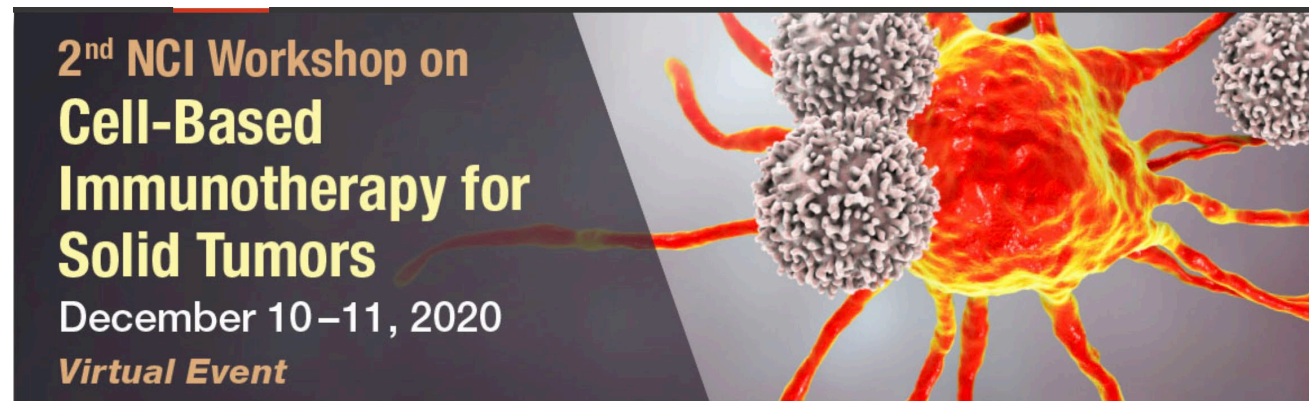
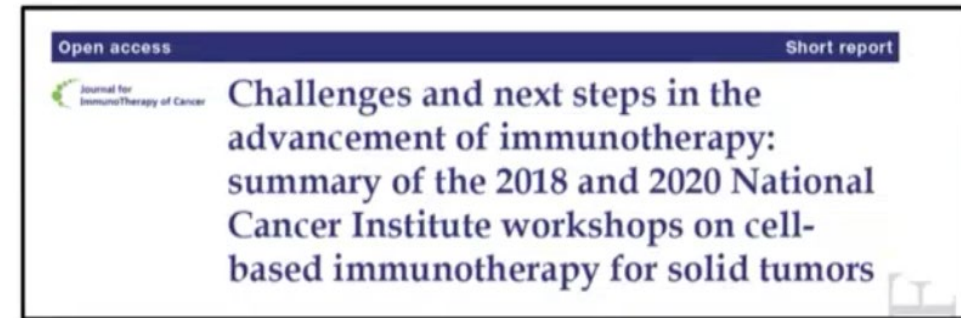


# UPDATE: Cellular Therapies for Solid Tumors (Priority Topic Identified by the NCAB Ad Hoc Subcommittee on Experimental Therapeutics)



# Outcome: NCI Workshops on Cellular Therapies for Solid Tumors

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## Areas of unmet need:

- Preclinical and translational research to advance cell therapy for solid tumors
- Small proof of concept studies to rapidly gain knowledge of new treatment approaches.
- Enhancement of cell manufacturing technologies
- Identification of biomarkers
- Imaging-based detection of experimental therapies

