Data Sharing for PACT and FNIH

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May 17, 2018

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Current Public-Private Partnerships at the FNIH

- **Accelerating Medicines Partnership** — $230 million
  NIH (OD), NIA, NIAMS, NIDDK, 10 companies, 9 not-for-profit organizations
- **Partnership for Accelerating Cancer Therapies** — $220 million
  NIH (OD), NCI, PhRMA, 10+Companies, 3+ Foundations
- **Grand Challenges in Global Health (GCGH)** — $201 million
  Bill & Melinda Gates Foundation
- **Lung-MAP: Master Lung Protocol Trial** — $163 million
  NCI (SWOG), FDA, Friends of Cancer Research, 5 companies to date
- **Alzheimer's Disease Neuroimaging Initiative (ADNI)** — $148 million
  NIA, NIBIB, 25+ companies, 3 not-for-profit organizations
- **Vector-Based Control of Transmission (VCTR)** — $78 million
  VRC/NIAID, Bill & Melinda Gates Foundation
- **The Biomarkers Consortium** — $73 million
  FDA, NIH, CMS, PhRMA, BIO, pharmaceutical and nutrition companies, not-for-profit organizations
- **Comprehensive T Cell Vaccine Immune Monitoring Consortium (CT-VIMC)** — $50 million
  Bill & Melinda Gates Foundation, NIAID
- **MAL-ED: The Interactions of Malnutrition and Enteric Infections, Effect on Childhood Development** — $46 million
  Bill & Melinda Gates Foundation, Fogarty Institute Center (NIH)

TOTAL: $1.209 billion

NOTE: Partnerships highlighted in green are part of the FNIH cancer portfolio.

Key Needs for Scientific Public-Private Partnership (PPP) Data Sharing

- A strong, motivating scientific need for multiple stakeholders to share their data
- Flexible data sharing models
- Project data generated available for broad public research use
- Neutral third party broker to facilitate the data sharing
- Inclusivity of appropriate partners for data generation, curation, and sharing
- Strong project management
- Pre-established IP and data sharing policies agreed to and binding all partners

PACT Data Sharing

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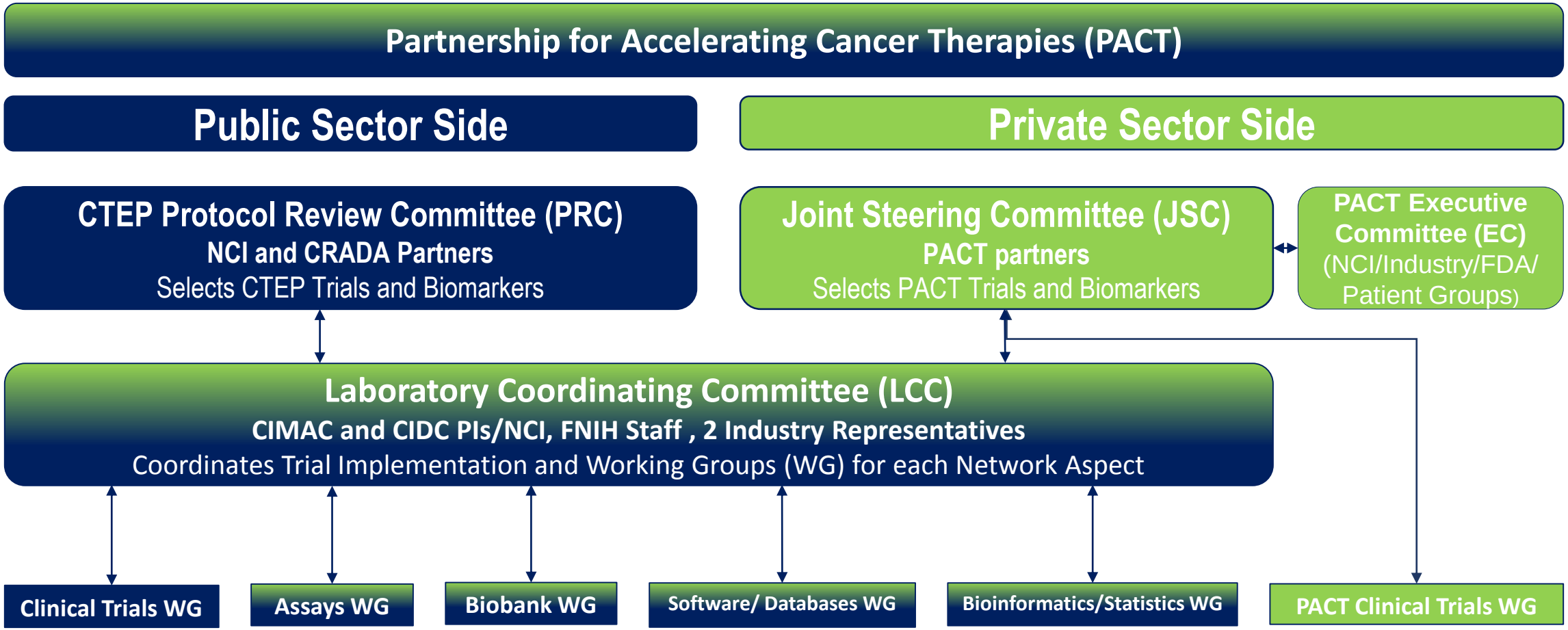
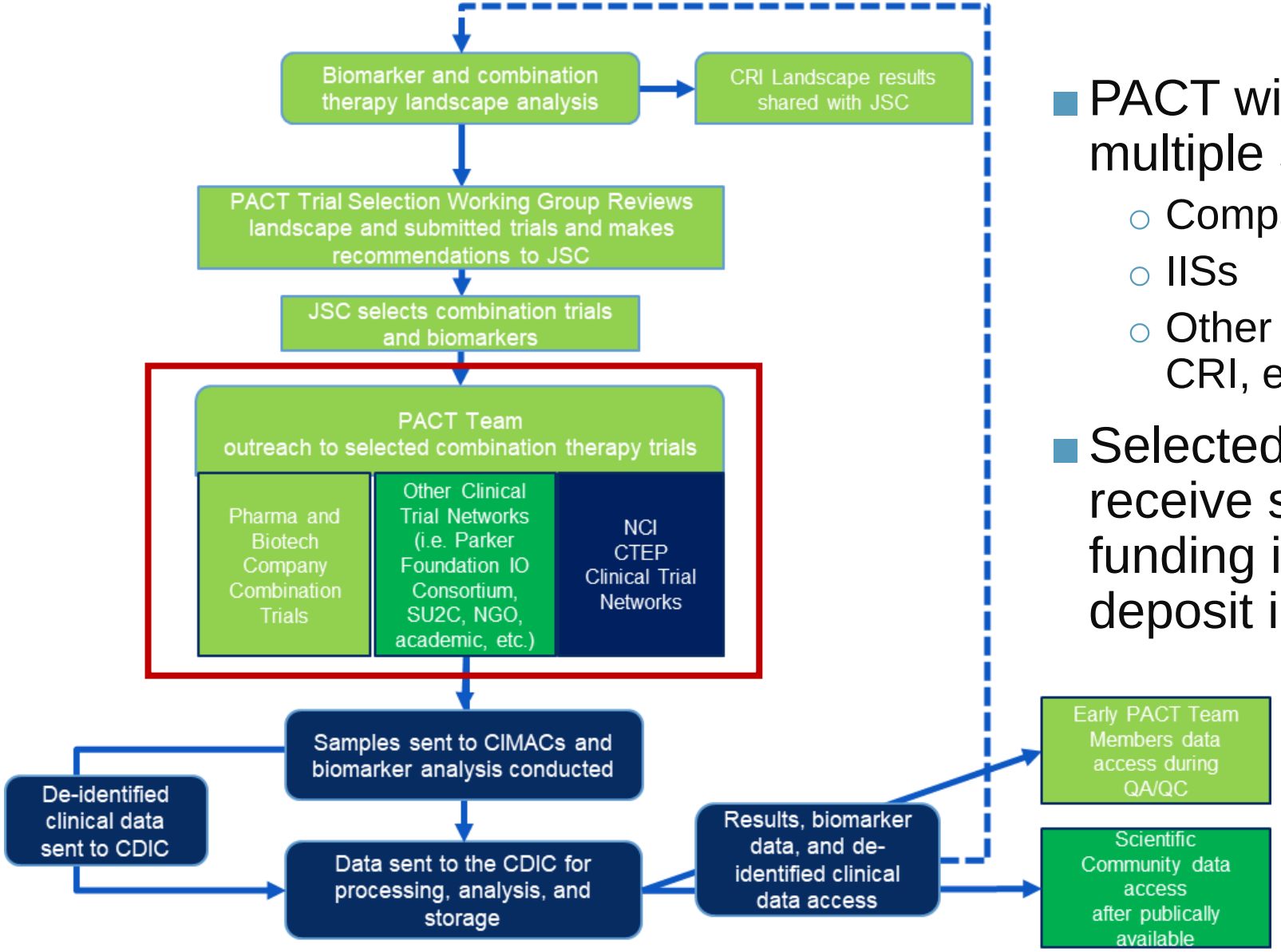
PACT Will Integrate Public and Private Sector Members



