



Update on the Pediatric Heart Network and How to Get Involved

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National Heart, Lung, and Blood Institute

Keys to Early Career Success in Pediatric Cardiology
American Heart Association Scientific Sessions

November 15, 2014



National Institutes of Health

The NIH is part of the U.S. Department of Health and Human Services (HHS)



Office of the Secretary
DHHS

Administration
for Children
and Families

Administration
on
Aging

**National
Institutes
of Health**

Agency for
Healthcare
Research and
Quality

Agency for
Toxic Substances
and Disease
Registry

Centers for
Disease Control
and Prevention

Centers for
Medicare &
Medicaid
Services

Food and Drug
Administration

Health
Resources
and Services
Administration

Indian
Health
Service

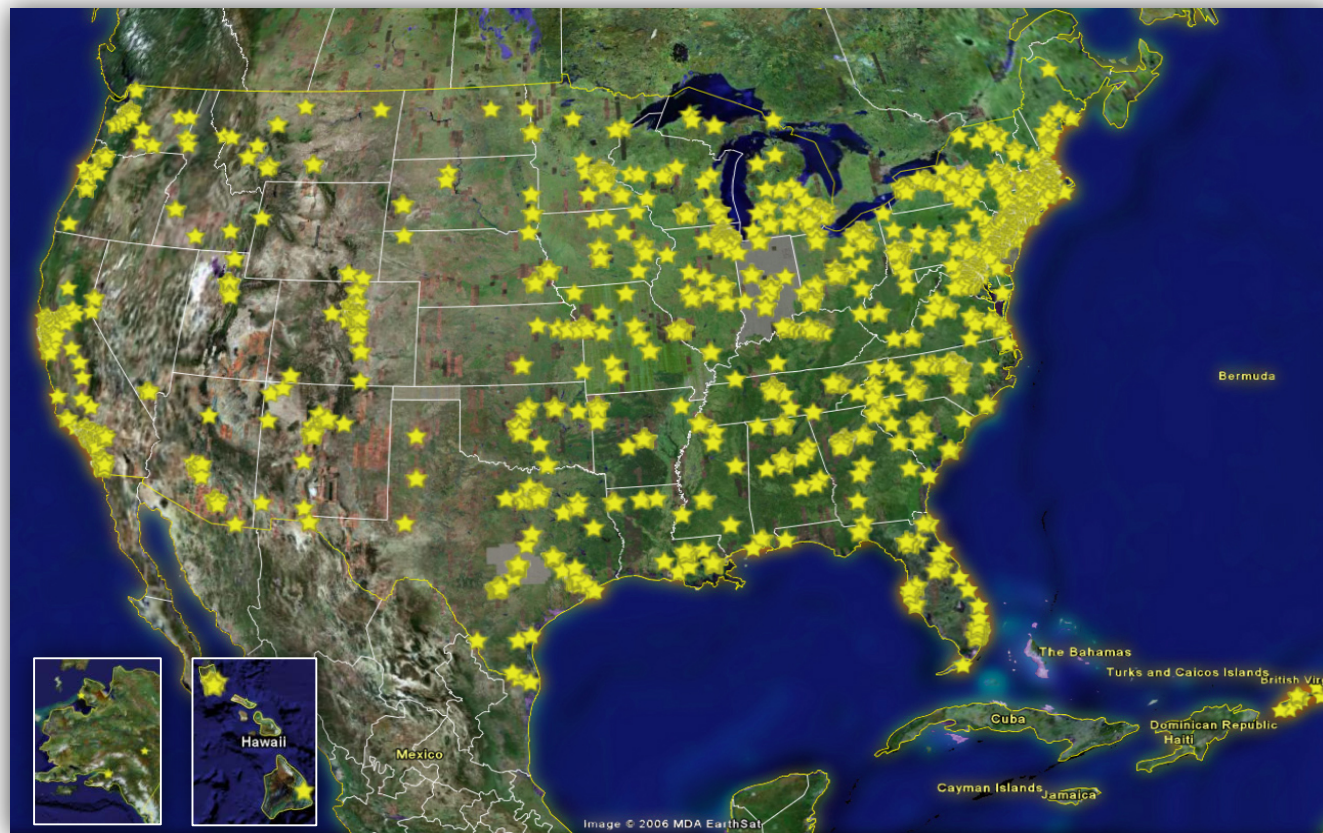
Substance Abuse
and Mental Health
Services
Administration