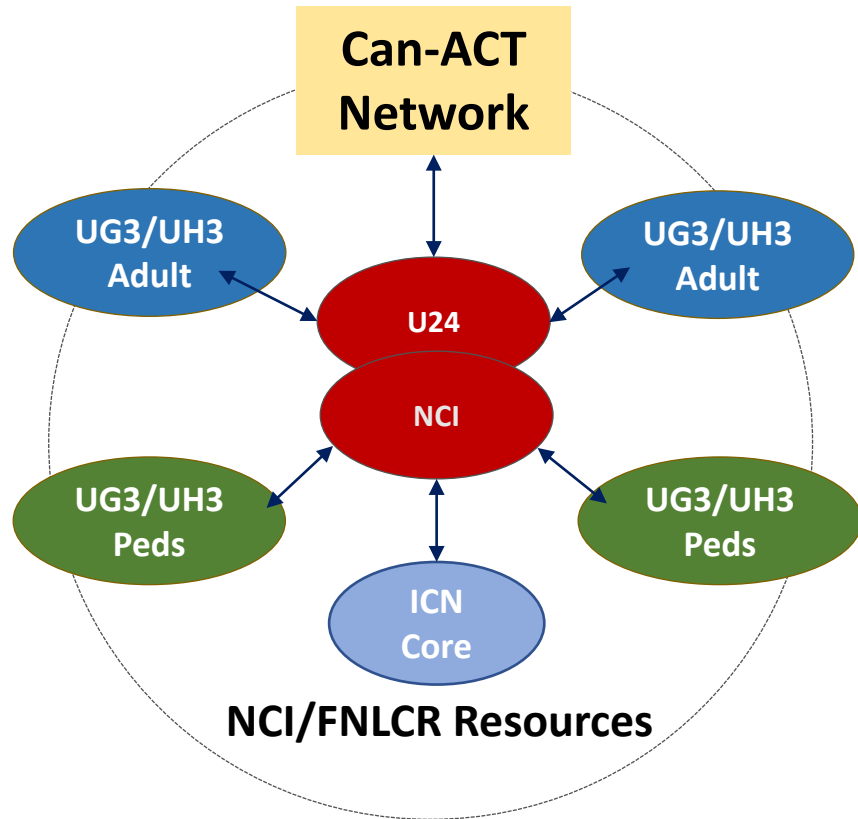
## Needed services:

- Standardization of cell product characterization, access to a core laboratory
- QC testing for cell therapy-related reagents
- Vector and cell therapy production services
- Guidance for investigators on preparing IND submissions

## Three companion FOAs for the **Cancer Adoptive Cell Therapy Network (Can-ACT)**

- Can-ACT for Adult Cancers (RFA-CA-22-028)
- Can-ACT for Pediatric Cancers (RFA-CA-22-029)
- Can-ACT Coordinating Center (RFA-CA-22-030)

# Can-ACT Organizational Structure



Network will be formed after grants are awarded

## Structure:

- Separate **UG3/UH3** for *adult* and *pediatric* cancers (Total 7)
  - each **UG3/UH3** will conduct
    - Preclinical, IND enabling studies of ACT (UG3)
    - Early Phase clinical trials of ACT for solid tumors (UH3)
- **U24** Coordinating Center (One)
  - Scientific and administrative coordination

## Networking and Synergy:

- **Steering Committee** consisting of U24 and UG3/UH3 PD/Pis, NCI extramural and intramural staff, associate members and expert advisors
- **Restricted funds** for intra-network collaborations
- **Working groups** address common goals, challenges, opportunities
- **Sharing** of tools, reagents, data, resources

