An Initiative for Speeding Innovation

September 2021
A Comprehensive Global Response to a Growing Threat

Our Focus on Driving Alzheimer’s Innovations

During the World Economic Forum’s Annual Meeting (Davos 2020), pharmaceutical executives, government leaders, non-governmental organization representatives and healthcare thought leaders met and decided to pursue collaboration in three areas to speed innovation.

1. Global Cohort Development
   - Build a global cohort with high-quality, detailed data on a well-characterized, diverse population, readily available to researchers, to increase discovery of targets for drug development with associated biomarkers.

2. Global Clinical Trials
   - Reduce the cost and time to bring new treatments to market globally.

3. Healthcare System Preparedness
   - Facilitate the implementation of national, regional and global commitments to provide access to future innovations in treatment, diagnosis and care.
A Comprehensive Global Response

Our Approach to Speeding Innovation

1. Achieving Global Scale

2. Linking Regional and Sectoral Efforts

3. Engaging LMIC
Addressing Global Unmet Needs
A Track Record of Spurring Innovation

Funds increased access to immunizations
$900M launch
$19B to date

Funds vaccines research for emerging infectious diseases
$750M launch
$2B to date

Funds innovation in Alzheimer's disease
$750M goal at launch

2000
2021
Taking the Next Step to Respond to Global Commitments

2013

Ministers from each of the G7 countries committed to a 12-point plan to set an ambition goal to speed innovation.

2017

Set a global action plan at the World Health Assembly aimed at making a difference to the lives of people affected by dementia.

2019

G20 commits to promote healthy and active ageing and implement comprehensive set of policies to address dementia.

2020

Presentation during the 2020 Annual Meeting in Davos charges WEF and CEOi to develop a multi-year collaborative to change the pace of innovation in Alzheimer’s disease research and care.

2021

A $700+M collaboration announced

Link: http://www3.weforum.org/docs/WEF_The_Davos_Agenda_Overview_2021.pdf
Building the Organization

A Sustainable Stand-Alone Global Organization
Governance Structure

Proposed Flow of Funds

- Funds from Governments and Sovereign Wealth Funds
- Funds from NGOs, Philanthropy and Grants
- Investments

Once $200M is raised

World Bank

Swiss-based Foundation

US-based 501c3

ROW Organization(s)

For-Profit Vehicle

TBD

Under evaluation
Founding Board Members include:

- Dr. Elias Zerhouni, Professor Emeritus, Johns Hopkins University; Former Director, National Institutes of Health; Former President R&D, Sanofi
- Dr. Freda Lewis-Hall, former Executive Vice President and Chief Medical Officer, Pfizer
- Dr. Margaret Chan, Dean, Yanke School of Public Health, Tsingua University; Former Director General, World Health Organization
- George Vradenburg, former Chief Legal Council, CBS; former Executive Vice President, AOL
- Julien Gattoni, Chief Financial Officer, World Economic Forum
- Drew Holzapfel, Executive Director, The Global CEO Initiative on Alzheimer’s Disease

- Investors Forum is 5 rotating members who invested in DAC (and will serve as an observer on the Board)
- Champions Council members are key ambassadors for the effort; group meets annually to review progress and provide input
- Scientific and Medical Advisory Council is the principal advisory group to the Board and the CEO on scientific, legal, regulatory and healthcare system issues
- Partners Coordination Council is comprised of DAC partners, co-creators and collaborators
- Task Forces are comprised of subject matter experts and advise each of the program leads
## A Comprehensive Global Response

Preliminary Approximate Expense Budget for Programs

<table>
<thead>
<tr>
<th>Goal</th>
<th>Foundational Phase (2021)</th>
<th>2022-2026</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td><strong>Global Cohort Development</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Build a global cohort with high-quality, detailed data on a well-characterized, diverse population to increase discovery of targets for drug development and identify associated biomarkers</td>
<td>$15M</td>
<td>$350M</td>
<td>$365M</td>
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<tr>
<td><strong>Global Clinical Trials</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Build a global platform and network to reduce the cost and time to bring new treatments to market globally</td>
<td>$4M</td>
<td>$241M</td>
<td>$245M</td>
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<tr>
<td><strong>Healthcare System Preparedness</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Facilitate the implementation of global commitments to provide access to future innovations in treatment, diagnosis and care</td>
<td>$3M</td>
<td>$100M</td>
<td>$103M</td>
</tr>
</tbody>
</table>

Total: $716M

Inc. $3M for DAC operations.
Project Budget Summaries

Proposed Initial Budgets by Work Groups
Global Cohort Development
Global Cohort Development

The Issues We Face

- Incomplete global understanding of the heterogeneity and the variability of Alzheimer's etiology
- Need for new targets and biomarkers for drug development

