



Roles for Public Foundations in Clinical Trial Enrollment and Retention

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President and Executive Director**

**NIH Workshop on the Enrollment and Retention of
Participants in NIH-funded Clinical Trials
July 25, 2014**

Why we are here...

I just heard there's a
drug in trials that might
stop my cancer!!

Great! Are you going to
volunteer to participate
for the trial?

Of course not...why
would I do that?

I wouldn't either.
Sure hope they get
some results soon...





FNIH

Building partnerships for discovery and innovation to improve health.

Purpose

- To support the NIH in its mission;
- To advance collaboration with biomedical researchers from universities, industry and not-for-profit organizations.

Structure

- 501(c)(3) not-for-profit organization;
- Independent Board of Directors;
- NIH Director and FDA Commissioner *ex-officio* Board Members

Highlights

- Raised >\$750 million since 1996;
- Supported >400 projects, ~100 currently active;
 - research partnerships
 - scientific education/training
 - conferences/events
 - capital programs
- 94 cents of every dollar spent directly supports programs;
- For 10 years Charity Navigator has rated FNIH as an organization that exceeds industry standards.

Our role...

What we do, how we do it...

Identify:

- Important scientific problem
- Key players
- Resources required and sources of support
- Neutral convener; trusted party to provide safe harbor for discussions

Establish:

- Highest level of ethical standards
- Clear goals and milestones
- Effective mechanism to generate scientific consensus
- Nimble infrastructure and project expert project management

Facilitate:

- Discussions with key opinion leaders and regulatory decision makers
- Integrated approach to cross-sector partnerships
- Communications; ensure all partners' voices are heard;

Enable:

- Sharing of data and expertise to collaboratively address medical needs
- Resource mobilization
- Manage grants, contracts, and projects; oversee and conduct research

2010 Symposium on “Overcoming Barriers to Early Phase Clinical Trials”



FNIH role: Enabler

- Formed a public-private partnership to support research on enrollment barriers and the 2010 meeting.
- Grants to 6 cancer centers.
- Participants: NCI, ASCO , 5 industry partners.
- Goal: Investigate barriers that prevent patients, especially minority and elderly populations, from participating in early-phase clinical trials of innovative cancer therapies.
- Results:
 - Publication in 2013 with suggested research in:
 - Patient- and Community-Centered ;
 - Physician/Provider-Centered;
 - Site-Centered.

The National Cancer Institute–American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and Recommendations

By Andrea M. Denicoff, MS, RN, Wortia McCaskill-Stevens, MD, MS, Stephen S. Grubbs, MD, Suanna S. Bruinooge, Robert L. Comis, MD, Peggy Devine, David M. Dils, PhD, MBA, CMA, Michelle E. Duff, DPT, Jean G. Ford, MD, Steven Joffe, MD, MPH, Lidia Schapira, MD, Kevin P. Weinfurt, PhD, Margo Michaels, MPH, Derek Ragbavan, MD, PhD, Ellen S. Richmond, MS, RN, Robin Zon, MD, FACP, FASCO, Terrance L. Albrecht, PhD, Michael A. Bookman, MD, Afshin Dowlati, MD, Rebecca A. Enos, RN, MPH, Mona N. Fouad, MD, MPH, Marjorie Good, RN, MPH, OCN, William J. Hicks, MD, Patrick J. Loehrer Sr, MD, Alan P. Lyss, MD, Steven N. Wolff, MD, Debra M. Wujcik, PhD, RN, FAAN, and Neal J. Meropol, MD

