

Cancer Immune Monitoring and Analysis Centers
& Cancer Immunologic Data Commons

The CIMAC-CIDC Network

OVERVIEW

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CIMAC-CIDC Network

OVERALL Goals and Structure

- CIMAC-CIDC Network is a pre-funded, standing laboratory and database resource to support correlative studies in early phase clinical trials involving immunotherapy
- Our goal: to help individual trials maximize its translational potential and to enhance the collective power of correlative studies across the NCI trial networks and funded programs
- Four (4) CIMACs and one CIDC are funded as U24 Cooperative Agreements
 - CIMACs provide assays and data analysis from biospecimens from NCI-funded immunotherapy trials
 - CIDC provides overall data integration platform to serve the network and eventually the larger IO research community

The CIMAC-CIDC Network

CIMACs

1. The University of Texas MD Anderson Cancer Center

PIs: Ignacio Wistuba and Chantale Bernatchez

2. Icahn School of Medicine at Mount Sinai

PI: Sacha Gnajatic

3. Dana-Farber Cancer Institute

PIs: Catherine Wu and F. Stephen Hodi

4. Stanford University

PIs: Holden Maecker and Sean Bendall

CIDC

Dana-Farber Cancer Institute

PIs: Xiaole Shirley Liu and Ethan Cerami

NCI Staff

Cancer Diagnostic Program:

- Magdalena Thurin (Program Director)

CTEP:

- Helen Chen
- Elad Sharon
- Howard Streicher
- Bill Merritt (CITN)
- Minkyung Song (Grant-supported trials)

CBIIT:

- David Patton

BRP:

- Yingdong Zhao
- Laura Yee

TRP:

- Andrew Hruszkewycz (SPORE grants)

Jeff Abrams, DCTD Associate Director, CTEP

Administrative Support:

- Rebecca Enos
- Melissa Bowman

Scope of Work

- Each **CIMAC** is a multidisciplinary team (oncologists, pathologists, lab scientists, bioinformaticians, statisticians).
- In conjunction with **CIDC**, will provide assays AND analysis for immune biomarkers (including genomic, phenotypic and functional characterization) using state-of-the-art, consistent methodologies.
- **All CIMACS will work as a network to collaborate on trials**
 - **Eligible trials** - Early (Phase 1 and Phase 2) immunotherapy trials
 - **CTEP Trial Networks** (NCTN, ETCTN, CITN, ABTC, PBTC)
 - **NCI Grant-supported trials** (eg. P01, R01, SPORE grants)
 - **600 patient-timepoint/year for comprehensive profiling**
 - More patients if not all assays are feasible with available tissues
 - **Can expand with supplemental funding** (e.g. **PACT** or other resources)

Partnership for Accelerating Cancer Therapies (PACT)

Press release - October 12, 2017 . NIH partners with 11 leading biopharmaceutical companies to accelerate the development of new cancer immunotherapy strategies for more patients

