



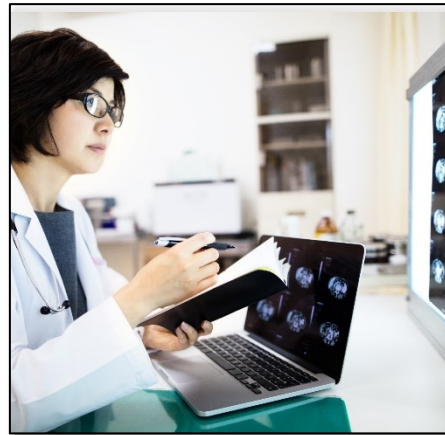
Foundation for the National Institutes of Health Biomarkers Consortium

BIOMARKERS
CONSORTIUM



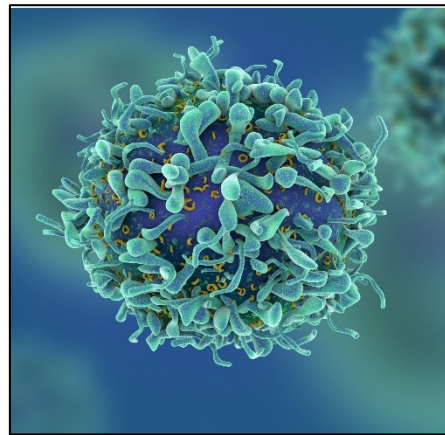
Dr. Althea Lang, PhD, PMP

About the FNIH



Mission

The mission of the Foundation for the National Institutes of Health (FNIH) is to support the mission of the NIH. The FNIH creates and leads alliances and public-private partnerships that advance breakthrough biomedical discoveries and improve the quality of people's lives.



The FNIH was created by Congress in 1990 as a not-for-profit charitable organization. The Foundation began its work in 1996 to facilitate groundbreaking research at the U.S. National Institutes of Health (NIH) and worldwide.



Founded by Congress to:

- Attract and share resources
- Enable insight and innovation
- Establish standards
- Distribute expertise
- Create consensus
- Drive competitiveness in marketplace

By the Numbers

3

\$1.5B

raised to date

\$0.89

of every dollar spent directly supports programs

600+

programs supported since inception

~125

active research partnerships, scientific education/training, conferences/events, capital programs

17

years of outstanding Charity Navigator ratings

Public Private Partnerships - the Role of the FNIH

Governance:

- Establishes and manages a variety of structures appropriate to each partnership

Policy Management:

- Provides a “safe harbor” for interactions between and among companies, government, academic entities
- Creates and implements policies that support NIH ethical and policy standards

Program Management:

- Drives consensus across all stakeholders about appropriate scientific selection and execution of projects

Fundraising and Relationship Management:

- Directly solicits contributions
- Stewards and manages donor funds

Project Management:

- Ensures projects meet established deliverables and “go/no go” milestones

Intellectual Property Management:

- Can provide “pre-competitive” structures for handling intellectual property, if needed

FNIH Partnerships Cover a Spectrum of Designs

Funded exclusively by public organizations

ACTIV



Funded by both public and private organizations



Funded exclusively by private organizations

BIOMARKERS CONSORTIUM

IMPROVING HEALTH THROUGH MEANINGFUL MEASUREMENTS



Select FNIH Partnerships

ACTIV

Accelerating COVID 19 Therapeutic Interventions and Vaccines (ACTIV)

NIH OD, BARDA, CDC, DOD, VA, EMA, OWS, FDA, 20 companies, 4 not-for-profit organizations

\$1+ billion



Accelerating Medicines Partnership® (AMP)

NIH OD, 15 NIH ICs, 25 companies, 23 not-for-profit organizations

\$733 million



Partnership for Accelerating Cancer Therapies

NCI, PhRMA, 12 pharmaceutical companies

\$220 million



Alzheimer's Disease Neuroimaging Initiative (ADNI)

NIA, NIBIB, 25+ companies, 3 not-for-profit organizations

\$206 million



Grand Challenges in Global Health (GCGH)

Bill & Melinda Gates Foundation

\$201 million



The Biomarkers Consortium

FDA, NIH, CMS, PhRMA, BIO, pharmaceutical and nutrition companies, not-for-profit organizations

