Helping Extramural Innovators Reach the Clinic: NCI Developmental Therapeutics Program
12:30 PM  Welcome Remarks/ Intro to DTP  Rose Aurigemma, PhD
12:40 PM  Funding Opportunities  Sundar Venkatachalam, PhD
12:50 PM  New Drug Development Resources  Rose Aurigemma, PhD
1:00 PM  Stepping Stones Program  Sharad Verma, PhD
1:10 PM  Immuno-oncology Initiatives & Services  Marc Ernstoff, MD
1:20 PM  Q & A
Welcome Remarks and Overview of the Developmental Therapeutics Program

Rose Aurigemma, PhD
Associate Director, DTP, DCTD, NCI
Division of Cancer Treatment and Diagnosis (DCTD), NCI

- Biometrics Research Branch (BRB)
- Cancer Diagnosis Program (CDP)
- Cancer Imaging Program (CIP)
- Cancer Therapy Evaluation Program (CTEP)
- Developmental Therapeutics Program (DTP)
- Radiation Research Program (RRP)
- Developmental Therapeutics Clinic (DTC)
- Translational Research Program (TRP)
- Office of Cancer Complimentary and Alternative Medicine (OCCAM)

**DTP Mission:** Support and assist the Extramural Community to advance New Cancer Therapies toward Clinical use
Overview of DTP Extramural Support Mechanisms

1. **Grant funding**: Over 900 funded awards pertaining to drug discovery and development of small molecules, natural products, biopharmaceuticals, etc.

2. **Repositories**: Collections of small molecules, pre-fractionated natural products, biologics, tumor models, and data are available to the public.

3. **Access to Discovery and Development Services**: DTP maintains drug discovery and development facilities at Frederick National Laboratory for Cancer Research (FNLCR) as well as contracted resources (CROs).

4. **Expertise**: Staff with multidisciplinary expertise provide consultations along the critical path of discovery and development (all extramural - academic, non-profit, pharma).
Overlapping Support for Discovery and Development

DTP Grants

DTP Services and Resources

Basic Research

Preclinical Research

Clinical Research

NCI Experimental Therapeutics (NeXT) Program
DTP Branches: Provide Funding, Repositories and Services

**Preclinical Therapeutics Grants Branch**
**Grants:** Small Molecule, Natural Product, drug targets, discovery & development of novel therapeutic concepts

**Immuno-oncology Branch**
**Grants:** Immuno-oncology
Canine Immunotherapy Network
Pediatric Immunotherapy Network
Cancer Adoptive Cell Therapy (CanACT)

**Biological Resources Branch**
**Grants:** Biopharmaceutical discovery & development
**Services:** Development of clinical grade biologics, adoptive cell therapies, analytical testing (at FNLCR)
**Repository:** Biologics (MAbs, cytokines)

**Information Technology Branch**
**Repository/Resources:** Extensive databases of compounds, activity/efficacy, computational tools (COMPARE, ALMANAC)

**Natural Products Branch**
**Repository:** Large pre-fractionated library; collections of extracts (marine, plant, soil, fungi)
**Services:** Natural product chemistry

**Drug Synthesis & Chemistry Branch**
**Repository:** NCI Compound Repository
**Services:** Synthetic chemistry, route optimization, scale-up

**Molecular Pharmacology Branch**
**Services:** NCI-60 tumor cell screen
Patient-derived models screen, target validation, combinatorial screening

**Toxicology & Pharmacology Branch**
**Services:** Non-GLP and GLP PK & toxicology, ADME, in vitro tox assays
**Investigative Toxicology Laboratory:** develop in vitro assays for discovery, development

**Biological Testing Branch**
**Repository:** Tumor repository, Patient Derived Tumor Models repository, immunodeficient & immunocompetent
**Services:** Model development, efficacy, dose schedule, MTD

**Pharmaceutical Resources Branch**
**Services:** Large scale GMP manufacture bulk API, analytical testing, dose formulation development, stability studies for final drug product
DTP Services Span Critical Path for Discovery and Development

