, cleaning, curation, & sharing in secure environment

Vanderbilt, Verily, Broad Institute

BIOBANK

Repository for processing, storing, & sharing biosamples (35+M vials)

Mayo Clinic

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web & phone-based platforms for participants

Vibrent Health

HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)

Clinical & scientific expertise network, recruitment & retention of participants

20+ regional med centers, FQHCs, VA

PARTICIPANT CENTER

Direct volunteer participant recruitment, digital engagement innovation, & mobile/wearable/consumer health technologies

Scripps Research Institute

COMMUNITY & ENGAGEMENT PARTNERS

Local, regional, national orgs to educate, recruit, & retain participants

Awards under review now

Pending testing results & IRB approval, aiming for Alpha/Beta launch in May & National launch in Oct

Estimated 10 year costs to fully fund program are \$4.3B

- National Participant Engagement/Retention Platform \$1.6B
 - Includes Health Care Provider Organization network
 - Includes Direct Volunteer capacity across country
 - Include Community Engagement Partner network
- National Biobank & Specimen Sharing Platform \$1.3B
 - Includes genotyping and whole genome sequencing pilots
- Big Data Repository, Security, & Sharing Infrastructure \$500M
 - Includes Electronic Health Records and mHealth pilots
- Data Cleaning & Curation Infrastructure \$350M
- Researcher Tools & Ecosystem Development \$350M
- Operations, Communications, & Coordination \$200M

Must wait for cost curves—Whole genome seq & wearables today cost \$1B each for 1M participants

Precision Medicine Funding in 21st Century Cures Act

Section 498E - "The Secretary... to establish and carry out... the 'Precision Medicine Initiative' includ[ing]..

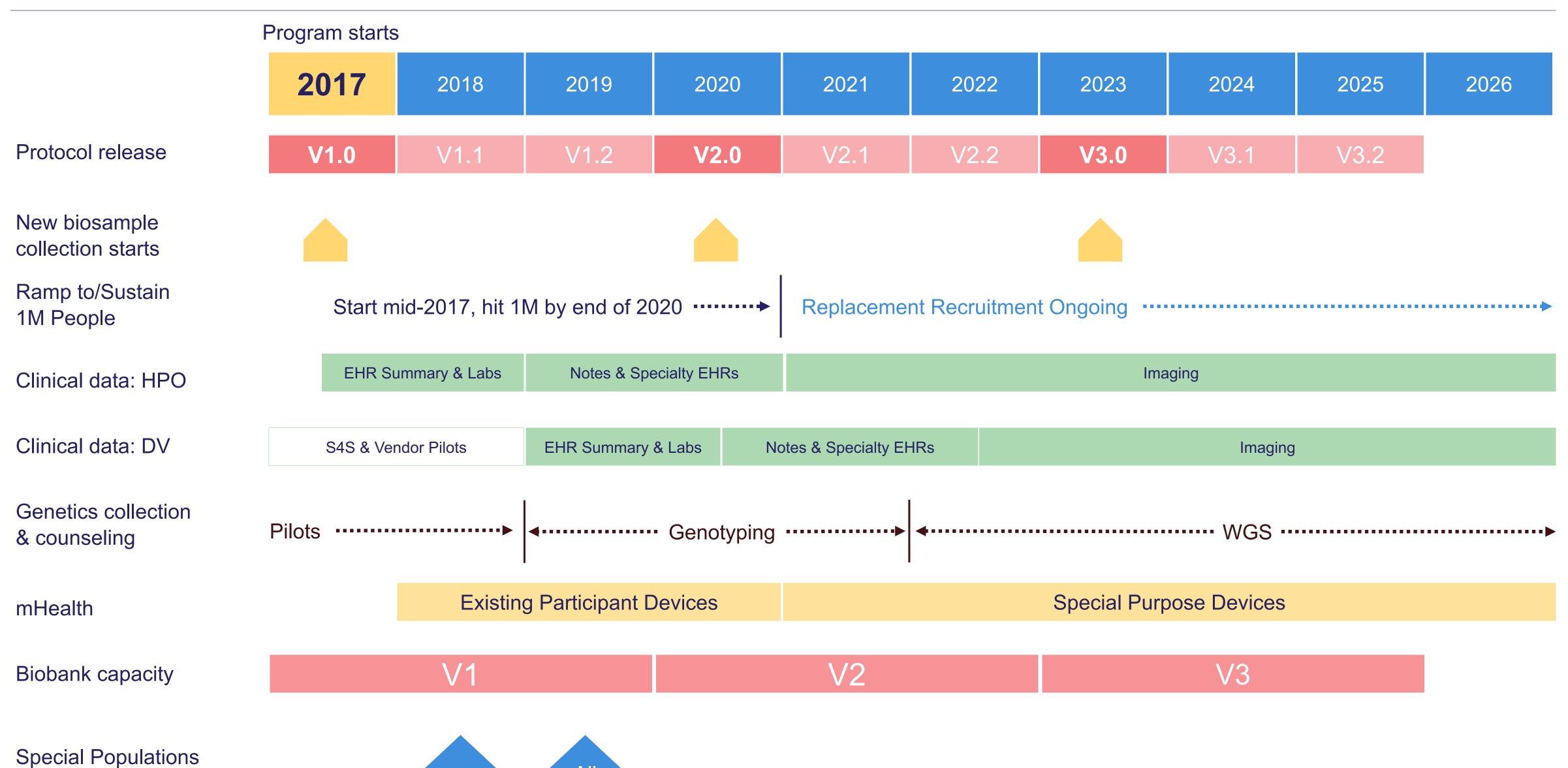
- Developing a network of scientists...
- Developing new approaches for addressing scientific, medical, public health, and regulatory science issues...
- Applying genomic technologies...to provide data on the molecular basis of disease...
- Collecting information voluntarily by a diverse cohort of individuals that can be used to better understand health and disease"

