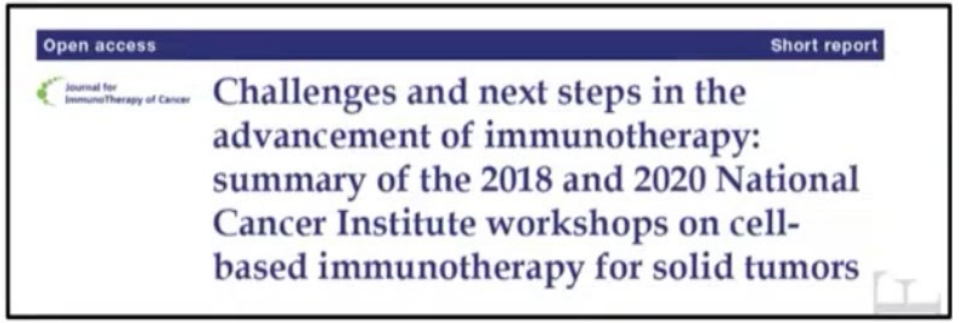
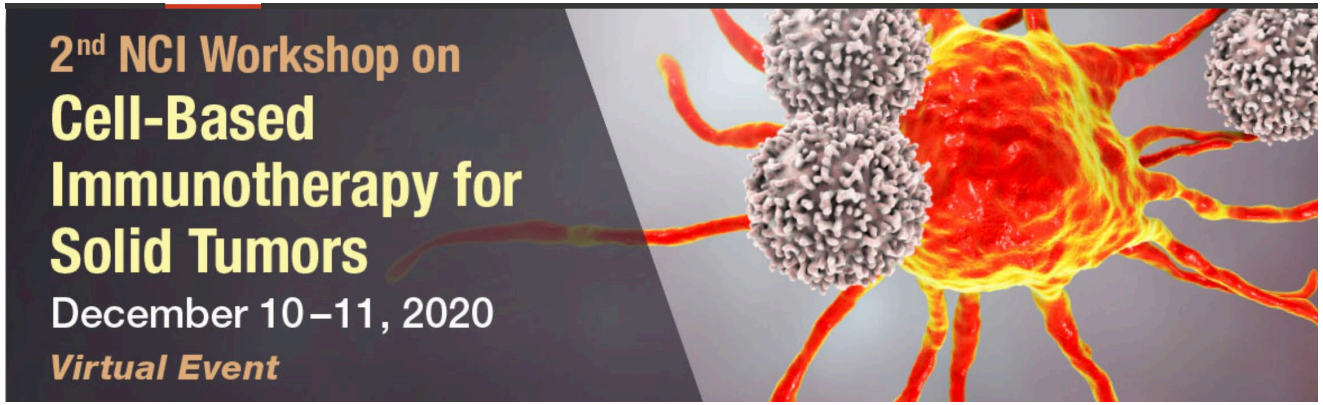
UPDATE: Cellular Therapies for Solid Tumors

(Priority Topic Identified by the NCAB Ad Hoc Subcommittee on Experimental Therapeutics)





Outcome: NCI Workshops on Cellular Therapies for Solid Tumors

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

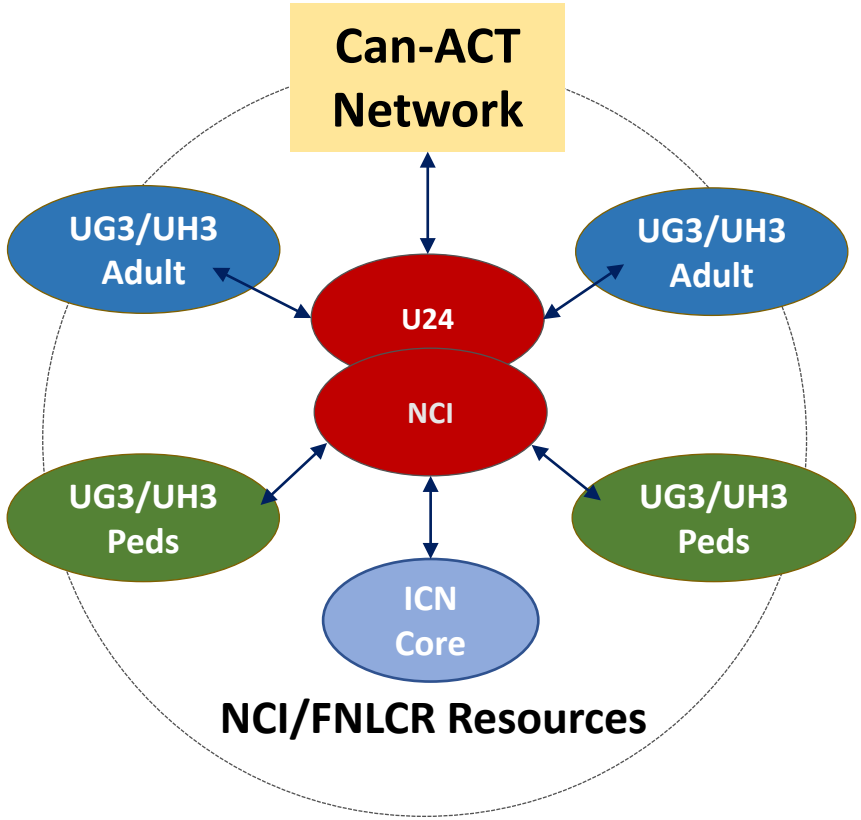
Needed services:

