

Proposed Make America Healthy Again (MAHA) Implementation Strategy & Governance Structure

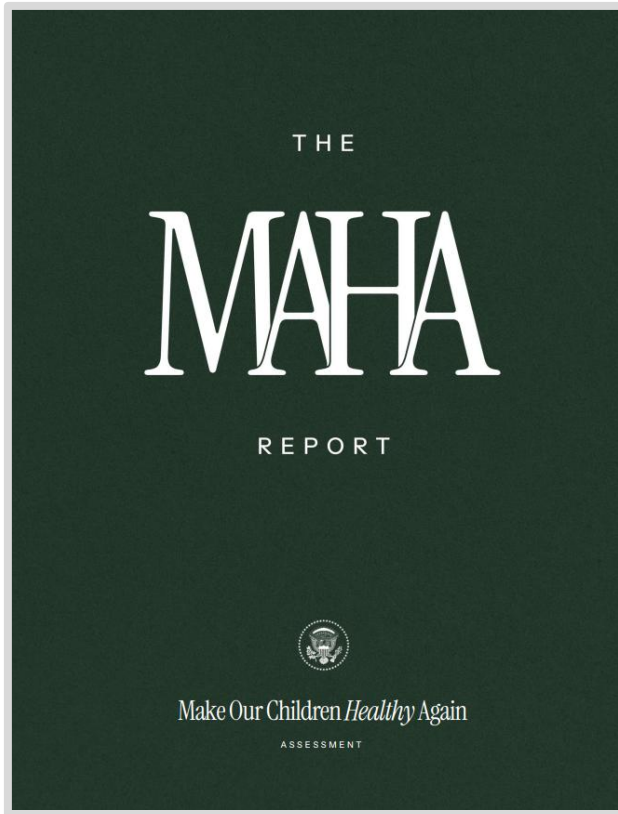
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Background

NIH MAHA Strategic Framework: Responding to HHS Priority Focus on the Chronic Disease Epidemic



- HHS **MAHA agenda** is focused on reforming America's food, health, and scientific systems to **identify the root causes of the chronic disease epidemic**.
- **HHS identified 33 scientific mandates** for NIH for the MAHA initiative focused on scientific research in nutrition, environment, physical activity, mental health, substance use, cancer, and vaccines.
- HHS Mandate: NIH will launch an Initiative on Chronic Disease to **leverage and align** existing NIH research projects, **improve NIH coordination** on chronic disease research, and **generate actionable results** for diseases arising in childhood and adulthood.

NIH MAHA Strategic Framework: Why it is Needed

- Chronic diseases arise from interacting genetic, environmental, behavioral, dietary, and social factors, **requiring an integrating, multi-faceted approach at NIH** that necessitates cross-ICO coordination.
- **NIH has world-class assets**—cohorts, data platforms, and specialized expertise—with much already focused on advancing chronic disease research.



NIH requires a strategic framework designed for the current resource-constrained environment that **can harmonize current efforts to address chronic disease** and identify gaps and areas of opportunity.

Proposed NIH MAHA Strategic Framework: Coordinated and Collaborative for an Agile NIH Response

- Overall goal: **NOT to create a new bureaucracy or replace what is working**, but rather **utilize the existing ICO organizational infrastructure** across the NIH.
- Will build on the organizational design used for the **Health Effect of Extreme Weather (HEW)**.
- **Aligns and builds on existing ICO efforts** and **leverages current cross-NIH platforms and collaborations** that grew up organically.
- Develops **shared infrastructure** through **Integration Platforms** for core capabilities for **data management and AI**, shared **cohort partnership**, and to promote the **Whole Person Health** framework.
- Establishes **Thematic Coordination Groups** to facilitate **collaboration and reporting** to increase **transparency and coordination**, **avoid duplication** of efforts, **leverage resources**, **promote cross-ICO synergy** and **generate awareness** of NIH activities and opportunities across **biomedical thematic focus areas**.