- In vitro screening: NCI-60, Patient Derived Models
- Target characterization, Target validation
- Analog synthesis, route optimization
- Natural product chemistry

- Efficacy: model development, dose schedule, MTD
- Nonclinical: PK, ADME, Toxicology (GLP and non-GLP)
- CMC: Process optimization, scale up, formulation, non-GMP and GMP manufacturing, final drug product
- Regulatory: Assistance with IND submissions
The Developmental Therapeutics Program (DTP)

Drug Discovery/Development – Anti-cancer activity screening and proof-of-concept studies in vitro and in vivo and support for product development through all phases of the critical path toward clinical use from medicinal chemistry through safety testing and cGMP manufacturing

- Small molecules
- Monoclonal antibodies
- Recombinant proteins
- Peptides
- Retroviral & lentiviral vectors
- Viral & DNA vaccines
- Gene therapy products
- CAR T-cell products
- Natural products

Grants Funding – FOAs:
- RFA-CA-22-028: Can-ACT Adult
- RFA-CA-22-29: Can-ACT Pediatric
- NOT-CA-21-101: Advancing tumor site-activated small molecules
- PAR-22-216: NCI Clinical and Translational Studies
- PAR-20-271: Assay development and screening

Stepping Stones Program – Discrete drug development studies for grantees
Consultation Service – Helping innovators to meet standards required for early-phase clinical trials via NeXT
Repositories – Tumors, cell lines, patient-derived models, chemicals, natural products, and biological reagents

Databases & Tools – including data search tools, bulk data download, COMPARE analysis, NCI-ALMANAC, and ROADMAPS datasets

dtp.cancer.gov
Grants Portfolio & Funding Opportunities

Sundar Venkatachalam, PhD
Preclinical Therapeutics Grants Branch (PTGB)

- Overview of the grants portfolio
- Information on current and upcoming funding opportunities
Preclinical therapeutics research up to but not including clinical trials

- Discovery, development and evaluation of small molecules (synthetic or natural product origin) for cancer therapy
- Drug delivery using various enabling technologies (e.g. ADC, nanotechnology)
- Validation of cancer drug targets: extracellular or intracellular processes (excluding immune interactions)
- Studies on mechanism(s) of action of therapeutic agents, drug resistance, rational drug combinations, novel preclinical models, drug efficacy, drug pharmacology, and drug toxicology
Active Awards - Top Targets
Snapshot: Visualization of FY2023 Active Awards
## Current DTP - PTGB Funding Opportunities

<table>
<thead>
<tr>
<th>FOA #</th>
<th>Title</th>
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<tr>
<td>PAR-20-271</td>
<td>Assay development and screening for discovery of chemical probes, drugs or immunomodulators (R01)</td>
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<tr>
<td>NOT-CA-21-101</td>
<td>Advancing the development of tumor site-activated small molecules (R01, R21, R15)</td>
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<tr>
<td>PAR-22-216</td>
<td>NCI Clinical and Translational Exploratory/Developmental Studies (R21 Clinical Trial Optional)</td>
</tr>
<tr>
<td>PA-19-056</td>
<td>NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)</td>
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[https://dtp.cancer.gov/](https://dtp.cancer.gov/)
Stages of discovery research: PAR20-271

“Assay development and screening for discovery of chemical probes, drugs or immunomodulators”

- Develop primary & secondary assays and run pilot screen
- Execute high or moderate throughput screen
- Validate hits; perform limited chemical analysis

- A trans-NIH Funding Opportunity focused on small molecules
- The aims of an application may span one or more of the stages
- Flexible “on- and off-ramps” along the discovery pipeline
- Up to 4 years of funding; time and budget should match scope

https://dtp.cancer.gov/
Targeting Fusion Oncoproteins in Childhood Cancers (TFCC) Network

• Projects to better understand basic mechanisms of fusion-driven oncogenesis
  • **Goal:** Identify novel drug targets and critical dependencies

• Next Generation Chemistry Centers for Fusion Oncoproteins
  • **Goal:** Identify and develop small molecules that disrupt activity of fusion oncoprotein drivers for high-risk solid tumors and brain cancers