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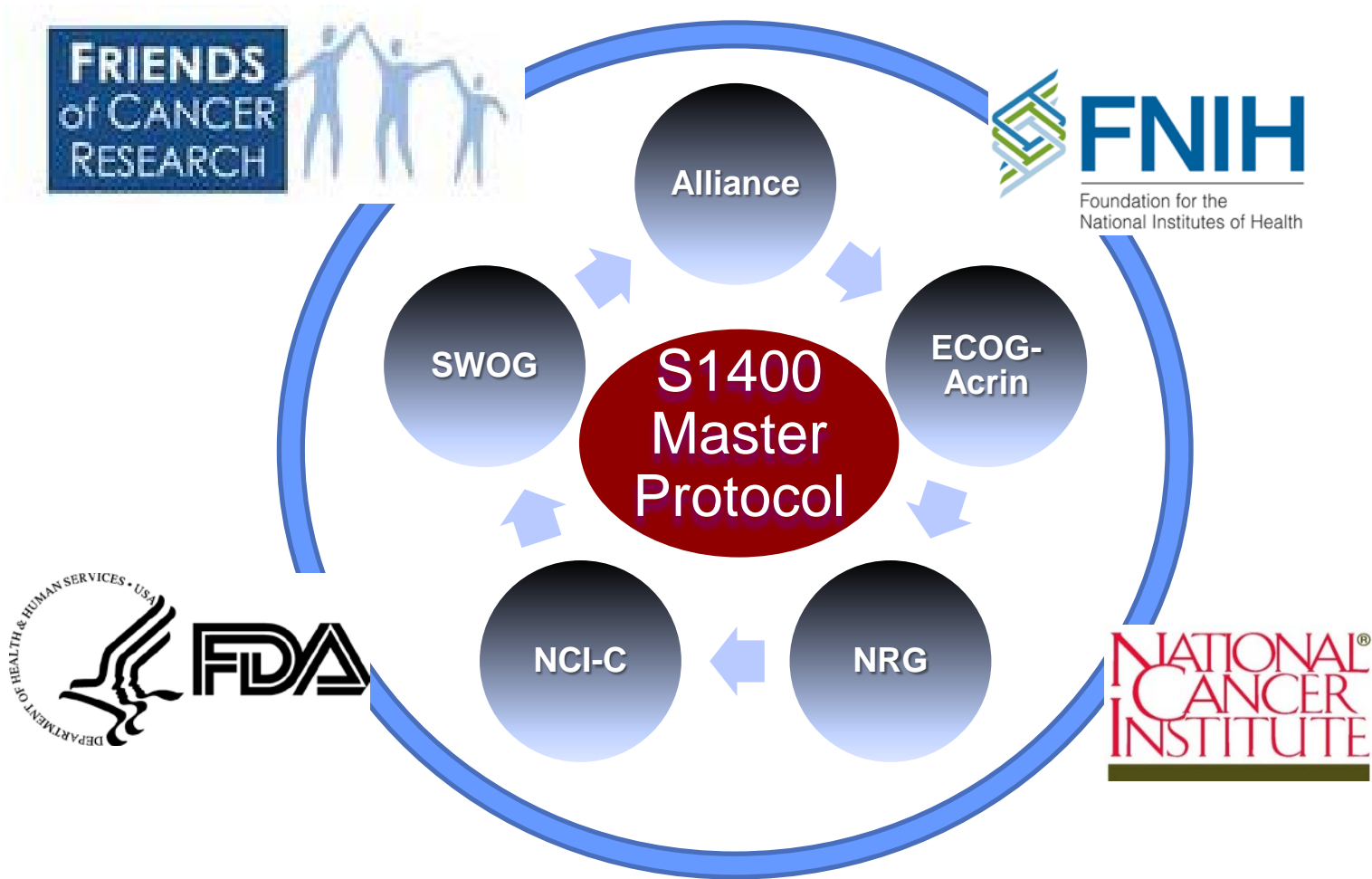
The challenge:

- Targeted drugs are predicted to work in only 5-20% of patients;
- To meet accrual goals, large patient populations must be screened.

