Immuno-Oncology Translational Network (IOTN) Pre-Application Webinar

RFA-CA-17-045: Cancer Immunotherapy Research Projects (U01)

RFA-CA-17-046: Cancer Immunoprevention Research Projects (U01)

RFA-CA-17-047: Data Management and Resource-Sharing Center (DMRC) (U24)

RFA-CA-17-048: Cellular Immunotherapy Data Resource (CIDR) (U24)

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/upcoming

https://www.cancer.gov/about-nci/organization/dcb

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Blue Ribbon Panel Recommendations

A. Establish a network for **direct patient involvement**

B. Create a translational science network devoted to **immunotherapy**

C. Develop ways to overcome **resistance to therapy**

D. Build a national cancer **data ecosystem**

E. Intensify research on the major drivers of **childhood cancer**

F. Minimize cancer treatment's debilitating **side effects**

G. Expand use of proven **prevention and early detection** strategies

H. Mine past patient data to predict future **patient outcomes**

I. Develop a 3D **cancer atlas**

J. Develop new cancer **technologies**

Blue Ribbon Panel - Recommendation B

The implementation plan outlined a network focused on:

- Discovering and evaluating novel immune-based approaches to increase the number of patients that benefit from immunotherapy; and
- developing vaccines to prevent cancers of all types.

Common Elements - Key Dates

Standard elements:

- **Letter of Intent Due Date** — **December 16, 2017**
- **Application Due Date** — **January 16, 2018**
  - by 5:00 PM local time of applicant organization
  - it's highly recommended to submit early!
- **No late applications will be accepted**
- **Scientific Merit Review** — **April/March 2018**
- **Advisory Council Review** — **August 2018**
- **Earliest Start Date** — **September 2018**

Common Elements - Letter of Intent (LOI)

Highly encouraged, but not required. ***Not binding and does not enter into the review. Important for staff to define the scope of expertise needed by peer reviewers.***

Standard elements:

- Descriptive title of the project
- Name(s), address(es), telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating Institution(s)
- Number and title of the funding opportunity

Additional recommended information:

- Provide a brief (3-5 sentence) description of the project
- Include relevant reviewer expertise for review of the application and Keywords

Common Elements – Cooperative Agreement

- All RFAs use the **cooperative agreement** U-mechanism.
- Grantees will be expected to **actively participate in a IOTN Consortium**.
- PIs will **serve on the Consortium Steering Committee** to discuss community issues, set policies, and plan and evaluate activities to meet program goals.
- The Steering Committee will **meet regularly** by teleconference, and Consortium members will meet in person at an Annual Program Meeting.
  - **PIs should include budget for travel.**
- Read cooperative agreement terms carefully.

Cancer Moonshot Data Sharing and Health Disparity Research

- Utilizing the provision outlined in the 21st Century Cures Act, NCI has established a data sharing strategy that requires public access immediately upon publication of all research results and underlying data for projects that are funded as part of the Beau Biden Cancer Moonshot Initiative:
  - https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy
- The data sharing plan will become terms and conditions of award.
- If applicable, address how the proposed studies have potential to reduce cancer burden in diverse populations, including minority and underserved populations.

