

Berkeley

 School of  
Public Health

 **EASL**  
European Association  
for the Study of the Liver



**Forum for  
Collaborative HIV Research**

# **FNIH: NASH Biomarker Consortium**

**Presenter: Roberto Calle  
on behalf of Foundation for the National  
Institutes of Health**

# LIVER FORUM

Development of Non-invasive Biomarkers for  
Non-alcoholic Steatohepatitis (NASH)/Non-  
alcoholic Fatty Liver Disease (NAFLD)

FNIH Biomarkers Consortium

A Public-Private Partnership

Nov 10, 2016

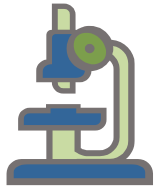
*ROBERTO CALLE, MD*



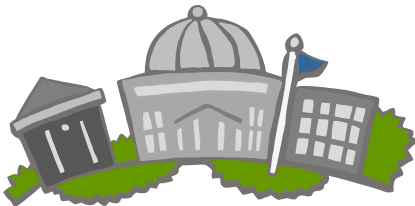
# Snapshot of the Foundation for the National Institutes of Health (FNIH)

## 1996

established by Congress to support NIH in its mission by



advancing biomedical research and training collaborations



among government, universities, industry and not-for-profit organizations



## 501(c)(3)

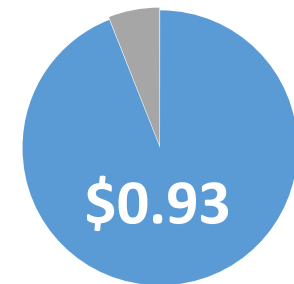
Non-governmental not-for-profit & independent Board of Directors