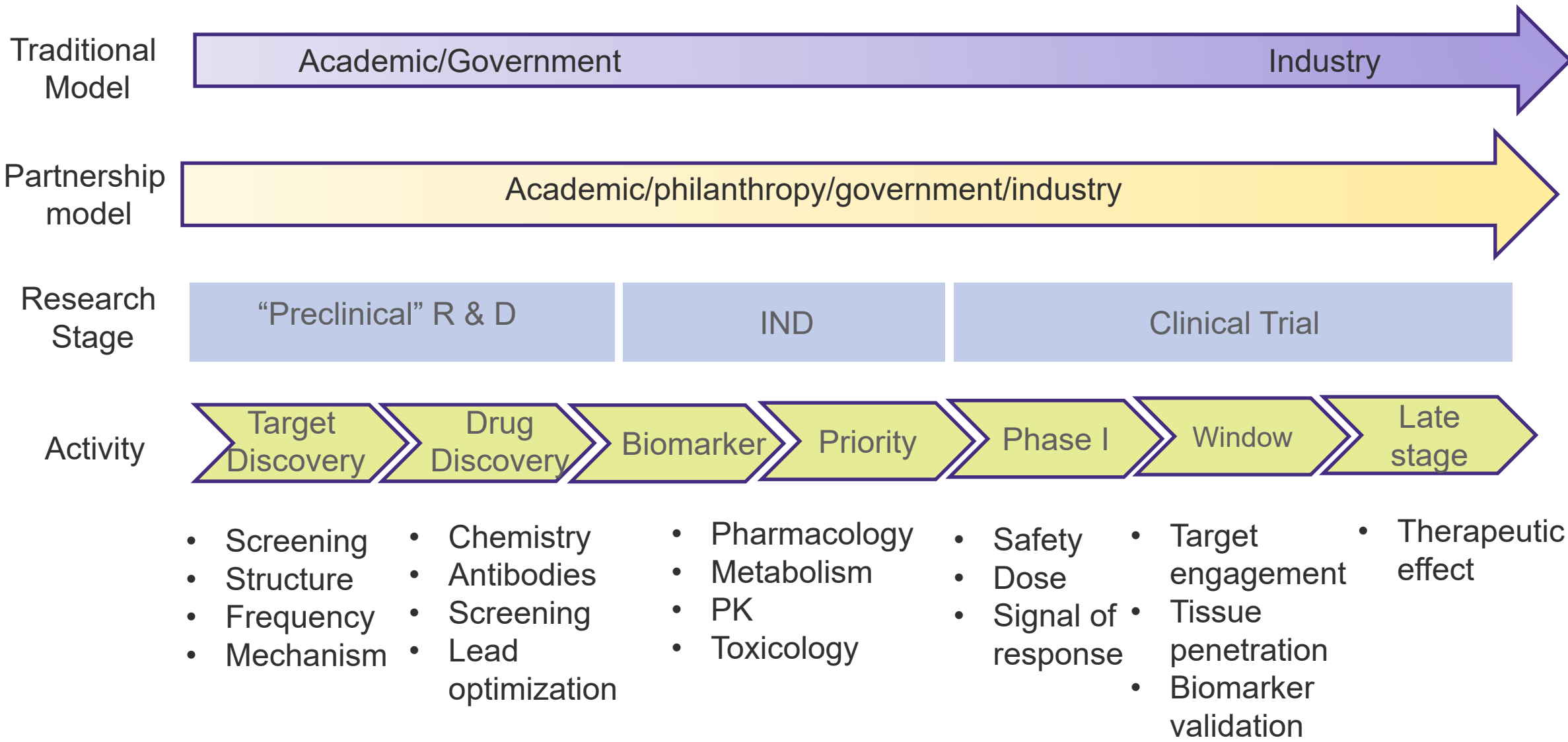
**Informational Webex: September 7, 2022**  
**4:00 PM**

<https://cbiit.webex.com/cbiit/j.php?RGID=r2f98bbe19d7ed72e93f3b7737900a3d3>

**NCAB Ad Hoc Subcommittee on Experimental Therapeutics:  
New Priority Topics for Consideration**



# Translational Research





# Translational Research



## Other Key Elements that need to be considered

- Reproducibility
- Clinical Relevance and Indication
- Competitive Landscape
- Return on investment
- Intellectual Property
- Regulatory
- Privacy Issue
- Funding alignment