National Institutes of Health

NIH-funded research uncovers new knowledge that leads to better health for everyone:

- **Conducts research** in its own laboratories
- **Supports research** of non-federal scientists in universities, medical schools, hospitals, and research institutions domestically and abroad
- **Trains** research investigators
- **Fosters communication** of medical information

Most NIH Funds Are Spent Beyond Bethesda

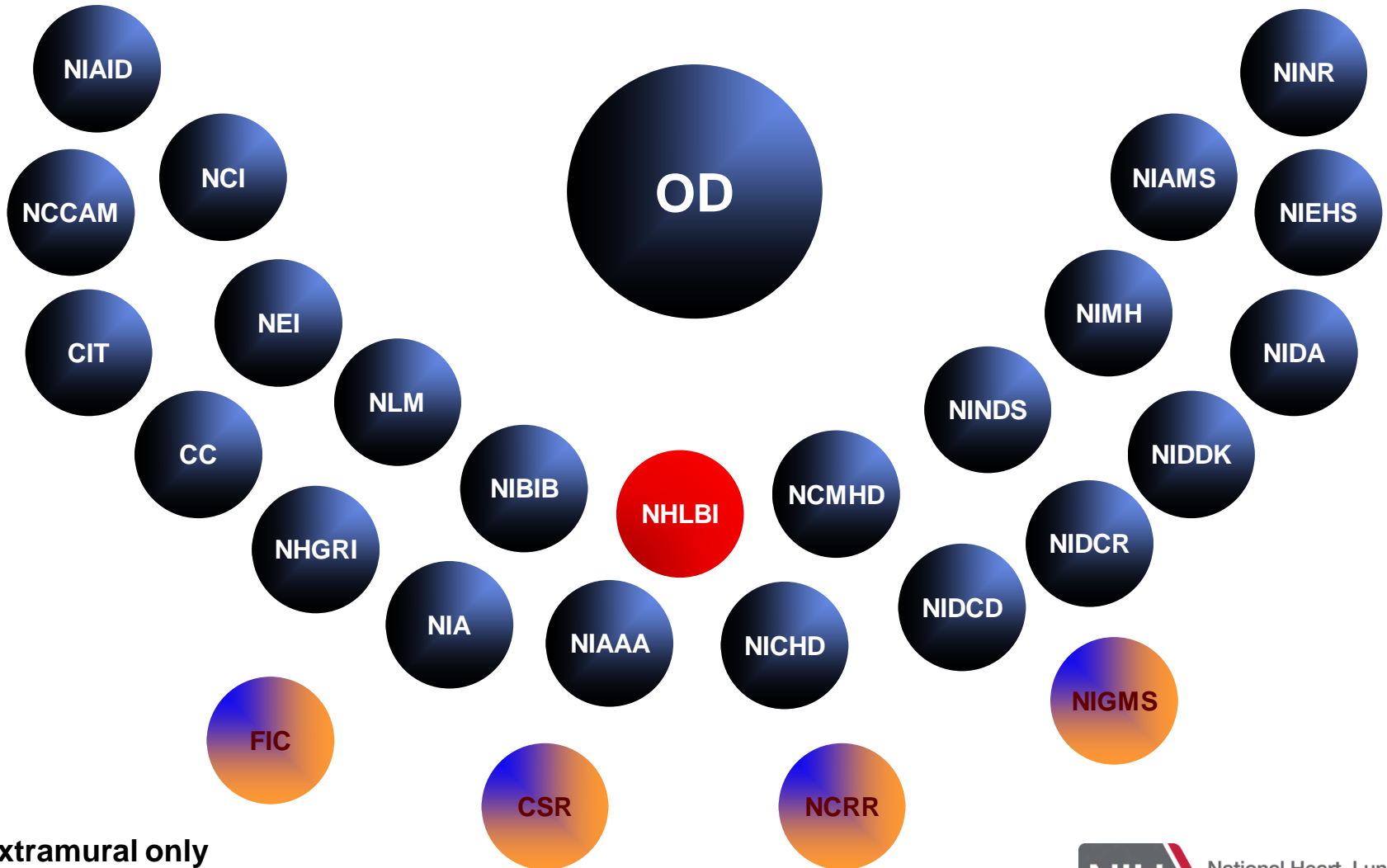


NIH Budget,
FY 2013:
\$29.2 B

At NIH
(intramural):
\$3.2B (11%)