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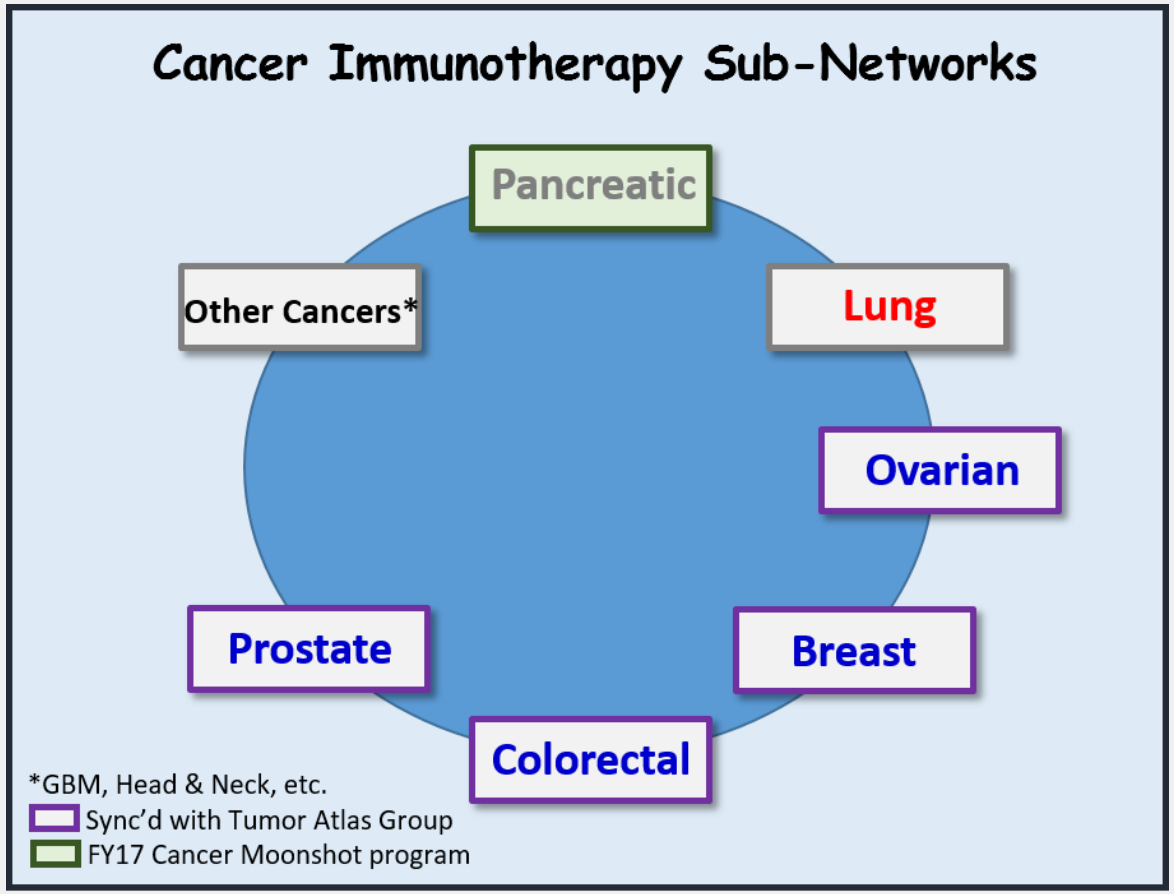
Cancer Immunotherapy Research Projects (U01)



Goal: Establish a consortium of collaborating research teams to develop improved tumor-specific immunotherapy approaches.

Objectives:

- Define immune interactions in tumor microenvironments.
- Identify novel immune checkpoints, tumor-specific T cell receptors and their cognate tumor targets (neoantigens).
- Uncover intrinsic and extrinsic resistance pathways.
- Test improved immunotherapies, including cancer vaccines, checkpoint inhibitors, cellular therapies, viral therapies, bispecific antibodies, and their combinations with other regimens for durable anti-cancer responses.
- Studies should be largely **pre-clinical** involving clinically-relevant models and endpoints for rapid translation.

Cancer Immunotherapy Research Projects (U01)

Scientific Goals of the Cancer ImmunoTherapy Projects

- Defining factors that contribute to escape from immune surveillance
- Improving antigen presentation and priming of anti-tumor cytotoxic T cells
- Discovering and optimizing novel immunotherapies and combination therapies
- Investigating mechanisms of acquired resistance following immunotherapy
- Identifying tumor subtypes or locations within the tumor exhibiting enhanced or reduced susceptibilities to immunotherapies, and establishing the mechanisms associated with these differential responses
- Identifying effective immunotherapy approaches in both the periphery and the CNS
- Avoiding or reducing off-target or immune-related adverse events