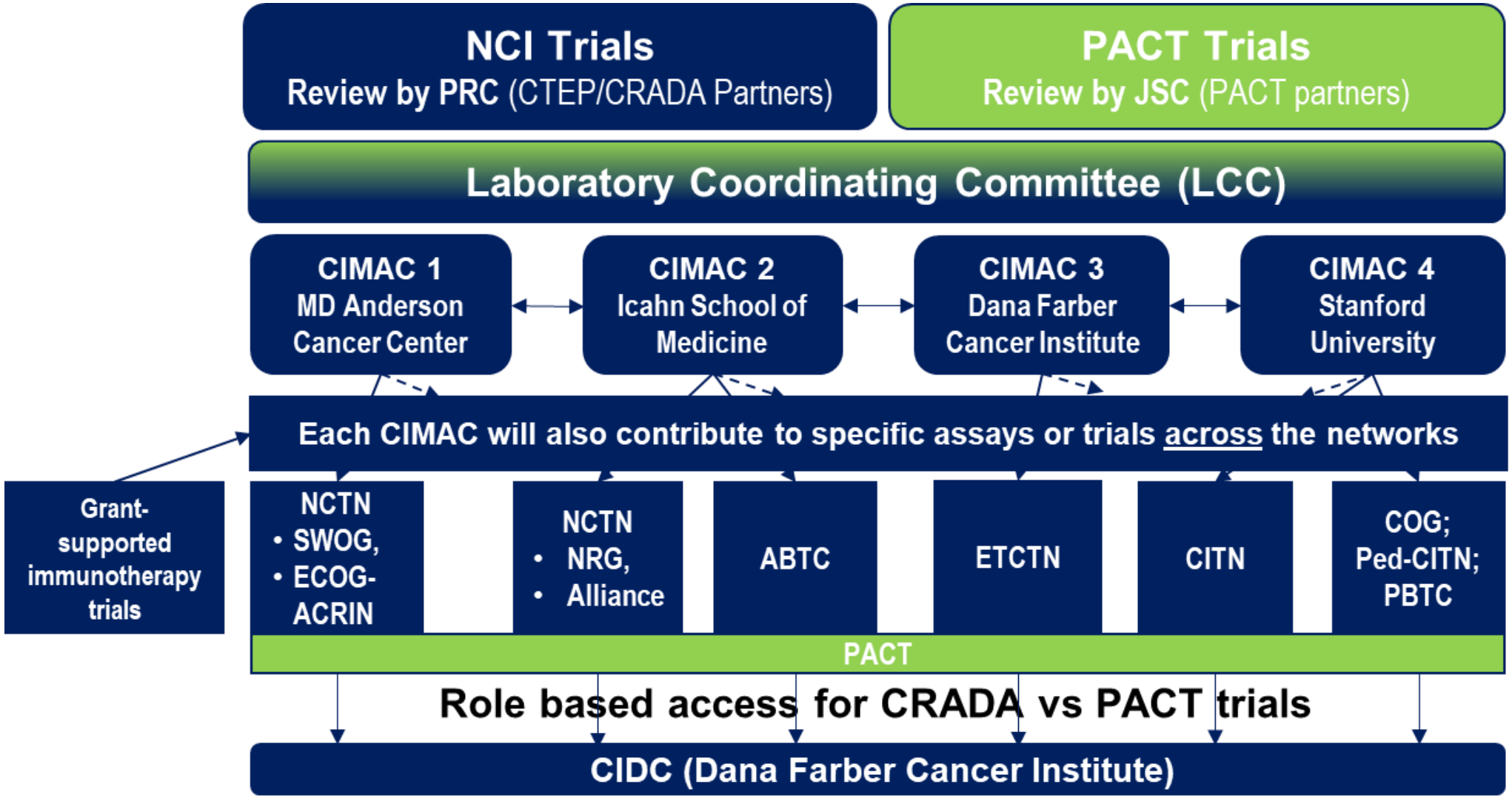
The JSC will select two private sector members to serve on each of the Working Groups based on qualifications of nominees submitted by participating companies.