Representative Examples of Cross NIH Initiatives

- Scientific Data Council (SDC)
- Implementing a Maternal Health and PRegnancy Outcomes Vision for Everyone (IMPROVE)
- The Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative
- Office of Nutrition Research's Nutrition Research Coordinating Committee (NRCC)
- The Helping to End Addiction Long-term®(HEAL) Initiative
- Common Fund Programs:
 - CARE for Health
 - Nutrition for Precision Health
 - Bridge to Artificial Intelligence (Bridge2AI)
 - SysBio

Leveraging a Whole Person Health (WPH) Framework: Promoting Precision Health

Figure A

- **Health and disease exist on a bi-directional continuum** with opportunities to **prevent disease and restore health** through **integrated health care with individual and social support**

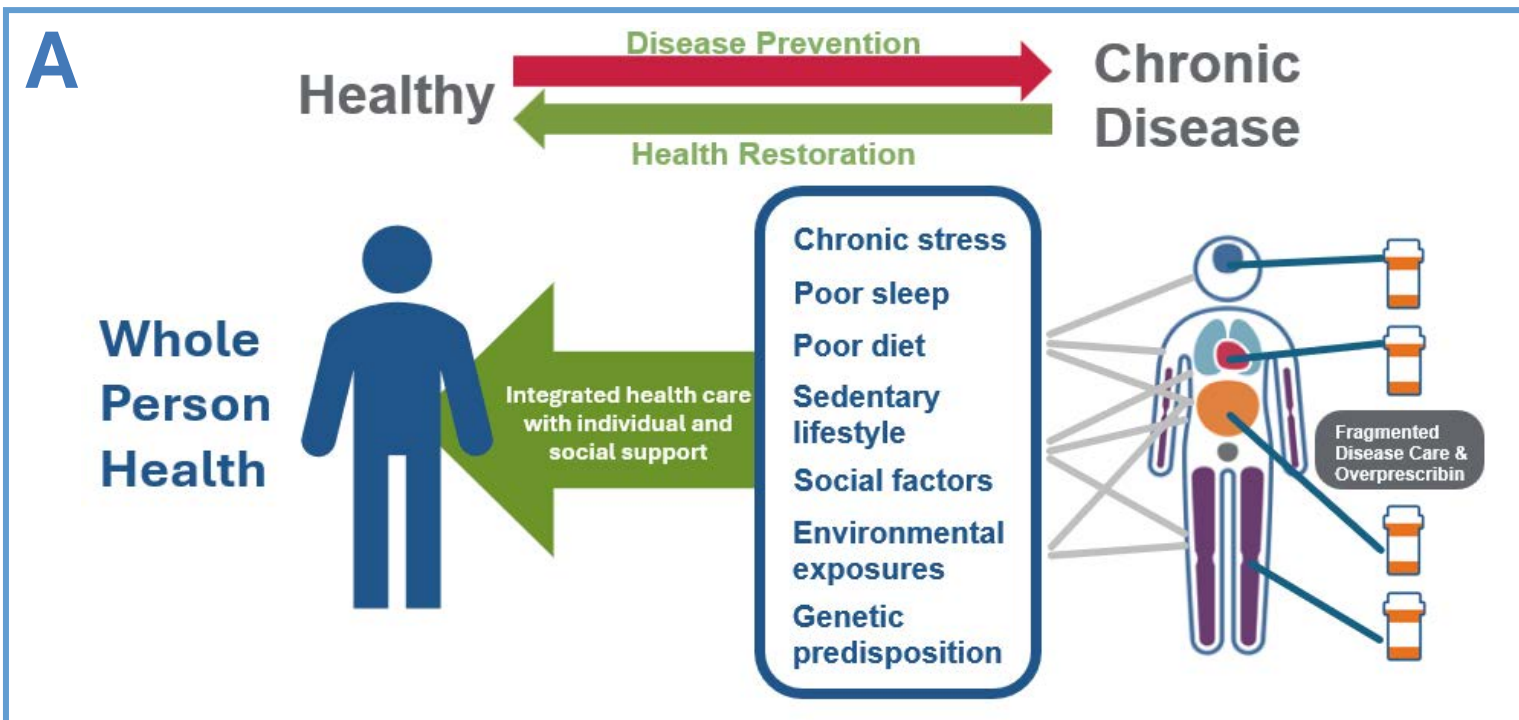
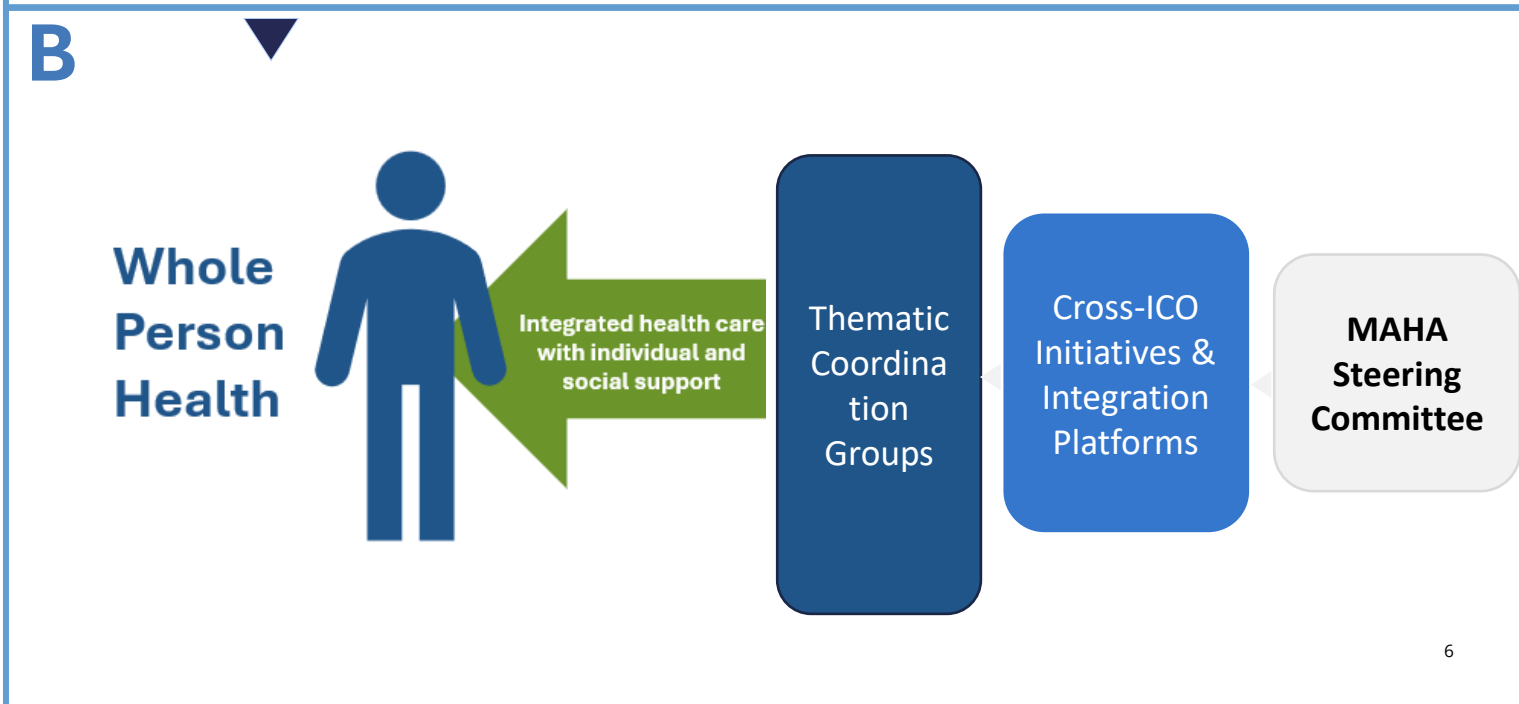