FY	Cures Funding
2017	\$40,000,000.00
2018	\$100,000,000
2019	\$186,000,000.00
2020	\$149,000,000.00
2021	\$109,000,000.00
2022	\$150,000,000.00
2023	\$419,000,000.00
2024	\$235,000,000.00
2025	\$36,000,000.00
2026	\$31,000,000.00

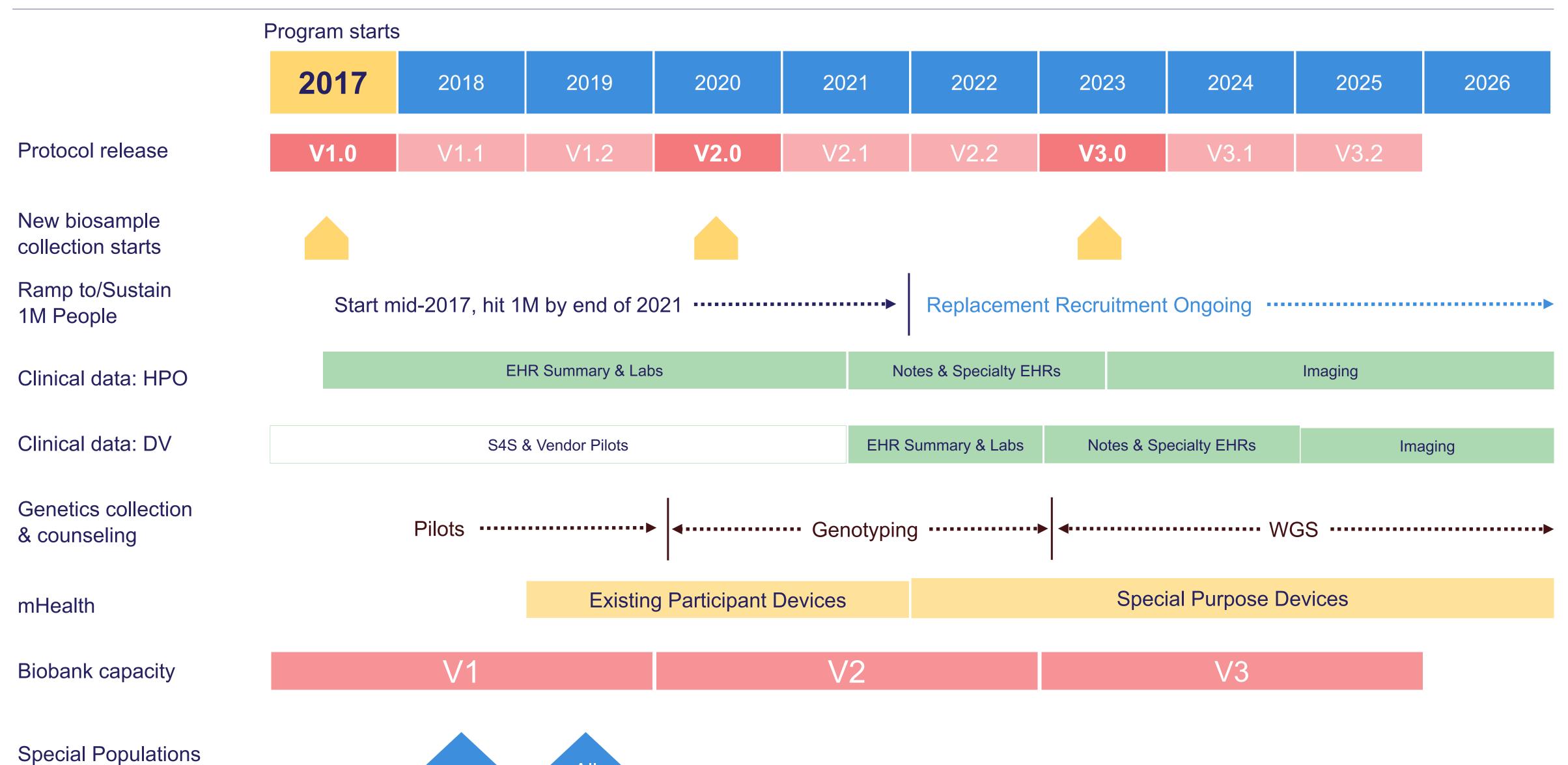
Cures Appropriation Assumptions

- Original proposed base budgets/plans aimed to ramp to \$430M by 2019
- Current uncertainty about our base funding, so assuming base is flat with 2 scenarios:
 - Scenario 1 base funding at FY 2017 requested level of \$230M
 - Scenario 2 base funding at FY 2016 Enacted level of \$130M
- The Cures funds are no-year funds which provide flexibility for when the funds can be obligated. In some fiscal years, we will utilize this flexibility to appropriately manage the program while ensuring the proper stewardship of federal funds.
- Without increase in base, will need to slow the study, change its scope, and/or seek public/private partnerships to fill budget gaps