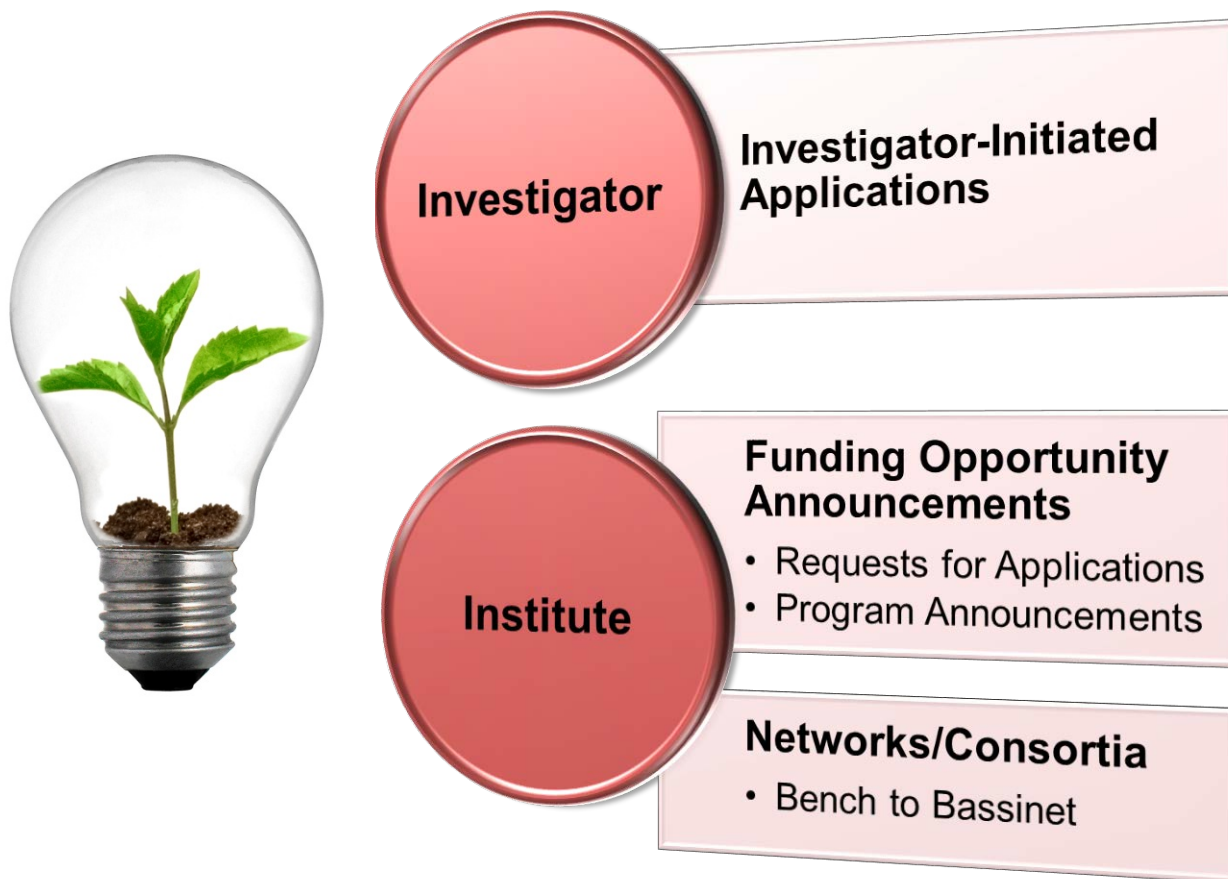
Outside NIH
(extramural):
\$22.8 B (78%)