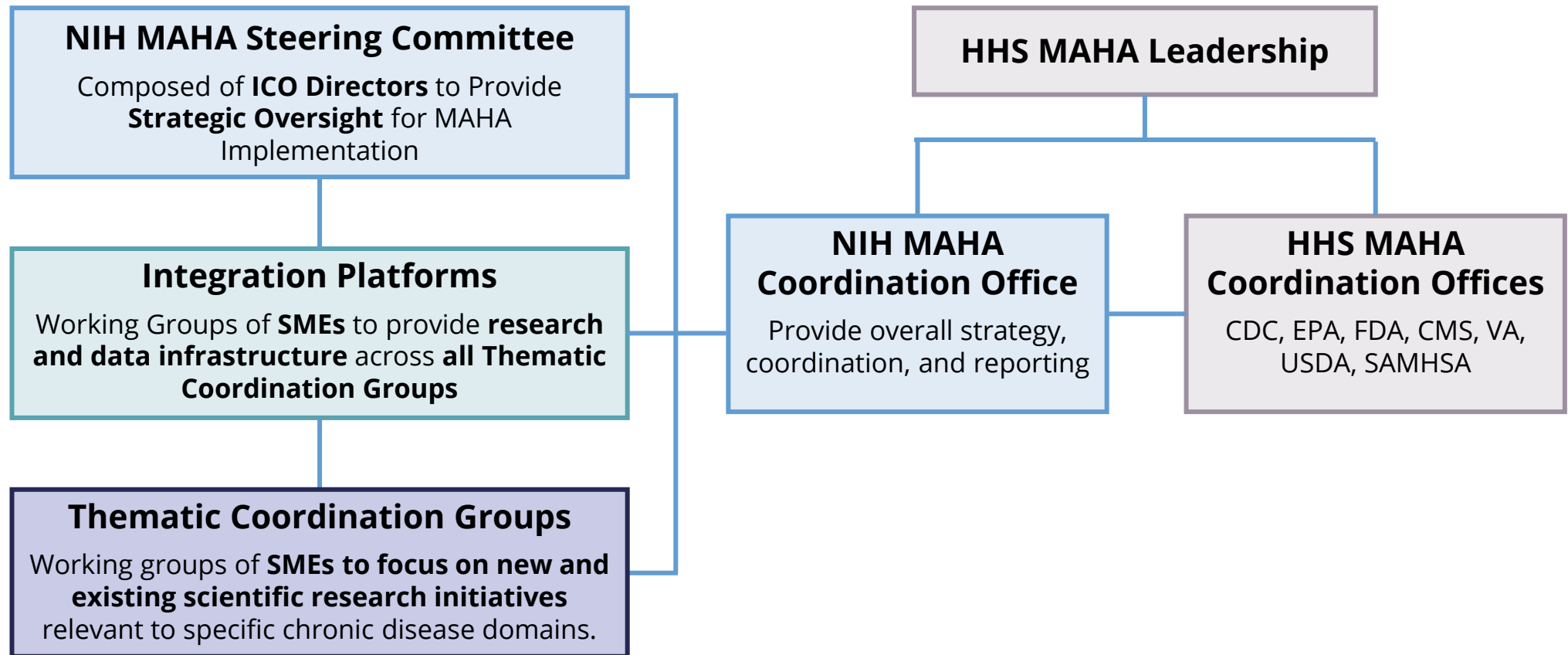
Figure B

- Proposed NIH mechanistic and clinical research strategy to fulfill the goals of the MAHA Chronic Disease Initiative.
- **Thematic Coordination Groups** are the scientific engines coordinating cross-IC work.
- **Integration Platforms** and existing cross-ICO Initiatives provide infrastructure supporting gold-standard science.



Proposed MAHA Strategic Framework

NIH MAHA Strategic Framework: Simple, Lightweight, & Impact-Oriented



Governance Structure: MAHA Steering Committee

Membership	• Chair: Senior Advisor to NIH Director ◦ Accountability to NIH Director (ultimate Decision Authority) ◦ Facilitate communication with NIH Director and Deputy Director • Members: ICO Directors leading the Integration Platforms and Thematic Coordination Groups, Deputy Director for Intramural Research (DDIR) • Ex-officio: Director DPCPSI
Key Responsibilities	• Monthly meeting attendance at the beginning, to be followed by quarterly cadence • Oversee annual MAHA strategic priorities from the Integration Platforms and the Thematic Coordination Groups • Make recommendations for Common Fund Programs and review NOFOs • Review portfolio performance across Thematic Coordination Groups and Integration Platforms • Resolve escalated conflicts • Oversee data coordination and reporting through MAHA Coordination Office using START platform in DPCPSI
Decision Process	• Consensus preferred • 2/3 majority vote for major decisions (Chair break ties)

Governance Structure: Integration Platforms

Membership	- Co-Chairs: Lead Co-Chairs are rotating positions selected by participating ICOs - ICO Directors nominate SMEs from their ICOs for each Integration Platform, including Intramural Research Program (IRP)
Key Responsibilities	- Monthly meetings for collaboration, with cadence adjusted based on needs - Identify related existing ICO and cross-NIH efforts and ensure work leverages/connects to current cross-NIH platforms and collaborations - Identify research gaps and set priorities within each integration platform Develop and coordinate ICO research portfolios and facilitate cross-ICO collaboration Recommend Common Fund investments to the Steering Committee - Facilitate chronic disease research at NIH through shared data and resource infrastructure - Support research across all Thematic Coordination Groups through direct participation in meetings and ongoing collaboration - Report on progress to Steering Committee and MAHA leadership
Decision Process	Provide recommendation to MAHA Steering Committee, NIH Director on catalytic Common Fund support No authority over ICO budgets; money remains with ICO to fund collaborative projects
Deliverables	- Portfolio assessment (summary of current, prospective research/work, recommendations for addressing gaps) - Strategy to achieve MAHA objectives, leveraging existing infrastructure and proposed new efforts