Timeline for Full Funding



*based on current estimates, not final plans

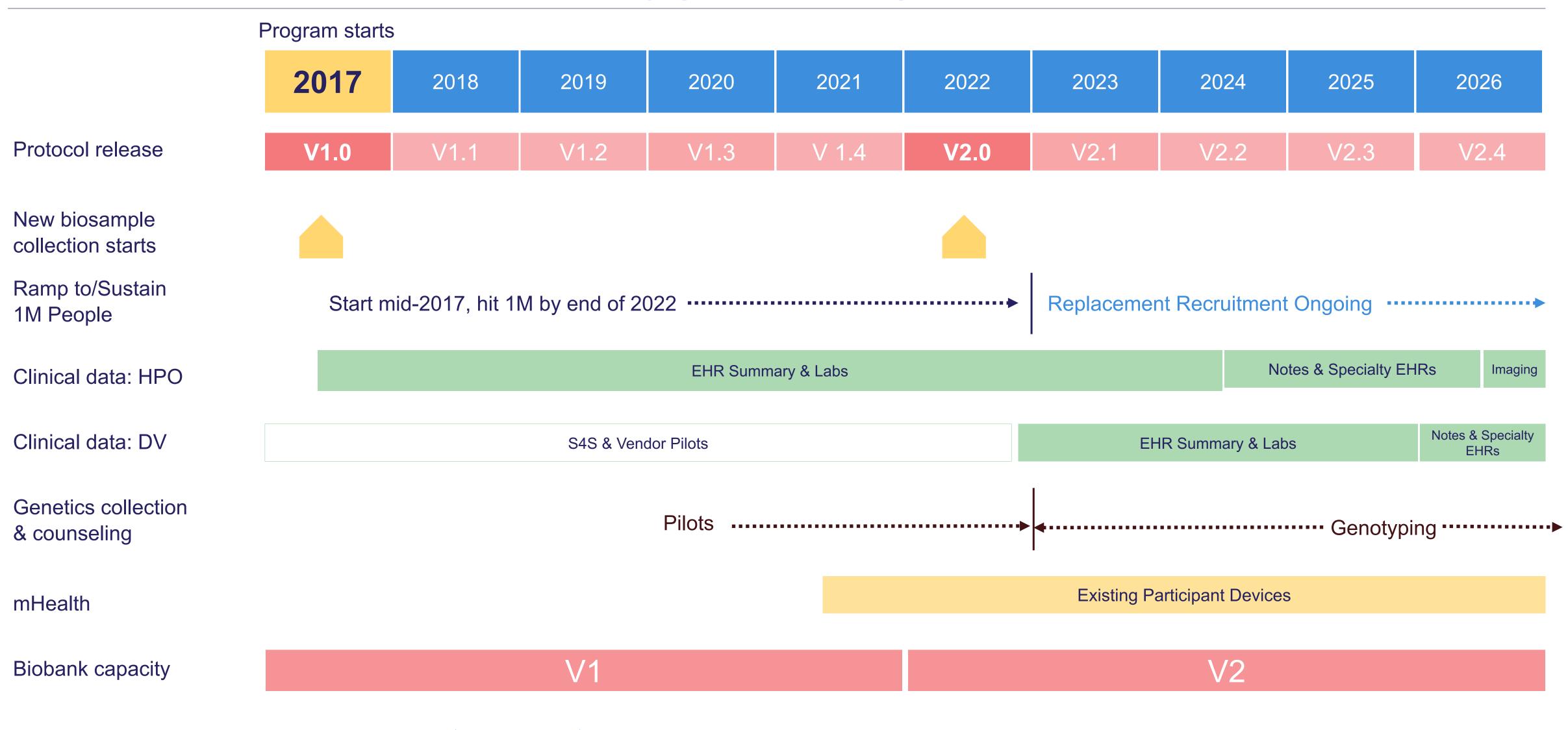


Timeline for \$130M Base Funding (Scenario 2)

Others

Special Populations

*based on current estimates, not final plans



Summary

- Good news: close to launching Version 1 protocol & platforms with participants
- Final 10-year work plans and budgets still in flux
 - Need to learn from alpha, beta, and first year of national launch
 - Congressional budgets still under consideration
 - Still soliciting public/expert input on key items like genomics plan, special populations
- Neither Scenario 1 nor 2 get us to full budget, so forces tradeoff discussions
- Three particular tradeoff dimensions for discussion:
 - Balance of Value to Participants and Value to Researchers
 - Breadth of Participants and Depth of Data Collection
 - Across the Board Cuts versus Stopping One of the Major Pillars of the Program