\$107 million

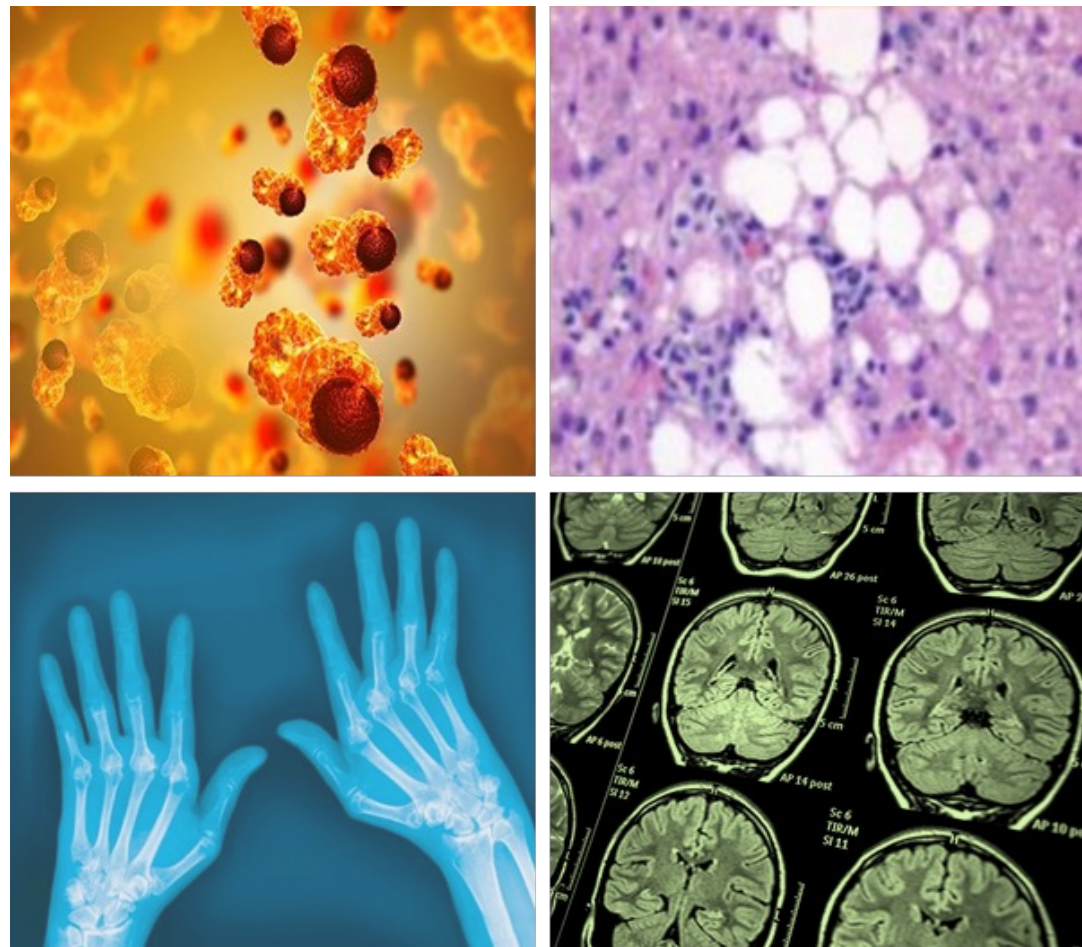


LungMAP: Master Lung Protocol Trial

NCI (SWOG), FDA, Friends of Cancer Research, 10 companies to date

\$42+ million

The Biomarkers Consortium



BIOMARKERS
| | | | | | | | | | **CONSORTIUM**

IMPROVING HEALTH THROUGH
MEANINGFUL MEASUREMENTS

Biomarkers Consortium

Vision

- Improving health through meaningful measurements

Mission

- To create and lead cross-sector efforts that validate and qualify biomarkers and other drug development tools to accelerate better decision making for the development of new therapeutics and health technologies.

