

**Early
Detection
Research
Network**



Translating Biomarker Discovery to Clinical Application

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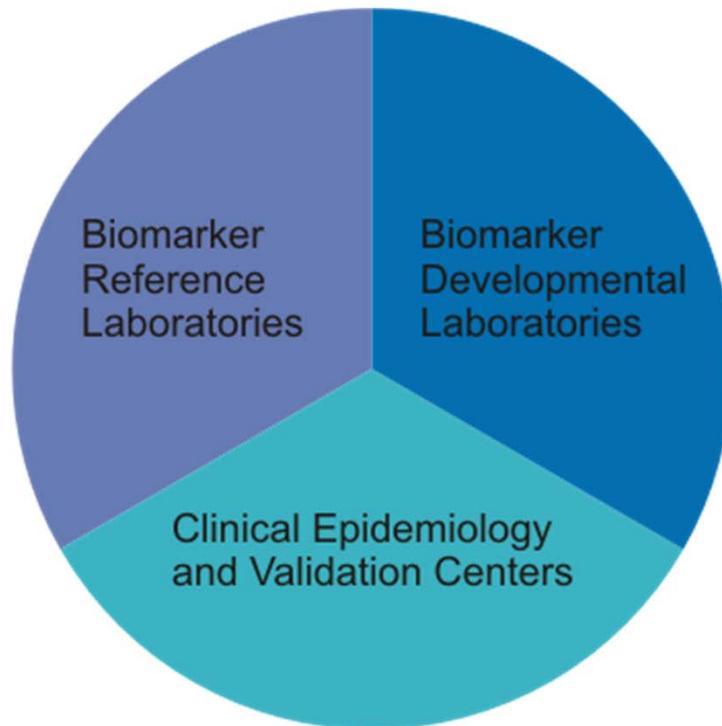


GOALS

- Discover, develop and validate biomarkers for cancer detection, diagnosis and risk assessment**
- Conduct correlative studies/trials to validate biomarkers as indicators of early cancer, pre-invasive cancer, risk, or as surrogate endpoints**
- Develop quality assurance programs for biomarker testing and evaluation**
- Forge public-private partnerships**

INVESTIGATOR-DRIVEN CONSORTIUM

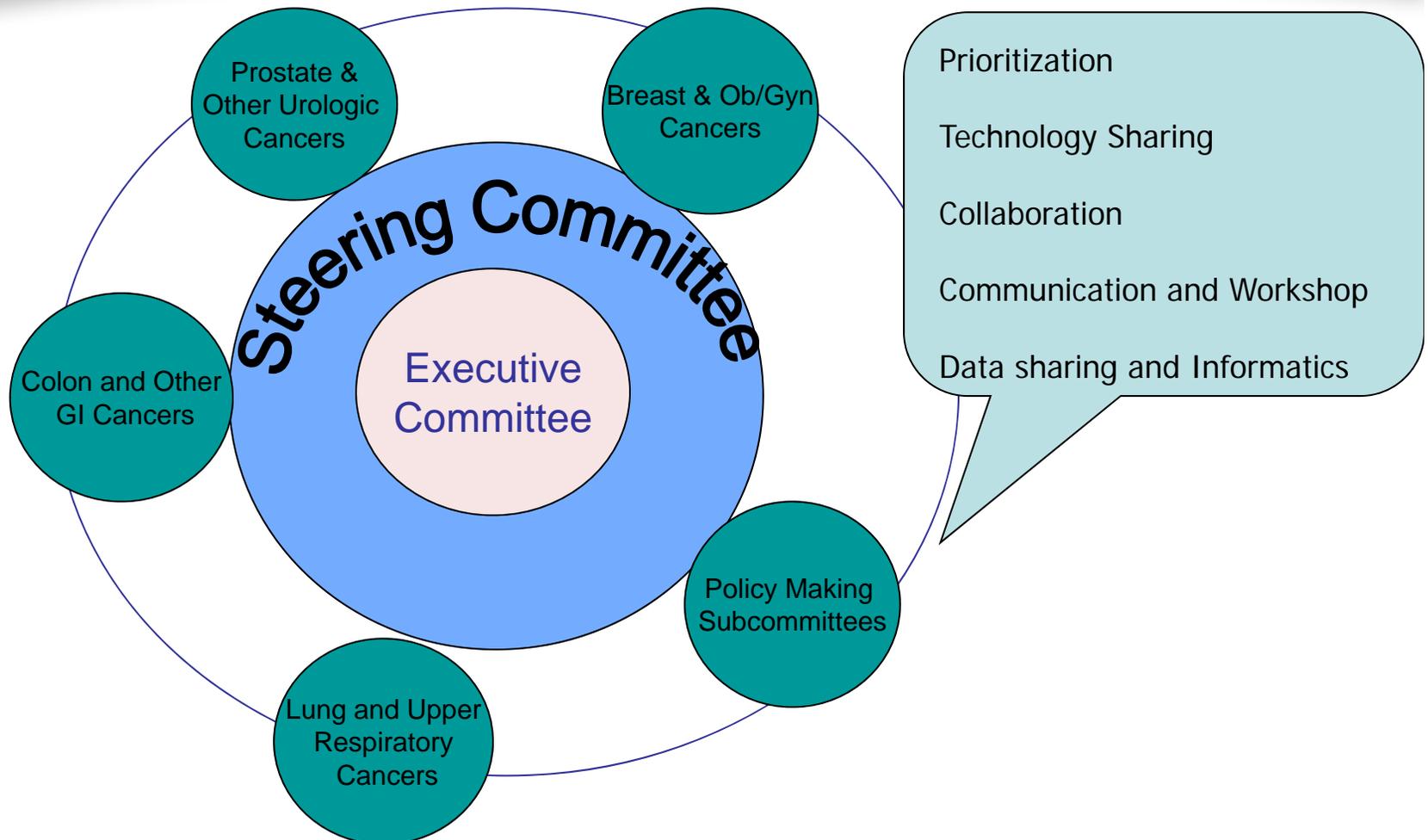
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***An “infrastructure”
for supporting
collaborative
research on
molecular, genetic
and other biomarkers
in human cancer
detection and risk
assessment.***