Back-Up Slides

Main Awardees So Far

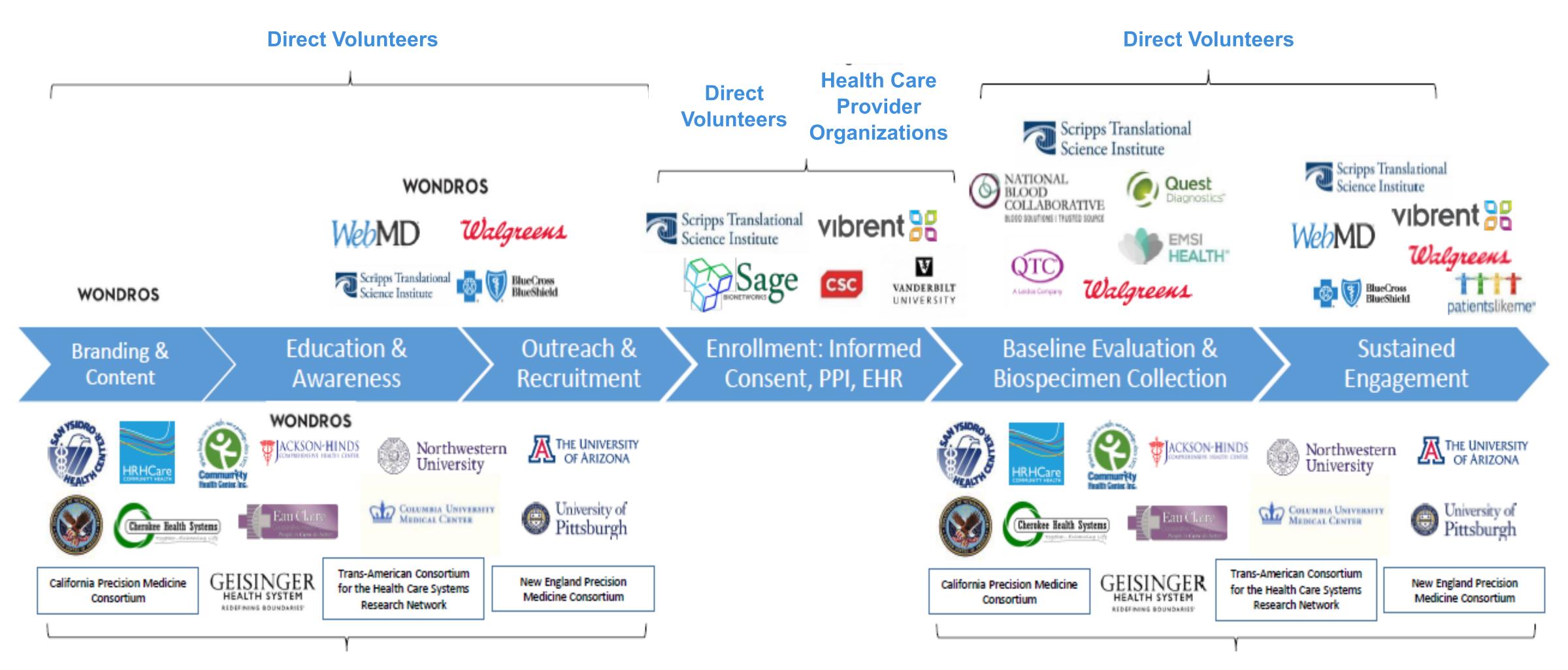
Building Block Partners

RMCs regional med centers

FQHCs



Current Consortium Members & Their Roles



Health Care Provider Organizations

Health Care Provider Organizations

Estimated Cures Obligations and Carryover Per Fiscal Year



Scenario 1: \$230M Base Appropriation

A base of \$230M would cover most of the basic people, specimen, and data platforms although some Cures funding would need to be utilized to support our current HPO network.

Some activities delayed past original planned date (e.g. mHealth data capture would start later than originally planned)

Areas of Focus for Cures Funding

- Genetics Collection and Counseling
- Digital ClinicalData/EHR
- mHealth/ConsumerDevices
- Researcher ToolsDevelopment

Additional Potential Areas for Cures Funding

- Deeper engagement with and enrollment of diverse populations
- Other Omics Sequencing
- Imaging
- Environmental Sensors
- ELSI and Policy Research
- Grants to Researchers

Scenario 1: Cures Funding Obligations by FY

FY	Annual Cures Appropriation	Projected Obligations	Projected Carry-Over
2017	\$40,000,000.00	\$14,000,000.00	\$26,000,000.00
2018	\$100,000,000	\$108,000,000.00	\$18,000,000.00
2019	\$186,000,000.00	\$152,000,000.00	\$52,000,000.00
2020	\$149,000,000.00	\$195,000,000.00	\$0.00
2021	\$109,000,000.00	\$109,000,000.00	\$0.00
2022	\$150,000,000.00	\$135,000,000.00	\$0.00
2023	\$419,000,000.00	\$332,000,000.00	\$72,000,000.00
2024	\$235,000,000.00	\$262,000,000.00	\$0.00
2025	\$36,000,000.00	\$36,000,000.00	\$0.00
2026	\$31,000,000.00	\$31,000,000.00	\$0.00
Total	\$1,455,000,000.00	\$1,455,000,000.00	

