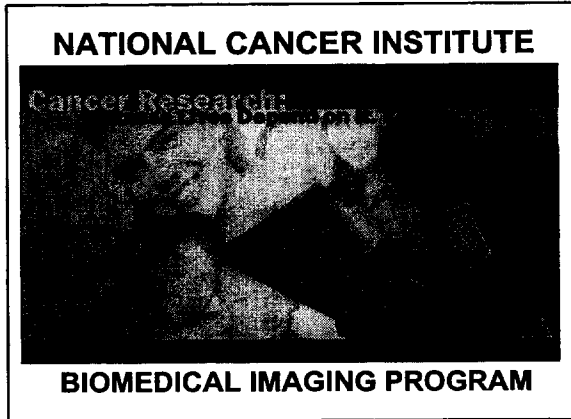


Presented
by
James Tatum, M.D.
at the
Nonclinical Studies
Subcommittee
of the
Advisory Committee for
Pharmaceutical Science

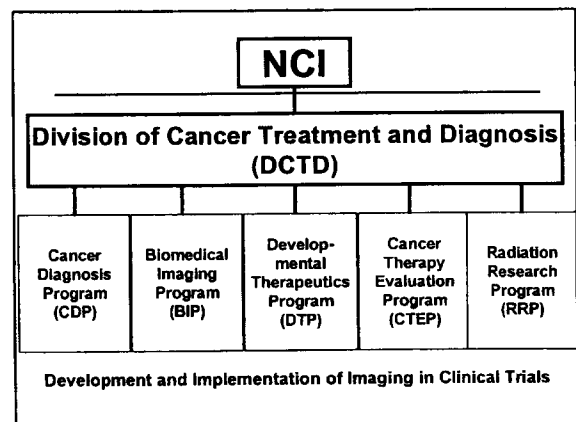
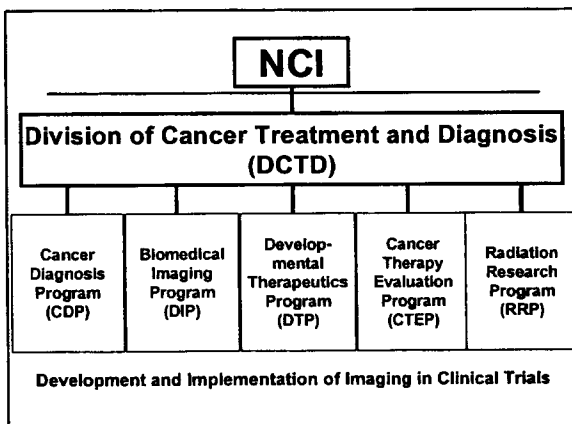
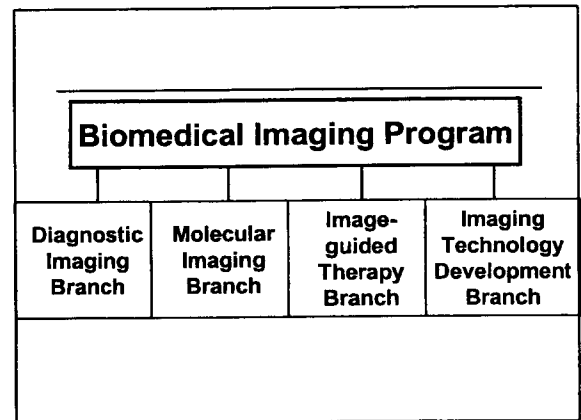
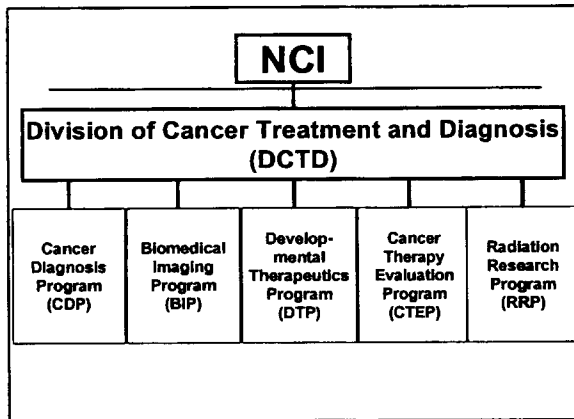
March 9, 2000



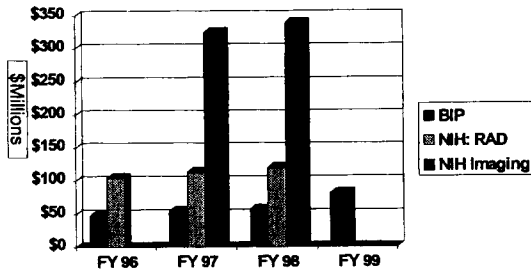
**Biomedical Imaging Program
Vision and Mission Statement**

§ **Vision** - Imaging Sciences are essential to understanding biologic systems, controlling disease, and enhancing health.