MANAGEMENT STRUCTURE



ORGANIZATIONAL SUCCESS: A Catalyst for Innovations and Partnership

- ❑ **EDRN Business Model and Project Management Reviewed and Cited by Many Scientific Journals and Working Groups for Best Practices:**
 - ❑ Informatics to Manage and Support Biomarker Research (NCI-FDA-AACR Biomarker Collaborative Working Group Reports, Institute of Medicine on Biomarker)
 - ❑ Conducting Discovery and Validation Research (JNCI, J. Proteome Research)
 - ❑ Collaborative Model for Biomarker Research (Nature)
 - ❑ Milestones-driven Project Management that Ensure Timely Completion
 - ❑ NCI Translational Research Working Group

The EDRN structure has been cited by the National Academy of Sciences Institute of Medicine as an effective team-based organization (*Large Scale Biomedical Science*, Institute of Medicine 2001); and for following best practices in *Biospecimen Resources for the Genomic and Proteomic Era* (Rand Science and Technology Publication, 2003), and *Cancer Informatics* (Eds. Silva, Ball, Chute, et. al., 2002 and in *Cancer Biomarkers*, Institute of Medicine 2007).

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ORGANIZATIONAL SUCCESS: A Catalyst for Innovations and Partnership

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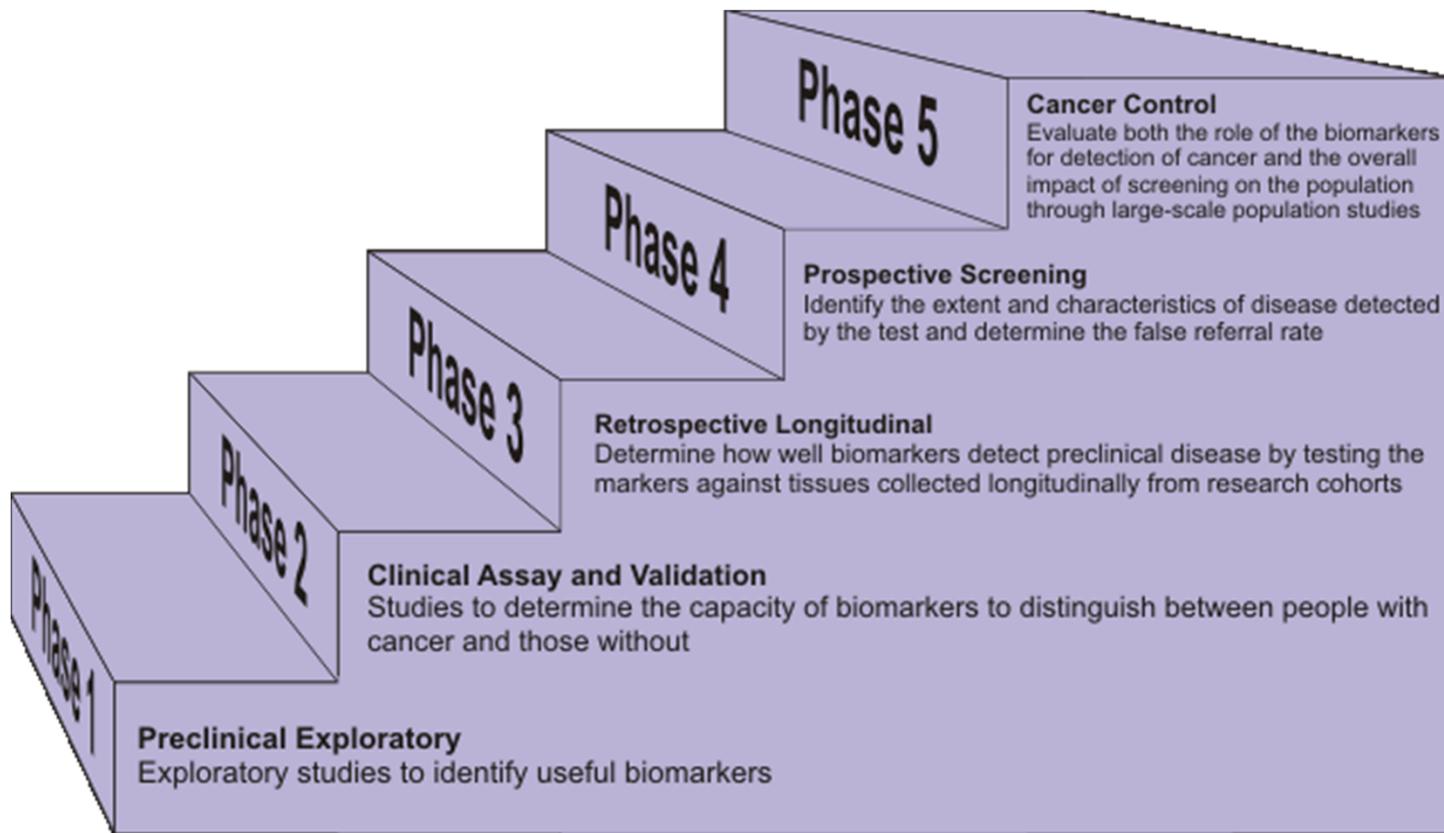