Governance Structure: Thematic Coordination Groups (TCGs)

Membership	• Co-Chairs: Lead Co-Chairs are rotating positions selected by participating ICOs • ICO Directors nominate SMEs from their ICOs, including Intramural Research Program (IRP) • Representation from the three Integration Platforms: - o RWD & AI Platform liaison - o WPH liaison - o Life-Course Cohort liaison
Key Responsibilities	• Focus on ICO research portfolios and facilitate cross-ICO collaboration • Identify research gaps and set priorities within each thematic scientific research area • Identify related existing ICO and cross-NIH efforts and ensure work leverages/connects to current cross-NIH platforms and collaborations • Report out on progress to Steering Committee and MAHA leadership
Decision Process	• TCG's recommend to Steering Committee, NIH Director funds catalytic Common Fund support • No authority over ICO budgets; money remains with ICO to fund collaborative projects
Deliverables	• Meeting minutes from recurring meetings, collaboration efforts • Portfolio assessment (summary of current, prospective research/work, recommendations for addressing gaps) • TCG-specific strategy to achieve MAHA objectives, leveraging existing initiatives and including proposed new efforts

MAHA Strategic Framework: Integration Platforms

Support chronic disease research through infrastructure development (e.g., data management, coordination, and cohort involvement).

Platform	Function	MAHA Mandates
 Real World Data (RWD) & Artificial Intelligence (AI) Platform	Inventories, integrates, and harmonizes diverse real-world data sources (clinical, environmental, dietary, chemical, behavioral, social, whole person physiology, and genomics) into a network-ready data platform for systems biology research, leveraging AI to analyze data. Includes SysBio and Drug Repurposing focus.	Real World Data Platform; New Approach Methodologies (NAMs); Drug Repurposing; Artificial Intelligence
 Clinical and Community Networks that Integrate the Whole Person Health Framework	Coordinates whole person health research principles, methods, standards, and system-based approaches. Integrates cross-network chronic disease research through CARE for Health, NIH CEAL, CTRs, CTSA's, and the NIH Collaboratory. These programs will identify integration opportunities across the lifespan by identifying and managing joint projects, overseeing demonstration sites, and ensuring comprehensive exposome measurement.	Whole Person Health, Rural and Tribal Health
 Life-Course Cohort Integration	Enables cohort-based chronic disease research across the life course by integrating genomic and exposomic approaches, developing gene-environment interaction analyses across networks, and incorporating CHAMPVA data.	Longitudinal Pediatric Health Insights; Longitudinal Research for Chronic Disease Prevention; Using Data Tools Focused on Children; Maternal Health

MAHA Strategic Framework: Thematic Coordination Groups (TCGs)

Scientific working groups to encourage NIH **coordination**, **leveraging of resources**, and **collaboration** in key chronic disease research areas. ICOs will be encouraged to apply their relevant strategic goals to the MAHA implementation strategy.