Trial Recruitment from External Networks Encouraged



- PACT will solicit trials from multiple sources
  - Company trials
  - IISs
  - Other trial networks: SU2C, PICI, CRI, etc.
- Selected for PACT trials will receive supplemental biomarker funding in exchange for data deposit in CIDC

PACT/CIMAC/CIDC Network Structure



PACT Data Sharing Considerations

Tiered Data Access Structure

- Trial Investigators and Trial Sponsors
- PACT Partners
- Public

- **Rules for CTEP CRADA Trials –** need to be consistent with CRADA agreement
- **Rules for PACT-specific trials –** will adhere to both pre-existing trial and network agreements and PACT Policies for IP and data sharing

ALL BIOMARKER DATA AND REQUIRED DE-IDENTIFIED CLINICAL DATA WILL BE MADE PUBLIC IN THE CIDC WHEN AGREEMENTS ALLOW.

PACT Data Sharing Challenges and Potential Solutions

- Speed of trial recruitment to match desired target goals
  - *Outreach to partners and other collaborators to spur interest*
- Patient consent for each trial – retrospective and prospective
  - *Provide minimum criteria to screen past trials and include in new trials*
- Potential international regulatory approval
  - *Still considering solutions*
- Standardization to a common clinical data standard (CDISC)
  - *Work with NCI and CIDC to establish a common data model*
- Pre-existing and newly generate Intellectual Property (IP)
  - *Use pre-established IP guidelines for all partners and participants*

Accelerating Medicines Partnership (AMP)
Data Sharing Examples

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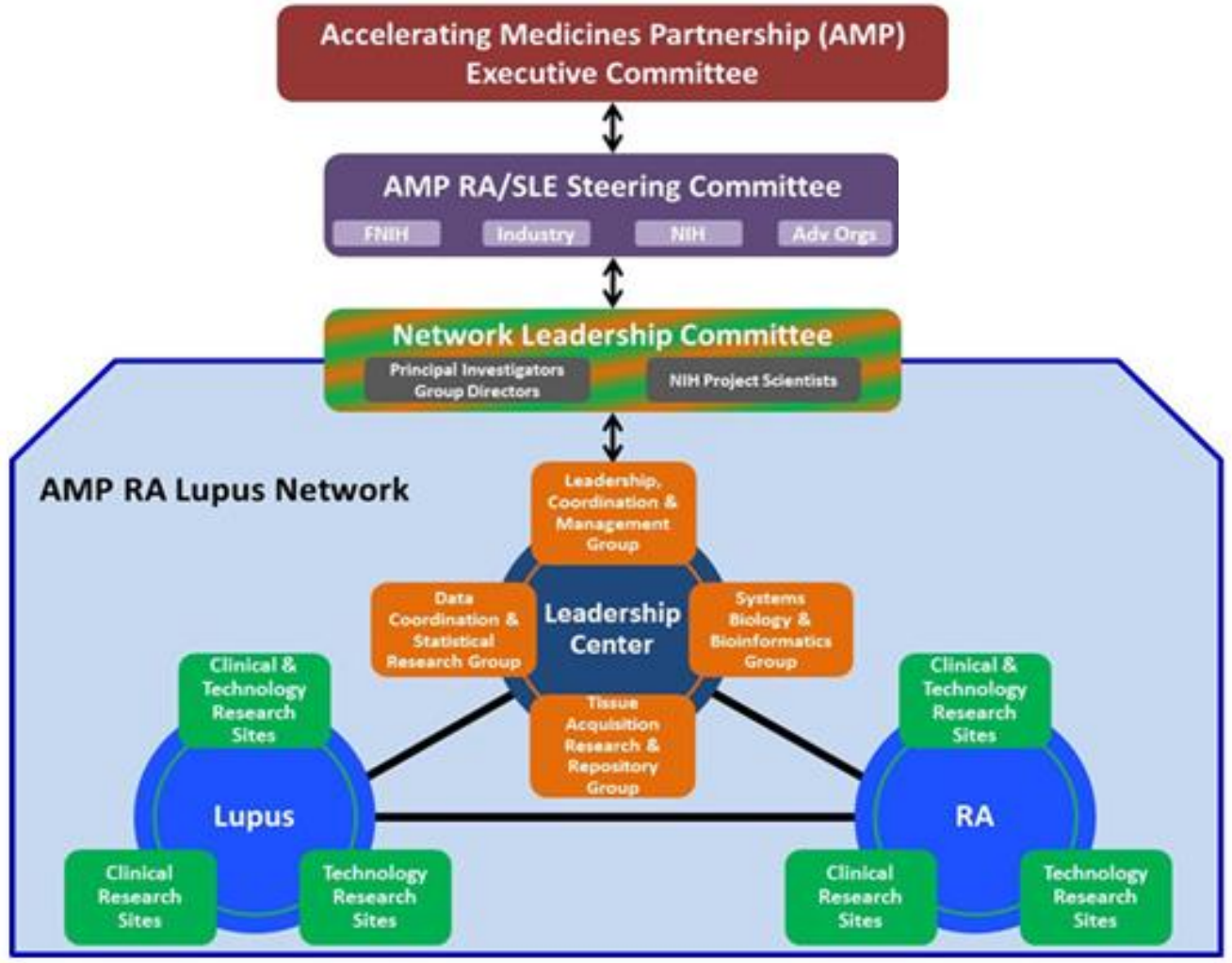
General AMP Data Sharing Principles and Project Structure

General AMP Data Sharing Principles

- Findings shared broadly and quickly
- Partnership participants have access to findings data quality control (up to 6 months of QA/QC).
- Protection of confidentiality may require limitations on sharing of raw genomic sequence, including raw RNA-seq data



