Oncology Co-Clinical Imaging Research Resources (U24s) to Develop Best Practices for Quantitative Imaging (QI) in Mouse Models

A Trans-NCI Initiative

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Trans NCI Initiatives
Role of imaging as an enabling technology

Cancer Biology (DCB)
Cancer Prevention (DCP)
Cancer Diagnosis (DCTD)
Cancer Informatics (CBIIT)
Cancer Genomics (DCB)

Cancer Imaging Program (DCTD)

Imaging must become relevant to other research domains

Precision medicine requires:
Better animal models & novel research methods

http://www.nih.gov/precisionmedicine
Challenges in co-clinical trial imaging

- Diverse range of preclinical imaging platforms
- Not optimized for multi-platform-site investigations
- Lack of resources to promote best practices for QI
- Preclinical QI methods need to be optimized to improve correlation studies for the co-clinical trial

New U24 Initiative: PA-15-226

Clinical Trial Goals

- Therapeutic goal: Prediction, staging and/or measurement of response to cancer therapies
- Screenings goal: Early detection or cancer risk stratification for lethal cancers versus non-lethal disease

Purpose of PAR

- Support multi-disciplinary teams
- Propose co-clinical trials using "best practices"
- Propose best practices for data collection and analysis
- Propose means to archive data, methods and software tools NCI existing resources (TCIA)
Coordination with other NCI PARs

- Oncology Models Forum (U24s)
- Quantitative Imaging Network (U01s)
- Academic Industry Partnership (R01s)
- ITCR Informatics (U01s, U24s)
- Co-clinical Imaging Research Resource (U24s)

Leverage research resources and methods

Modeled after the QIN U01’s

PAR-14-116: Quantitative Imaging for Evaluation of Response to Cancer Therapies (U01):
- Develop innovative methods for data collection and analysis
- Collect image data from ongoing phase I-III clinical trials to generate a clinical research technical resource
- Explore a means to develop a consensus on quantitative imaging methods for validating clinical imaging tools

QIN is a test bed for ITCR and AIP Activities

QIN is a test bed for ITCR and AIP Activities
NCI: The Cancer Imaging Archive (TCIA) being modified to host DICOM for pre-clinical data

Linked to The Cancer Genome Atlas (TCGA)
- TCIA - Imaging Genomic Correlation
- TCIA: National CT Lung Screening Trial Data (NLST)
- Quantitative Imaging Network Data (QIN)

Requirements: Co-clinical Trial

- Prospective co-clinical therapy trial
  - State of the art quantitative imaging methods
  - Commercially supported imaging platforms
    - Exception: Cancer risk or prevention studies
    - Same Class of imaging platform (PET-CT, MRI)
    - Trial costs not covered; additional QI methods are
    - Data size and quality should be sufficient to provide:
      - Robust statistical comparison of QI methods

- Retrospective co-clinical trial
  - State of the art QI methods at the time of the trial,
  - Methods must be well documented

Requirements: Co-clinical Trial

- The therapeutic goal:
  - The primacy or secondary drug to be tested should be known to have a response in tumors that match histologically or genomically to the mouse model

- For the prevention goal:
  - The form of intervention shown to be effective with the context of early cancer detection or prevention

- For the mouse model goal:
  - Should be available, validated and credentialed using published recommended best practices
  - Animal care meet IACUC best practices: Longitudinal studies
**Requirements: Co-clinical Trial**

- Populate an internet accessible research resource:
  - Collected co-clinical trial data, detailed methods, related software tools (metrology tools, and results of the correlation studies)
  - The use of NCI-funded research resources is highly recommended as being implemented by the trans-NCI Oncology Models Forum:
    - The Cancer Imaging Archive (TCIA)
    - The NCI NCIP HUB
    - Network wide consensus approaches will be explored when the U24 network is established, similar to the QIN network

- Demonstrate the resource functionality
  - Software “grand challenges”, similar to the QIN network
  - Compare the performance of current and improved tools

**Suggestions for planned applications**

- Organize multiple disciplinary teams experienced in:
  - Mouse model research
  - Human investigations
  - Imaging platforms
  - QI methods,
  - Clinical decision support tools
  - Informatics as required to create the research resource

- Before the full development of the application
  - Have all key members read the full PAR
  - Contact NCI to set up a TCON to ensure you are being responsive to the full requirements of this complex PAR