§ **Mission** - Promote and Support outstanding basic, translational, and clinical research in the imaging sciences and apply the discoveries to solving the challenges of Cancer.



NIH Funding for Imaging



Biomedical Imaging Program Research Portfolio

Recent Programs

Programs	Awards	Amount
RFA: CA-97-020: Cooperative Trials in Diagnostic Imaging (ACRIN)	2 U01	\$ 3.0 M yr. 1 \$ 22 M Tot
RFA: CA-98-024: Development And Application of Imaging In Therapeutic Studies	9 R01's	\$ 2.8 M yr. 1 \$ 11.6 M Tot
CA-98-023: Small Animal Imaging Resource Programs (SAIRPs)	5 U01's	\$ 5.3 M yr. 1 \$ 15.3 M Tot

Current Programs

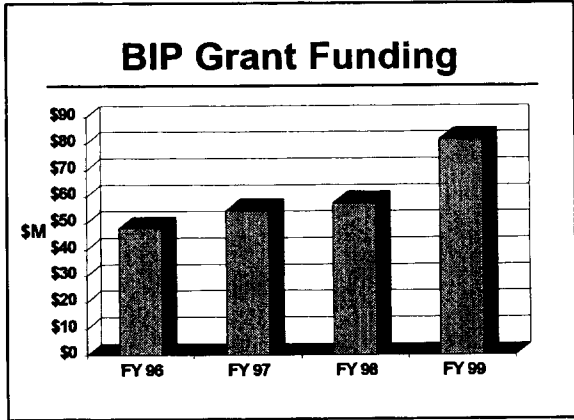
Program	Awards	Amount
RFA: CA-99-002 - Planning Grants - Molecular and Cellular Imaging Centers (Pre-ICMCs):	6-8 P20's	\$ 2.4 yr. 1 \$ 7.2 M Tot
RFA: CA-99-004: Molecular and Cellular Imaging Centers (ICMCs):	2 P50's per year	\$4.0 M yr. 1 \$48.0 M Tot
RFA CA-99-015: Diagnostic Imaging and Guided Therapy in Prostate Cancer (Phased Innovation Award)	6-8 R21/R33	\$1.6 M yr.1 \$13.6Tot
PAR-99-149: Diagnostic Imaging and Guided Therapy in Prostate Cancer: SBIR/STTR Initiative	R43/R44	Payline

Current Programs

Program	Awards	Amount
PA: 99-022/053: Development and Testing of Digital Mammography Displays and Workstations	R01/SBIR/STTR)	Payline
PA: 98-008: Exploratory/Developmental Grants for Diagnostic Cancer Imaging	R21's	\$5.7 M yr. 1
PAR-99-101: Innovative Technologies for the Molecular Analysis of Cancer: Phase Innovation Award	R21/R33 SBIR/STTR (PAR-99-100)	Payline
PAR-99-102: Applications Of Innovative Technologies For The Molecular Analysis Of Cancer: Phased Technology Application Award	R21/R33 SBIR/STTR (PAR-99-103)	Payline
PAR-99-010: Bioengineering Research Partnership Programs (BRP)	R01's	Payline
PAR-99-009: Bioengineering Research Grants (BRG)	R01's	Payline
BAA No. N01-CM-97065-32 Novel Technologies for Noninvasive Detection, Diagnosis and Treatment of Cancer	Contracts	\$ 4 M yr.1 \$16 M Tot

CTEP Collaborative Programs

Program	Awards
CTEP Protocol Review	Contracts; U10's
CA-98-007: Pediatric Brain Tumor Clinical Trials Consortium	U10's; imaging required
RFA for new Centers	U54's; imaging required
RFP for Phase I & II clinical trials	Contracts; imaging required



Interdisciplinary Meetings and Workshops



ANGIOGENESIS IMAGING METHODOLOGY: AIM for Clinical Trials

The Role of Imaging in Clinical Trials
of Anti-Angiogenic Therapies in Oncology

Incline Village, Nevada
February 28-27, 2002

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**Need for New
Approved Probes and
Contrast Agents**

Imaging Agent Facilitation Program

DCIDE

Development of Clinical Imaging Drugs and Enhancers

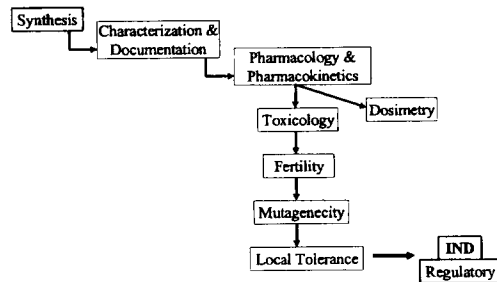
Purpose

- Facilitate the pre-clinical development of promising imaging enhancers (contrast agents) and molecular probes