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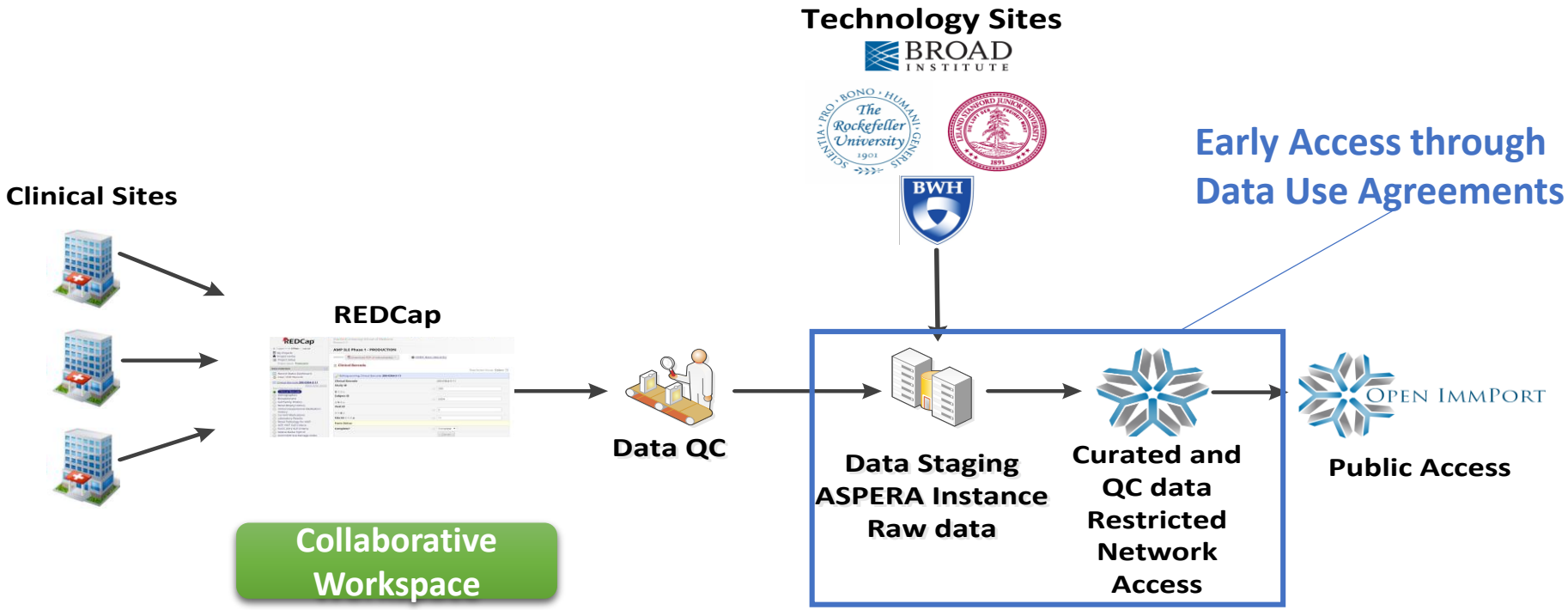
AMP Rheumatoid Arthritis/Systemic Lupus Erthymatosus (RA/SLE)

Key Aspects of Data Sharing in AMP-RA/SLE

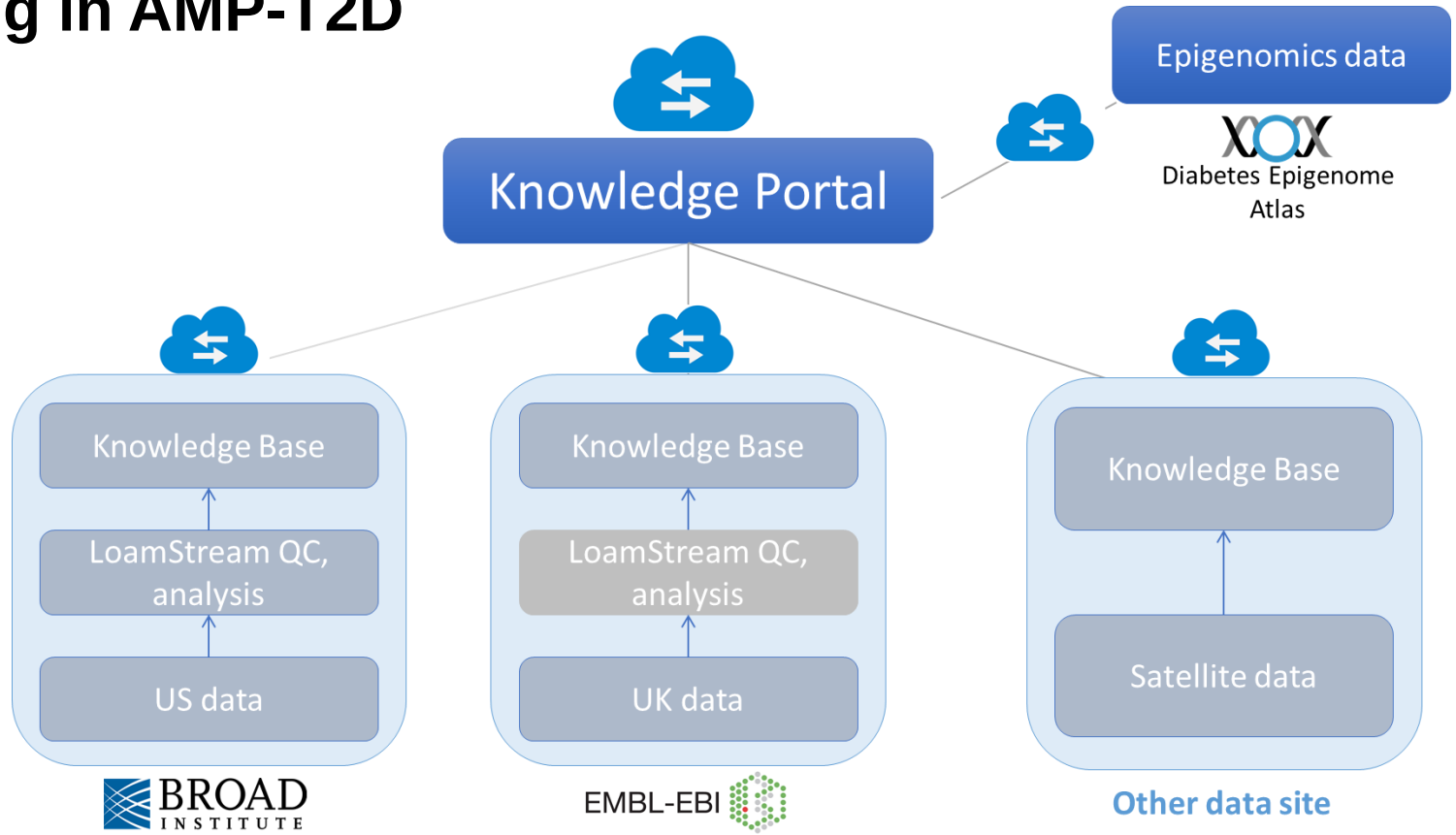
- Data management system & repository for patient phenotype/ demographics plus analytic data
- ImmPort not built for genetics or for pathway analysis/demonstration
- Government hosted at NIAID
- Freely available to research community