Cancer Immunotherapy Research Projects (U01)

Research Topics of Interest to Partnering NIH Institutes

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

- Applications that have the potential to identify the role played by alcohol use on intrinsic resistance mechanisms and generation of an immunosuppressive tumor microenvironment that influence alcohol-induced cancers, and to accelerate the development of guidelines to improve outcomes of immunotherapy for these forms of cancer

National Institute of Dental and Craniofacial Research (NIDCR)

- Research that aims to treat head and neck squamous cell carcinomas (HNSCC) through stimulation of the immune response focusing on checkpoint inhibition, adoptive T cell transfer, and vaccine therapies

National Institute of Environmental Health Sciences (NIEHS)

- Applications that explore how environmental exposures might affect cancer immunotherapy outcomes; Animal studies exploring the interaction of common environmental toxicants with cancer immunotherapies that would inform subsequent human clinical trials

National Institute of Neurological Disorders and Stroke (NINDS)

- Research on development of immunotherapies for primary brain tumor

RFA-CA-17-045: Cancer Immunotherapy Research Projects (U01), Part 2. Section I.

Cancer Immunotherapy Research Projects (U01)

Research that will <u>not</u> be considered for this FOA

- Projects that focus on immune microenvironment of pancreatic ductal adenocarcinoma supported by RFA-CA-17-015
- Projects that focus on pediatric cancer immunotherapy solicited by RFA-CA-17-050 and -051
- Specimen Collection and banking that are not associated with experimental hypothesis
- Initiation of new clinical trials of investigational treatment regimens

Cancer Immunotherapy Research Projects (U01)

Budget, Mechanism, and Eligibility

- **Direct Costs:** Application budgets are limited to **$500,000 in Direct Costs per year**.
- **Anticipated # of Awards:** The NCI intends to fund 8-9 awards.
- **Project Period:** A project period of 5 years must be requested.
- **Mechanism:** A **U01** Research Project - Cooperative Agreement.
- **Eligibility:** Foreign Institutions **are not** eligible to apply; foreign components **are** allowed.

Cancer Immunotherapy Research Projects (U01)

Scientific Review

Scored Review Criteria: Significance, Investigator(s), Innovation, Approach, Environment

Specific review elements for this FOA include:

- Does the application propose innovative plans for leveraging expertise and resources, integrating clinically-relevant information, and utilizing relevant pre-clinical models that can accelerate translation of basic discoveries to improved clinical application of immunotherapeutic approaches?
- How well do the proposed studies have potential to reduce cancer burden in diverse populations, including minority and underserved populations?
- Are proposed studies appropriately powered, controlled, randomized, and blinded?
- Which project resources could be *potentially* shared with the Cancer Immunotherapy Consortium, the IOTN and the broader scientific community?
- Does the application address the NCI Cancer Moonshot℠ Public Access and Data Sharing Policy?

Cancer Immunotherapy Research Projects (U01)