Goals

- Facilitate the development and the seeking of regulatory approval for biomarkers using new and existing technologies;
- Develop evidence to help qualify biomarkers for specific applications in diagnosing disease, predicting therapeutic response or improving clinical practice;
- Generate information useful to inform regulatory decision making;
- Make consortium project results broadly available to the entire scientific community.



Driving Principles of the Biomarkers Consortium

- BC projects bridge the gap between basic research and practical needs for advancing drug development and regulatory science.
- All work is pre-competitive, and results are released to the public as early as possible.
- Drug development tool projects are developed collaboratively with involvement from academic, government and industry scientists. Projects can be generated in any therapeutic area.
- All projects have specific, well-defined goals and are milestone-driven, including interim “go/no-go” funding gates.

>35+ projects have been approved and initiated since the founding of the Consortium in 2006

Principles and Policies

- Specific policies and other information available at:
<https://fnih.org/our-programs/biomarkers-consortium/about>
- Key governing policies negotiated prior to launch of Biomarkers Consortium with principals/legal counsel representing the FNIH, NIH, FDA, PhRMA and BIO:
 - Intellectual property (IP) and data sharing
 - Antitrust
 - Selection and award of grants/contracts
 - Confidentiality
 - Conflict of interest



Biomarkers Consortium

15 years of collaboration,
research, and progress



14 therapeutics advanced based on
tools generated

9 clinical tools being used in drug
development

5 FDA guidance documents
supported by work of the BC

1 qualified composite biomarker



>50 publications

800+ citations



60+ member organizations

Biomarkers Consortium Private Sector Members (as of 23 August 2023)

Represent large and small companies, trade groups and not-for-profit organizations

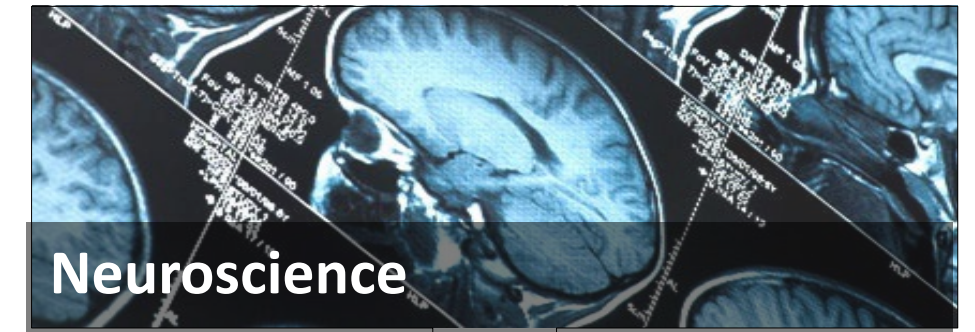
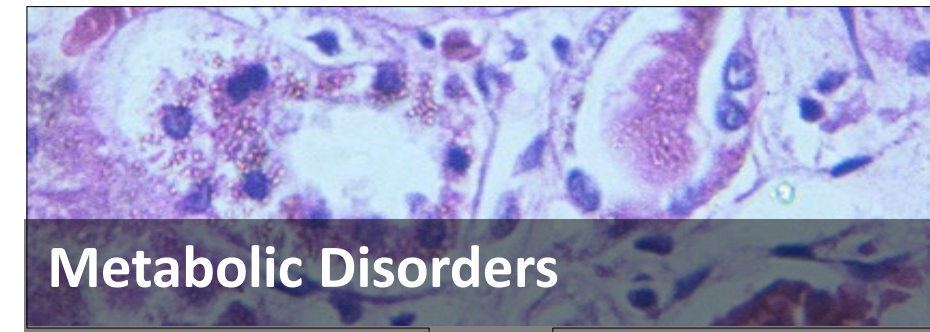
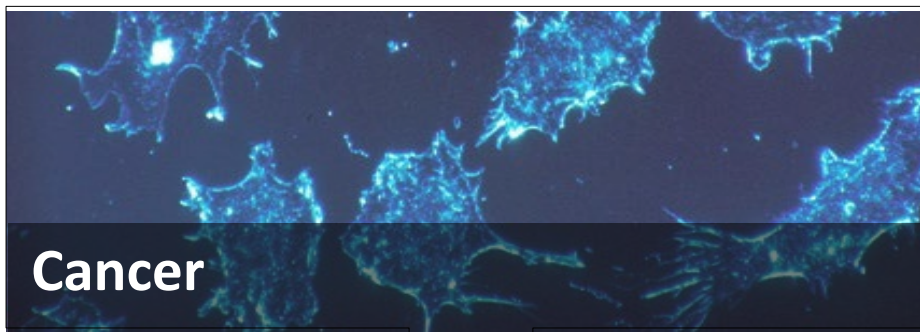
The image displays a grid of logos for private sector members of the Biomarkers Consortium. The logos are arranged in approximately 10 rows and 10 columns. The members include:

