OSC (Common Fund)

The Common Fund

Concept Clearance: New Common Fund Program

TITLE: Nutrition for Precision Health, powered by the *All of Us* Research Program

Objective: To provide the evidence base for individualized dietary/nutrition recommendations

Initiatives:

1. Data and Study Coordination
2. Clinical Centers
3. Data Generation Centers
4. Artificial Intelligence, Bioinformatics and Data Modeling Center
5. Biobank

Funds Available $155,900,00

Program Duration: 5 years

Council Action: Vote on support of Program

Nutrition for Precision Health, powered by the *All of Us* Research Program

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases

September 11, 2020
NIH Council of Councils

National Institutes of Health
Office of Strategic Coordination - The Common Fund

Nutrition for Precision Health Working Group

The Common Fund

Program Co-Chairs

Griffin Rodgers, NIDDK
Diana Bianchi, NICHD
Gary Gibbons, NHLBI
Ned Sharpless, NCI

Common Fund Program Leaders

Felicia Qashu, OSC
Ananda Roy, OSC

Program Coordinators

Holly Nicastro, *All of Us*, NIDDK
Christopher Lynch, NIDDK

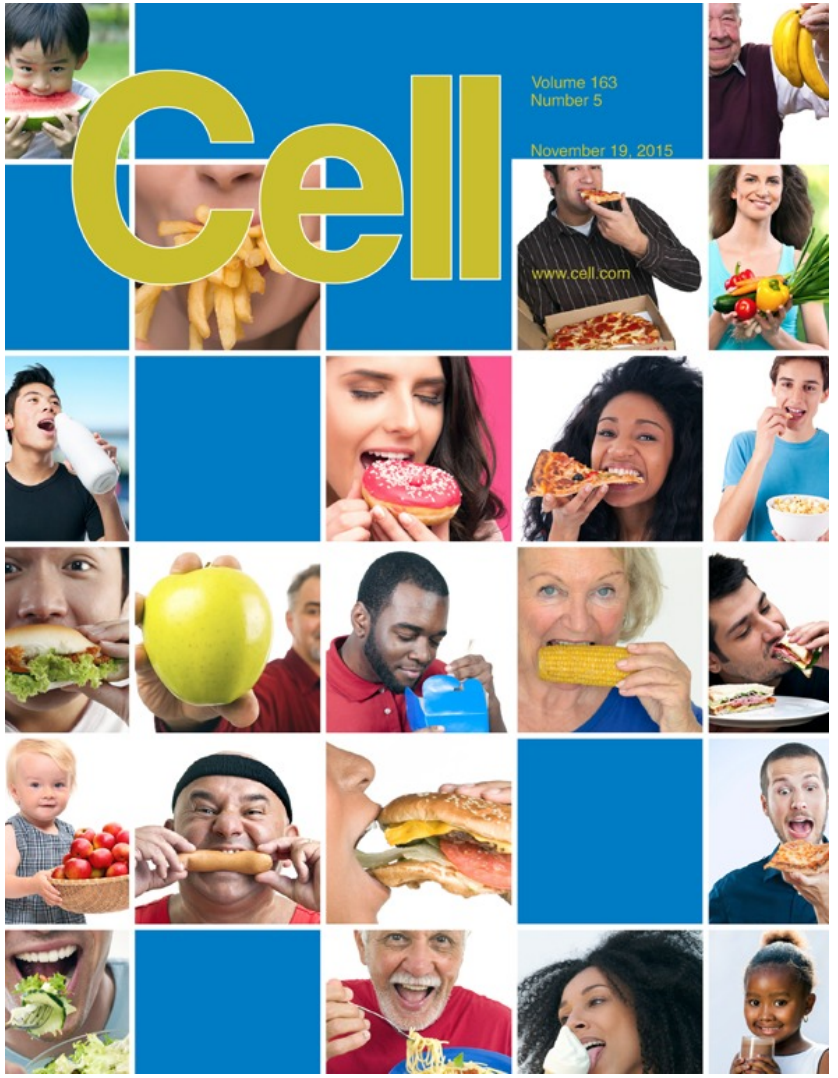
Working Group Members

Samantha Adas, NIDDK
Andrew Bremer, NICHD
Cindy Davis, ODS
Qi Duan, NIBIB
Mary Evans, NIDDK
Roberto Flores, NCI
Kelly Gebo, *All of Us*
Chris Hartshorn, NCI
Kirsten Herrick, NCI
Craig Hopp, NCCIH
Robert Karp, NIDDK
Yasmin Kloth, *All of Us*
Roger Little, NIDA
James Luo, NHLBI
Padma Maruvada, NIDDK
George Papanicolaou, NHLBI
Charlotte Pratt, NHLBI
Jill Reedy, NCI
Sharon Ross, NCI
Katie Rush, *All of Us*
Sheri Schully, *All of Us*
Shurjo Sen, NHGRI
Daniel Shaughnessy, NIEHS
Pothur Srinivas, NCI
Derrick Tabor, NIMHD