UPCOMING FUNDING OPPORTUNITY

U01

FusOnc NGCC (UM1)
Planned Structure of the Targeting Fusion Oncoproteins in Childhood Cancers (TFCC) Network
Notice of Intent to Publish a Funding Opportunity Announcement for Next Generation Chemistry Centers for Fusion Oncoproteins (UM1 Clinical Trial Not Allowed)

Notice Number: NOT-CA-23-058

Key Dates

Release Date: April 05, 2023

Estimated Publication Date of Notice of Funding Opportunity: June 29, 2023

First Estimated Application Due Date: November 17, 2023

Earliest Estimated Award Date: July 01, 2024
Notice of Intent to Publish a Funding Opportunity Announcement for Mechanisms of Fusion-Driven Oncogenesis in Childhood Cancers (U01 Clinical Trial Not Allowed)

**Notice Number:**  NOT-CA-23-057

**Key Dates**

**Release Date:** April 05, 2023

**Estimated Publication Date of Notice of Funding Opportunity:** June 29, 2023

**First Estimated Application Due Date:** November 17, 2023

**Earliest Estimated Award Date:** July 01, 2024
Purpose: To help investigators reduce the translational risk of selected candidates during later stages of product development and increase the chances of entering clinical evaluation.

Workshop content: Six webinar sessions addressing specialized topics important for preclinical development of small molecule cancer drugs. Lectures will be 60 - 90 minutes, followed by 15-minute Q&A.

Session I. Considerations for Lead Optimization of Small Molecules (Thursday, June 22, 1 pm – 2:45 pm, ET)
Session II. Considerations for Advancing to Late Preclinical Development (Friday, June 23, 1 pm – 2:45 pm, ET)
Session III. Safety and Toxicity Studies for Small Molecules (Thursday, July 13, 1 pm – 2:15 pm, ET)
Session IV. Formulation of Small Molecules (Friday, July 14, 1 pm – 2:45 pm, ET)
Session V. Nanoparticle Delivery of Cancer Drugs (Thursday, July 27, 1 pm – 2:45 pm, ET)
Session VI. Good-to-know IP Knowledge (Friday, July 28, 1 pm – 2:15 pm, ET)

Target Audience: Scientists who are interested in preclinical drug development for cancer

Registration is free and open to the public: www.events.cancer.gov/dctd/drugdevelopment (scan QR code to register)

Contact: Weiwei.Chen@nih.gov; Sundar.Venkatachalam@nih.gov; or, Jason.Yovandich@nih.gov
PTGB Members

- Joseph Agyin, Ph.D.
- Weiwei Chen, Ph.D.
- Suzanne L. Forry, Ph.D.
- Yali Fu, Ph.D.
- Sudhir B. Kondapaka, Ph.D.
- Morgan O'Hayre, Ph.D.
- Sundar Venkatachalam, Ph.D.
New Drug Development Resources

Rose Aurigemma, PhD
**Molecular Pharmacology Branch**

**Chief:** Bev Teicher, PhD

**GOAL:** Provide HTS platform and 3D cultures to provide more innovative drug screening, molecular pharmacology data

Collaboration with Advanced Development and Research Directorate, Frederick National Laboratory for Cancer Research

Complex Tumor Spheroids, a Tissue-Mimicking Tumor Model, for Drug Discovery and Precision Medicine

Gurmeet Kaur, David M Evans, Beverly A Teicher, Nathan P Coussens

![Diagram of tumor spheroids and drug screening process]

Molecular Pharmacology: 384-well NCI60 and Organoids HTS
GOAL: Provide quality-controlled human tumor models derived from fresh patient samples that are genetically characterized and

Patient-Derived Models Repository – now distributing internationally
  • Over 600 PDX tumor models now publicly available
  • 429 cancer associated fibroblast lines, 384 tumor cell lines, 87 paired sets of tumor & fibroblast, and 397 organoid cultures are available for distribution