AMP Type 2 Diabetes (T2D)

Key Aspects of Data Sharing in AMP-T2D

- Data obtained from institutions in multiple countries
- Example of data that must be retained at site of origin
  - Data federation
  - Mirrored pipelines

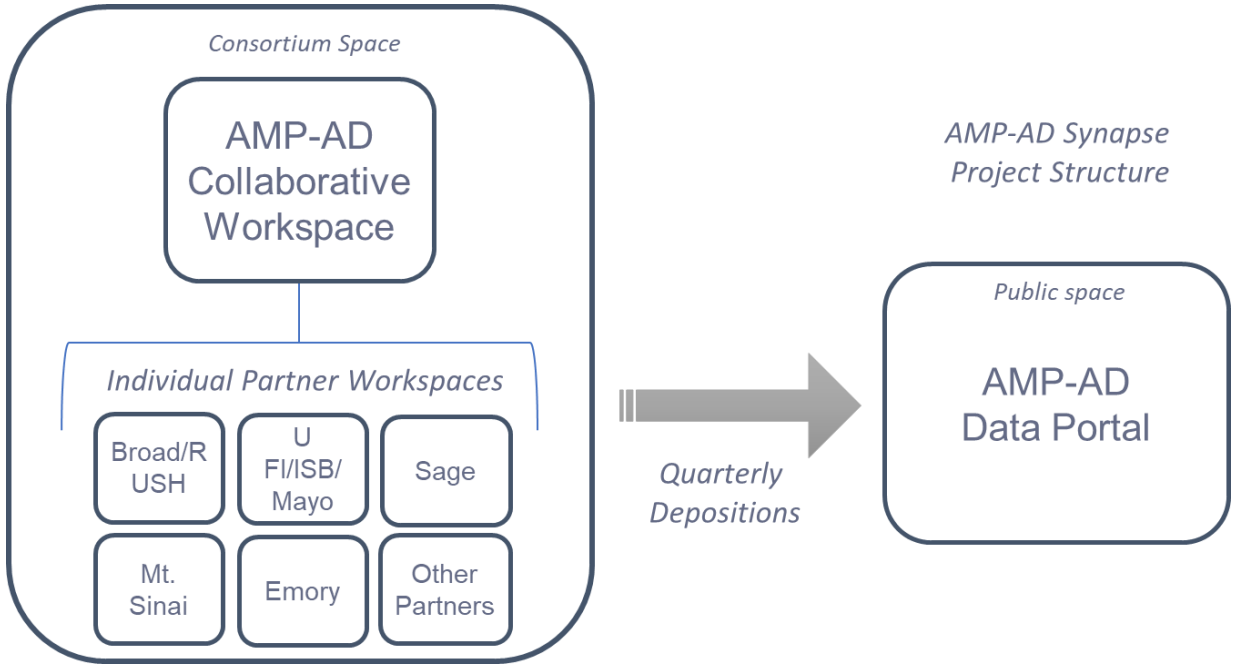


AMP Alzheimer's Disease (AD)

Key Aspects of Data Sharing in AMP-AD

Data Use Conditions on sharing of human data determined by each institution based on study consent and IRB determination

- Open Access
- Controlled Access - Individual user agreement
- Controlled Access - Institutional agreement