Ashley Vargas, NICHD
Lu Wang, NIDCR
Xujing Wang, NIDDK
Jamie White, ORWH
Kenneth Wilkins, NIDDK
Deborah Young-Hyman, OBSSR
Giovanna Zappala, NIA

Why precision nutrition?

The Common Fund

- Poor diet is a leading cause of preventable death and disease and preventable healthcare costs in the US
- Current dietary recommendations provide a one-size-fits-all approach
- Interactions between dietary intake, microbiome ecology, metabolism, nutritional status, genetics, and the environment are still poorly understood



Why do we need a Common Fund Program?

The Common Fund

- Nutrition research is a cross cutting issue at most NIH ICOs accounting for ~$1.8 billion in research expenditures per year
- A large harmonized effort to comprehensively analyze the metabolic status of a diverse population is needed before precision nutrition can be widely applied in clinical/public health settings
- The project requires expertise in a wide range of areas spread across NIH
- First ever Strategic Plan for NIH Nutrition Research emphasizes the importance of studying precision nutrition

Current Approach to Precision Nutrition

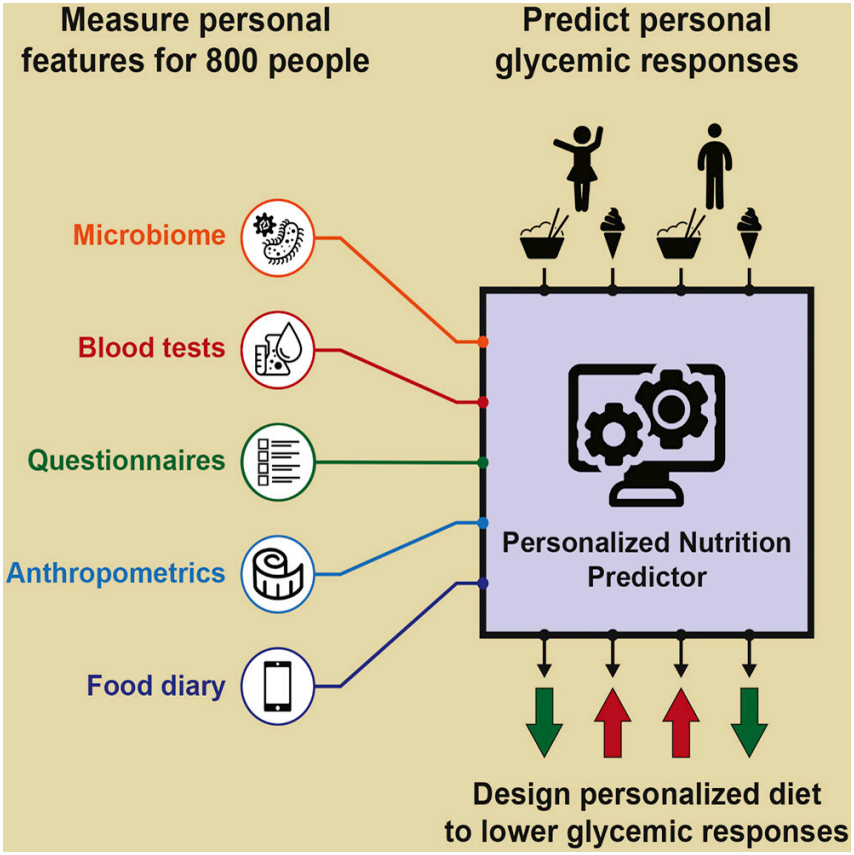
The Common Fund

Cell

Authors
David Zeevi, Tal Korem, Niv Zmora, ...,
Zamir Halpern, Eran Elinav, Eran Segal

Personalized Nutrition by Prediction of Glycemic Responses

- 800 individuals, representative of adult non-diabetic Israeli population
- Individual glycemic excursions in response to the same foods were highly variable
- Intervention study: personally tailored meals significantly improved postprandial glucose responses
- ~90% of predictive model came from microbiome compositional data



