Technology funding opportunities at the National Cancer Institute

Through the Cancer Diagnosis Program

http://cancerdiagnosis.nci.nih.gov/index.html

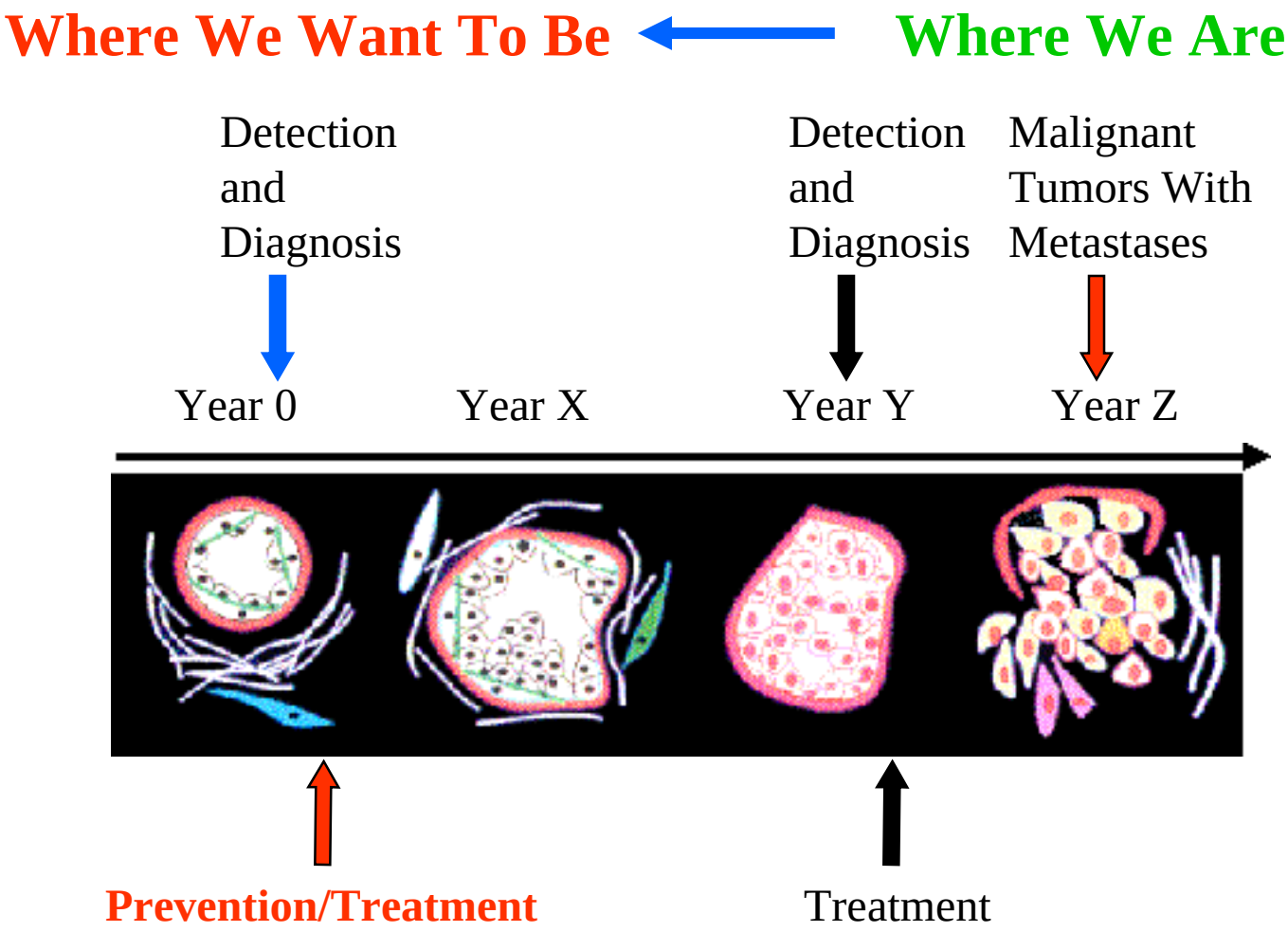
Avraham Rasooly Ph.D.