Scenario 2: \$130M Base Appropriation

- With a base of \$130M, the Cures funding would need to be utilized to support the basic participant, specimen, and data platforms of the program:
 - Health Care Provider Organization network (No additional large RMCs; get to 1M in 2023)
 - Participant Technology Systems Center and Participant Center
 - Engagement Partner Awards (No growth)
 - Biobank (limited growth in sample collection)
 - Data and Research Center and basic data analytics (e.g. genotyping, some small pilots)

- Basic Evaluation/Protocol Testing
- In FY 2023, when the Cures funding is \$419M, we would have flexibility to perform additional activities outside of funding for the basic infrastructure (e.g. we could start whole genome sequencing of participants).
- If our base is \$130M, do we continue to enroll 1M participants with more limited data (e.g. limited EHR data) and specimen collection, or do we enroll less participants and strive for a greater depth of data?

Scenario 2: Cures Funding Obligations by FY

FY	Annual Cures Appropriation	Projected Obligations	Projected Carry-Over
2017	\$40,000,000.00	\$21,500,000.00	\$18,500,000.00
2018	\$100,000,000	\$118,500,000.00	\$0.00
2019	\$186,000,000.00	\$144,600,000.00	\$41,400,000.00
2020	\$149,000,000.00	\$190,400,000.00	\$0.00
2021	\$109,000,000.00	\$109,000,000.00	\$0.00
2022	\$150,000,000.00	\$150,000,000.00	\$0.00
2023	\$419,000,000.00	\$262,000,000.00	\$157,000,000.00
2024	\$235,000,000.00	\$227,000,000.00	\$165,000,000.00
2025	\$36,000,000.00	\$166,000,000.00	\$35,000,000.00
2026	\$31,000,000.00	\$66,000,000.00	\$0.00
Total	\$1,455,000,000.00	\$1,455,000,000.00	