NIH Structure: 27 Institutes and Centers

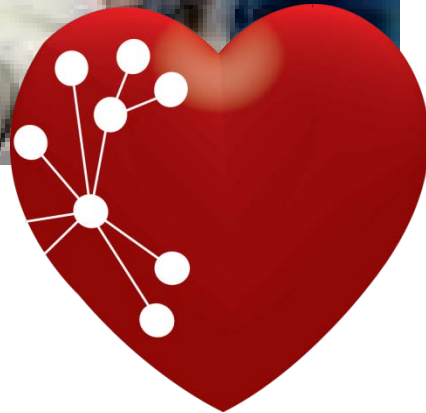
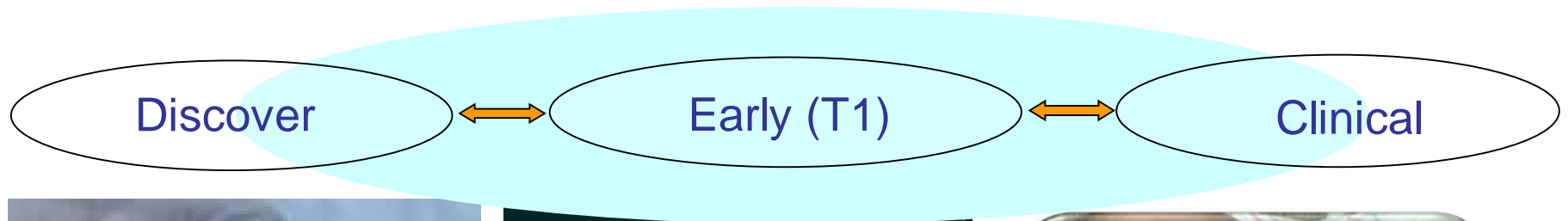


Extramural only

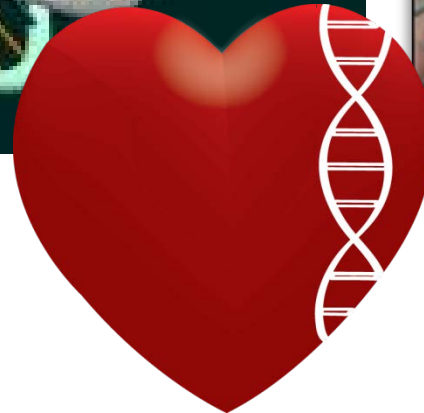
NHLBI Funding Mechanisms



Pediatric Cardiovascular Translational Research



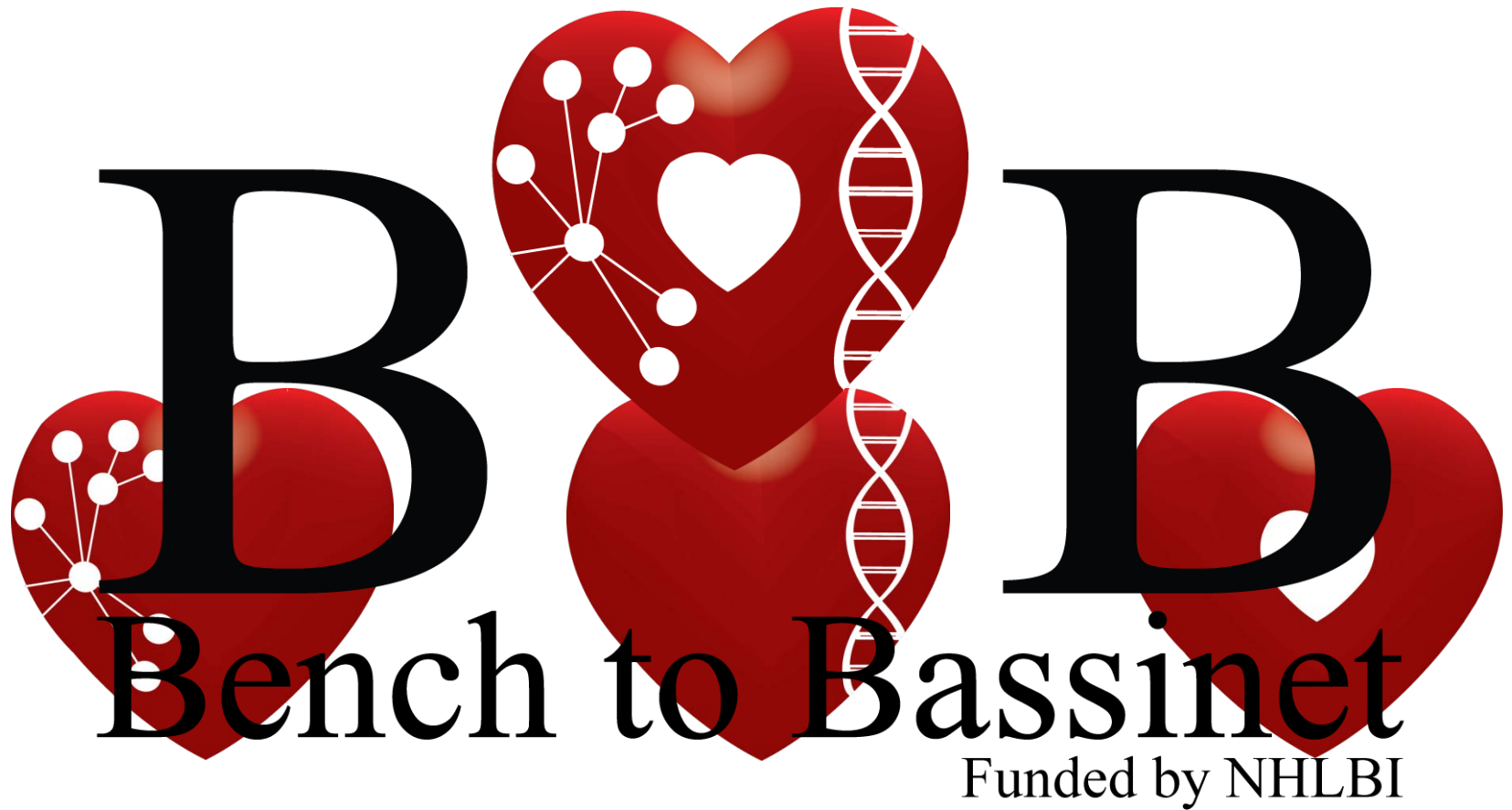
Cardiovascular Development Consortium (CvDC)