Stage		Criterion	Points	Score
Preclinical	Target	Frequency of expression within cancer	*0-33% (1)	
			*34-66% (2)	
			66-99% (3)	
			100% (4)	
		Expression retained at recurrence	1	
		Tumor driver	1	
		Well-defined mechanism	2	
		Mechanism of Resistance	1	
		Target in tumor relative to normal	Enriched (2)	
			Exclusive (4)	
		Cancers that express the target	Point per indication	
		Frequency of expression within indication	*0-33% (1)	
			*34-66% (2)	
			66-99% (3)	
	100% (4)			
	Competitive landscape assessment	New therapeutic category	2	
	Compound Properties	Target inhibition <i>in vitro</i>	2	
		Compound selectivity to target	2	
		Anti-stem cell activity	1	
		Toxicity profile relative to normal cells	100-fold (4)	
10-fold (2)				
Hits target <i>in vivo</i>		4		
<i>In vivo</i> signals of response	PK (Exposure consistent with <i>in vitro</i> estimates of potency)	2		
	Clonotypic	1		
	PDX	1		
	GEMM/xenograft	1		
	Large animal model of cancer	2		
<b>Total</b>				
Clinical Readiness	Patent granted/still on patent	1		
	License granted to company	2		
	IND filed	4		
	Commitment of industry	2		
	IRB clinical trial prepared/submitted/approved	4		
<b>Total</b>				

\*will likely need a companion biomarker

# DTP/DCTD Preclinical Development Consultation Service

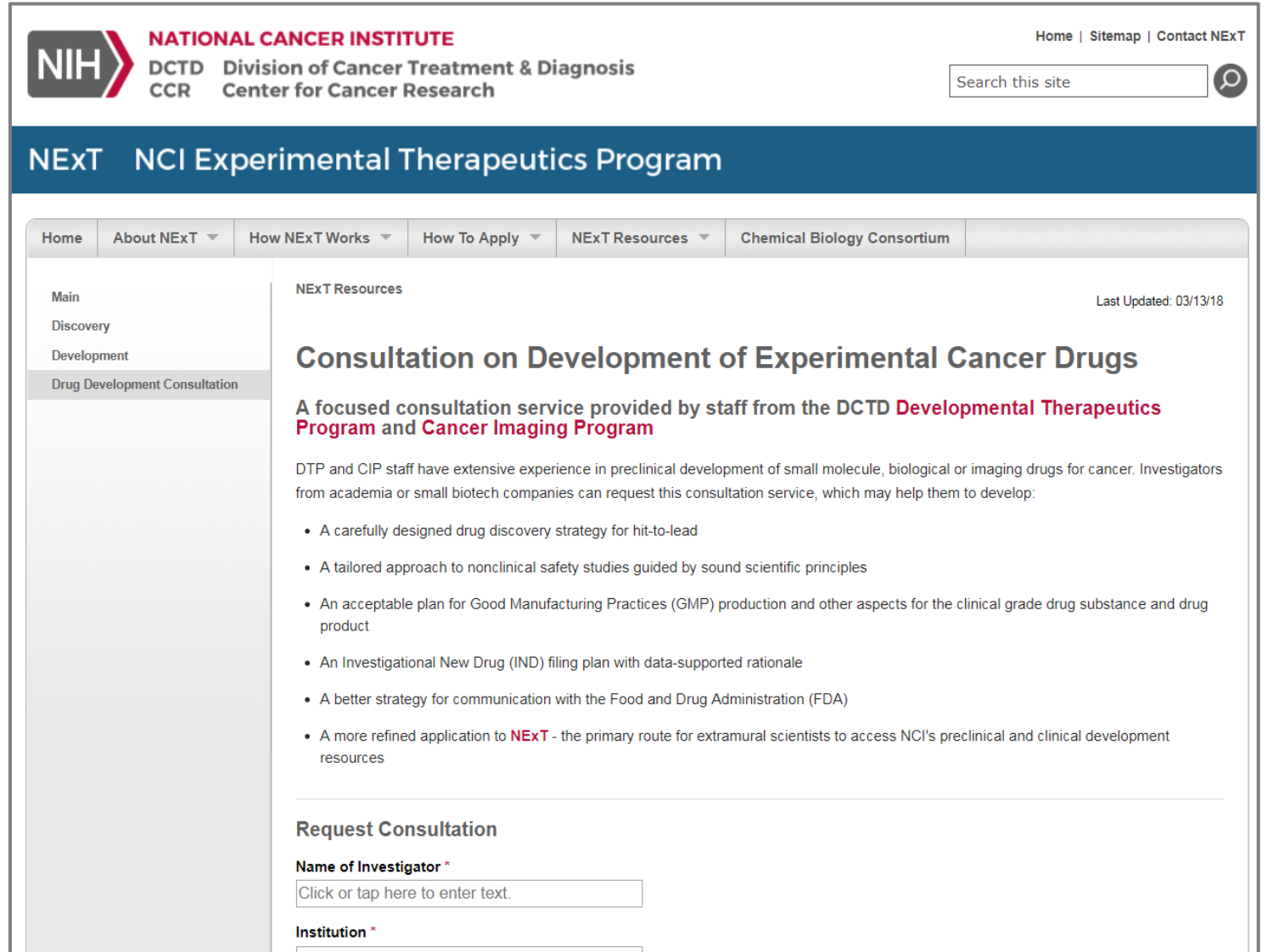
<https://next.cancer.gov/experimentalTherapeutics/form.htm>