Our Commitment

- Build a global cohort with high-quality, detailed data on a well-characterized, diverse population, readily available to researchers, to increase discovery of targets for drug development with associated biomarkers
Creating the Davos Alzheimer’s Collaborative Research Institute to Facilitate Global Research

Building A Global Cohort to Speed Innovation

DAC Research Institute
Chairs and funds global effort

Research Institute Partner

<table>
<thead>
<tr>
<th>Data integration/harmonization</th>
<th>Biosample management</th>
<th>Communications and publication</th>
</tr>
</thead>
</table>

Regional Research Institute Partner(s) – *as needed*
Key Regions Inc: North America, Africa, Asia, Europe

Pre-Competitive Research

- Common element data collection protocols - Measurements added per the prioritized list developed by 2020 DAC working group
- Access to researchers globally *(through ADDI’s ADWB)*
- Data used for DAC analytical challenges
- Coordinates with other DAC programs

Sponsored Research

- Measurements of specific interest to a sponsor(s) to enrich specific populations
- Access terms to be defined with sponsors
- After period of sponsor data exclusivity, data available publicly

Consulting Services

- Protocol development
- Grant development
- Tools assessment and incubation
Global Cohort Development

Engagement Process for Cohorts in the Foundational Phase

1. Recruitment
   - Attract cohorts with an increased focus on LMIC
   - DAC Targets Cohort Based on Scientific Aims
     - Cohort Expresses Initial Interest

2. Initial Engagement
   - Engage in foundational phase data development and organization actions
   - Cohort Signs DAC Commitment Letter
   - Cohorts Provide Data Dictionaries
     - Cohorts Catalogued

3. Enrichment
   - Data funded to increase cohort’s application to Alzheimer’s research
   - DAC Funds Cohorts to Enrich Based on Scientific Plan
     - One time measurement
     - Longitudinal measurement

4. Discovery
   - Data available to researchers
   - Cohort Data Harmonized and Made Available
   - Biosamples Stored
     - Regional storage/handling as dictated by national and regional regulations

5. Capability Building
   - Tools and services available to participating cohorts
   - DAC-Cohort Partnerships to Advance Shared Scientific Plan

As of September, representing over 1.5M people with data dating back over 25 years
## Cohort Development
### Funding Needs

<table>
<thead>
<tr>
<th>Foundational Phase</th>
<th>Year 1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Uniform Data Set</td>
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<td></td>
<td></td>
<td></td>
<td>$5M</td>
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<tr>
<td>Establishment of DAC Research Center</td>
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<td>$10M (regional)</td>
<td>$10M (regional)</td>
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<td>$30M</td>
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<tr>
<td>Enrichment and Recruitment</td>
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<td>$45M</td>
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<tr>
<td>Biosample Mgt and Data Infrastructure</td>
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<td>$2M</td>
<td>$2.5M</td>
<td>$3M</td>
<td>$3.5M</td>
<td>$13.5M</td>
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<tr>
<td><strong>Approx Total Budget</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>$365M</strong></td>
</tr>
</tbody>
</table>
Healthcare System Preparedness
Healthcare System Preparedness

The Issues We Face

• The aging global population, which increases the number of families with Alzheimer’s, has a dramatic impact on national budgets, global economic growth and monetary policy

• Healthcare systems are not prepared to detect cognitive change, diagnose accurately, identify the right intervention or deliver future treatment

• Facilitate the implementation of national, regional and global commitments to provide access to future innovations in treatment, diagnosis and care

Our Commitment
Patient Pathway

DAC Intends to Catalyze and Scale Innovation Across the Individual and Family Journey

<table>
<thead>
<tr>
<th>Awareness and Activation</th>
<th>HCS Patient Flow</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>Health Promotion</td>
<td>Integrated Healthcare</td>
</tr>
</tbody>
</table>

**Encourage Targeted Innovation**

**Initial Focus**

- Screening and early detection
- Diagnosis of MCI and dementia

- Consumer Awareness & Activation
- Consumer & HCS/ Payer Connection
- HCP Education & Activation

- Public Awareness & Education

- Health Care Mgmt and Delivery
- Care Planning
- Dementia Care
- Services and Social Support
Foundational Phase Flagship Project – Early Detection

Concept Overview

**Annual Wellness Visit**
- **HCS Option:** AD Specialist Consult (In-person or Virtual)

**Digital Cognitive Assessment**
- No cognitive decline identified

**Rule Out Other Causes**
- Blood Test
  - No pathology detected
  - Specialist Exam

**Diagnosis**
- Clinical Trial Referral
  - Surveys
- Care and Services
  - Surveys

**MEASUREMENT CONCEPT:** Brain health mindset - proportion of target population with standardized baseline cognitive test scores in electronic medical records and reviewed annually