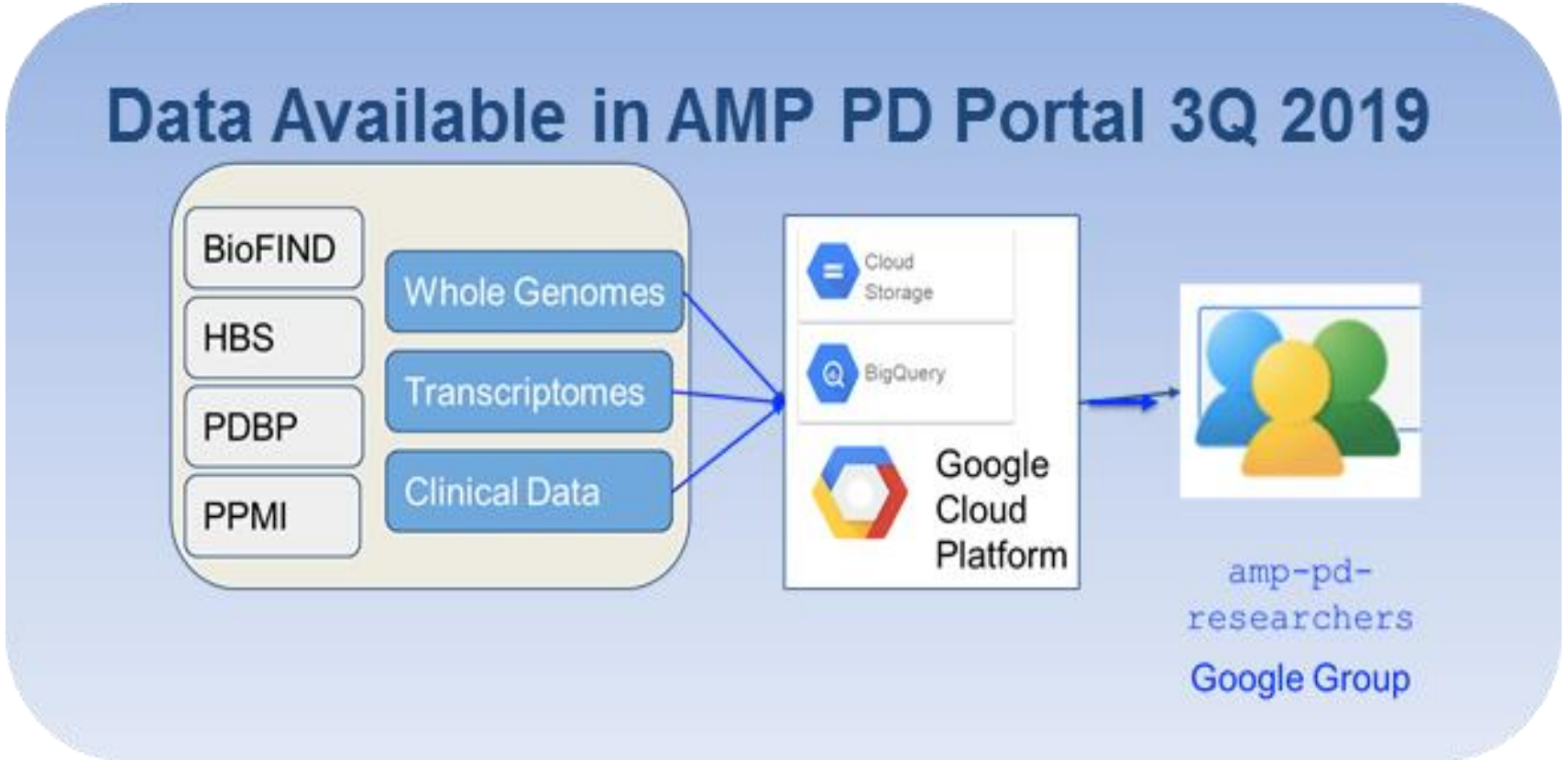
AMP AD Knowledge Portal: https://www.synapse.org/#!Synapse:syn2580853

Partner	Data Source	Data Use Condition
Mt. Sinai	MS Brian Bank	Open
Broad/Rush	ROS/MAP	Controlled – Institutional Agreement Required
UF/Mayo/ISB	Mouse Human	Open Controlled – Individual Agreement Required
Emory	ACT BLSA ROS/MAP	*In IRB Review* Controlled – Individual Agreement Required Controlled – Institutional Agreement Required

AMP Parkinson's Disease (PD)

Key Aspects of Data Sharing in AMP-PD

- Part of NIH Data Commons pilot
- Unique Google Cloud Infrastructure and Governance
- Working with a private sector data storage, curation, and analytics partner (Verily)
- Generating a biobank sample repository from which researchers apply for samples
- Full partnership with another large non-profit



AMP PD Knowledge Portal

The Biomarkers Consortium Data Sharing Example

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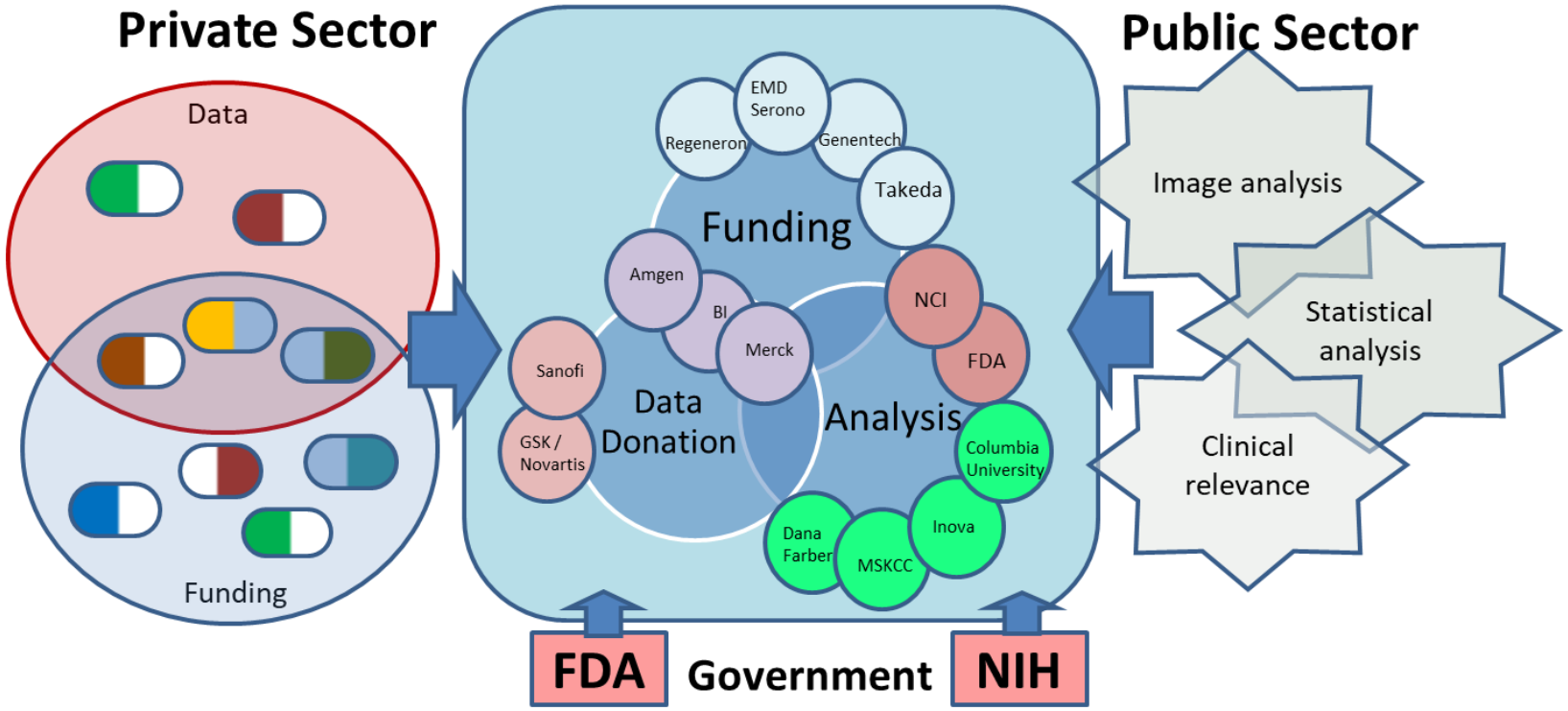
Advanced Metrics and Modeling with Volumetric CT for Precision Analysis of Clinical Trial results (Vol-PACT)

Goal: Assess which quantitative metrics for phase II trial analysis most accurately and reliably predict phase III results across multiple treatment regimens and cancer types.



