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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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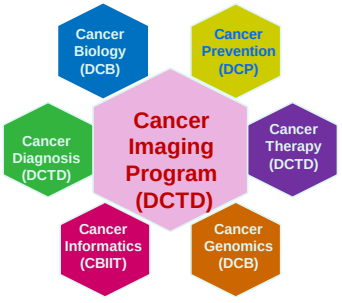
Trans NCI Initiatives
Role of imaging as an enabling technology



Imaging must become relevant to other research domains

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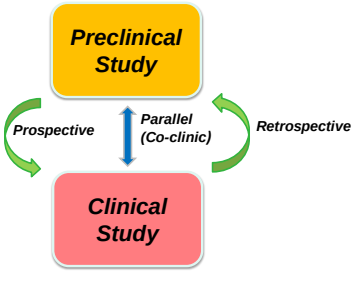
Precision medicine requires:
Better animal models & novel research methods

Collins FS, and Varmus H, ***A new initiative on precision medicine,*** **NEJM, 329:794 (2015)**
http://www.nih.gov/precisionmedicine/



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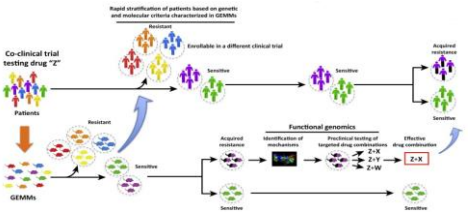
Challenges in co-clinical trial imaging

- 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



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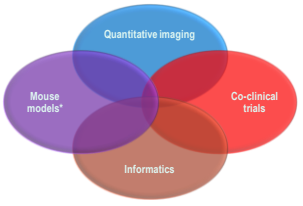
New U24 Initiative: PA-15-226 Clinical Trial Goals

Oncology Co-Clinical Imaging Research Resources to Encourage Consensus on Quantitative Imaging Methods and Precision medicine (U24).

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



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Purpose of PAR

- Support multi-disciplinary teams
  - Mouse modelers, quantitative imaging, informatics-resources
- Propose co-clinical trials using "best practices"
  - Validated and credentialed mouse and human-in-mouse models
- Propose best practices for data collection and analysis
  - Permit quantitative correlation studies,
  - Imaging and other commercial biomarker assays
- Propose means to archive data, methods and software tools NCI existing resources (TCIA)
  - Share methods and results in the OMF Hub
  - Provide a framework to exercise software "grand challenges".

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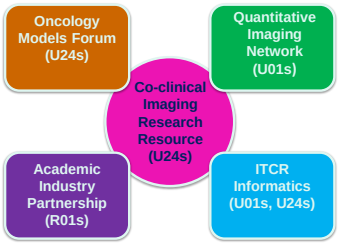
Coordination with other NCI PARs



Leverage research resources and methods

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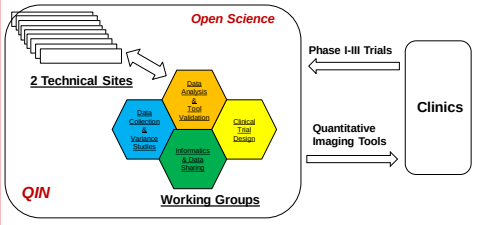
Modeled after the QIN U01's

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 clinic imaging tools**



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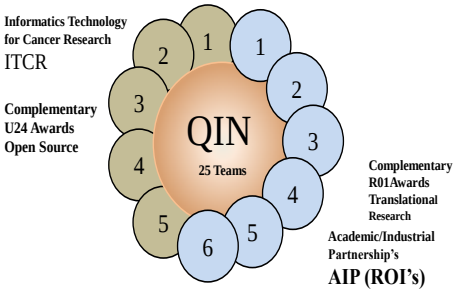
QIN is a test bed for ITCR and AIP Activities



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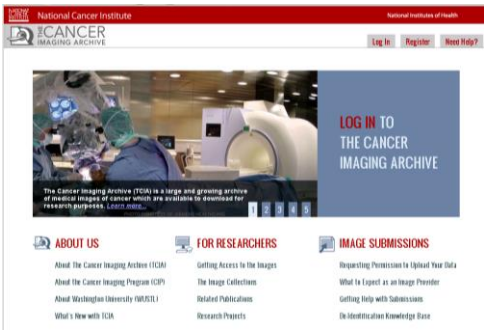
NCI: The Cancer Imaging Archive (TCIA)

Being modified to host DICOM for pre-clinical data



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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**

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Requirements: Co-clinical Trial

- **The therapeutic goal:**
  - **The primacy or secondary dug to be tested should be known to have a response in tumors that match histologically or gnomically to the mouse model**
- **For the prevention goal:**
  - **The form of intervention shown be known 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**

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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

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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