National Cancer Institute, Cancer Diagnosis Program

The NCI Goal

To prevent and to cure cancer

Cancer results from the gradual accumulation of multiple genetic changes in single cells



Challenges for Detection of Cancer

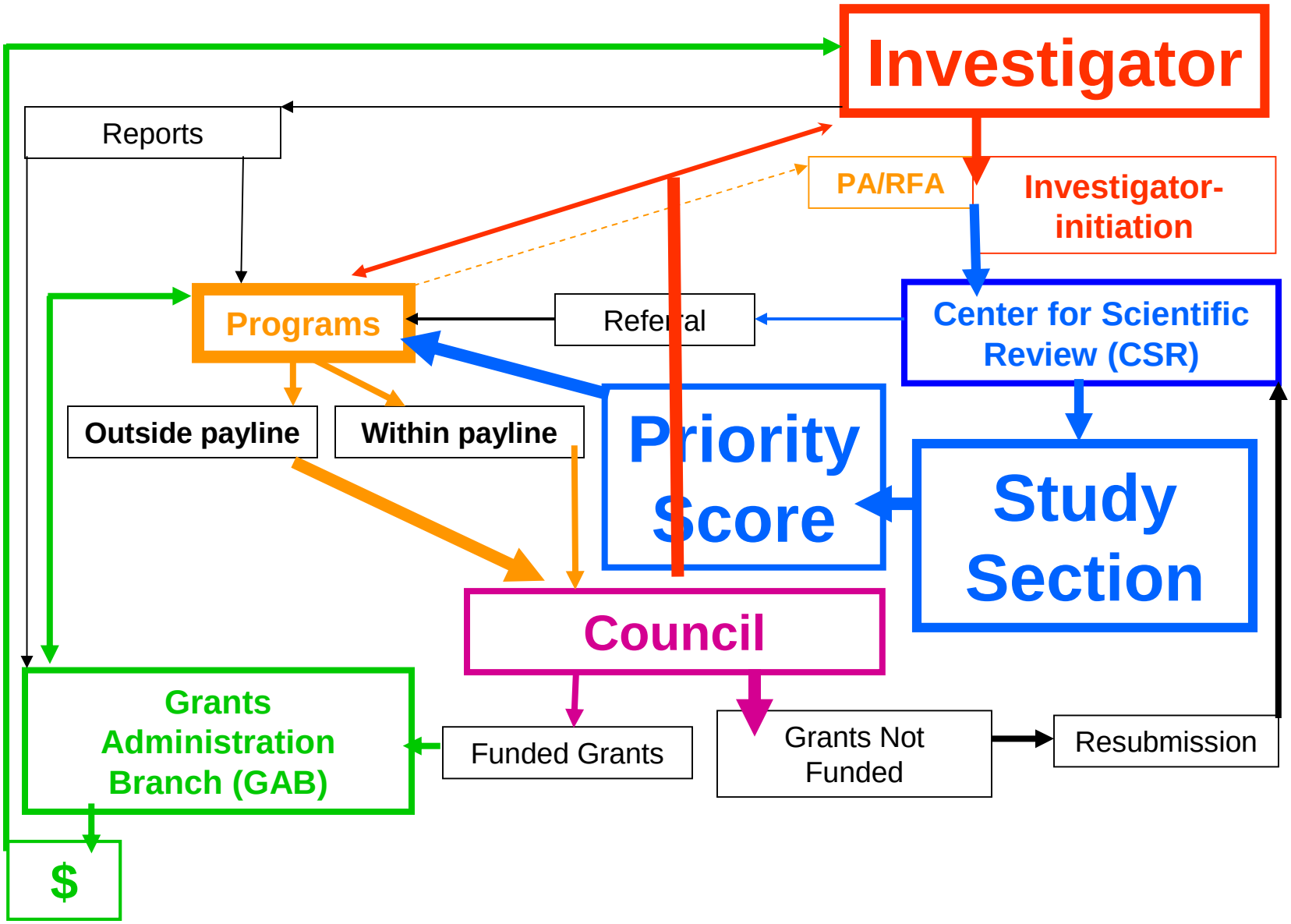
- **Identification of risk populations**
- **Lack of validated biomarkers**
- **Technology limitations**
- **Availability of annotated and quality assured tissues**
- **Lack of new business model - engagement of the private sector**
- **Regulatory science for early detection**