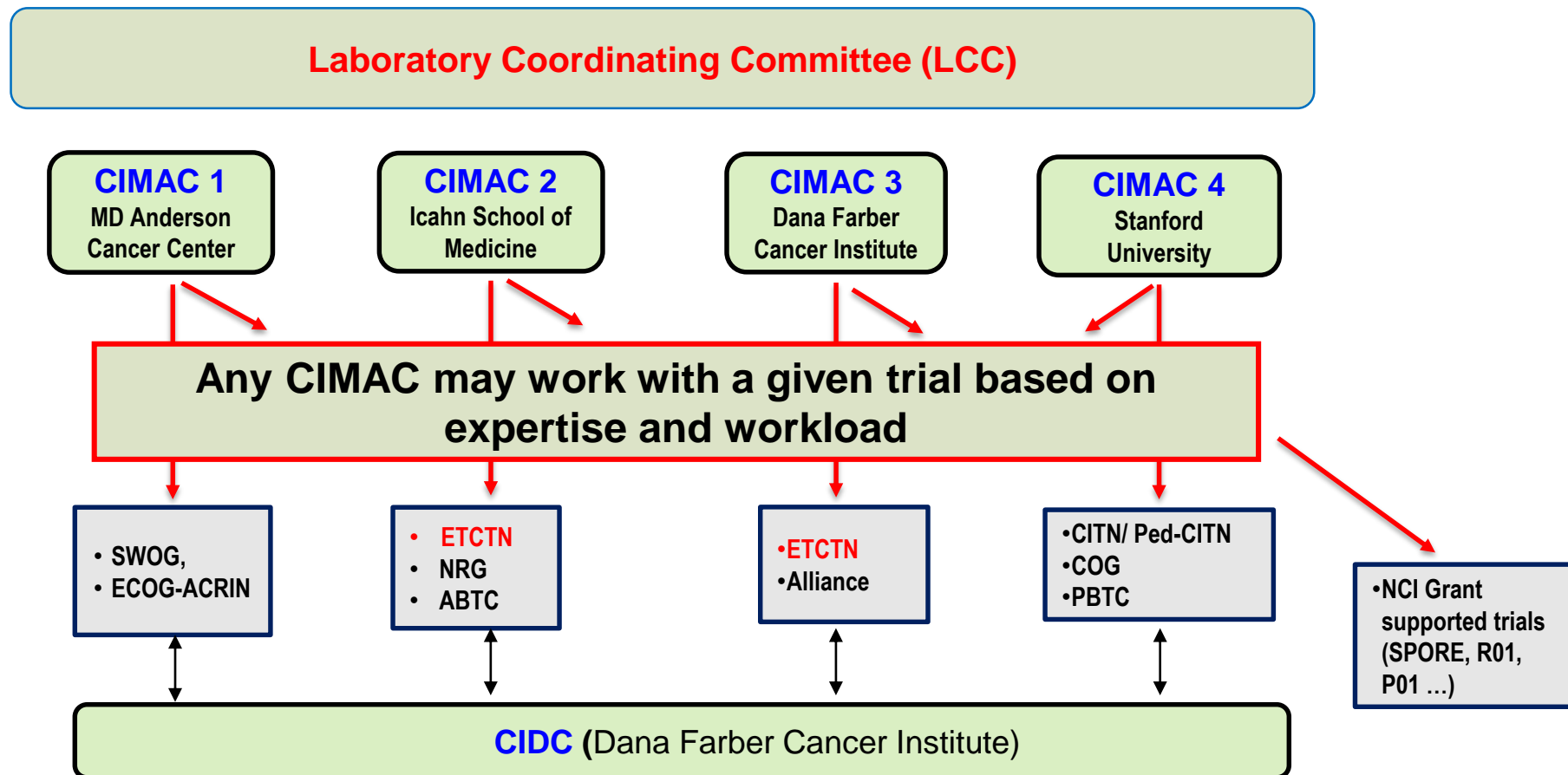


FNIH

Foundation for the
National Institutes of Health

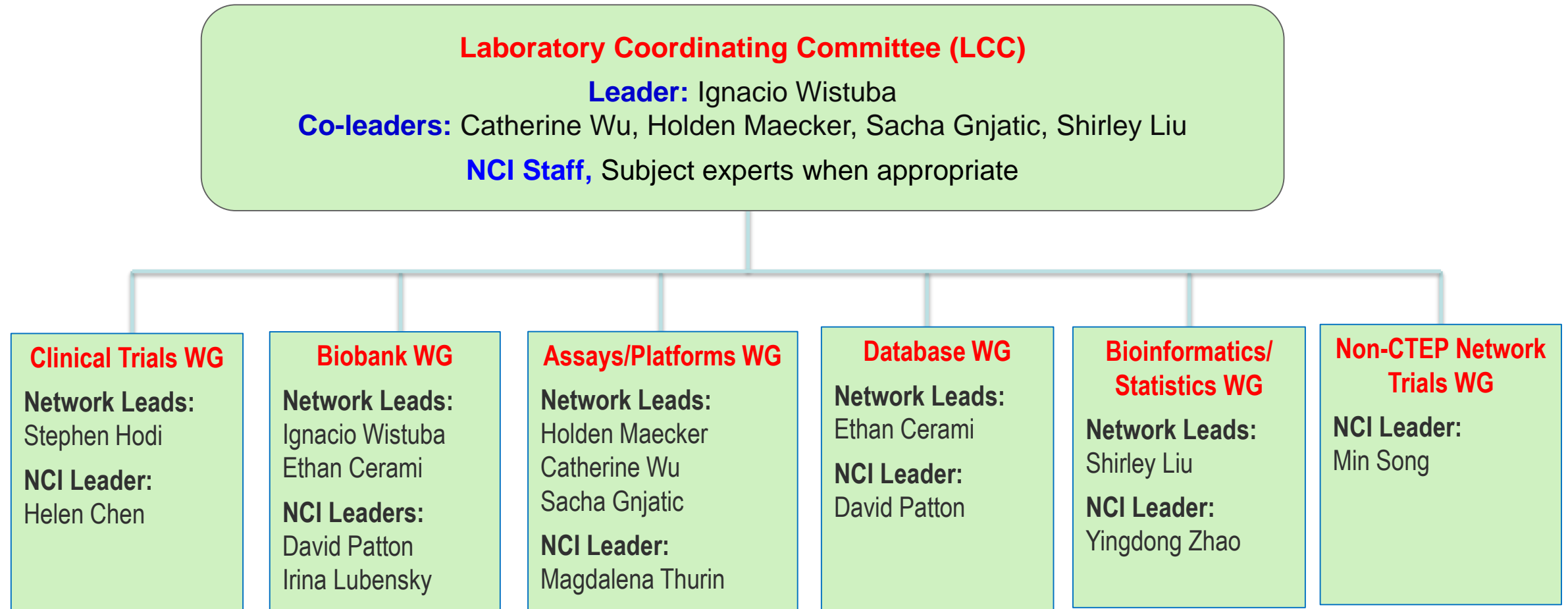


CIMACs-CIDC Network Structure



- **ALL CIMACs can work with any trial networks, depending on specific needs, expertise and work load**
- **Each CIMAC will be in a Primary Alignment with 1-2 trial Networks** – to facilitate scientific planning, Biobank interactions
- **A given CIMAC may perform a specific assay for all trials**

Oversight of CIMAC-CIDC Functions



Assays/Platforms in CIMACs

(Status as of March 2018)

- Blue text = Tier 1 assays
- Black text = Tier 2 assays