Pediatric Cardiac Genomics Consortium (PCGC)



Pediatric Heart Network (PHN)



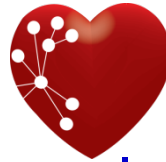
B to B

Bench to Bassinet

Funded by NHLBI

Bench to Bassinet Program

- CVDC Objectives



- To characterize the molecular networks and pathways that regulate cardiovascular development

- PCGC Objectives



- To identify genetic causes of congenital heart disease
- To relate genetic variants to clinical outcomes

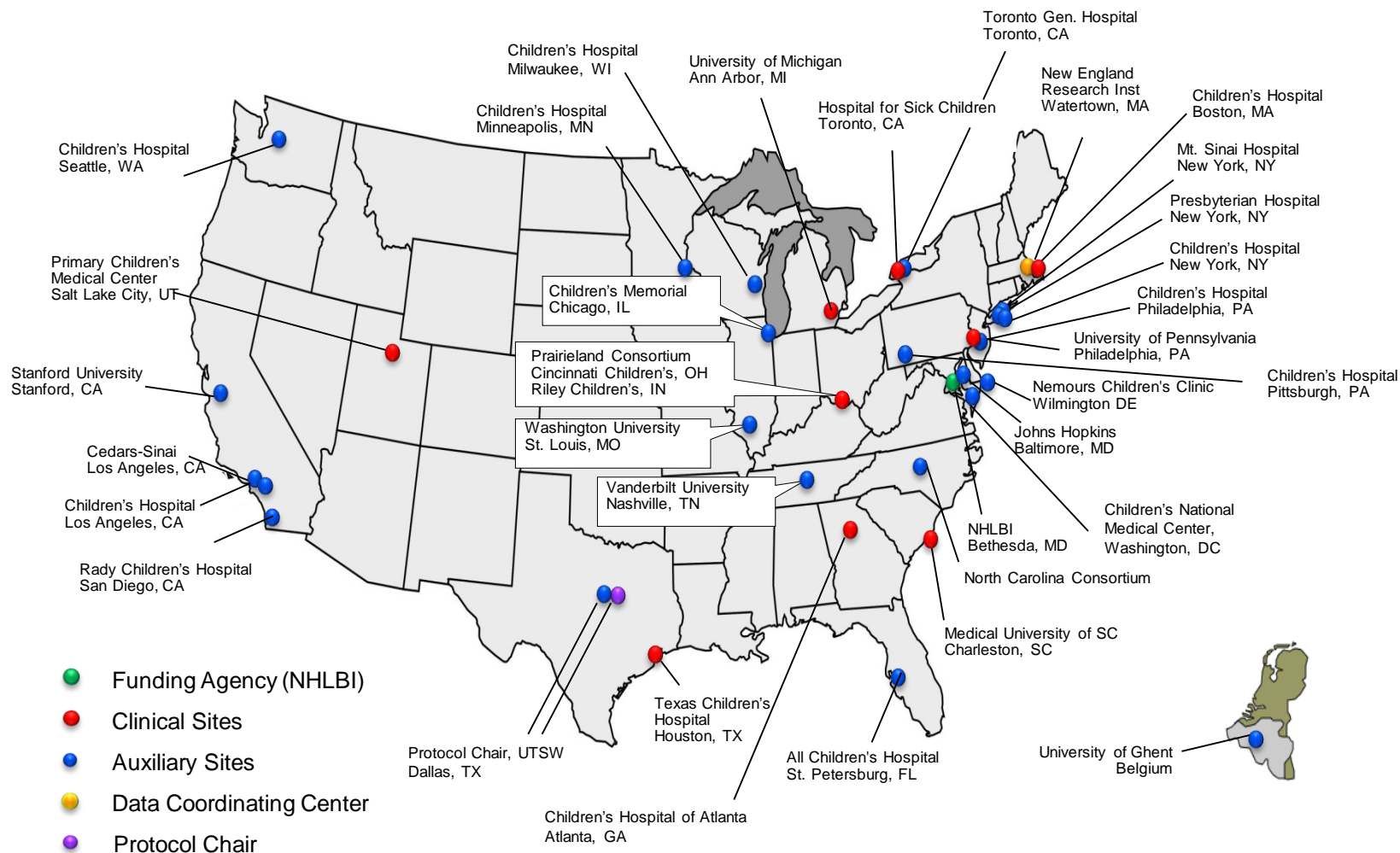