**BARRIER IDENTIFICATION:** Operational challenges and key stakeholder feedback
Our Process

Funding Innovation through Flagship Projects and Local Grants

- **Q1 2022**
  - Early detection
  - Screening and early detection

- **Q1 2023**
  - Early detection
  - Centrally-driven flagship project (12-15 months)

- **Q1 2024**
  - Early detection
  - Grants for locally-driven projects (18-24 months)
  - Diagnosis of MCI and dementia
  - Centrally-driven flagship project (12-15 months)

- **Q1 2025**
  - Scale and agile dissemination via learning lab
  - Grants for locally-driven projects (18-24 months)

- **Q1 2026**
  - Scale and agile dissemination via learning lab
  - Grants for locally-driven projects (18-24 months)

- **Q1 2027**
  - Scale and agile dissemination via learning lab
  - Grants for locally-driven projects (18-24 months)

- **Care Planning**
  - General Assembly Dissemination
  - Learning Lab
Our Process
Building the Foundation to Scale Results

Mechanisms for Scaling New Pathways of Care

Bring together global stakeholders to share learnings and work towards adopting and implementing new models.

- Learning Lab
  - Comprised of committed government policy leads and key policy influencers
    - Meet 2x per year
  - World Health organization serves as a technical advisor

- Communities of Practice
  - Consolidate lessons learned from cross-site implementation through a CFIR framework
  - Creating a durable digital toolkit to help scale learnings globally
## Healthcare System Preparedness

### Five Year Costs

<table>
<thead>
<tr>
<th>Foundational Phase (2021)</th>
<th>Year 1</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grant/Investment Funding</strong></td>
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<td>$5M</td>
<td>$13M</td>
<td>$20M</td>
<td>$20M</td>
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<tr>
<td><strong>Learning Laboratory</strong></td>
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<td>$800K</td>
<td>$900K</td>
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| Approx Total Budget | $103M |

Five Year Costs: $103M
Global Clinical Trials Support Platform
Global Clinical Trial Support Platform

The Issues We Face

- Alzheimer’s clinical trials are slow, laborious and expensive
- There is limited coordination, data collection and efficiency across global clinical trial sites for Alzheimer’s disease
- Research participation is largely not possible outside N. America, Europe and Japan

Our Commitment

- Build a global platform and network to increase the speed, efficiency and quality of Alzheimer’s clinical trials worldwide
2021 Anticipated Milestones – Clinical Trials

- Develop and deploy a network of more than 40 European sites organized for accelerating studies and implementing novel trial designs
  - The European network will include the 11 countries covered by EPAD
  - Establish recruitment teams, study/IT infrastructure and regulatory start up processes by region or country to optimize site performance

- Evaluate and establish site networks in Singapore, Australia, Japan and China and an exploratory trial site(s) in South America and Africa
  - Design and establish a global rater certification program and an imaging center certification for the global network to ensure pre-qualified centers and experts when a study protocol is approved

- Initiate the first transatlantic therapeutic clinical trial with a minimum of 110 sites

- Evaluate leading biomarkers (blood and digital) in a “prognostication” study and design and develop a biomarker-based screening program for inclusion in therapeutic clinical trials for global use

- Develop a set of performance metrics (focusing on reporting and measuring quality, acceleration and lower cost, etc.) for each region/country on the 6-year roadmap

- Continued development of the North American network of more than 80 sites and design federated data collection process.
# Clinical Trials

## Five Year Costs

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<tr>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>Total</th>
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<tr>
<td>Global Coordination</td>
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<td>North America</td>
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<td>$11M</td>
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<td>$11.5M</td>
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</tr>
<tr>
<td>Australia and Singapore</td>
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<td>$7.5M</td>
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<td>$7.5M</td>
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<tr>
<td>Japan</td>
<td>$4M</td>
<td>$10M</td>
<td>$13M</td>
<td>$20M</td>
<td>$24M</td>
<td>$71M</td>
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**Approx Total Budget** $245M
How We Worked in 2020

Deep Engagement with Top Thought Leaders Across the Field
Leadership Group
Coordinate time-bound work groups, development of concept/coalition and operational framework

Co-Chairs of Leadership Group
George Vradenburg (CEOi), Amaud Bernaert (WEF)
General oversight, advocacy and sustainability of the initiative

Secretariat
CEOi (Drew Holzapfel), WEF (Kelly McCain), CEOi-WEF Fellow (Alissa Kurzman)
Coordination of Leadership Group, Advisory Committee, and Work Groups