- AbbVie, Adaptive Biotechnologies, ADX, Alector, Alkermes, Alzheimer's Association, Alzheimer's Drug Discovery Foundation, Amgen, AMRA (Precision for Decision), Arthritis Foundation, ANRF (Arthritis National Research Foundation), AFTD (The Association for Frontotemporal Degeneration), AMP (Association for Molecular Pathology), Astellas, AstraZeneca, Bayer, Biogen, BIOGNOSYS (Next Generation Proteomics), BIO-RAD, BLUEFIELD PROJECT (Curing FTD), Boehringer Ingelheim, BrightFocus Foundation (Cure in Mind. Cure in Sight.), Bristol Myers Squibb, C2N Diagnostics, CHDI (Accelerating therapeutic development for Huntington's disease), CLARIO (The Best of ERT & BioClinica), Clinical Ink, CROHN'S & COLITIS FOUNDATION, FOUNDATION MEDICINE, Frederick National Laboratory for Cancer Research (sponsored by the National Cancer Institute), FUJIREBIO, Gates Ventures, Genentech (A Member of the Roche Group), Genmab, GSK, ikena ONCOLOGY, Jazz Pharmaceuticals, Johnson & Johnson, labcorp, Lilly, MERCK (INVENTING FOR LIFE), MMRF (Multiple Myeloma Research Foundation), NAMI (National Alliance on Mental Illness), NDC (National Dairy Council), National Scleroderma Foundation, NORDIC BIOSCIENCE, NOVARTIS, novo nordisk, Olink, OXFORD BIODYNAMICS, PACKARD CENTER (ALS Research at Johns Hopkins), PathAI, Pfizer, PROLAIO (at the heart of health), prosciento (ADVISE • ADVANCE • ACHIEVE), radiomics (INSIGHT-BASED DECISION MAKING), RSNA (Radiological Society of North America), REGENERON, Sage Therapeutics, sanofi, SAPIENT, Schizophrenia & Psychosis Action Alliance, somalogic, Seagen, sengenics (THE Functional Proteomics Company), Sjögren's FOUNDATION, sitc (Society for Immunotherapy of Cancer), Takeda, ucb (Inspired by patients. Driven by science.), ultragenyx, VivoSense, BIOMARKERS CONSORTIUM, and FNIH.

Biomarkers Consortium Governance

Executive Committee
NIH / FDA / CMS / Industry / FNIH

Steering Committees



Multiple Project Teams
Representatives from NIH, FDA, Industry, Non-Profits and Academia

Working Groups and Project Development Teams
Representatives from NIH, FDA, Industry, Non-Profits and Academia

Executive Committee

Provides overall steering committee direction and final project approval

Executive Committee Chair

- **Paul Herrling**, FNIH Board of Directors

Centers for Medicare and Medicaid Services

- **Shari Ling**, Center for Clinical Standards and Quality (CCSQ)

FNIH

- **Ellen Sigal**, Friends of Cancer Research
- **TBD** (soliciting nominations)

Food and Drug Administration Research

- **David Strauss**, Director, Division of Applied Regulatory Science, CDER
- **Jeff Siegel**, Office Director of the Office of Drug Evaluation Sciences, CDER
- **Vasum Peiris**, Chief Medical Officer, Pediatrics and Special Populations, CDRH
- **Barbara Buch**, Associate Director for Medicine, CBER
- **Francisca Reyes Turcu**, Team Lead, Molecular Pathology and Cytology Branch, CDRH