Bench to Bassinet Program

■ PHN Objectives

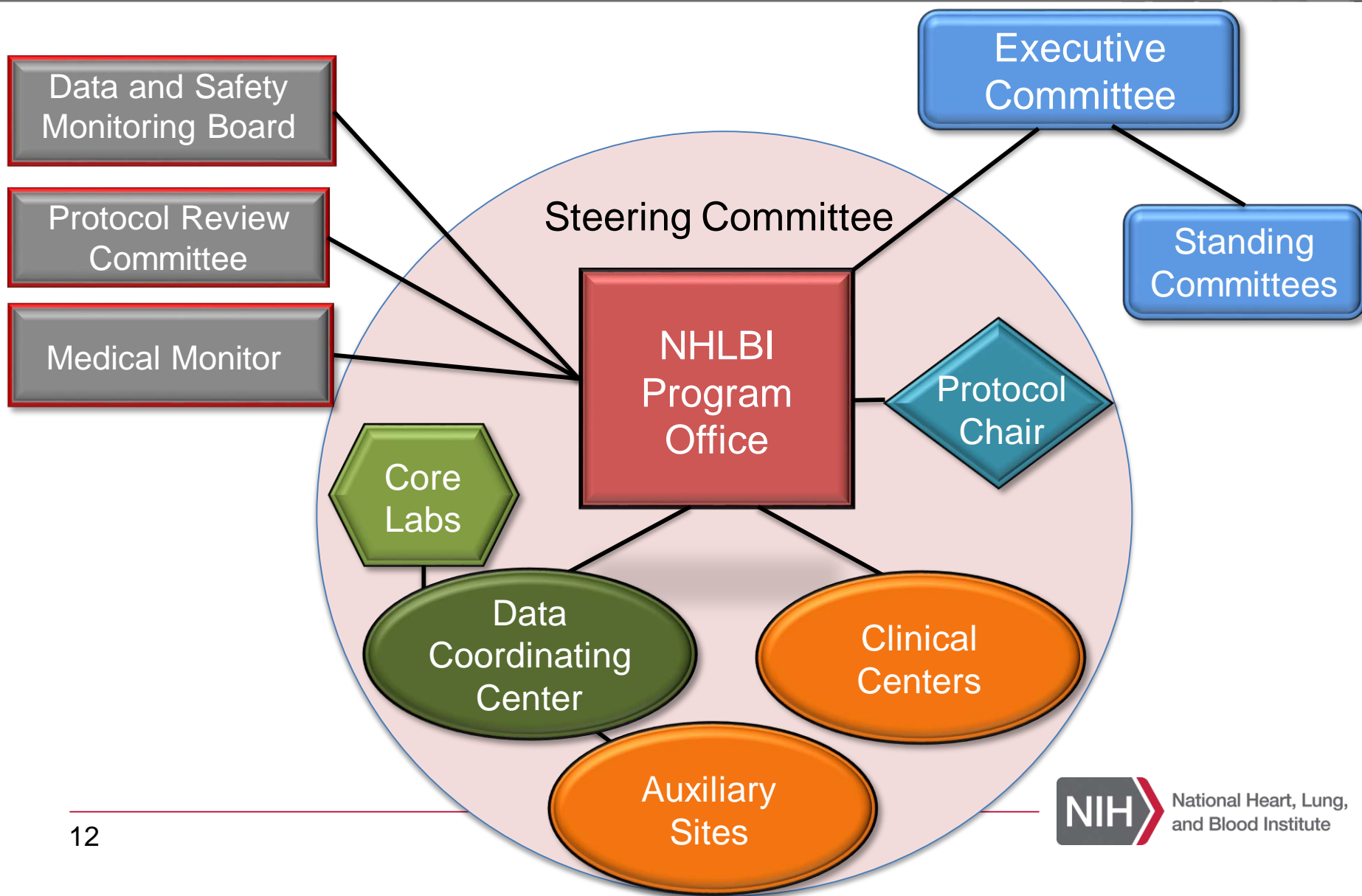


- To improve health outcomes in patients with pediatric acquired and congenital heart disease
- To disseminate collaborative findings as the basis for improved evidence-based treatment options and standards of care
- To train and to educate new investigators
- To provide support and advocacy for families during the conduct of excellent, ethical clinical research