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Robert Shoemaker, Ph.D.
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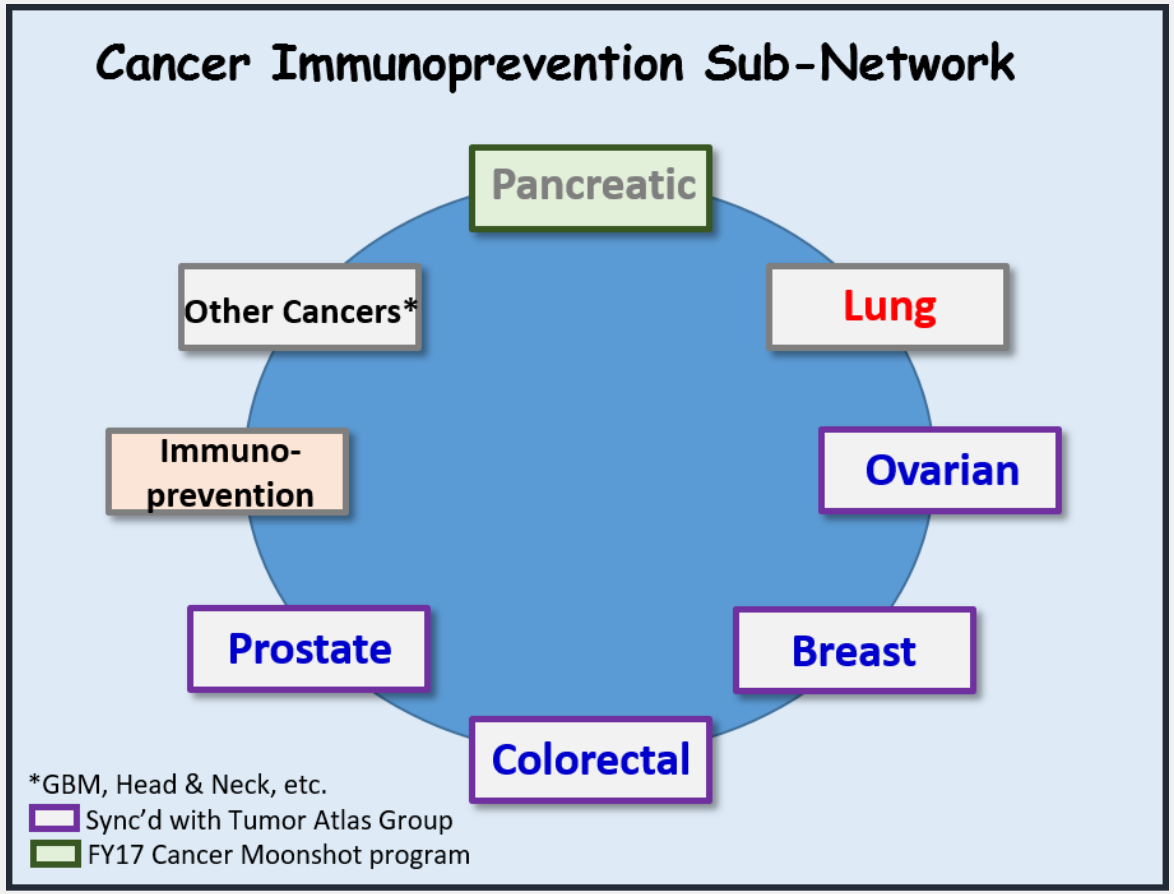
Cancer Immunoprevention Research Projects (U01)



Goal: Identify actionable targets arising in pre-cancerous lesions; develop and validate early intervention vaccines based on these targets.

Strategy:

Focus on cancers that occur in specific organ sites in high-risk cohorts.

- Lynch Syndrome (colon and endometrial cancer)
- Familial Adenomatous Polyposis (colon cancer)
- BRCA1/2 Carriers (breast and ovarian cancer)
- NF and TSC (neurologic and other cancers)
- Other Genetic Predisposition Syndromes
- Populations exposed to environmental carcinogens
- Other definable high-risk cohorts

Cancer Immunoprevention Research Projects (U01)

Scientific Goals of the Cancer Immunoprevention Projects

- Define an experimental setting that enables the definition of changes in potential immune targets as a function of time during carcinogenesis.
- Evaluate the validity of identified targets for immunoprevention as a function of time.
- Devise interventions with practical potential for translational studies.
- Produce the preclinical reagents necessary for demonstration of cancer preventive efficacy.
- Demonstrate and reproduce preventive efficacy in preclinical models.

Cancer Immunoprevention Research Projects (U01)

Budget, Mechanism, and Eligibility

- **Direct Costs:** Application budgets are limited to **$500,000 in Direct Costs per year**.
- **Anticipated # of Awards:** The NCI intends to fund four awards.
- **Project Period:** A project period of 5 years must be requested.
- **Mechanism:** A **U01** resource-related cooperative agreement.
- **Eligibility:** Foreign Institutions **are not** eligible to apply; foreign components **are** allowed.

