NCI Funding Opportunities in Image Guided Interventions

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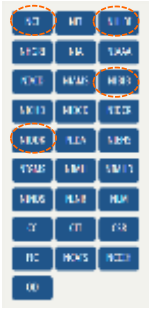
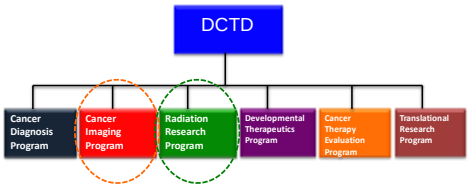
NIH NATIONAL CANCER INSTITUTE

AAPM 2018

NIH Institutes and Centers



NCI Division of Cancer Treatment and Diagnosis (DCTD)



Current NCI Funding Opportunities in Cancer Imaging

1. NIH Research Project Grant (R01)
2. NCI's Investigator-Initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01)
3. NCI Clinical and Translational Exploratory Studies (R21)
4. Academic Industry Partnerships (R01)
5. Early Phase Clinical Trials (R01)
6. Quantitative Imaging (U01)
7. Image-Guided Drug Delivery (R01)

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NIH Research Project Grant [PAR-18-484] (Parent R01 Clinical Trial Not Allowed)

- Supports discrete, specified, circumscribed project in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions
- CSR Review
- Standard receipt dates

➢ https://grants.nih.gov/grants/guide/pa-files/PA-18-484.html

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NCI's Investigator-Initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis

(R01 Clinical Trial Required) [PAR-18-560]

- Supports projects early phase (Phase 0, I, and II) investigator-initiated clinical trials focused on cancer-targeted diagnostic and therapeutic interventions of direct relevance to the research mission of NCI's Division of Cancer Treatment and Diagnosis (DCTD).
- Applicants strongly encouraged to consult the NCI DCTD website at https://dctd.cancer.gov/ for program goals, research priorities.
- Applications submitted to this FOA must include studies that meet the National Institutes of Health (NIH) definition of a clinical trial (see NOT-OD-15-015 for details) and provide specific clinical trial information as described in this FOA
- Standard receipt dates
- CSR review
- Expires Jan 2021
- https://grants.nih.gov/grants/guide/pa-files/PAR-18-560.html

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NIH Clinical Trial Definition

NIH Clinical Trial Definition
A research study in which one or more human subjects are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[5]
[3]The term "*prospectively assigned*" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
[4]An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
[5]*Health-related biomedical or behavioral outcome* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

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NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

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4 Questions to determine the difference between a Clinical Study and a Clinical Trial

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

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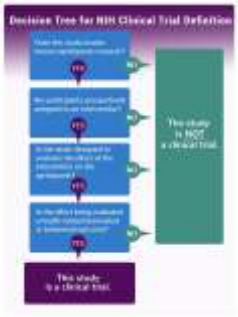
4 Questions to determine the difference between a Clinical Study and a Clinical Trial



Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (placebo / control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

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NCI Clinical and Translational Exploratory/Developmental Studies (R21) [PAR-18-020]

- **Development of exploratory research in cancer diagnosis, treatment, imaging, symptom/toxicity, and prevention clinical trials; novel cancer therapeutic, and preclinical studies**
- **NCI Review**
- **Expires: March 2019**

➢ **https://grants.nih.gov/grants/guide/pa-files/PAR-18-020.html**

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Academic-Industrial Partnerships to Translate and Validate in vivo Cancer Imaging Systems (R01) – [PAR-18-530]

- **Purpose: Stimulate translation of imaging technologies into tools addressing problems in cancer biology, prevention, diagnosis, staging, and/or treatment.**
- **Requires formation partnership between academic and industrial investigators**
- **Expires: Jan 2021**
- **SEP Review (CSR)**

➢ **https://grants.nih.gov/grants/guide/pa-files/PAR-18-530.html**

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Early Phase Clinical Trials in Imaging & IGI (R01) [PAR-18-011]

- 3 year clinical trials in novel imaging or 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)
- Expires: Feb 2020

➢ https://grants.nih.gov/grants/guide/pa-files/PAR-18-011.html

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Quantitative Imaging Tools and Methods for Cancer Therapy Response Assessment- (UG3/UH3) [PAR-18-248]

- QI tool development and optimization for treatment planning, prediction or measurement of response to cancer therapy, including IGI
- Development, optimization, and validation (in clinical setting) of QI tools to demonstrate value for decision support in clinical trials
- Funded teams join the QI Network (QIN)
- Expires: Jan 2020

➢ https://grants.nih.gov/grants/guide/pa-files/PAR-18-248.html

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Quantitative Imaging Tools and Methods for Cancer Therapy Response Assessment- (U01) [PAR-18-249]

- QI tool development and optimization for treatment planning, prediction or measurement of response to cancer therapy, including IGI
- Clinical translation of optimized QI tools for measuring or predicting the response of cancer to clinical therapies
- Funded teams join the QI Network (QIN)
- Expires: Jan 2020

➢ https://grants.nih.gov/grants/guide/pa-files/PAR-18-249.html

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Image-Guided Drug Delivery (R01) [PAR-18-252]

- **Development of integrated platforms for multifunctional / multiplexed IGDD systems**
- **Development of quantitative in-vivo imaging methods in IGDD for cancer and other indications**
  - **interrogate tumor/drug interaction**
  - **imaging studies of biodistribution, PK/PD, Tx response**
- **CSR Review: SEP**
- **Receipt dates: June and November: 2016-2018**

➢ **http://grants.nih.gov/grants/guide/pa-files/PAR-18-252.html**

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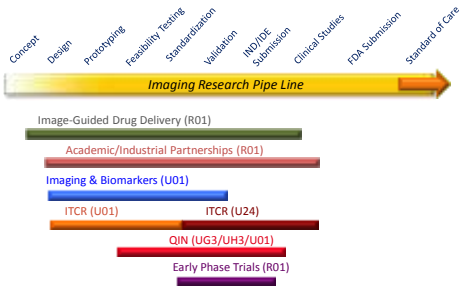
NCI Imaging Research Support Pipeline



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