Over **550** projects supported

**100+** *active* research partnerships, scientific education/training, conferences/events and capital programs

## \$875 million

raised by the FNIH since 1996



**93%** of funds directly support programs

**13 years** of outstanding Charity Navigator ratings

THE biomarkers CONSORTIUM



# Biomarkers Consortium

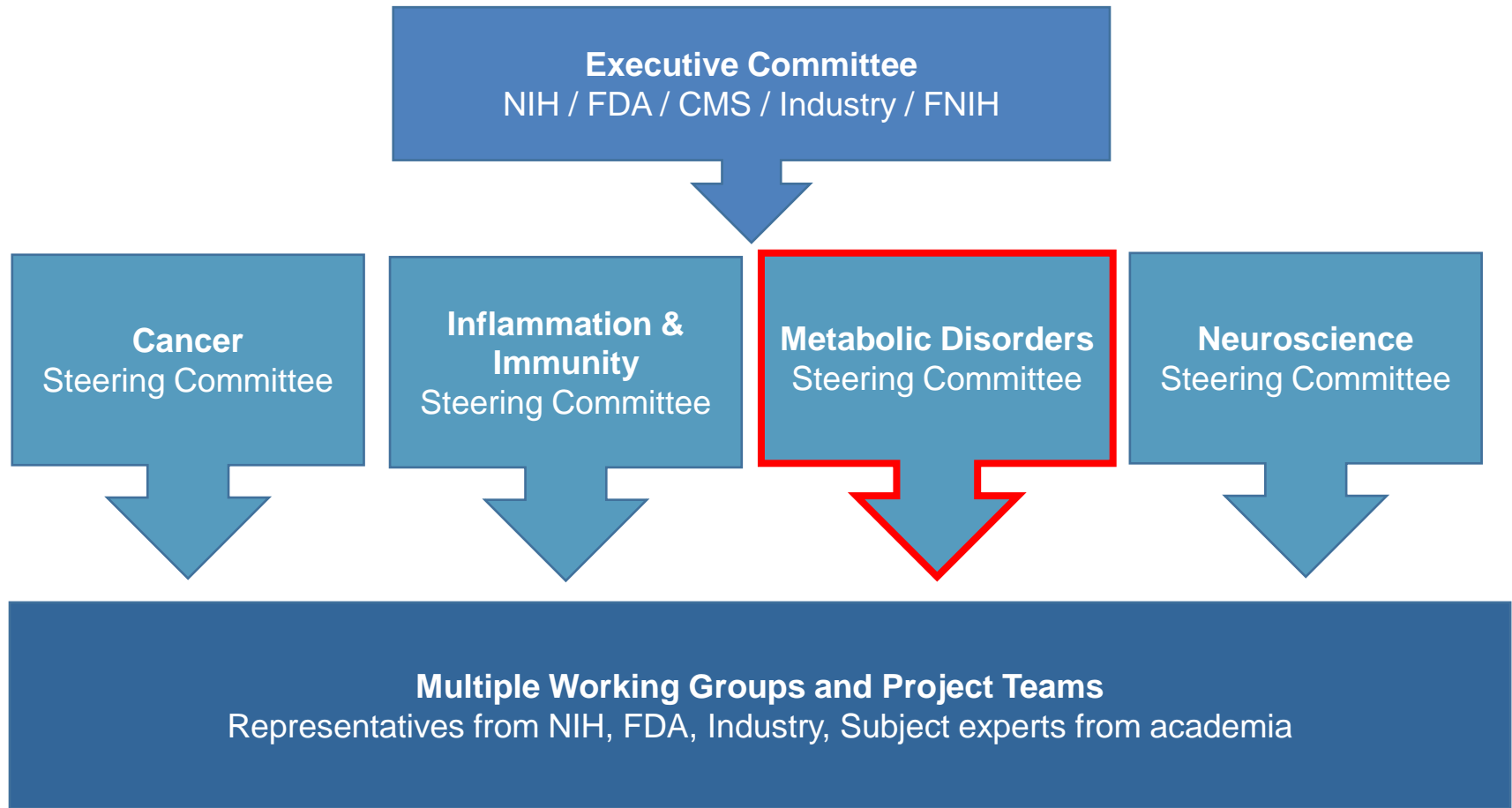
## Mission Statement

To discover, develop, and seek regulatory approval for biomarkers to support and accelerate development of new drugs, preventive medicine, and medical diagnostics by combining the forces of the public and private sectors.

## Biomarkers Consortium 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.
- Generate pre-competitive projects; makes consortium project results broadly available to the entire scientific community
- Raise funds from outside sources who support mission (e.g., private industry)

# Biomarkers Consortium Governance Structure and Accomplishments



## Academic & Industry Co-chairs:

- Myrlene Staten, MD (NIDDK)
- Roberto Calle, MD (Pfizer)

# Overview of Biomarkers Consortium Accomplishments and MDSC Activities

- **FNIH Biomarkers Consortium track record of managing projects, which has directly impacted**
  - Development of 6 drugs
  - Generation of 4 Guidance Documents
  - Over 40 publications with collectively 700+ citations
  
- **Metabolic Disorders Steering Committee Portfolio:**

Completed Projects	Active Projects	Pipeline (in development)
<ul style="list-style-type: none"> <li>• Adiponectin</li> <li>• Carotid MRI Reproducibility</li> <li>• Sarcopenia 1 Consensus Definition</li> </ul>	<ul style="list-style-type: none"> <li>• Atherosclerosis <i>In-Silico</i> Modeling</li> <li>• Beta Cell 1 Clinical Studies</li> <li>• Bone Quality</li> <li>• Cardiac Troponin</li> <li>• Sarcopenia 2 Consensus Definition</li> </ul>	<ul style="list-style-type: none"> <li>• Beta Cell 2 Clinical Studies</li> <li>• Non-alcoholic Steatohepatitis (NASH)</li> </ul>