Collaboration with Advanced Development and Research Directorate, Frederick National Laboratory for Cancer Research

https://pdmr.cancer.gov/
ORAL presentation 5720 - Combination therapies in matched 3D in vitro and in vivo preclinical models of rare and recalcitrant cancers from the National Cancer Institute’s Patient-Derived Models Repository
April 18, 2023, 3:22 PM - 3:37 PM   Room W414   Thomas Dexheimer, PhD FNLCR

Oral presentation 5776 - Advancing a screening platform with panels of patient-derived organoid models for drug discovery and development Annamaria Rapisarda, PhD  FNLCR
April 18, 2023, 3:22 PM - 3:37 PM   Room W304 A-D   Annamaria Rapisarda, PhD, FNLCR

POSTER Session PO.ET05.02 - Anticancer Approaches Targeting Signal Transduction Pathways
4884 / 27 - Targeted investigational oncology agents (IOA) in the NCI60: a phenotypic systems-based resource
April 18, 2023, 1:30 PM - 5:00 PM   Section 13   Mark Kunkel, PhD, DTP

POSTER Session PO.TB05.01 - 3D and Tissue Recombinant Models
4555 / 6 - Aryl-hydrocarbon receptor inhibitors in combination with anticancer agents, especially proteasome pathway inhibitors, in a complex spheroid screen using patient-derived cell lines can result in greater-than-additive cytotoxicity
April 18, 2023, 1:30 PM - 5:00 PM   Section 2   Beverly Teicher, PhD, DTP
POSTER Session PO.TB05.02 - Novel Models of Human Cancer
40 / 8 - NCI patient derived models repository: PDX, organoid and cell lines from the same patient - bridging the translational pipeline
April 16, 2023, 1:30 PM - 5:00 PM Section 2 Yvonne Evrard, PhD FNLCR

POSTER Session PO.TB05.02 - Novel Models of Human Cancer
36 / 4 - Comparing twenty-two matched patient-derived cell lines developed from either patient, PDX, or organoid tumor cell material
April 16, 2023, 1:30 PM - 5:00 PM Section 2 Cindy Timme, PhD, FNLCR

POSTER Session PO.ET02.02 - Chemotherapeutic Combinations
2665 / 1 - Biochemical inhibition profiles of 370 wild type human kinases provide a basis for selecting alternative combinations of EGFR and VEGFR inhibitors
April 17, 2023, 1:30 PM - 5:00 PM Section 14 Nathan Coussens, PhD, FNLCR

POSTER Session PO.MCB08.02 - Multi-omics Tumor Profiling
6072 / 12 - Chromosomal aneuploidy, whole-genome doubling and mutational signatures in NCI PDMR models
April 19, 2023, 9:00 AM - 12:30 PM Section 12 Li Chen, PhD FNLC
Natural Products Branch

Chief: Barry O’Keefe, PhD

Director, Molecular Targets Program, Center For Cancer Research, and Chief, Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, USA
**GOAL:** Prepare prefractionated, plated samples from NCI’s extensive collection of natural product extracts (>230,000 crude extracts) to allow more accessible screening and identifying of active compounds.

- **Plant Extract Library**
  - ~161,000 extracts (organic + aqueous)
  - ~44,000 plants, including 81,400 raw materials (leaves, roots, fruit, etc.) collected from Africa and Madagascar; North, Central and South America; and Southeast Asia.

- **Marine Extract Library**
  - ~41,000 extracts (organic + aqueous)
  - ~20,500 organisms collected from the Indo-Pacific region.

- **Microbial Extract Library**
  - ~30,000 extracts (organic + aqueous)
  - ~26,000 organisms collected from US
  - **New Collection:** 20,000 Fungal strains from USA (Univ. of Oklahoma)
Why Have Natural Products Not Been Included in HTS?