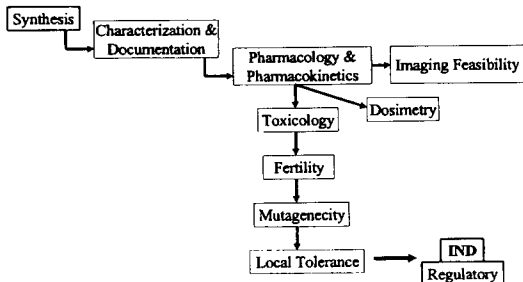
Process

- Call for proposals twice a year
- Proposals – written not to exceed 20 pages
- Two-stage review process

Pre-Clinical Drug Development



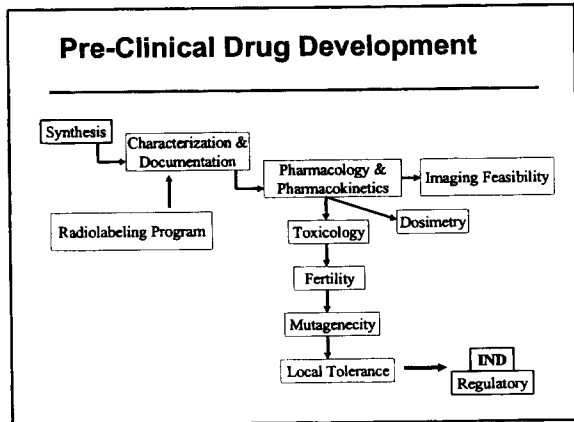
Pre-Clinical Drug Development



Imaging Feasibility Program

Purpose

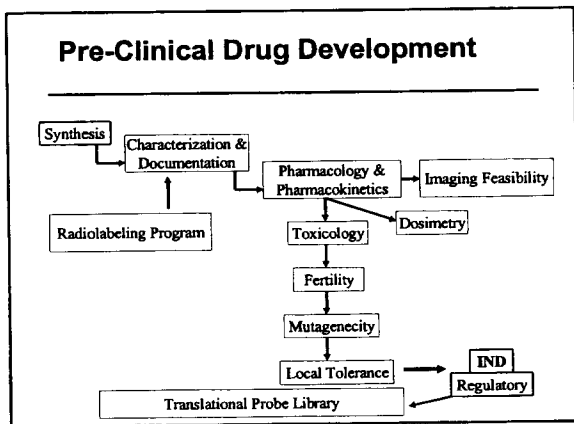
- Determine feasibility of agent or probe as imaging agent in appropriate model
- Determine optimal imaging parameters
 - Timing
 - Usable dose range
 - Imaging modality characteristics



Radiolabeling Program

Mechanism

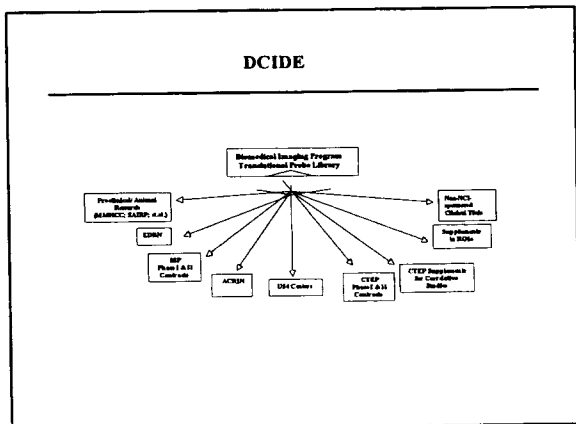
- Radiolabeling centers
- Program includes agents with potential for radiolabeling - either technique has not been perfected by investigator or PET distribution is required
- Centers perfect labeling of agent and/or optimize labeling for distribution as kit



Translational Probe Library

Purpose

- House developed probes (IND filed)
- Facilitate access by clinical trials groups, investigators, or pre-clinical researchers interested in *in vivo* imaging studies, including proof-of-principle animal model studies



Real Challenge Real Potential

- Targeted probes
- Highly specific imaging
- Integrated therapy

A small diagram of a molecular structure, possibly a probe or drug, with a central sphere and several smaller spheres attached to it.

Real Challenge Real Potential

- Targeted probes
- Highly specific imaging
- Integrated therapy



Ultrasound Example –

Targeted Imaging and Therapy Delivery

Disruption of Drug Capsule -Image Controlled Targeted Delivery