- ❑ **Rewards Collaboration and Promotes Team Science (EDRN Investigator received the first-ever AACR Team Science Award: Arul Chinnaiyan).**
- ❑ **EDRN is as an Unexpected Catalyst for Innovation, Partnerships, and Biomarker Research Know-How (An EDRN investigator received a DOD Innovator Award on research ideas supported by EDRN).**
- ❑ **Diagnostic firms, large or small, are seeking partnerships with EDRN.**

ORGANIZATIONAL SUCCESS: A Model System for Translational Research

An integrated, collaborative model that:

- ❑ Uses a novel mechanism to reward collaboration and promotes inclusiveness through its Associate Membership Program.
- ❑ Has developed a roadmap for [biomarkers discovery and validation](#).
- ❑ Has helped developed *biomarker metrology* to develop, design and deliver biomarker research free of chance, bias and over-fitting (Pepe et.al., Ransohoff).
- ❑ Has championed protocol-driven, phase-approach to proteomics evaluation for cancer diagnostic.
- ❑ Disseminates resources for extramural communities on protocols, reagents, reference sets, study designs and statistical methodologies.

PHASES OF BIOMARKER VALIDATION



Source: J. Natl. Cancer Inst. 93, 1054-1061, 2001

EDRN PROGRAM FOR RAPID INDEPENDENT DIAGNOSTIC EVALUATION (PRIDE)

A RAID-like mechanism that:

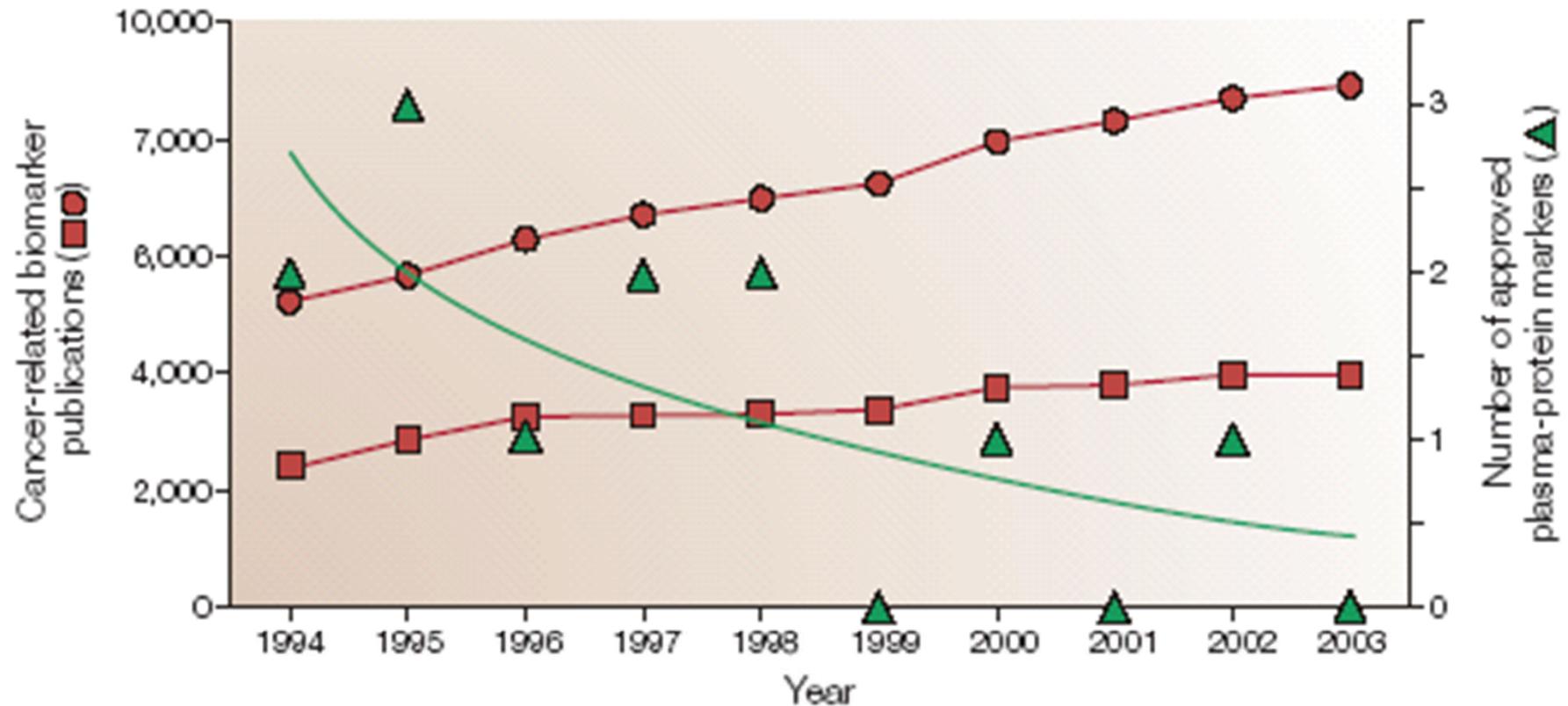
- Encourages extramural investigators to seek assistance from EDRN in cross-laboratory validation of their biomarker assays.**
- Helps develop and institutes quality assurance programs for biomarker testing and evaluation.**
- PRIDE announcement is published in NIH Guide yearly.**

PRESENT AND FUTURE

- ❑ EDRN already practices management philosophy promoted by TRWG.
- ❑ TRWG- supported Risk Device Pathways are already being supported by EDRN.
- ❑ The Network's productivity, funding opportunities and infrastructure have fashioned a new environment for biomarker research.
- ❑ A number of biomarker tests will be ready for submission to FDA, a remarkable achievement considering the history of [approval of diagnostic markers by FDA](#).

FDA APPROVAL OF CANCER BIOMARKERS

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Joseph A. Ludwig*† and John N. Weinstein* Nature Rev. Cancer 2005

SIGNIFICANT NOTES

- ❑ EDRN 4th Report Released
January 2008
- ❑ EDRN 5th Annual Workshop
March 16-19, Bethesda, MD
- ❑ AACR Sunrise Session on EDRN
April 15, 2008



- ❑ **BIOMARKER DISCOVERY: Dr. Sam Hanash**
- ❑ **BIOMARKER VALIDATION: Dr. Ian Thompson**
- ❑ **BIOMARKER REFERENCE LABORATORIES:
Dr. Dan Chan**
- ❑ **STATISTICAL AND INFORMATICS:
Drs. Ziding Feng, Mark Thornquist, and
Dan Crichton**