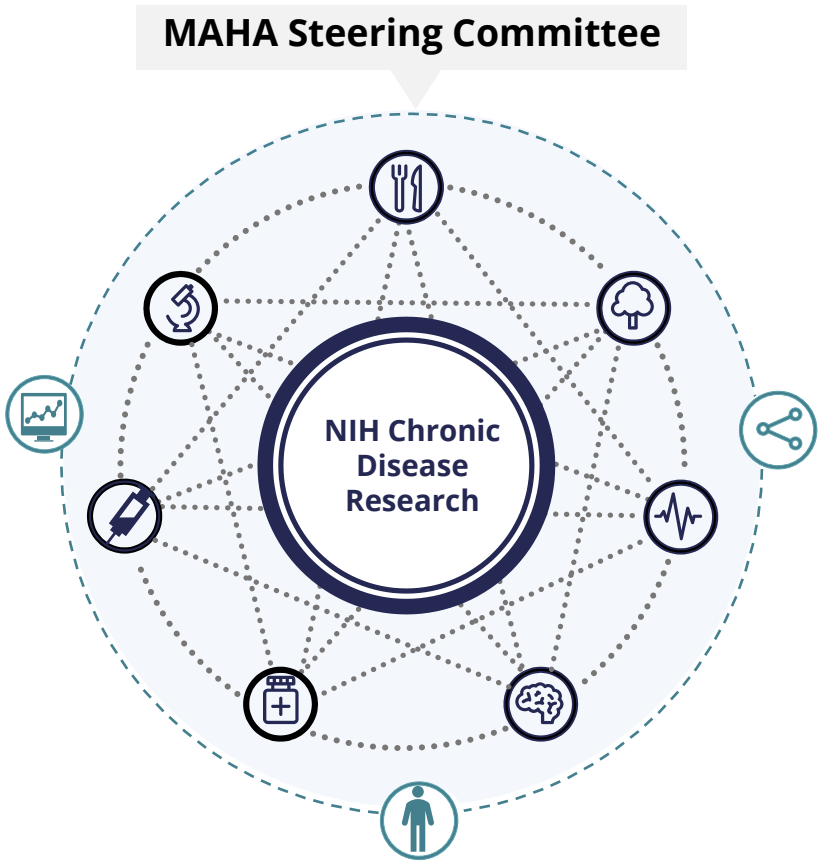
	Focus	Function	MAHA Mandates
	Nutrition, Metabolism & Health Promotion	Drives evidence-based diet and lifestyle strategies to prevent and manage obesity, diabetes, and cardiometabolic risk.	Food for Health; Nutrition; Gut Microbiome Research Initiative; Longitudinal Research for Chronic Disease Prevention
	Environmental & Chemical Exposures (Exposomics)	Generates evidence on cumulative environmental, chemical, and digital exposures using biomonitoring and modern testing methods to inform health protections and policy.	Cumulative Exposure; Water Quality, Air Quality; Microplastics & Synthetics, Electromagnetic Radiation; Water Quality, Fluoride, PFAs
	Oral-Systemic Health, Physiologic Resilience & Inflammation	Studies activity, sleep, and oral-health impacts, leveraging approaches from genetics to wearables, to identify and address ways to reduce inflammation and strengthen physiologic resilience.	Oral Health & Systemic Disease Connection
	Neurodevelopment, Mental Health & Cognitive Resilience	Advances preventative and treatment interventions to ensure optimal neurodevelopment and mental health, integrating prenatal factors, school programs, and genetics-informed impacts of digital media.	Autism; Mental Health & Addiction
	Substance Use, Prescribing & Therapeutic Safety	Improves prescribing and treatment safety by combining utilization research with pharmacogenomics and addiction-risk prediction, including non-opioid pain strategies.	Prescribing Patterns and Impact on Mental Health; Repurposed Drugs
	Immunologic Interventions & Differential Response	Studies how immune interventions work differently in different individuals and groups using genetics and pharmacogenomics, to strengthen vaccine safety science and personalized prevention.	Vaccine Injury; Longitudinal Pediatric Health Insights; Longitudinal Research for Chronic Disease Prevention
	Cancer Etiology, Early Detection & Survivorship	Investigates cancer causes and rising early-onset trends, advances AI-enabled early detection and precision oncology, and improves survivorship by addressing treatment toxicity and quality-of-life impacts.	Clinical Trials for Pediatric Cancer; Artificial Intelligence

NIH MAHA Strategic Framework: Interacting Networks and Platforms

MAHA Steering Committee: Provides strategic oversight of MAHA initiatives at NIH and is **composed of representatives from each Thematic Coordination Group and Integration Platform.**

Integration Platforms:	
	1. Real World Data (RWD) & Artificial Intelligence (AI) Platform
	2. Clinical and Community Networks that Integrate the Whole Person Health Framework
	3. Life-Course Cohort Integration Platform

Thematic Coordination Groups (TCGs):	
	1. Nutrition, Metabolism & Health Promotion
	2. Environmental & Chemical Exposures (Exposomics)
	3. Oral-systemic Health, Physiologic Resilience & Inflammation
	4. Neurodevelopment, Mental Health & Cognitive Resilience
	5. Substance Use, Prescribing & Therapeutic Safety
	6. Immunologic Interventions & Differential Response
	7. Cancer Etiology, Early Detection & Survivorship