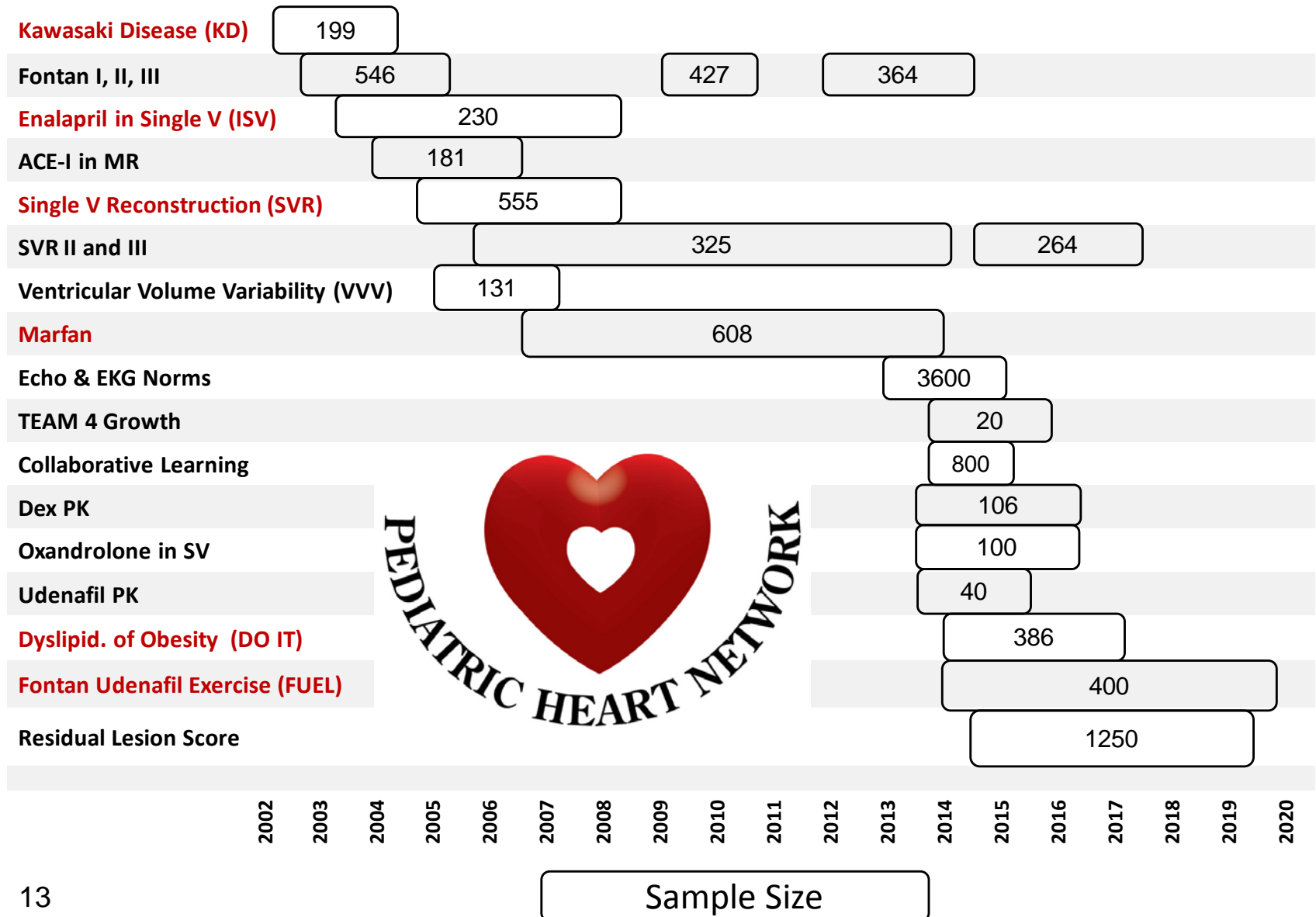
Pediatric Heart Network 2014



Pediatric Heart Network Organization



PHN Studies and Trials



Pediatric Heart Network Efforts

Phase III Trials
~2400 subjects

Quality
Improvement
~2000 subjects

Phase I/II Trials
~265 subjects



Nursing
Research

Observational
Studies
~3700 subjects

Health Services
Research Core

Study Progress

Completed

Kawasaki Disease

Fontan I

Infants with Single Ventricle (ISV)

ACE in MR

Single Ventricle Reconstruction (SVR)

Ventricular Volume Variability (VVV)

Data Analysis/ Writing

Fontan II

Fontan III

SVR II

Marfan

Enrolling

Echo/ECG
Z-score

Collaborative
Learning

Dex PK

Udenafil PK

Team 4
Growth

Planning

Do It

FUEL

Oxandrolone

Residual
Lesion Score

SVR III

How to Get Involved

- Analyze Existing PHN Data
- Propose a Study
- Develop an Ancillary Study
- Attend PHN Career Day
- Apply to be a PHN Scholar



Analyze Existing PHN Data

Public Use Datasets

- De-identified raw data
- Access for 6 months

www.pediatricheartnetwork.com



NHLBI R21: PAR-13-009

Secondary Dataset Analyses in Heart, Lung,
Blood Diseases and Sleep Disorders

Analyze Existing PHN Data



Available PHN Public Use Datasets

Fontan Cross Sectional Study

546 children; 6-18 years old, s/p Fontan

Endpoints: Functional Health Status

Ventricular performance: echo, exercise testing, ECG, CMR, BNP

Infant Single Ventricle Trial (ISV)

230 infants; <45 days old, single ventricle, randomized to enalapril vs. placebo

Primary endpoint: weight-for-age z-score at 14 months

Secondary endpoints: Somatic growth, Ross heart failure class, BNP, echo, neurodevelopment, and functional status

Single Ventricle Reconstruction Trial (SVR)

555 newborns, single ventricle, randomized to RVPAS vs. MBTS

Data: Pre-Norwood, at Norwood, Prior to Stage II, and 14 months