Cancer Immunoprevention Research Projects (U01)

Scientific Review

Scored Review Criteria: Significance, Investigator(s), Innovation, Approach, Environment

Specific review elements for this FOA include:

- Are the high-risk cohorts addressed by this application well-defined?
- Is there potential for mechanism-based cancer preventive intervention development?
- Does the application contain acceptable plans for addressing the NCI Cancer Moonshot℠ Public Access and Data Sharing Policy

Cancer Immunoprevention Research Projects (U01)

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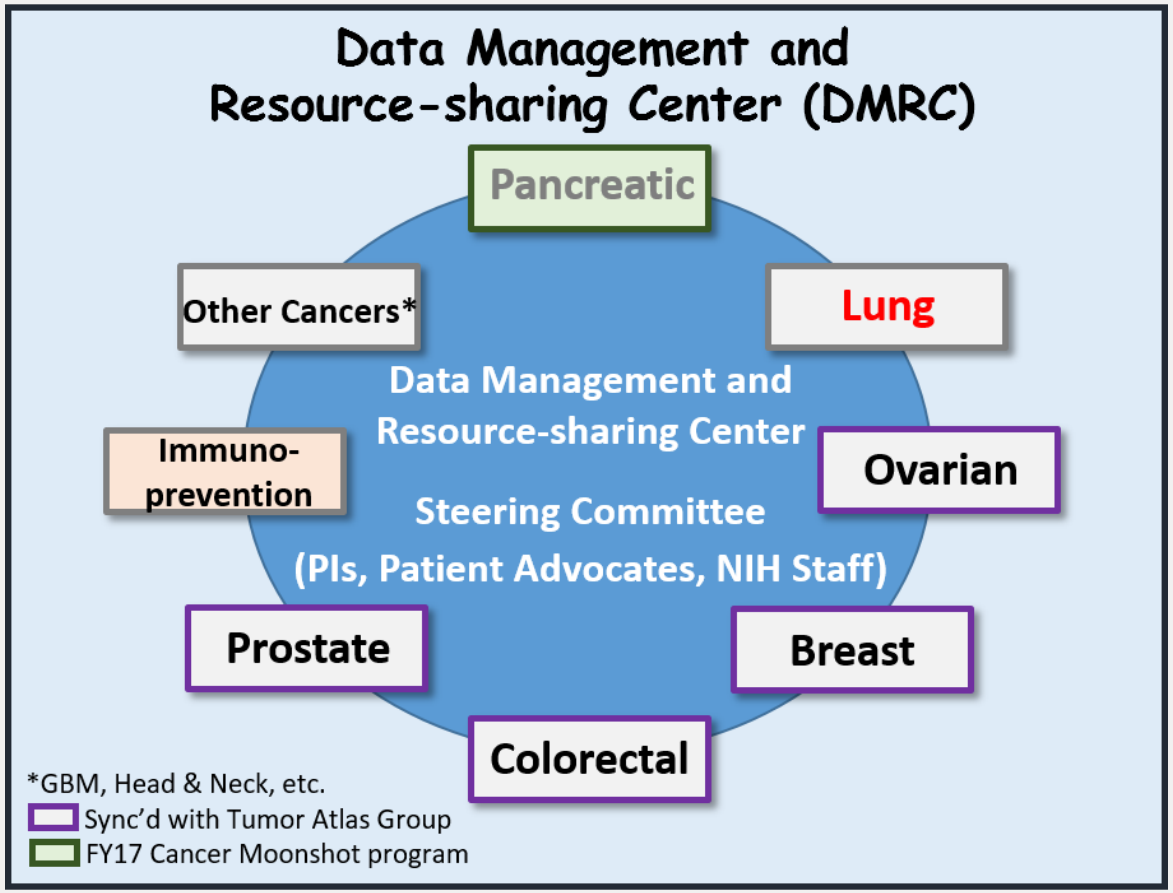
Kevin Howcroft, Ph.D.
Division of Cancer Biology, NCI

Data Management and Resource-Sharing Center (U24)



Goal:

The DMRC will provide overall support for the IOTN, promote collaboration across IOTN components, and enhance the integration of IOTN research activities with other Cancer Moonshot programs.