Advisory Committees
Our Leadership Group

Esko Aho
Former Prime Minister, Finland

Arnaud Bernaert, Co-Chair
Head, Health and Healthcare, World Economic Forum

Niranjan Bose
Managing Director, Health and Life Sciences, Gates Ventures

Vint Cerf
Chief Internet Evangelist, Google

Amitabh Chandra
Professor of Public Policy and Business Administration, Harvard University

Rachelle Doody
Global Head of Neurodegeneration, Roche/Genentech

Hilary Doxford
Former Vice Chair, European Working Group for People with Dementia; Ambassador, Alzheimer’s Society

John Dwyer
President, Global Alzheimer’s Platform Foundation

Andrew von Eschenbach
Former Commissioner, U.S. Food and Drug Administration

Howard Fillit
Founding Executive Director, Innovative Medicines Initiative

Margaret (Peggy) Hamburg
Former Commissioner, U.S. Food and Drug Administration

Nancy Ip
Dean of Science and Director of the State Key Laboratory of Molecular Neurosciences, The Hong Kong University of Science and Technology

Christoph Koenen
Executive Vice President and Chief Medical Officer, Otsuka America Pharmaceutical

Margery Kraus
Founder and Executive Chairman, APCO Worldwide

John Lim
Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School; Deputy Director of Medical Services, Ministry of Health, Singapore; Chairman, Singapore Clinical Research Institute

David Mayhew
Vice Chairman, JP Morgan; Chairman, Alzheimer’s Research UK

Haruo Naito
Representative Corporate Officer and CEO, Eisai Co., Ltd.

Brad O’Connor
Chief Executive Officer, Cogstate

Andrea Pfeifer
Co-founder and Chief Executive Officer, AC Immune SA

Kathleen Sebelius
Former Secretary, U.S. Department of Health and Human Services

Daniel Skovronsky
Senior Vice President and Chief Scientific Officer, Eli Lilly and Company

Paul Stoffels
Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Michel Vounatsos
Chief Executive Officer, Biogen

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Convener, Global CEO Initiative on Alzheimer’s Disease

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Executive Vice President and Chief Medical Officer, Otsuka America Pharmaceutical

Margery Kraus
Founder and Executive Chairman, APCO Worldwide

John Lim
Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School; Deputy Director of Medical Services, Ministry of Health, Singapore; Chairman, Singapore Clinical Research Institute

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Global Cohort Working Group and Advisors

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Boston University School of Medicine; Framingham Heart Study

Philip Awadalla
Ontario Institute for Cancer Research, University of Toronto

Sinead Chapman
Broad Institute of MIT and Harvard

Aled Edwards
Structural Genomics Consortium; University of Toronto

Geoffrey Ginsburg
Duke Center for Applied Genomics & Precision Medicine; International HundredK+ Cohorts Consortium

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University of Pennsylvania; Children’s Hospital of Philadelphia; International HundredK+ Cohorts Consortium

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The Stanley Center for Psychiatric Research, Broad Institute of MIT and Harvard

Allan Levey
Emory University; Emory Alzheimer’s Disease Research Center

Mihaela Levitchi Bena
Biogen

Husseini Manji
Johnson & Johnson

Paul Maruff
Cogstate

Adesola Ogunniyi
University of Ibadan; University of College Hospital, Ibadan

Jane Rylett
Canadian Institutes of Health Research, Institute of Aging; Schulich School of Medicine & Dentistry, University of Western Ontario

Nadeem Sarwar
Eisai Center for Genetics Guided Dementia Discovery (G2D2), Eisai Co., Ltd.

George Yancopoulos
Regeneron Pharmaceuticals

Elias Zerhouni, Co-Chair
Johns Hopkins University; National Institute of Health; Sanofi
Clinical Trials Working Group and Advisors

Jeffrey Cummings
University of Nevada, Las Vegas; Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, Nevada

John Dwyer, Co-Chair
Global Alzheimer’s Platform Foundation

Chris Edgar
Cogstate

Lynne Hughes, Co-Chair
Formerly IQVIA

Takeshi Iwatsubo
Graduate School of Medicine, The University of Tokyo

Simon Lovestone
Janssen Inc.; University of Oxford Medical Sciences Division

Emer MacSweeney
Re:Cognition Health

Ronald Petersen
Mayo Clinic Alzheimer’s Disease Research Center; World Dementia Council

Craig Ritchie
University of Edinburgh, Centre for Dementia Prevention

Christopher Rowe
The University of Melbourne; University of Melbourne Australia Dementia Network

Marwan Sabbagh
Luo Ruvo Center for Brain Health, Cleveland Clinic

Philip Scheltens
VU University Medical Center, Amsterdam; Amsterdam University Medical Centers, Alzheimer’s Center Amsterdam

Alison Searle
Roche

Pascale Witz
Horizon Therapeutics
Thank You

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