Next Steps

MAHA Strategic Framework: Next Steps and Timeline

- **ICO Directors review and provide input** and finalize the implementation strategy (by March 13th) → *Complete*
 - **Ask:** Would like for all ICOs to participate in one of the Integration Platforms or TCGs
- Utilize capabilities within DPCPSI to conduct **NIH-wide portfolio analysis against the 32 HHS mandates** to inform Thematic Coordination Group and Integration Platform activities, **leverage existing research and resources, identify gaps, establish and align on future priorities** (April)
- **Standup Thematic Coordination Groups and Integration Platforms** (April) and establish accountability reporting platform to the Steering Committee. Nominations open first week of April, and close **by 4/24**.
- **Establish and convene Steering Committee** (May) based on nominations from the TCG's and Integration Platform's meeting on biweekly and then monthly cadence

Integration Platforms (Detailed)

Integration Platform 1: Real World Data (RWD) & Artificial Intelligence (AI) Platform

Potential ICOs*

ODSS, NLM, NCATS, NIBIB, NHGRI, NHLBI, NIA, OBSSR, NEI, NIAAA, NIDCR, NIMH, NCCIH, CIT, OCIO, OCAIO, NIGMS

Key Responsibilities



- AI driven approaches for harnessing RWD
- Drug repurposing enterprise
- ORIVA bringing NAMs capabilities
- OREPA brings Gold Standard Science across networks
- Inventory and integrate NIH supported Data Repositories relevant to RWD
 - Clinical (EHR and outcomes)
 - Environmental according to exposome framework
 - Dietary (SNAP/WIC, school meals, biomarkers)
 - Chemical (PFAS, pesticides, heavy metals)
 - Behavioral (wearables, screen time)
 - Social (neighborhood, stress)
- Coordinate with All of Us on genomics integration and WPH data integration
- Governance Oversight by the Scientific Data Council (SDC)
- Leverage AI/RWDP for drug repurposing

MAHA Mandates



Real World Data Platform; New Approach Methodologies (NAMs); Drug Repurposing; Artificial Intelligence

Integration Platform 2: Clinical and Community Networks that Integrate the Whole Person Health Framework

Potential ICOs*	NCCIH, NINR, ODP, ODS, NEI, NIDCD, NIDCR, OBSSR, NIAAA, NHLBI, NIMHD, THRO, NLM, ORWH, NIMH, NIA
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Key Responsibilities



- Inform CARE for Health Community implementation through WPH perspective
- Leverage NIH Community Engagement Alliance (CEAL) support research on health promotion and chronic disease prevention.
- Study pediatric and adult chronic disease across the lifespan
- Platform to integrating work across all ICO's
- Coordinate WPH multilevel, multisystem research using integrative methods
- Design and oversee integrated demonstration sites
- Ensure comprehensive exposome measurement across networks
- Identify cross-TCG opportunities leveraging WPH principles and methods

MAHA Mandates



Whole Person Health; Rural and Tribal Health

Integration Platform 3: Life-Course Cohort

Potential ICOs*

All of Us, ECHO, NIDA, NHLBI, NICHD, NIDDK, NIA, NIEHS, NHGRI, ODP, CC, NIDCD, NEI, NIMH, NIAAA, ORWH, OBSSR, NLM, NIDCR

Key Responsibilities



- Study chronic diseases at various stages of the life cycle to get a root causes of chronic disease
- Bring genomic, exposomic, and gene x environment interaction strategies to cohorts studying chronic disease (obesity, diabetes, dementia, asthma, autism, ADHD, addiction, cardiorespiratory conditions, pharmacogenomics) across NIH and to TCGs
- Integrate data from Civilian Health and Medical Program from VA (CHAMPVA)

MAHA Mandates



Longitudinal Pediatric Health Insights; Longitudinal Research for Chronic Disease Prevention; Using Data Tools Focused on Children

Thematic Coordination Groups (Detailed)

Group 1: Nutrition, Metabolism & Health Promotion

Potential ICOs*	NIDDK, NHLBI, NIA, NCI, NIMHD, ODS, ONR, ODP, CC, OBSSR, NIAAA, NEI, NINR, NIEHS, NCCIH
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Scope



- Dietary Guidelines implementation and research
- Ultra-processed foods and food additives
- Precision nutrition research
- Implement food and lifestyle interventions to improve health
- School nutrition programs
- Food for health interventions
- Dietary interventions that support metabolic health across lifespan

Key Partners



USDA Food and Nutrition Service, FDA CFSAN

MAHA Mandates



Food for Health; Nutrition; Gut Microbiome Research Initiative; Longitudinal Research for Chronic Disease Prevention