Primary endpoint: transplant-free survival 12 months post randomization

Secondary endpoints: hospital morbidity, unintended cardiovascular interventions by 12 months, echo, and angiography

Propose a Study



Idea

Standard study: All PHN Sites will participate
Pilot study: Fewer sites permissible

PHN Leadership
Triage

1 page synopsis OR
<10 page proposal
Support from PHN site PI

Steering Committee
Presentation

Executive
Committee Vote

Protocol
Development

Funding:

- PHN
- External Sources
 - AHA, NIH R01, etc.

Develop an Ancillary Study



Idea

Submit to DCC

Ancillary Study Application Form
Support from PHN site PI

Ancillary Studies
Committee Review

Grant Application
Letter of Support

PHN DSMB
Review

Steering Committee
Announcement

Funding:

- External Sources Only

Attend PHN Career Day

When



1 day session at the spring PHN Steering Committee Meeting

Who



Fellows and junior faculty from PHN clinical centers and auxiliary sites

What



PHN infrastructure
Protocol development
Research career planning
Professional development
Networking

Apply to be a PHN Scholar

Who



Location: One of the 9 clinical centers
Expertise: Pediatric cardiovascular subspecialty
Level: Junior faculty (<5 years out of training)
Senior fellows
Pre-doctoral/doctoral nurses
Career Plan: Pursue formal research funding

What



New pilot studies
Ancillary studies to PHN studies

How
Much



\$75,000 for 1 year

How to Get Involved

Contact NHLBI:

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Medical Officer

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NHLBI PHN Team

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- Jonathan Kaltman, MD
- Kristin Burns, MD
- Ellen Rosenberg, RN
- Mario Stylianou, PhD
- John Diggs





National Heart, Lung,
and Blood Institute