- Extracts are difficult to screen in their crude form
- Contain numerous compounds at different concentrations
- Purification and structure elucidation of active compounds was time consuming; did not mesh with HTS screening schedules
- Need to address these challenges to efficiently access the unique chemical diversity in natural products
Natural Product Extract Pre-fractionation Plans and Progress

PLAN:
• Create a library of ~1,000,000 semi-pure natural product fractions more amenable to modern screening technologies
• Supply the library of chemical diversity to researchers for free
• Open use for all screening labs, against all disease targets
• Method development:
  - Purification based on polarity
  - Optimized for mass, compound separation, biological activity

PROGRESS:
• >580,000 fractions produced
• First 500,000 fractions released to the public
• >25,000,000 wells of fractions plated in 384-well plates for shipping, stored in repository
• >5,000,000 samples shipped to screening centers worldwide
• New, marine aqueous pre-fractionated library in production
Goal: Provide resources to manufacture clinical-grade adoptive cell therapy products to accelerate research in the extramural community

- Expanded to 5 GMP suites for cell therapy and vector manufacturing
- Established expertise and capability to support multi-center cell therapy clinical trials
  - Active: Anti-CD33 CAR T for pediatric AML
  - Active: Anti-GD2 CAR T for pediatric sarcoma and neuroblastoma
- CRISPR/cas-based editing capability (near completion)
Stepping Stones Program

Sharad K. Verma, PhD
Supporting and Assisting the Extramural Community to Advance New Therapeutic Concepts toward Clinical Use

Product Development Stepping-Stones

Program manager: Dr. Morgan O'Hayre (morgan.o'hayre@nih.gov)
Leverage Extramural R&D

DTP Grants

DTP Stepping-Stones Program

DTP Services and Resources

Basic Research

Preclinical Research

Clinical Research

NCI Experimental Therapeutics (NExT)

Commercial development

Initiative:
Advancing new therapeutic concepts toward clinical testing by providing resources and data “stepping-stones”

Tox/PK/PD

Synthesis

Formulation
Stepping-Stones Mission

**Assist academic innovators with critical data gaps**

- Limited access to full range of development resources
- Academic funding may not cover iterative/routine product development tasks
- Unavailable expertise in full range of regulatory critical path steps toward IND

**Support NCI investment in the grant portfolio**

- Limited to NIH-funded therapeutic concepts
- Small investment (<$100K) to advance promising lead candidates
- **Provide critical data** a PI can’t easily obtain or not covered by funding (e.g. formulation work, synthesis optimization, discrete DMPK/ADME studies, etc.)
- **Improves chances for gaining other resources** (NExT, VC, SBIR/STTR)
- Special emphasis on area of unmet need and institutions with fewer resources
Examples of Stepping-Stones Project Support

Formulation Development
• Enabled PI to produce an orally available drug formulation
  ▪ PI continuing with startup and received STTR Ph I and II funding
• Unable to achieve sufficient bioavailability (few projects)
  ▪ PIs considering other analogs, formulation options

Synthesis and PK studies
• Synthesis improvements, multi-gram quantities of non-GMP API, and salt-forms
• PK studies (mouse, rat) to characterize bioavailability
  ▪ 2 PIs continuing and plan to apply to NExT and/or SBIR

Biomarker studies
• Connected to resources for pilot PD studies
  ▪ PI continuing with startup and aiming to file IND in 2024

In Vitro ADME and safety studies
• De-risking and ID of liabilities early (CYP, UGT, metabolic stability, hERG, etc)
Stepping-Stones has supported NIH-funded projects targeting a variety of malignancies with a focus on areas of unmet need

- Uveal Melanoma
- Pancreatic Cancer
- Melanoma
- K-Ras (G12D) mutant cancers
- Glioblastoma multiforme (GBM)
- Castration Resistant Prostate Cancer (CRPC)
- Acute Myeloid Leukemia (AML)
- Triple Negative Breast Cancer (TNBC)
- Chemotherapy Induced Peripheral Neuropathy (CIPN)

*With more to come to help patients!*
Drug Development Consultation Service

https://next.cancer.gov/experimentalTherapeutics/form.htm

- Open to all innovators
- Confidential
- Assess critical path for product development
- On-ramp for Stepping-Stones
- Expert advice for:
  - chemistry and synthesis, tox/pharm, molecular pharmacology, biology, immunooncology, biological products, natural products, in vivo models and testing, manufacturing and formulations
NCI Experimental Therapeutics (NExT) Program