Key Objectives:

- Study different characteristics of objective progression and their association with improved OS.
- Validation of immune-RECIST (iRECIST), and development of alternate iRECIST metrics, for prediction of clinical outcomes.
- Comparison of tumor measurements derived from case report forms (CRFs) with those derived directly from imaging for accurate description of response and progression kinetics

Summary of FNIH PPP Data Sharing

- Multiple examples of successful data sharing models
- Neutral third party broker and central hub for contracting agreements
- Needs of each PPP drive the type of data sharing model
- Necessary stakeholders are recruited to ensure success
- Public release of data is a mandate, but can be structured to incentivize participation by all stakeholders
- Encourage fast sharing of data

FNIH has many examples of successful data sharing models. But, the true key for current and future PPPs is the flexibility to allow the needs of partnership to dictate the model.

BACK-UP SLIDES

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PACT IP Policy – Tackling One Important Data Sharing Challenge

- PACT partners/participants:
  - Are not obligated to contribute pre-existing intellectual IP.
  - Can contribute existing IP but will permit such use, solely for the PACT Project only; no fee will be charged.
  - Will notify FNIH/PACT of pre-existing agreements would restrict free use of PACT de-identified data sets and PACT research results in the CIDC.
  - Can file patent application(s) on a PACT Invention, but must grant the PACT partners and CIMAC-CIDC grantees royalty free, non-exclusive license.
- The permitted access and use of data and research results are governed under the full PACT Data Use and Sharing Policies.
- Pre-existing CRADA and/or collaborative agreements for use of trial data will supersede this PACT IP Policy for the use of non-PACT funded data.

NOTE: These are just highlights of the full policy

Advanced Metrics and Modeling with Volumetric CT for Precision Analysis of Clinical Trial results (Vol-PACT)

- **PIs:** Geoff Oxnard, MD; Lawrence Schwartz, MD; Mithat Gonen, PhD; Michael Maitland, MD, PhD
- **Goal:** Assess which quantitative metrics for phase II trial analysis most accurately and reliably predict phase III results across multiple treatment regimens and cancer types.
- **Key Objectives:**
  - Study different characteristics of objective progression and their association with improved overall survival, towards the development of improved criteria for progression.
  - Validation of immune-RECIST (iRECIST), and development of alternate iRECIST metrics, for prediction of clinical outcomes in patients with advanced cancer receiving immune therapy.
  - Comparison of tumor measurements derived from case report forms (CRFs) with those derived directly from imaging for accurate description of response and progression kinetics in patients receiving immune therapies.
- **Funders:** Amgen, Inc., Boehringer Ingelheim, EMD Serono, Genentech, Inc., Merck Sharp & Dohme Corp., Regeneron Pharmaceuticals, Inc., Takeda Pharmaceuticals International, Inc.
- **Data Donors**: Amgen, Inc., Boehringer Ingelheim, Merck Sharp & Dohme Corp., Novartis Pharmaceuticals Corporation, Sanofi (With more companies reviewing data sharing agreements)
- **Additional Partners**: FDA, NCI