Tissue-based Imaging

- Multiplex immunohistochemistry
- Conventional immunohistochemistry
- FISH DNA
- Multiplexed Ion-Beam Imaging (MIBI)

Cell Profiling

- Mass Cytometry (CyTOF)
- High-dimensional flow cytometry
- ELISpot

Cytokines/Serum Analytes

- O-link serum cytokine analysis
- Luminex
- Seromics – ELISA/Grand serology
- MesoScale Discovery

Sequencing

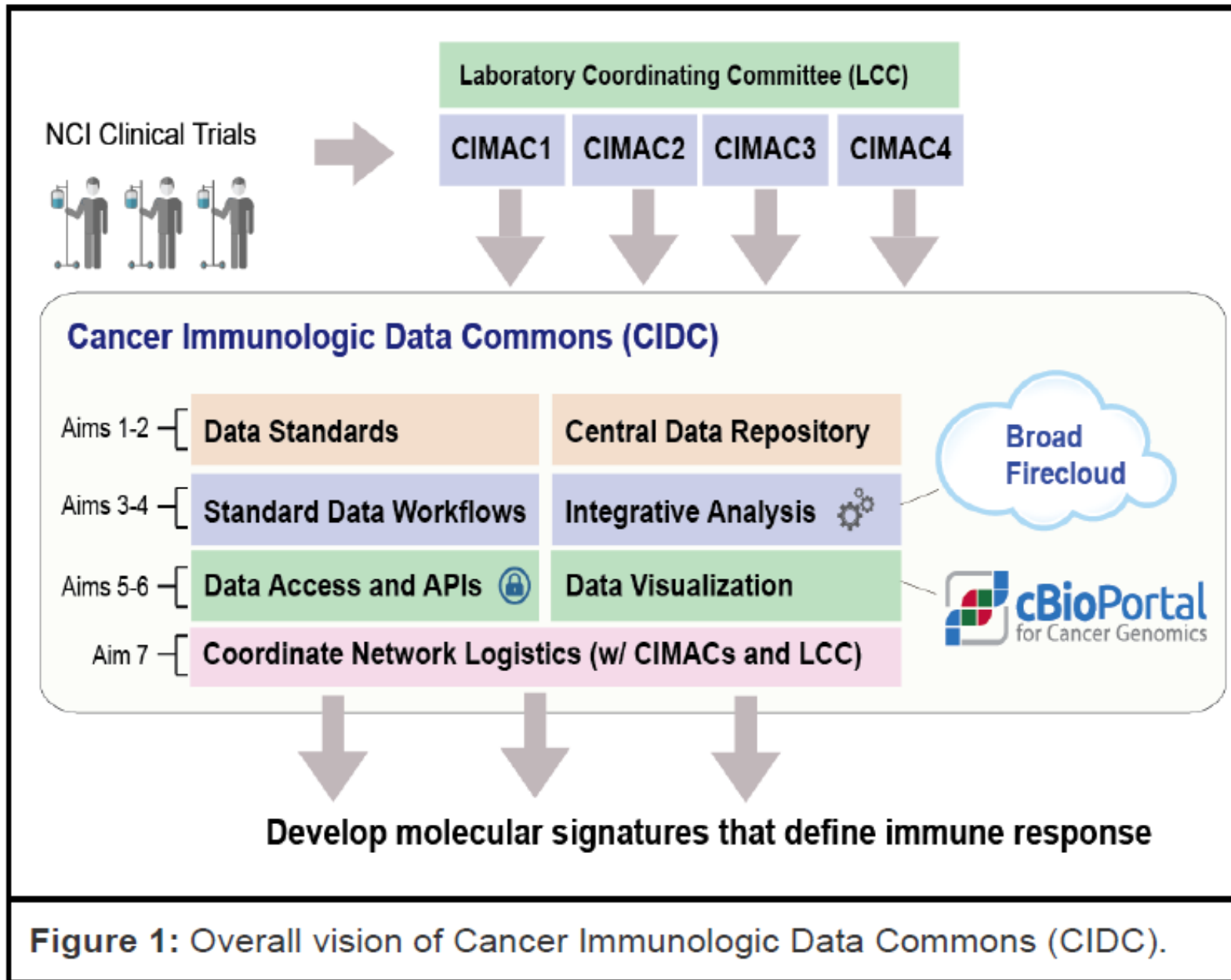
- Whole Exome Sequencing
- RNA-Seq
- NanoString
- TCR/BCR clonality
- Single-cell TCRseq
- HLA-Seq, Epitope prediction
- Cell-free DNA (circulating tumor DNA)
- HTG-EdgeSeq (gene expression)
- Single-cell transcriptome