Challenges for Cancer Technology Development Projects

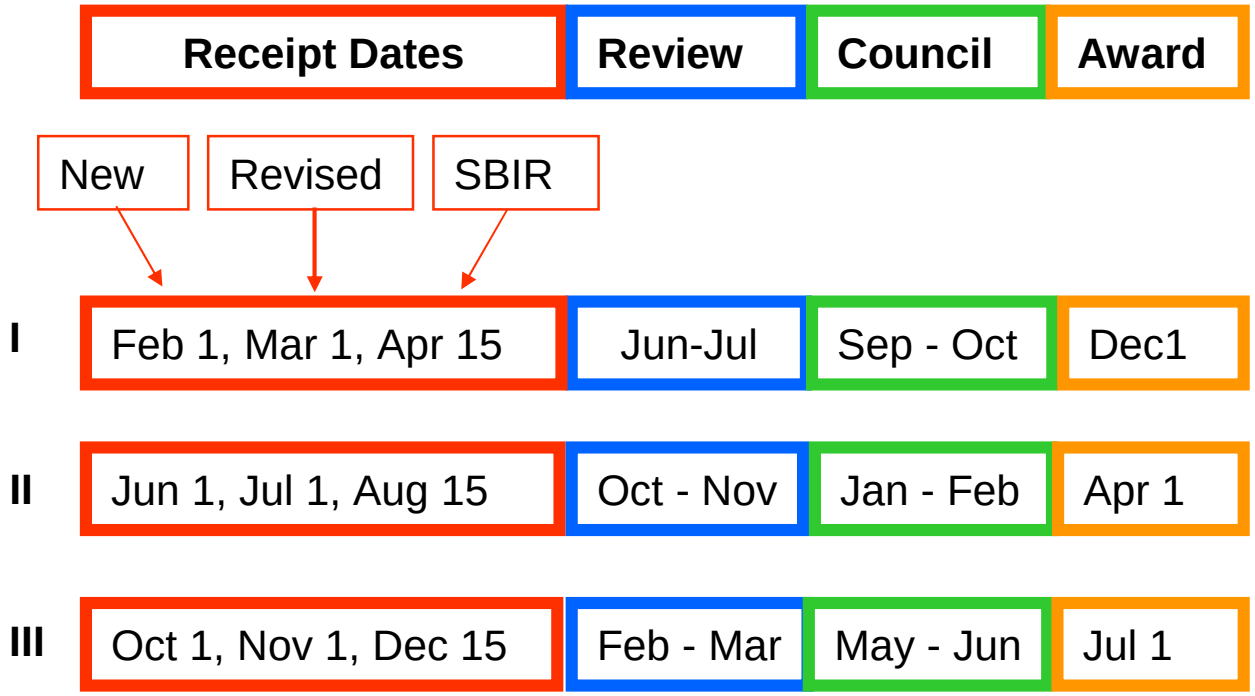
Multidisciplinary collaborative team of:

- **Biologists**
- **Engineers**
- **Oncologists**

NIH EXTRAMURAL FUNDING



Funding Timeline



Eligibility for funding

Universities

Businesses

Hospitals

Medical centers

Research institutions

Government organizations

Throughout the United States and abroad

NIH Main Funding Mechanisms

R01-Traditional Grants

P01-Program Projects

R15-AREA Grants

R21-Exploratory Grants

R33-Exploratory Grants Phase II

K-Training Grants

R41-STTR

R42-STTR Phase II

R43-SBIR

R44-SBIR Phase II

Small Business Funding Opportunities

http://otir.nci.nih.gov/cgi-bin/editsbir.cgi

Extramural Programs
Reserved for Small Business

SBIR: Set-aside Program for Small Business to engage in Federal R&D with potential for commercialization.

STTR: Set-aside Program to facilitate cooperative R&D between Small Business and U.S. Research Institutions- with potential for commercialization.