- Projects can enter at any stage of discovery or development
- Applications are peer reviewed by NExT Special Emphasis Panels
- Submission deadlines: February 15, June 15 and October 15
- NExT program provides resource, not funding or money, for approved studies
- Applicants retain ownership of intellectual property that they bring to the program

To learn more about NExT, please join the following Meet-the-Expert (MTE) lecture:
“NCI Experimental Therapeutics (NExT) Program: A Government, Academic, Industry Partnership for Cancer Drug Discovery and Development”  **Tuesday April 18, 3:00pm ET @ the NCI Kiosk**
Immuno-oncology Initiatives and Services

Marc Ernstoff, MD
Immuno-Oncology Branch (IOB)
Marc S. Ernstoff, MD
Chief, ImmunoOncology Branch, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, USA

Biological Resources Branch (BRB)
Jason Yovandich, PhD
Chief, Biological Resource Branch, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health, USA

American Association for Cancer Researcher Annual Meeting
April 14-19, 2023
Orlando, Florida
Today’s Topics

I. ImmunoOncology (IO) and Biological Resource (BR) Branches
   • Who we are and what we do

II. Programs in IOB
    • K9CIN, PIN, Can-ACT
    • Opportunities

III. Resources Available in BRB
    • Reagents
    • Consultation Services
    • Production Services
DTP ImmunoOncology Branch (IOB) established Dec 2016: Areas of Focus

- **Preclinical therapeutics research up to but not including clinical trials**

  - Discovery, development and evaluation of Immunotherapeutic agents and approaches (humoral, cellular, genetically modified cells, TME regulators)
  - Guidance on preclinical and clinical PK/PD, toxicology, drug formulation and production, and IND-directed regulatory requirements for IO agents.
  - Coordination within DCTD by identifying new immunotherapeutic agent candidates to recommend for development.
  - Identification of scientific gaps and opportunities.

https://dtp.cancer.gov/organization/iob/default.htm
IOB Members

Program Officers
Connie Sommers, PhD
Anju Singh, PhD
Marco Cardone, PhD
Zhang Zhi Hu, MD

Program Specialist
Monica Cooper
IOB RFAs as of 2023

• RFA-21-050 Canine Cancer Immunotherapy Network (K9CIN)
  • RFA-21-051 Coordinating Center for Canine Cancer Immunotherapy Network (K9CIN)
    goal – to perform cancer immunotherapy clinical trials and correlative studies in pet dogs to inform potential treatments for human cancer

• RFA 22-016 Pediatric Immunotherapy Network (PIN)
  goal – to develop novel immunotherapies for children and adolescents with solid tumors including brain tumors

• Cancer Adoptive Cellular Therapy Network (Can-ACT) for Adult Cancers (UG3/UH3)
• Cancer Adoptive Cellular Therapy Network (Can-ACT) for Pediatric Cancers (UG3/UH3)
• Cancer Adoptive Cellular Therapy Network (Can-ACT) Coordinating Center (U24)
  goal – to advance new cell therapy for cancer strategies into clinical testing for the treatment of solid tumors in adult and pediatric cancer patients
goal – to perform cancer immunotherapy clinical trials and correlative studies in pet dogs to inform potential treatments for human cancer
PIN Network Structure

• The RFA had one round of competition and is completed (2/14/2023 review meeting)
• Sites under consideration

Patient advocates and additional NIH-funded pediatric immunotherapy researchers will be added as associate members

goal – to develop novel immunotherapies for children and adolescents with solid tumors including brain tumors
The goal of Can-ACT RFAs is to foster innovation and promote **early-stage clinical testing** of novel cell-based immunotherapies for solid tumors in adult and pediatric patients and leverage NCI resources to support the cell therapy community.