Lung-MAP (SWOG S1400):

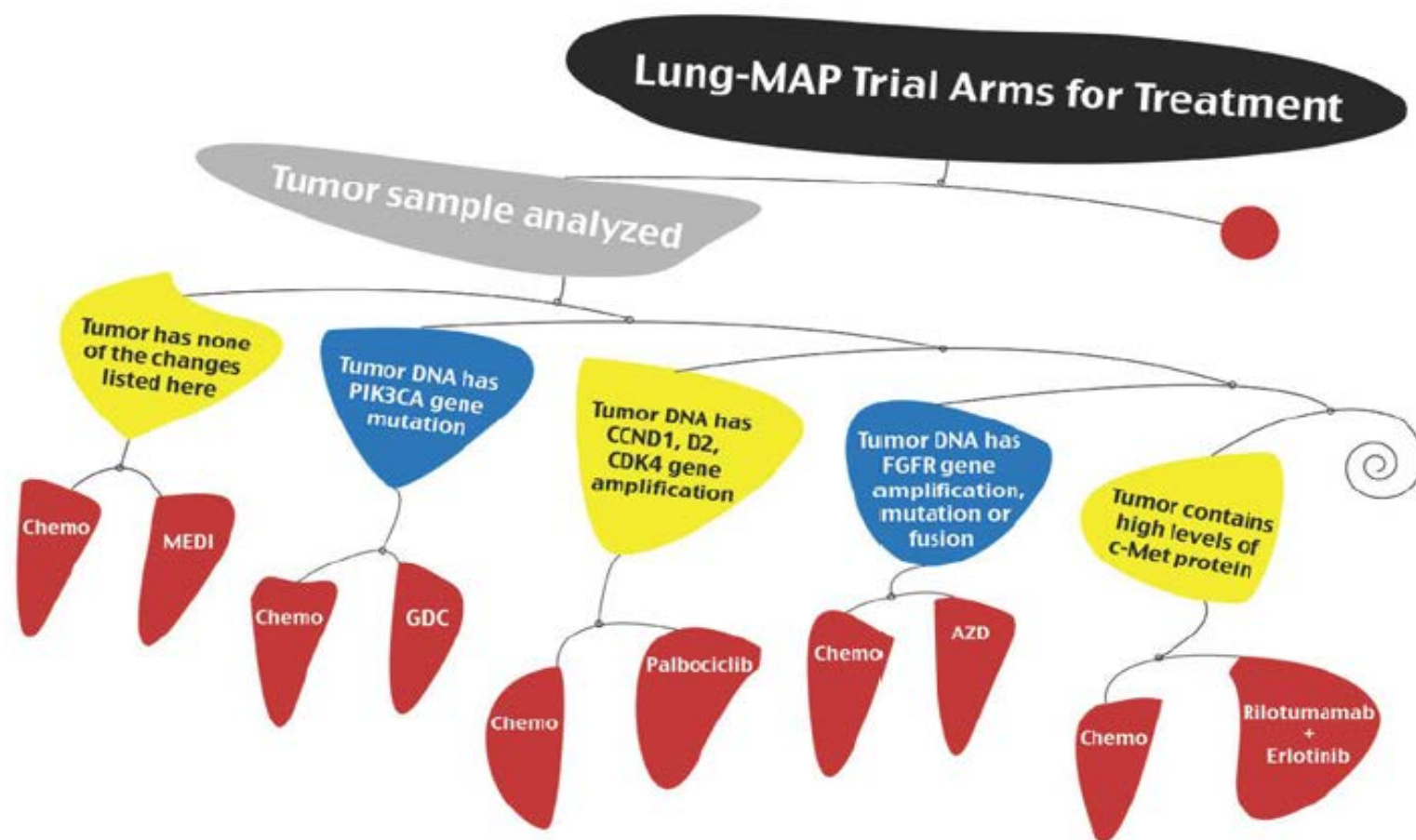
- 5-year multi-drug, multi-arm, biomarker-driven squamous cell lung cancer clinical trial;
- Phase 2 – 3 registration trial, under a master protocol;
- Uses next-gen sequencing platform for genomic profiling to match patients to investigational treatments
- 5 drug companies currently participating

LUNG-MAP



Patients with squamous cell lung cancer

2nd Line Therapy





LUNG-MAP



Trial Oversight Committee
 NCI, FDA, FNIH, FOGR, Advocates, PI's (ex-officio)



Executive Operations Committee
 Roy Herbst, co-chair
 Vali Papadimitrakopoulou, co-chairs