Cell 2015 163, 1079-1094, doi: 10.1016/j.cell.2015.11.001, ©

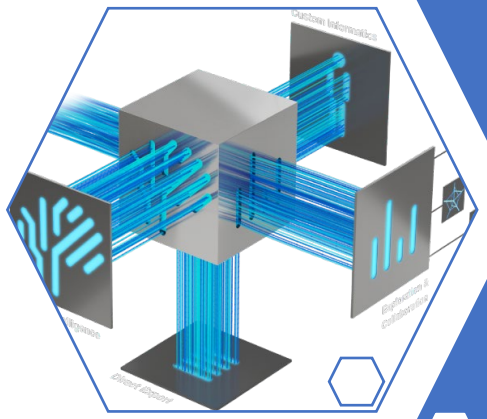
Challenges with Current Approach

The Common Fund

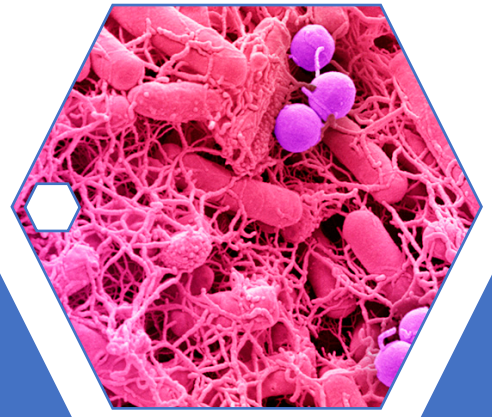
- Problems with collection and analysis of self-reported dietary intake data
- Challenges with adherence to dietary prescriptions
- Need for accurate information about calorie expenditure
- Costs of -Omic Measures
- Models have employed selected, not comprehensive inputs
- Small precision nutrition studies with *limited diversity of participants*

Why now?

The Common Fund

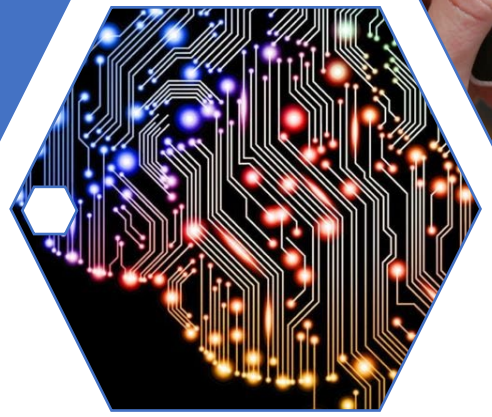


Advances in analyzing and understanding microbiome ecology



Improvements in multi-omic data generation, throughputs, costs, and analysis methods

Advances in artificial intelligence and deep learning



Development or refinement of digital health technologies for dietary assessment

Emergence of the *All of Us* Research Program

All of Us RESEARCH PROGRAM

Why *All of Us*?

The Common Fund

- Large diverse cohort with commitment to inclusion
- Established infrastructure
- Existing data: genomics, electronic health records, digital health data, physical measurements, and surveys
- Data access and sharing policy, Researcher Workbench
- A precision nutrition program can add new data types to *All of Us* and provide high value information for participants

Proposal

The Common Fund

Leverage existing NIH investments - including the *All of Us* Study - and emerging technologies and tools to make the critical discoveries to steer nutrition research toward personalized approaches.

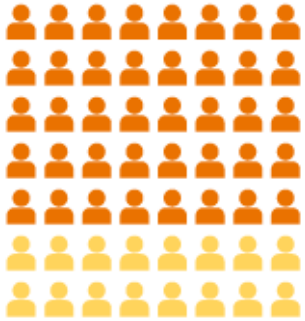
STUDY GROUP NESTED IN *ALL OF US*

1 MODULE 1
Examine usual diet with continuous glucose monitoring, followed by a mixed meal challenge, and micro-biome/metabolic phenotyping

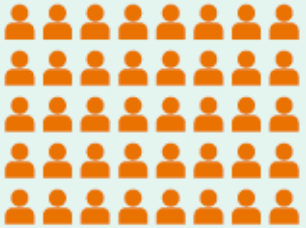
2 MODULE 2
Randomized dietary interventions done at home as a subset of Module 1

