NCI Programs in Image-Guided Cancer Interventions

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Outline

1. Image-Guided Drug Delivery (R01)

2. Academic Industry Partnerships (R01)

3. Early Phase Clinical Trials in Imaging and IGI (R21)

4. Quantitative Imaging for Evaluation of Response to Cancer Therapies (U01)

5. Small Business Grants (R43/R44; R41/R42)
Mission: to promote and support the integration and validation of imaging and interventional oncologic treatments and their applications toward improved clinical management of cancer.
Drug Delivery Systems

- Focused Ultrasound

- Chemoembolization
IG- Local Triggering of Drug Release

- Temperature sensitive nanocarriers (*phase III & pre*-

- Pressure sensitive microbubbles (*preclinical*)

- Ultrasound-induced tissue permeability (*preclinical*)

- FUS-induced ablation + microbubble cavitation (*preclinical*)
Drug Delivery Systems

- Nanocarrier platforms enable drug delivery
  
  - Multifunctional
    - Contrast
    - Drugs
    - Targeting
    - Activation
  
  - Multiplexed
    - Molecular signals
    - Targeting
    - Monitoring
IGDD Shifting Paradigms

- Imaging as an enabling tool:
  - Biodistribution
  - Pharmacokinetics (PK)
  - Pharmacodynamics (PD)
  - Evaluation of response to therapy
Image-Guided Drug Delivery (IGDD)

• A form of personalized therapy where imaging guides the target localization, controlled release, and monitoring of drug delivery.

• Goal: to optimize the therapeutic ratio.

• Requirements:
  – Drugs that can be imaged and possibly targeted
  – Mechanisms for controlled release and activation
  – Imaging: Anatomic / Physiologic / Molecular / Quantitative
First Receipt Date: Feb 5, 2010

Expiration: May 8, 2013

Single or Multiple PIs

Reviews assigned to various Study Sections (CSR): MEDI, CMIP, GDD, RTB, NANO, etc.
Goals of IGDD PA

- Development of integrated platforms for multifunctional and multiplexed oncologic IGDD systems

- Development of quantitative in-vivo imaging methods in IGDD in cancer
  - interrogate tumor/drug interaction
  - imaging studies of biodistribution, PK/PD, Tx response
  - perform imaging studies in non-human primates or large animal models for toxicity screening
Academic-Industrial Partnerships (R01) – [PAR-10-169]

- **Purpose:** Development and Validation of Imaging Systems and Methods

- Requires Partnership between academic and industrial Co-Pis

- Includes investigations of IGI-systems

- Standard R01 Application Receipt Dates

- SEP Review (CSR)
Early Phase Clinical Trials in Imaging & IGI (R21) - [PAR-11-216]

- Quick (2 yr) clinical trials of novel imaging and IGI
  - Intended to accelerate the development of imaging and IGI modalities, methodologies, and agents through the early stages of clinical development - such as trials evaluating safety and preliminary efficacy
- Phase I & II studies to establish treatment parameters and early therapeutic efficacy
- SEP Review (CSR)
Quantitative Imaging for Evaluation of Response to Cancer Therapies (U01) – [PAR-11-150]

• Quantitative imaging of response to therapies, including IGI, to facilitate clinical decision making

• Development and implementation of QI methods and tools and their applications to current or pending Phase I/II clinical trials

• Funded teams join the Quantitative Imaging Network (QIN)
The QIN Map (Q2-2011)
QIN Working Groups

- Data Collection
- Image Analysis & Performance Metrics
- Bioinformatics/IT & Data Sharing
- Clinical Trial Design & Development
- Outreach: External/Industrial Relations
Image-Guided Cancer Interventions
PA-10-079 (SBIR); PA-10-080 (STTR)

• Development and optimization of integrated cancer imaging and therapy systems

• Validation of integrated IGI systems through clinical evaluations

  Phase I: up to 2 years
  Total costs: $150,000 per year

  Phase II: up to 3 years
  Total Costs: $1,000,000 (clinical studies), $750,000 (otherwise)
Other Initiatives

- **Bioengineering Research Funding Opportunities**
  - Exploratory Bioengineering Research Grants (EBRG) – PA-10-010
  - Bioengineering Research Grants (BRG) – PA-10-009
  - Bioengineering Research Partnerships (BRP) – PAR-10-234

- **Innovations in Biomedical Computational Science & Technology**
  - R21: PAR-09-219
  - R01: PAR-09-218
  - SBIR: PAR-09-220
  - STTR: PAR-09-221
TCIA: The Cancer Imaging Archive

http://cancerimagingarchive.net
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Funded by CIP/NCI, is a large archive of clinical images of cancer accessible for download.

TCIA de-identifies, organizes, and catalogs the images for use by the research community.

The archive is already home to high value data sets including a growing collection of cases that have been characterized in the Cancer Genome Atlas (TCGA)

http://cancerimagingarchive.net
Translational Research Support

- **Concept**
- **Feasibility & Design**
- **Feasibility Testing**
- **Validation**
- **Clinical Studies**
- **IND/IDE Submission**
- **FDA Submission**
- **CMS / Standard of Care**

**Imaging Translational Research Pipeline**

- **Prototyping**
- **Standardization**

**Projects**

- Image-Guided Drug Delivery (R01)
- Quantitative Imaging Network (U01)
- Academic/Industrial Partnerships (R01)
- Early Phase Trials (R21)
- ACRIN (U01)

**Stages**

- Phase I
- Image-Guided Cancer Interventions (SBIR/STTR) Phase II
- Phase IIB
Shifting Paradigms

Imaging

- Early detection
- Characterization
- Treatment
- Follow-up

Lower and focused energy or drug dosing for improved safety & efficacy

Macro Anatomy

Micro Anatomy

Biochemical

Systemic

Targeted

Therapy

Courtesy of G. Lanza
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