Objectives:

DMRC applicants must address three activities:

- Network Administration and Coordination
- Resource-sharing and Scientific Outreach
- Data Integration and Sharing

Data Management and Resource-Sharing Center (U24)

Objectives (cont):

Network Administration and Coordination (NAC):

- Act as the organizational hub to provide **overall administrative support** among IOTN components and between the IOTN and the NCI.
- Develop a **consortium website** to foster member communication and collaboration.

Resource-sharing and Scientific Outreach (RSO):

- Oversee the tracking and distribution of network biospecimens, models, and resources (**virtual biorepository**).
- Develop an **outfacing IOTN website** that will constitute the main entry point for the sharing of resources and information related to IOTN activities with the scientific community.

Data Integration and Sharing (DIS):

- Provide **centralized bioinformatic and computational support**.
- **Establish SOPs and quality control** for all network generated data - including genomic data, tumor targets, and cellular analyses and their deposition in appropriate databases.
- **Coordinate with Cancer Moonshot components** (Tumor Atlas, Data Ecosystems, Cancer Immunologic Data Commons, others).

Data Management and Resource-Sharing Center (U24)

Budget, Mechanism, and Eligibility

- **Direct Costs:** Application budgets are limited to **$750,000 in Direct Costs per year**.
- **Anticipated # of Awards:** The NCI intends to fund one award.
- **Project Period:** A project period of 5 years must be requested.
- **Mechanism:** A **U24** resource-related cooperative agreement.
- **Eligibility:** Foreign Institutions **are not** eligible to apply; foreign components **are** allowed.

Data Management and Resource-Sharing Center (U24)

Scientific Review

Scored Review Criteria: Significance, Investigator(s), Innovation, Approach, Environment

Specific review elements for this FOA include:

- Prior **experience and/or qualifications** to implement the proposed DMRC activities?
- Does the applicant propose **innovative strategies** (e.g., data coordination solutions, data analysis approaches, and outreach) for advancing the DMRC activities?
- Are the proposed plans for **websites and virtual repository** adequately described?
- How optimal are the applicant institution resources for supporting the goals of DMRC?
- Does the application address the NCI Cancer Moonshot℠ Public Access and Data Sharing Policy?

Data Management and Resource-Sharing Center (U24)