3 MODULE 3
Randomized dietary interventions conducted in inpatient controlled feeding centers where precise nutritional intakes, microbiome ecology, and physio-metabolic data can be rigorously obtained

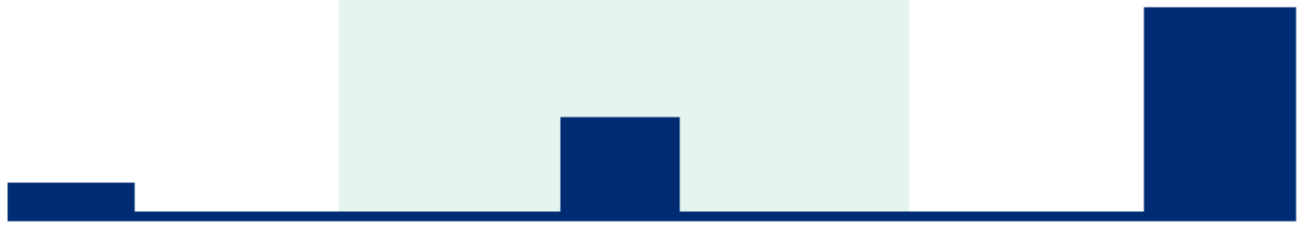
USUAL DIET PARTICPANTS



LARGER FREE LIVING STUDY



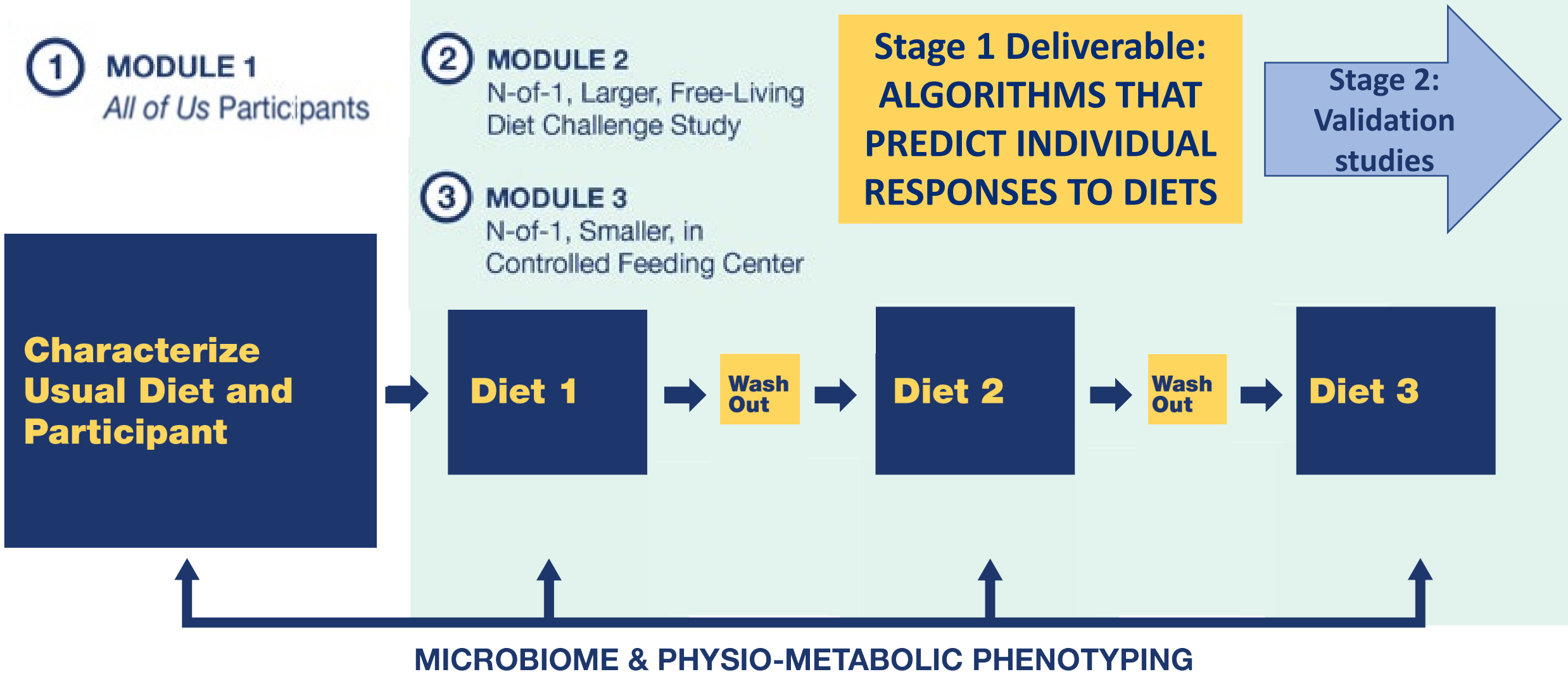
SMALLER CONTROLLED FEEDING CENTER



LEVEL OF MICROBIOME, PHYSIO-METABOLIC AND DIET RESPONSE DATA AVAILABLE FROM PROPOSED MODULES

Proposal

The Common Fund



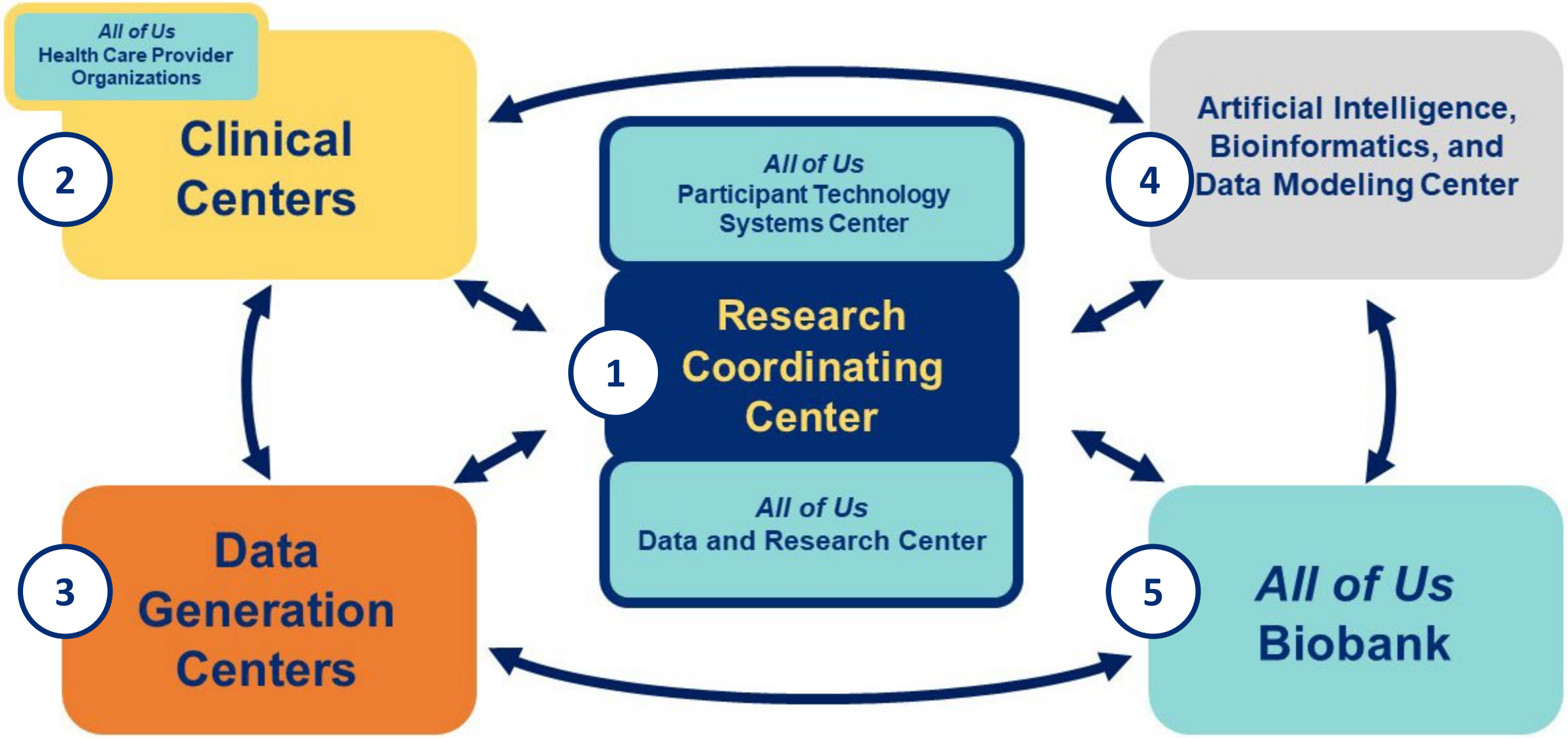
Innovative Measures

The Common Fund

Programs	Genetics	Microbiome Ecology	Continuous Glucose Monitoring	Hormones/Proteome	Physio-sensors	Mixed Meal Testing	Diet	Nutritional Status	Metabolome	24 h Urine Omics	Exposome	Socioeconomic Factors	Electronic Health Records	Psychosocial Factors	Behavioral Factors	Long Term Outcomes
Nutrition for Precision Health	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Company 1	●															
Company 2	●	●	●	●	●	●	●	●	●							
Company 3	●			●		●										
Company 4	●	●		●	●		●	●		●						
Company 5	●	●														
Company 6	●	●	●		●	●										

Proposed Components

The Common Fund



Initiatives – Data and Study Coordination

The Common Fund

1

Research Coordinating Center

new solicitation

***All of Us* Participant Technology Systems Center**

supplement to existing award

***All of Us* Data and Research Center**

supplement to existing award

GOAL: Provide administrative management and coordination across all sites and collect, curate, aggregate, store, distribute, and ensure quality control of all data