SMALL BUSINESS ELIGIBILITY

- For- profit privately owned U.S. business
- At least 51% U.S.- owned and independently operated
- Small Business located in the U.S.
- 500 employees or fewer

SBIR/STTR: 3-Phase Program

- **PHASE I**
  - **Feasibility study**

(*no preliminary data needed*)

  - **$100K and 6 months (SBIR) or 12 months(STTR)**

- **PHASE II**
  - **Full R/R&D**
  - **2-Year Award and $750K (SBIR) or $500K (STTR)**

- **PHASE III**
  - **Commercialization Stage**
  - **Without SBIR Support**

Review criteria

- Significance
- Approach
- Innovation
- Investigator
- Preliminary results
- Resources and Environment
- Additional criteria for specific PAs, RFAs

Other factors

- Safeguards for animal and human subjects
- Appropriateness of the budget

Factors Institute Considers In Making Awards

- **Scientific Merit**
- Contribution to the Mission of the Institute
- Program Balance
- Availability of Funds/Funding Strategy

Common Problems with Applications

- Conceptual problem
- Inadequately defined test of feasibility
- Diffuse, superficial, or unfocused research plan
  - Lack of sufficient experimental detail
- Questionable reasoning in experimental approach
  - Uncritical approach
  - Failure to consider potential pitfalls and alternatives
- Lack of innovation
- Lack of preliminary results
- Significance-unconvincing scientific importance, commercial potential or societal impact
- Lack of expertise/lack of appropriate collaborators
- Unfamiliar with relevant published work
- Unrealistically large amount of work proposed

Amended Applications

- **Two amended applications allowed**
- **Generally half of the reviewers are new**
- **Request for change of reviewers must be supported**
- **Address ALL the reviewers concerns**
- **An opportunity to revise and improve your application**

Cover Letter: A Valuable Tool

- Suggest study section(s)
- Indicate individual(s) or organization(s) that would be in conflict
- Discuss areas of expertise appropriate for the application’s review

Research areas of interest to the

Diagnostic Biomarkers and Technology Branch.

Technologies relevance to *in vitro* cancer diagnosis

http://cancerdiagnosis.nci.nih.gov/about/index.html#tdb

Devices:

- Microtechnology
- Nanotechnology
- Microfluidics
- MEMS systems for molecular analysis
- Biosensors
- Automated sample preparation
- High-throughput systems
- Integration of technologies

Other Research areas:

- Genomic
- Proteomic
- Bioinformatics

New NCI Request For Applications (RFA) for technology development:

Innovative Technologies for Molecular Analysis of Cancer
(CA-05-002, CA-05-006) R21 or R33 (R41,R42,R43,R44)

Application of Emerging Technologies for Cancer Research
(CA-05-003, CA-05-007) R21/R33 (R41/R42 or R43/R44)

Cancer **Sample Preparation** Methodologies
(CA-05-004, CA-05-008) R21/R33 (R41/R42 or R43/R44)

NIH Research Funding

http://grants.nih.gov/grants/oer.htm

- NIH funding opportunities: http://grants1.nih.gov/grants/guide/index.html

- NCI funding opportunities: http://www.nci.nih.gov/researchandfunding#fundingopportunities

Nanotechnology: Critical Endeavor in Cancer

http://nano.cancer.gov/resource_video_journey_wmv-high.asp

- **Imaging agents** for diagnostics that will allowing detection at earliest stages
- **Real-time assessments** of therapeutic and surgical efficacy
- Multifunctional, **targeted devices for delivering** therapeutic agents directly to cancer cells.
- Agents that can **monitor predictive molecular changes** for cancer prevention
- Novel methods to **manage the symptoms** of cancer that adversely impact quality of life
- **Research tools** that will enable rapid **identification of new targets** for clinical development

NIH Roadmap

http://nihroadmap.nih.gov/

To identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone but that the **Agency as a whole must address** to make the biggest impact on the progress of medical research.

NIH Roadmap

http://nihroadmap.nih.gov/

- **New Pathways to Discovery pathways**
  - Molecular libraries
  - Molecular imaging
  - Structural biology
  - Bioinformatics/Computational biology
  - **Nano-medicine**

- **Research Teams of the Future**
  - High risk research
  - Interdisciplinary teams
  - Public-private partnerships

- **Re-engineering the Clinical Research Enterprise**

Bioengineering

- **BECON:** The mission of the Consortium is to foster new basic understandings, collaborations, and transdisciplinary initiatives among the biological, medical, physical, engineering, and computational sciences.