Group 2: Environmental & Chemical Exposures (Exposomics)

Potential ICOs*	NIEHS, ECHO, NIBIB, FIC, ORIP, THRO, NEI, NIDCD, NIDCR, ORIVA, NIAMS, NCATS, NHLBI, NCCIH, NIA
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Scope



- Contribute data on health effects of electromagnetic radiation to HHS
- New Approach Methodologies (NAMs)
- Water quality (fluoride, PFAS, contaminants)
- Air quality impacts on children
- Cumulative chemical exposure including pesticides and agricultural chemicals
- Microplastics and synthetic chemicals
- Microbiome and metabolic health

Key Partners



EPA (Chemical Safety, Water, Air), FDA, USDA, HHS for electromagnetic radiation

MAHA Mandates



Cumulative Exposure; Water Quality, Air Quality; Microplastics & Synthetics; Water Quality, Fluoride, PFAs

Group 3: Oral-Systemic Health, Physiologic Resilience & Inflammation

Potential ICOs*	NHLBI, NIAMS, OBSSR, NIDCR, NIA, NIAAA, NEI, ORWH
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Scope



- Oral Health and systemic chronic disease
- Physical fitness interventions and research
- Sleep research: sleep deprivation and sleep disorders and mind-body practices/therapies
- Impact of quality supplements in the diet
- Oral microbiome relationship with gut health and immune function
- Sleep disorders in children
- Inflammation and metabolic fitness
- Wearables and digital phenotyping

Key Partners



President's Council on Sports, Fitness & Nutrition, Department of Education

MAHA Mandates



Oral Health & Systemic Disease Connection

Group 4: Neurodevelopment, Mental Health & Cognitive Resilience

Potential ICOs*	NIMH, NICHD, NIDCD, NINDS, NEI, NIMHD, NIAAA, NIDA, OBSSR, ODP, NIA, NIEHS, NCCIH
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Scope



- Autism root causes research
- Dementia and aging
- ADHD and developmental disorders
- Screen time and digital media impacts
- Stress reduction programs
- School-based interventions on mental health
- Prenatal and maternal mental health
- Leverage BRAIN and NIH Blueprint

Key Partners



SAMHSA, ACF, CDC, FDA

MAHA Mandates



Autism; Mental Health & Addiction

Group 5: Substance Use, Prescribing & Therapeutic Safety

Potential ICOs*

NIAAA, NHGRI, NIDA, NINDS, NIMH, NIDCD, NIMHD, NCCIH, NIAMS, NINR

Scope



- Pediatric prescribing patterns (SSRIs, antipsychotics, stimulants)
- Evaluate Rx patterns for SSRI's, anti-psychotics, stimulants, etc.
- Opioid prescribing and General Pain Management Research
- Therapeutic harms and benefits of current Dx thresholds and overprescription trends
- Repurposed drugs research
- Non-opioid pain treatment strategies (BACPAC, INTERACT)
- Alcohol addiction

Key Partners



FDA CDER; SAMHSA; ATF; DEA; CMS

MAHA Mandates



Prescribing Patterns and Impact on Mental Health; Mental Health & Addiction

Group 6: Immunologic Interventions & Differential Response

Potential ICOs*

NIAID, NIGMS, CC, NIA, NCCIH, NIDCR, NIDCD, NCI, NICHD, NIEHS

Scope



- Vaccine injury research and vaccine framework
- Vaccination Impacts on Health Trajectories And Life Course (VIHTAL)
- Evidence-based preventive practice
- Heterogeneity in immune-based interventions
- Immunogenomics and immune variants

Key Partners



FDA (CBER, CDER); CMS

MAHA Mandates



Vaccine Injury; Longitudinal Pediatric Health Insights; Longitudinal Research for Chronic Disease Prevention

Group 7: Cancer Etiology, Early Detection & Survivorship

Potential ICOs*

NCI, NHGRI, NHLBI, NIDCR, NIDCD, NIEHS, NIAAA, NIMHD, NCCIH

Scope



- Cancer risk, prevention, detection, treatment response, and long-term outcomes
- Cancer Genomics
- Environmental and metabolic carcinogenesis
- Pediatric and early-onset cancers
- Early detection, biomarkers, AI diagnostics
- Survivorship and late effects

Key Partners



CDC; AHRQ; CMS ; FDA; VA

MAHA Mandates



Clinical Trials for Pediatric Cancer; Artificial Intelligence