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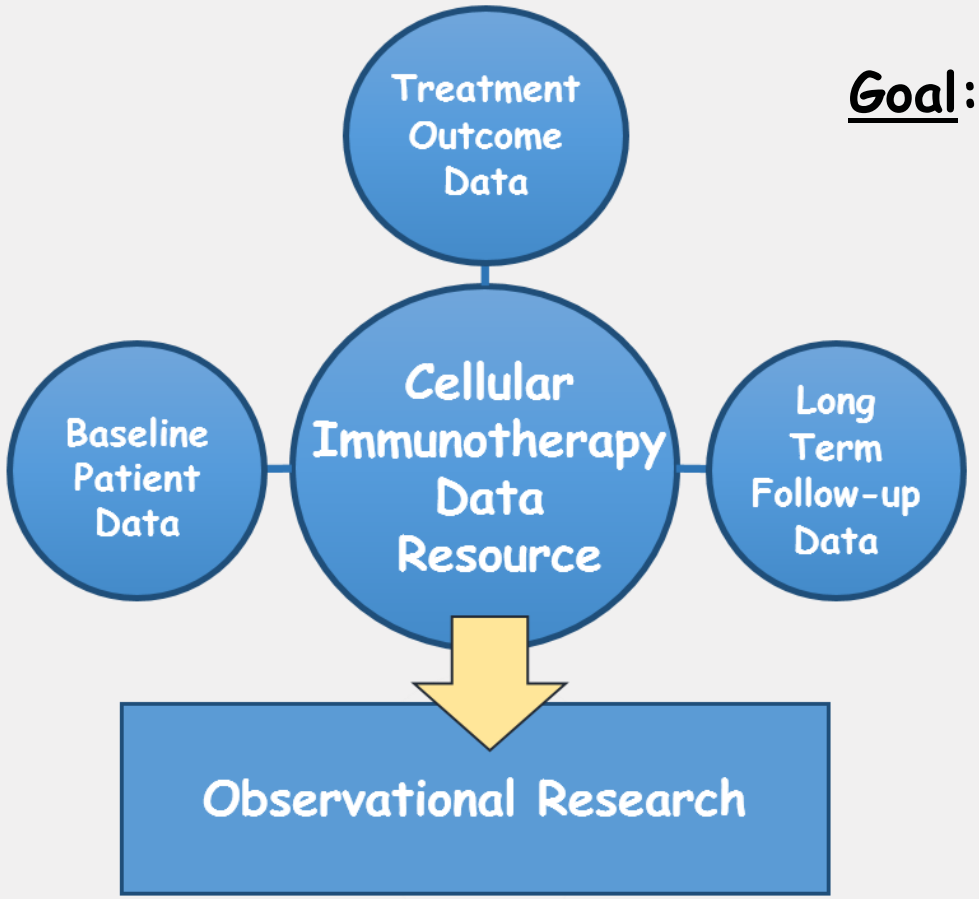
Cellular Immunotherapy Data Resource (U24)



Goal: Accelerate optimization of cell-based immunotherapies; High impact for cancers with low mutation burden.

Objectives:

- Establish a Data Registry to collect baseline patient data, treatment outcomes, and long term follow-up
- Support all cellular immunotherapy trials (NCI-sponsored, investigator-initiated, or pharmaceutical company-sponsored) or treatment with an FDA-approved agent
- Facilitate analysis of the observational data for the design of pre-clinical research in the Cancer Immunotherapy Consortium (CIC) and elsewhere, as well as inform design of future trials

Cellular Immunotherapy Data Resource (U24)

Objectives (cont):

Resource establishment:

- The electronic process for data collection including the data forms for each of the various steps in a cell therapy procedure
- Strategies to collect long-term data from patients on genetically modified cellular therapies
- Data quality control procedures, via data validation and data auditing

Resource utilization:

- Establish a Scientific Working Committee and biostatistical support for the review, prioritization and implementation of the proposed observational studies requesting use of resource data

Resource Sharing:

- Establish common data elements and quality control metrics to ensure that the data are findable, accessible, interoperable, and reusable (FAIR) and ensure it is maximally useful to the public
- Develop an Application Programming Interface (API) to facilitate interactions with other Cancer Moonshot data coordinating centers

Cellular Immunotherapy Data Resource (U24)

Budget, Mechanism, and Eligibility

- **Direct Costs:** Application budgets are limited to **$1,200,000 in Direct Costs per year**.
- **Anticipated # of Awards:** The NCI intends to fund one award.
- **Project Period:** A project period of 5 years must be requested.
- **Mechanism:** A **U24** resource-related cooperative agreement.
- **Eligibility:** Foreign Institutions **are not** eligible to apply; foreign components **are** allowed.

Cellular Immunotherapy Data Resource (U24)

Scientific Review

Scored Review Criteria: Significance, Investigator(s), Innovation, Approach, Environment

Specific review elements for this FOA include:

- Does the data resource address the current and future needs of the cellular immunotherapy investigator community?
- Are directions and approaches for potential areas of observational research cutting-edge and novel?
- How conducive is the environment of applicant institution(s) to the goals of the CIDR, including enhancing the information technology required for data registry support?

Cellular Immunotherapy Data Resource (U24)

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Questions