# The FNIH Biomarker Consortium's NASH Working Group – Leadership Team

## An academic-industry collaborative effort

- **Dr. Arun Sanyal** (Virginia Commonwealth): FNIH NASH Initiative Co-Chair
- **Dr. Sudha Shankar** (Lilly): FNIH NASH Initiative Co-Chair
  
- **Dr. Rohit Loomba** (UCSD): FNIH NASH Circulating Markers Work Stream Co-Chair
- **Dr. Anthony Samir** (MGH-Harvard): FNIH NASH Imaging Work Stream Co-Chair
- **Dr. Claude Sirlin** (UCSD): FNIH NASH Imaging Work Stream Co-Chair
  
- **Dr. Roberto Calle** (Pfizer): FNIH Metabolic Disorders Steering Committee Co-chair and NASH Initiative Sponsor
- **Dr. Sanya Whitaker** (FNIH): FNIH Metabolic Disorders Steering Committee Scientific Program Manager

# Goals & Objectives of this Project

- **To advance qualification of one or more, fit-for-purpose, non-invasive tools, that integrate circulating and quantitative imaging markers:**
  - *Enable confident and accelerated decision-making for early- and late-phase drug development, towards expediting the availability of novel therapies for patients with NAFLD/NASH.*
  - Set the stage for data-driven clinical care of NAFLD/NASH patients once pharmacologic therapies are available.



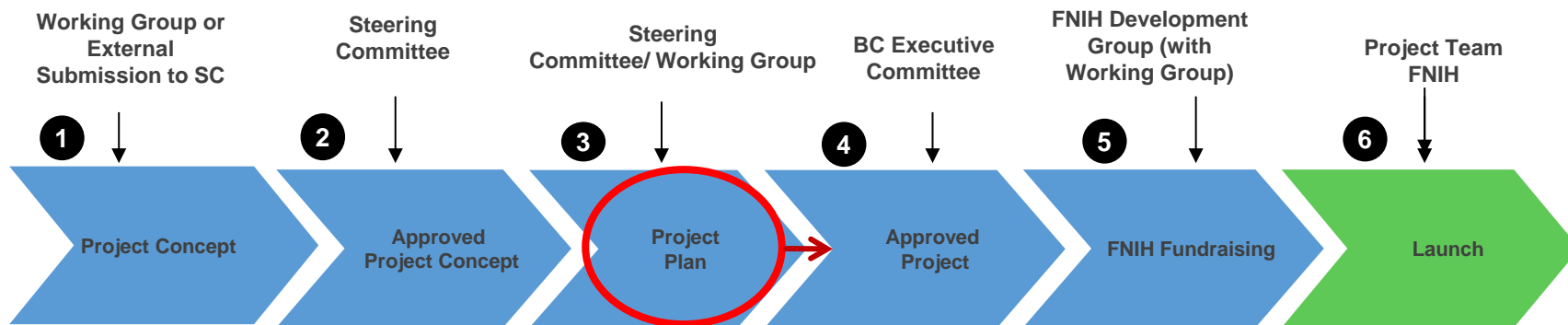
- **Priorities for the FNIH initiative:**

- Biomarker qualification to identify “at risk” subject
- Biomarker to evaluate disease progression versus regression
- Biomarker to evaluate response to treatment



# Ways Organizations Can Partner through FNIH Biomarkers Consortium

- **Working Group stage: welcoming input on design from interested partners**
  - Circulating biomarkers work stream
  - Imaging biomarkers work stream
- **Partners can provide:**
  - In-kind support (e.g., assay platforms, reagents, samples, relevant data sets, instruments) that can be quantified financially
  - Financial support



**Project plans are developed by Project Teams and reviewed by the BC Steering Committees and Executive Committee**

**Projects are launched after funding is secured secured from stakeholders**

# To partner with the FNIH Biomarkers Consortium on the NASH Initiative

- Contact Dr. Sanya Whitaker, Scientific Program Manager – Metabolic Disorders at [swhitaker@fnih.org](mailto:swhitaker@fnih.org)