Project Management Office
 FNIH, SWOG, FOGR



Contracts, Fundraising, Data Sharing, IP

Scientific Partner Focus Group

Project Management

Drug and Biomarker Selection Committee

Assay Company selection (RFP)

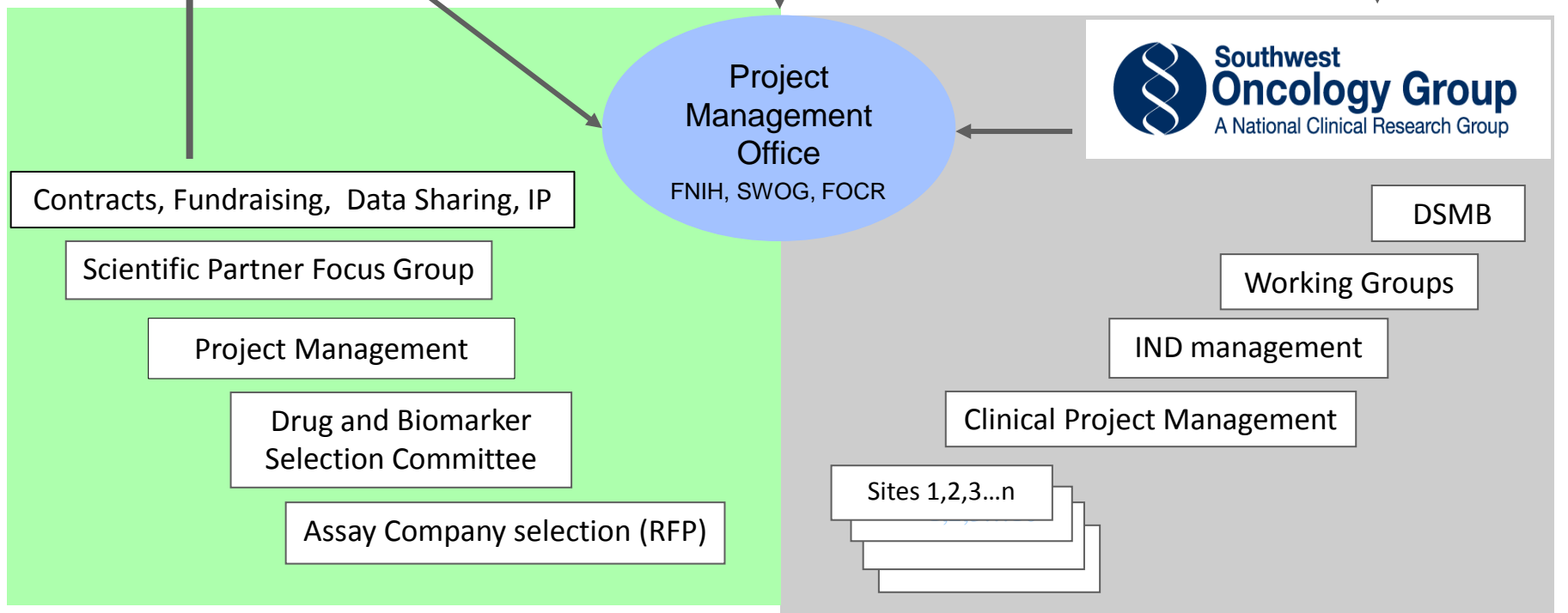
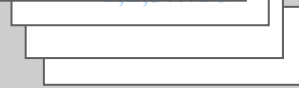
DSMB

Working Groups

IND management

Clinical Project Management

Sites 1,2,3...n



Thank You

Rationale for Lung-MAP

- **Multi-arm Master Protocol**
 - Homogeneous patient populations & consistent eligibility from arm to arm
 - Each arm independent of the others
 - Infrastructure facilitates opening new arms faster
 - **Phase II-III design** allows rapid drug/biomarker testing for detection of “large effects”
- **Screening** large numbers of patients for multiple targets by a broad-based NGS platform reduces the screen failure rate
- Provides a **sufficient “hit rate”** to engage patients & physicians
- **Bring safe & effective drugs to patients faster**
- Designed to facilitate **FDA approval** of new drugs