- Can-ACT for **Adult** Cancers (RFA-CA-22-028) – UG3/UH3
- Can-ACT for **Pediatric** Cancers (RFA-CA-22-029) – UG3/UH3
- Can-ACT **Coordinating** Center (RFA-CA-22-030) – U24

The RFAs have two rounds of competition:

- Round 1 is completed (3/2/2023 review meeting)
- Round 2 submission due June 30, 2023
- The U24 Coordinating Center has only one round
## Current Funding Opportunities

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<tr>
<td>RFA-22-028</td>
<td>Cancer Adoptive Cellular Therapy Network (Can-ACT) for Adult Cancers</td>
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<tr>
<td>RFA-22-029</td>
<td>Cancer Adoptive Cellular Therapy Network (Can-ACT) for Pediatric Cancers (UG3/UH3 Clinical Trial Required)</td>
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<tr>
<td>RFA-22-050</td>
<td>NCI Cancer Moonshot Scholars Diversity Program (R01 Clinical Trial Optional)</td>
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<tr>
<td>PAR-22-085</td>
<td>Microbial-based Cancer Imaging and Therapy – Bugs as Drugs (R01)</td>
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<tr>
<td>PAR-22-086</td>
<td>Microbial-based Cancer Imaging and Therapy – Bugs as Drugs (R21)</td>
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<tr>
<td>PAR-20-284</td>
<td>Innovative Research in Cancer Nanotechnology (R01)</td>
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<tr>
<td>PAR-22-071</td>
<td>Toward Translation of Nanotechnology Cancer Interventions (R01)</td>
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<tr>
<td>PAR-22-216</td>
<td>NCI Clinical and Translational Exploratory/Developmental Studies (R21 Clinical Trial Optional)</td>
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<tr>
<td>PA-20-185</td>
<td>NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)</td>
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Biological Resources Branch

Repository of Biological Reagents:
- Monoclonal Abs
- Murine & Human Cytokines, Growth Factors
- Interferons & Interleukins

https://frederick.cancer.gov/resources/repositories/Brb/#/preclinicalRepository
NCI established the BDP (formerly MARP) in 1993 to:

- Provide specialized and unique technical expertise and services
- Perform feasibility studies of novel candidates
- Develop manufacturing processes and assays
- Conduct GMP manufacturing, filling, testing, and release
- Generate and submit FDA and international regulatory filings
- Conduct technology transfer to commercial entities

**BDP Website** – [https://frederick.cancer.gov/Science/Bdp/](https://frederick.cancer.gov/Science/Bdp/)

- >300 SOPs, manufacturing, testing, quality system, and training documents FREE to download
- *Sponsors Guide to Regulatory Submissions for an Investigational New Drug* FREE to download
NCI Leverages BDP to Address Cell Therapy Manufacturing Challenges

- Closed manufacturing systems
- Aseptic process qualification / validation
- cGMP lenti- and retroviral production
- Standardized product testing and rapid product release
- Shipping validation and product chain logistics to support multi-center trials
## Cell Therapy GMP Expansion at the Frederick National Lab

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<th>FUTURE ADDED TECHNOLOGY</th>
<th>ADDED FACILITY</th>
<th>ADDED CAPACITY</th>
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| • G-Rex (disposable flask) and Wave manufacturing platforms  
• CRISPR-based gene editing | • 3 new GMP suites: Q2 2023  
• Freezer farm: Q1 2023 | ~ 12 cell therapy products/month  
~ 8 virus vector campaigns/year  
• Controlled storage for cell and virus products |

- **Prodigy System**
- **Vector production bioreactor**
- **Biobubble with Wave bioreactor**
QUESTIONS FOR OUR TEAM

Funding Opportunities
Sundar Venkatachalam, PhD
Chief, Preclinical Therapeutics Grant Branch

New Drug Development Resources
Rose Aurigemma, PhD
Associate Director, DTP, DCTD, NCI

Stepping Stones Program
Sharad Verma, PhD
Special Assistant to the Associate Director

Immuno-oncology Initiatives & Services
Marc Ernstoff, MD
Chief, ImmunoOncology Branch