Initiatives – Clinical Centers

The Common Fund

2

Clinical Centers

new solicitation

***All of Us* Health Care Provider Organizations**

supplement to existing award

GOAL: Recruit, consent and enroll *All of Us* participants into nutrition program. Assess usual diet, conduct mixed-meal challenges, and collect biospecimens in 10,000 participants (Module 1); conduct a series of controlled feeding studies in a subset of 1,500, free-living participants (Module 2); and conduct a series of controlled feeding studies in 500 domiciled participants (Module 3).

Initiatives – Data Generation Centers

The Common Fund

3

Metagenomics Center

new solicitation

GOAL: Perform epigenetic analyses and microbiome metagenomic and metatranscriptomic analyses on all participants.

Metabolomics and Clinical Assay Center

new solicitation

GOAL: Perform metabolic and proteomic analyses on biosamples from stool, urine, and plasma using targeted (e.g., metabolites and nutrients) and untargeted metabolomics.

Dietary Assessment Center

new solicitation

GOAL: Develop innovative approaches to address dietary assessment challenges by integrating and improving measurement error in mobile dietary assessment technologies using data from free-living and controlled feeding studies.

Initiatives

The Common Fund

4

Artificial Intelligence, Bioinformatics, and Data Modeling Center

new solicitation

GOAL: Integrate data-driven and mechanistic approaches, with mathematical and computational modeling, to develop comprehensive dietary intervention algorithms that can predict biological responses. Enhance visualization and accessibility of data for broader scientific community.

5

***All of Us* Biobank**

supplement to existing award

GOAL: Receive, process, record, and store biosamples and metadata related to the samples from clinical centers

Budget - numbers are ($1000s)

The Common Fund

	Lead IC	FY2022 (planning)	FY2023	FY2024	FY2025	FY2026	Total
Overall Program Administration	NIDDK	$650	$650	$650	$650	$650	**$3,250**
(1a) Research Coordinating Center	TBD	$1,500	$1,500	$1,500	$1,500	$1,500	**$7,500**
(1b) Data and Research Center	*All of Us*	$3,000	$3,000	$3,000	$3,000	$3,000	**$15,000**
(1c) Participant Technology Systems Center	*All of Us*	$1,500	$1,500	$1,000	$1,000	$500	**$5,500**
(2a) Clinical Centers	TBD	$7,000	$12,000	$12,000	$12,000	$12,000	**$55,000**
(2b) Health Care Provider Organizations	*All of Us*	$220	$220	$220	$220	$220	**$1,100**
(3a) Metagenomic Center	TBD	$550	$3,500	$3,500	$3,500	$3,500	**$14,550**
(3b) Metabolomics and Clinical Assays Center	TBD	$400	$5,000	$5,000	$5,000	$5,000	**$20,400**
(3c) Dietary Assessment Center	TBD	$1,500	$2,200	$2,200	$2,200	$1,500	**$9,600**
(4) AI, Bioinformatics, and Data Modeling Center	TBD	$2,000	$2,000	$3,000	$3,000	$3,000	**$13,000**
(5) Biobank	*All of Us*	$2,000	$2,500	$2,500	$2,500	$1,500	**$11,000**
Total		**$20,320**	**$34,070**	**$34,570**	**$34,570**	**$32,370**	**$155,900**

Thank you

National Institutes of Health

Office of Strategic Coordination - The Common Fund