Industry

- **Gregory Friberg**, Amgen
- **Jennifer Hamilton**, Regeneron
- **Robert Iannone**, Jazz Pharmaceuticals
- **Husseini Manji**, Johnson & Johnson
- **Michael Vincent**, Pfizer

Chair/Director Appointee

- **John Wagner**, Koneksa

National Institutes of Health

- **Diana Bianchi**, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
- **Lindsey Criswell**, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- **Josh Gordon**, National Institute of Mental Health (NIMH)
- **Douglas Lowy**, National Cancer Institute (NCI)
- **Bruce Tromberg**, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Steering Committee Co-Chairs

Steering Committees identify, develop, approve and manage portfolios of projects

Cancer

- **Gary Kelloff**, National Cancer Institute (NCI)
- **Emmett Schmidt**, Merck
- **Geoff Oxnard**, Foundation Medicine

Metabolic Disorders

- **Hank Burch**, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- **Roberto Calle**, Regeneron
- **Vandana Sachdev**, National Heart, Lung and Blood Institute (NHLBI)

Inflammation and Immunity

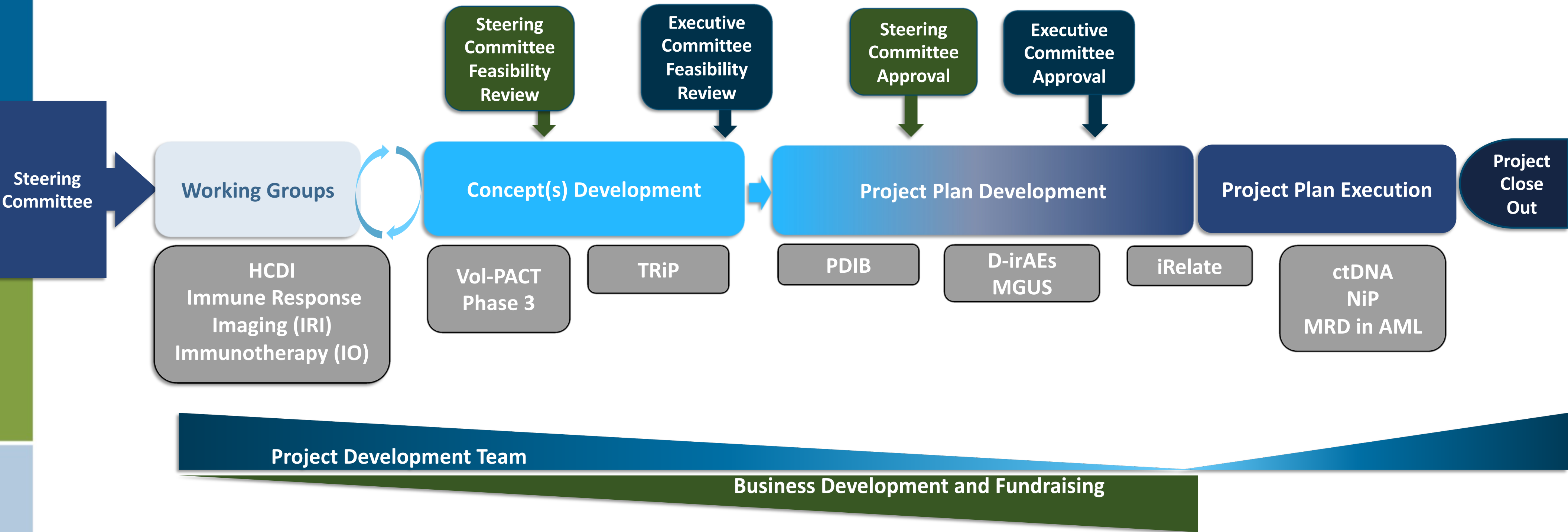
- **David Fox**, University of Michigan
- **Carolyn Cuff**, Janssen

Neuroscience

- **Linda Brady**, National Institute of Mental Health (NIMH)
- **Hartmuth Kolb**, Janssen

Cancer Steering Committee

Project Development Pipeline



Completed Projects & Efforts

FDG-PET	ChIIME
MRD in ALL	MRD in MM
HD-SCA	Big Data Guidance
Vol-PACT	