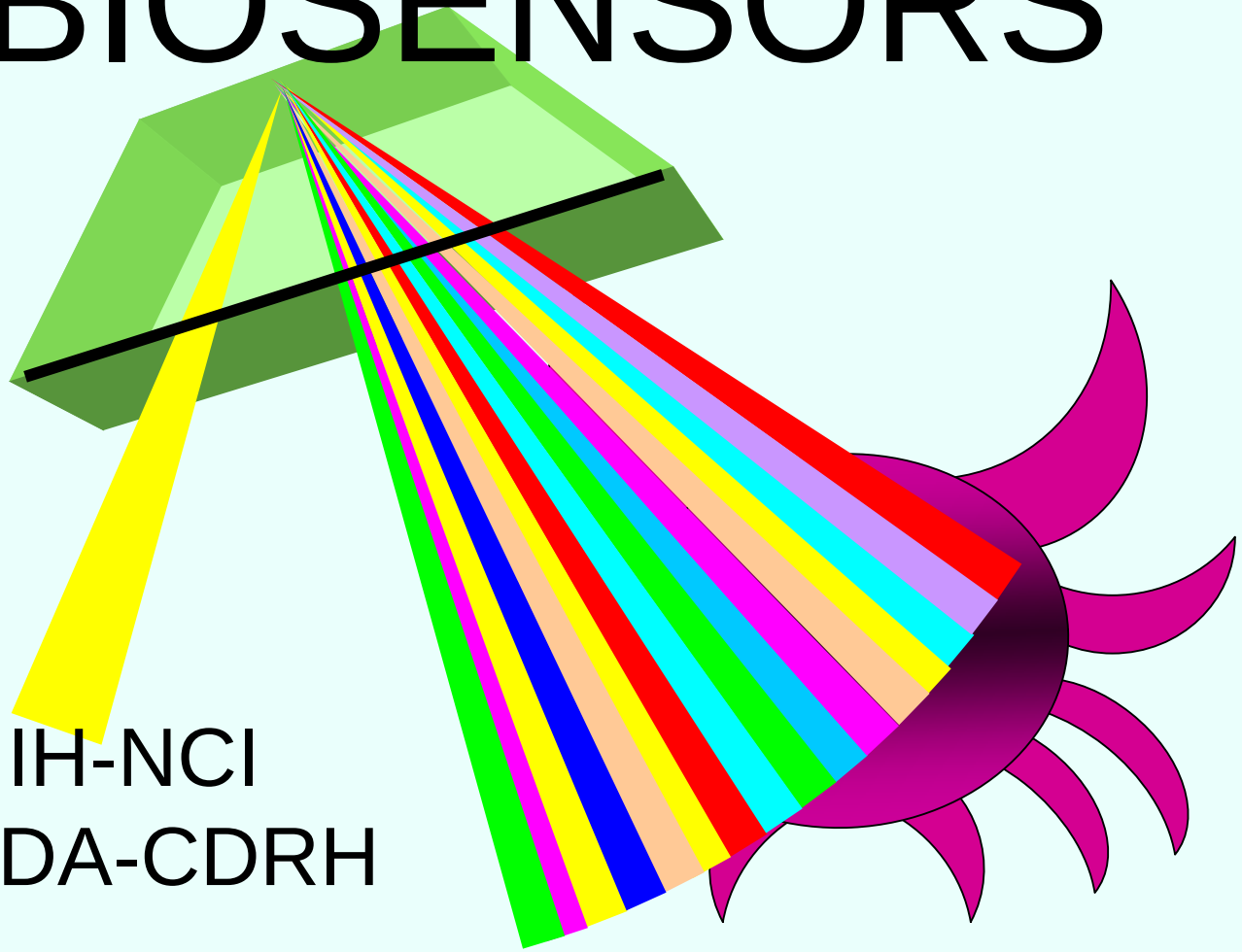
- http://www.becon.nih.gov/becon_funding.htm

Exploratory/Developmental Bioengineering Research Grants

- http://grants1.nih.gov/grants/guide/pa-files/PA-03-058.html


NATIONAL®
CANCER
INSTITUTE

BIOSENSORS



NIH-NCI
FDA-CDRH

Symposium on biosensors and their applications for cancer
June 2005

rasoolya@mail.nih.gov