Other:

- Neoantigen Prediction
- Mass spectrometry epitope detection
- Epigenomics (ATAC-Seq)
- Microbiome (16S Deep Sequencing)
- CRISPR

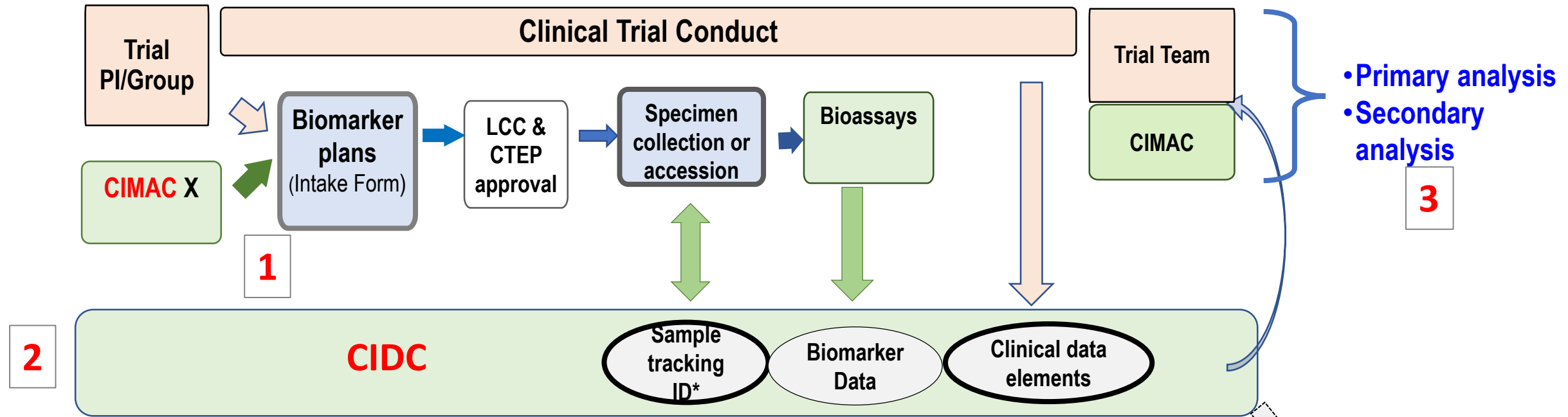
- Assays may be standardized and harmonized across Centers, **or** directed to a select center
- All assays must meet analytical characteristics that are fit for purpose

A. Overall Vision of CIDC



- **Central Data Repository** for CIMAC generated biomarker data, using standardized data format
 - Genomics, transcriptomics, proteomics, flow, IHC etc
- Secure **Informatics Platform** for integration of biomarker data and clinical data
- Role-based, time-controlled **data access** with **web visualization** by **collaborating CIMAC and clinical team...** and in the future, outside community
- **Coordination of all network activities** for biomarker discovery and validation

Work flow for CIMACs/CIDC Studies Linked to Network Clinical Trials



1. **Proposal of Biomarker plans** - to be jointly developed by CIMAC and Clinical trial team → LCC Review/Approval → CTEP approval.