- Confidential
- Provides broad product development
- Small molecules, biologics, cell therapies, imaging agents and nanotechnology products

Coordinators:

Morgan O'Hayre– Small Molecules

Rachelle Salomon - Biologics

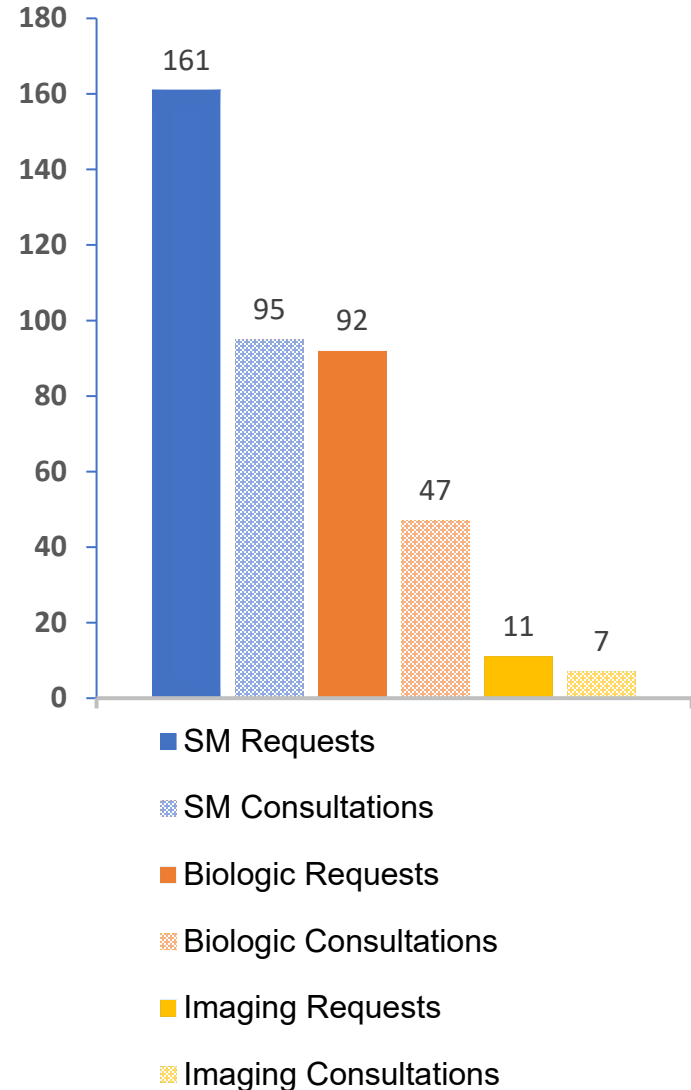


The screenshot shows the NCI Experimental Therapeutics Program (NExT) website. The header includes the NIH logo, the text 'NATIONAL CANCER INSTITUTE', and 'DCTD Division of Cancer Treatment & Diagnosis CCR Center for Cancer Research'. There are links for 'Home', 'Sitemap', and 'Contact NExT', and a search bar. The main navigation bar is 'NExT NCI Experimental Therapeutics Program'. A secondary navigation bar includes 'Home', 'About NExT', 'How NExT Works', 'How To Apply', 'NExT Resources', and 'Chemical Biology Consortium'. The left sidebar has a menu with 'Main', 'Discovery', 'Development', and 'Drug Development Consultation' (which is highlighted). The main content area is titled 'NExT Resources' and 'Consultation on Development of Experimental Cancer Drugs'. It describes a focused consultation service provided by staff from the DCTD Developmental Therapeutics Program and Cancer Imaging Program. A list of services includes: a carefully designed drug discovery strategy for hit-to-lead, a tailored approach to nonclinical safety studies, an acceptable plan for GMP production, an IND filing plan, a better strategy for communication with the FDA, and a more refined application to NExT. At the bottom, there is a 'Request Consultation' section with input fields for 'Name of Investigator' and 'Institution'.