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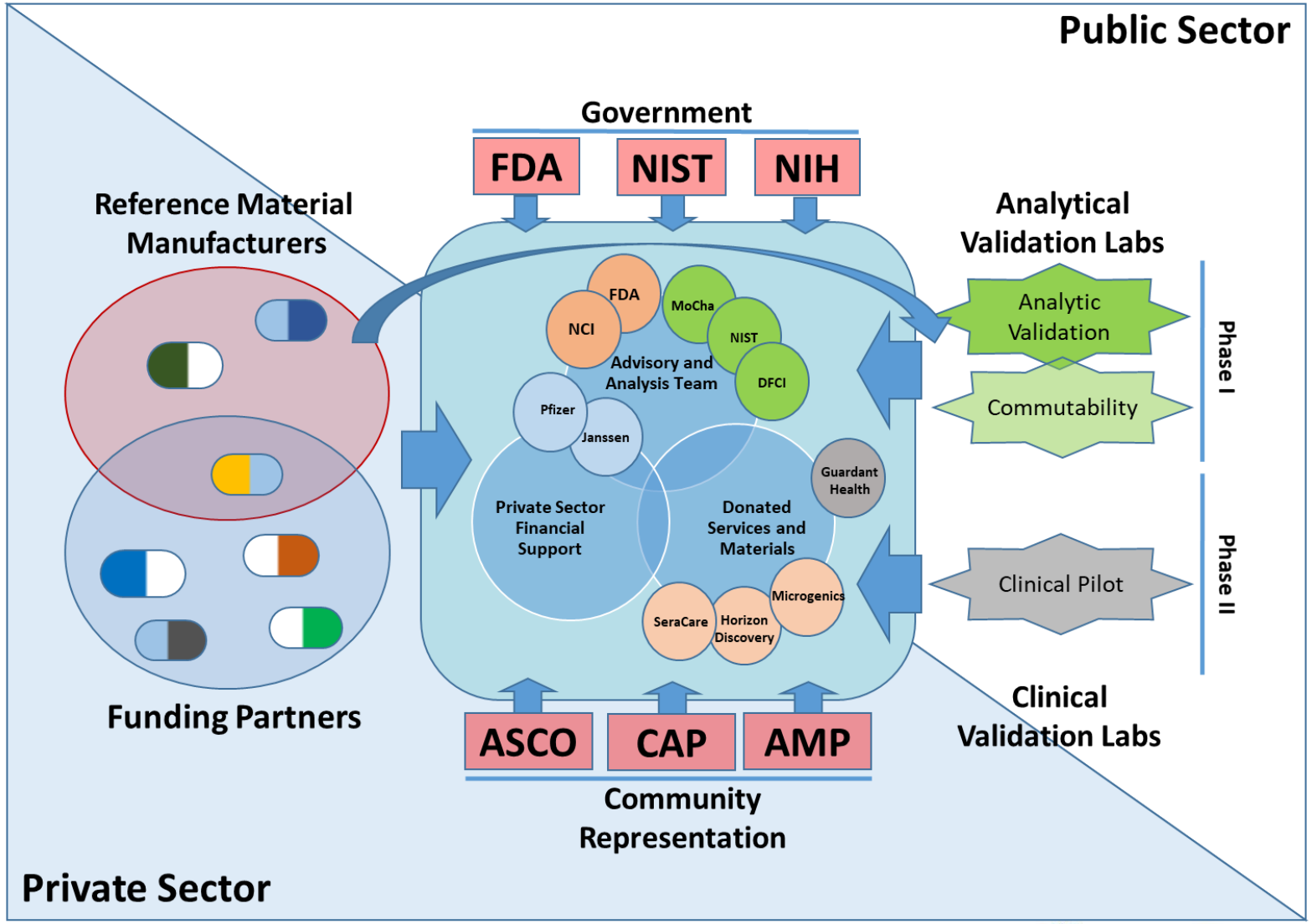
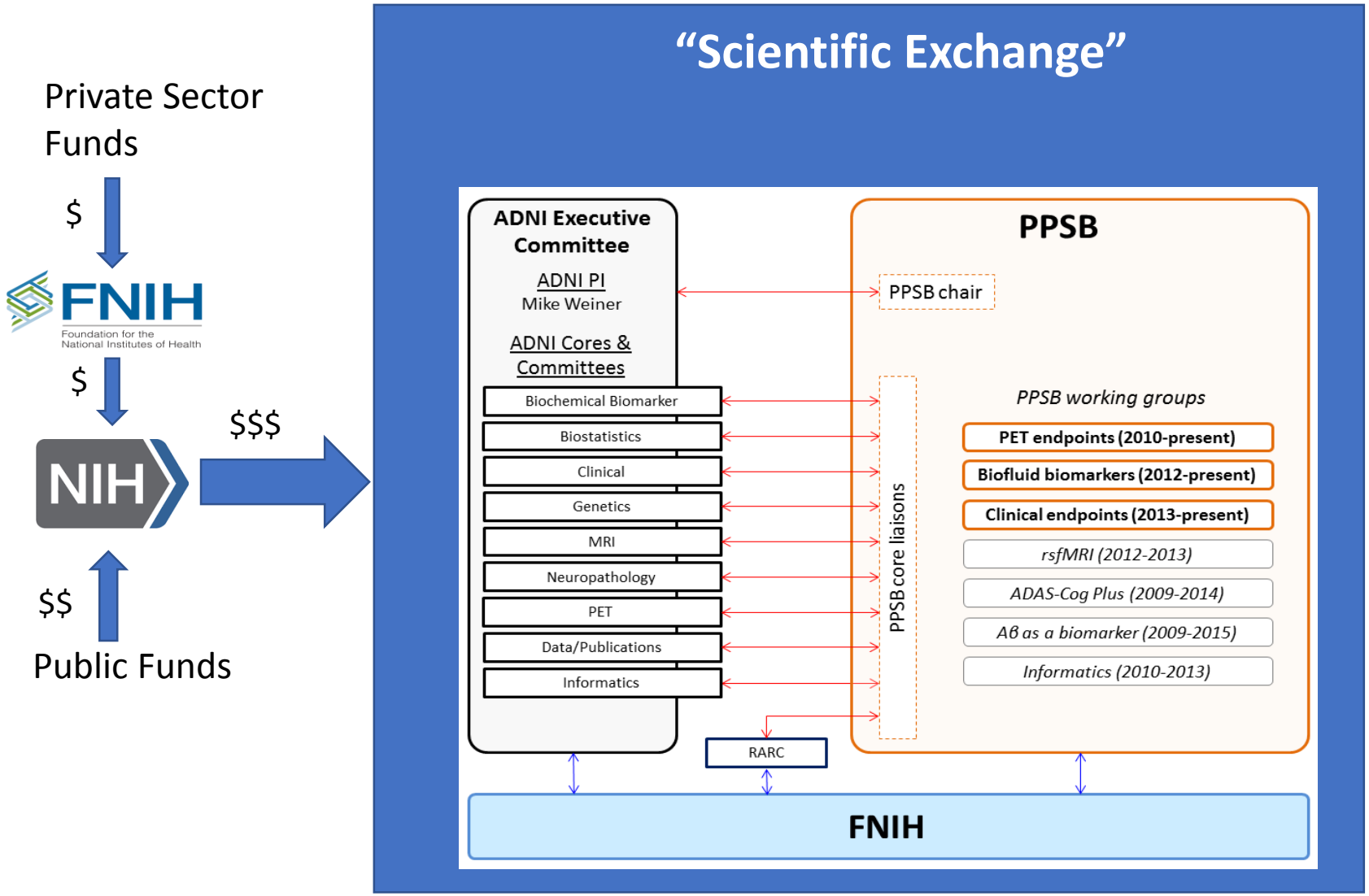
Developing an Analytically and Clinically Validated Reference Material for ctDNA Testing (ctDNA)

- **PIs:** Bob McCormack, PhD; Mickey Williams, PhD; Ken Cole, PhD; Geoff Oxnard, MD; Carl Barrett, PhD
- **Goal:** Enable the production of reference materials in partnership with commercial manufacturers that can be used to establish the analytical validation and accurate interpretation of clinical assays for widespread use in liquid biopsy testing.
- **Key Objectives:**
  - Define key parameters/requirements for the reference material and intended uses
  - Develop analytical validation studies with commercial control companies as they develop and assemble final working reference materials
  - Perform a Clinical Pilot study in Phase II of the project
  - Orchestrate, manage and submit publications on developing ctDNA reference material
- **Funders:** Janssen, Genentech, Pfizer, Merck
- **In-Kind Donors:** SeraCare, Horizon Discovery, ThermoFisher, Fredrick National Laboratory

ctDNA Reference Material Creation Project Team



ADNI Governance and Resource allocation committee (biospecimens)



Arrows indicate direct communication points

PPSB: Private Partner Scientific Board

RARC: Resource Allocation Review Committee

RARC has the decision power to allocate bospecimens from this important longitudinal study in AD

Liu E et al. (2015) ***Alz & Dem***