2. **Database at CIDC** - including clinical data elements critical to correlative analysis

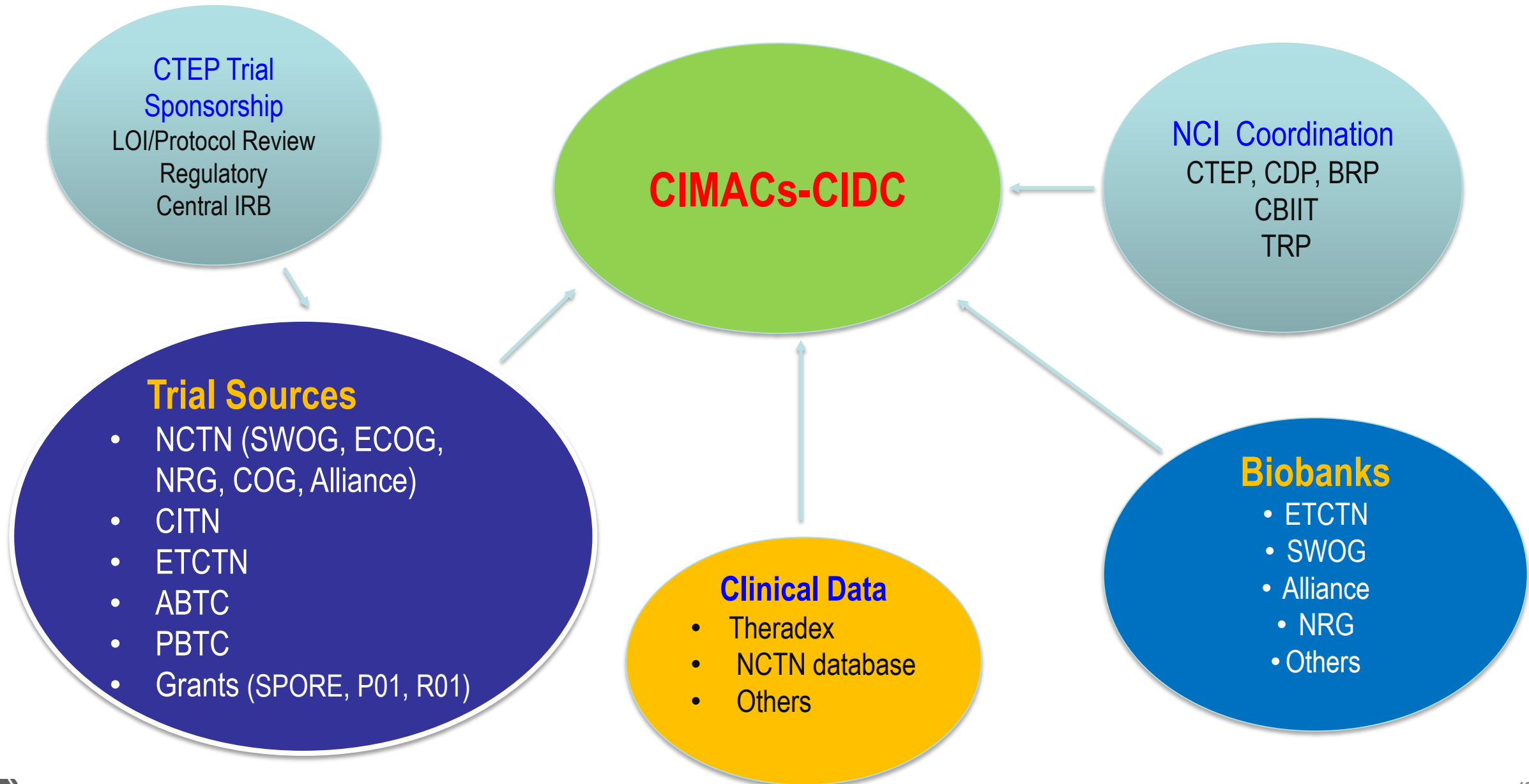
3. **Data analysis and Publication** – data analysis will be done collaboratively between the Trial Team and CIMAC

Controlled release for outside investigators

Current Status

- **Pilot projects** selected to demonstrate the function and optimize the process of CIMAC
- **Harmonization/standardization** for key platforms in progress ... in addition to assay validation documents
- **Database and informatics pipeline** being selected for key platforms
- **Specimen tracking system** across CIMACs and Biobanks and sites
- Various agreements under review (data access, data sharing, MTA, Institutional Certificates, specimen manifest...)

It Takes a Village!





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