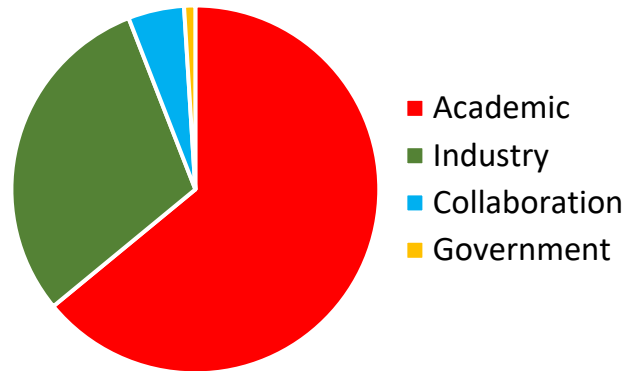
# Product Development Consultation Service

~3.5 years: 264 Requests; 149 Consultations (via WebEx)

## Type of Product:



## Institution Type:



## NIH Funding Status:

Active grant = 125

## Location:

33 states; 12 countries

## Topics Requested:

Communication with FDA	112
Preclinical tox and pharm	160
Efficacy and POC	145
Scale-up synthesis/GMP manufacturing	121
Medchem and small-scale synthesis	74
Immunotherapy	41
Nanotechnology	17

State (number of requests)		
AL (4)	MA (19)	OH (10)
AZ (2)	MD (8)	OK (1)
CA (28)	MI (10)	OR (1)
CO (2)	MN (3)	PA (12)
CT (4)	MO (5)	TN (7)
FL (13)	MS (1)	TX (20)
GA (10)	NC (5)	VA (18)
IA (4)	NE (3)	WA (6)
IL (4)	NH (3)	WI (1)
IN (2)	NJ (5)	WV (2)
LA (5)	NY (31)	*DC (1)
International: Australia, Canada, Chile, Egypt, India, Italy, Norway, Pakistan, Portugal, Sri Lanka, Sweden, Ukraine (14 total)		



# Objectives for Current Meeting

Evaluate whether NCI serves at the key hub for basic translation training via an Electronic Format

- Archive library of topics for rapid access
- Harmonization of training
- Reduces redundancy of developing curriculum nation-wide
- Instruction by the leaders in the field

Cancer Centers with unique expertise instruct in a given domain and become part of the lecture series  
Certification?

Can we use the current curriculum offered by the NCI as a starting point for this initiative?