- 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:

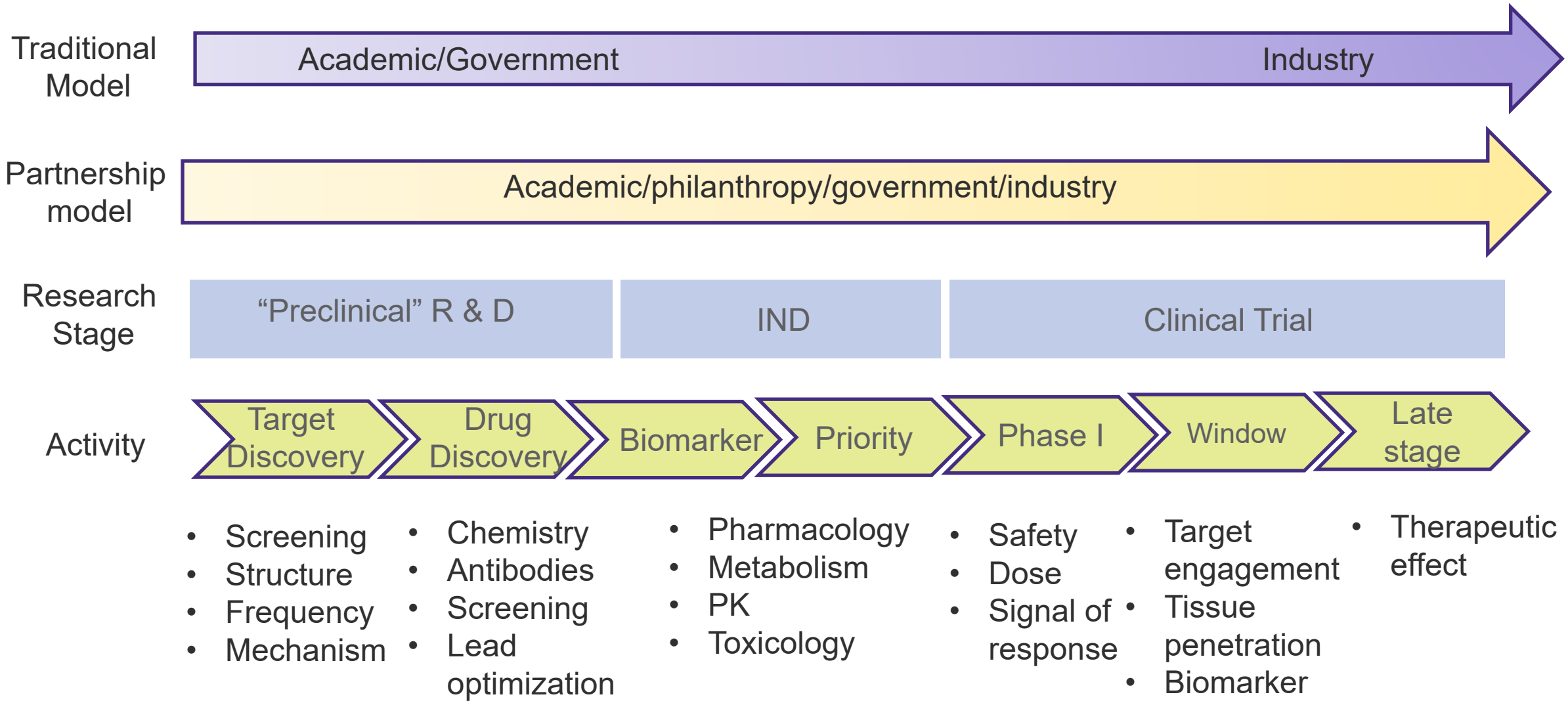
- **Steering Committee** consisting of U24 and UG3/UH3 PD/PIs, NCI extramural and intramural staff, associate members and expert advisors
- **Restricted funds** for intra-network collaborations
- **Working groups** address common goals, challenges, opportunities
- **Sharing** of tools, reagents, data, 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 *in vitro*	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 in vivo	4	
		PK (Exposure consistent with *in vitro* estimates of potency)	2	
	In vivo signals of response	Clonotypic	1	
		PDX	1	
		GEMM/xenograft	1	
		Large animal model of cancer	2	
Total				
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	
Total				

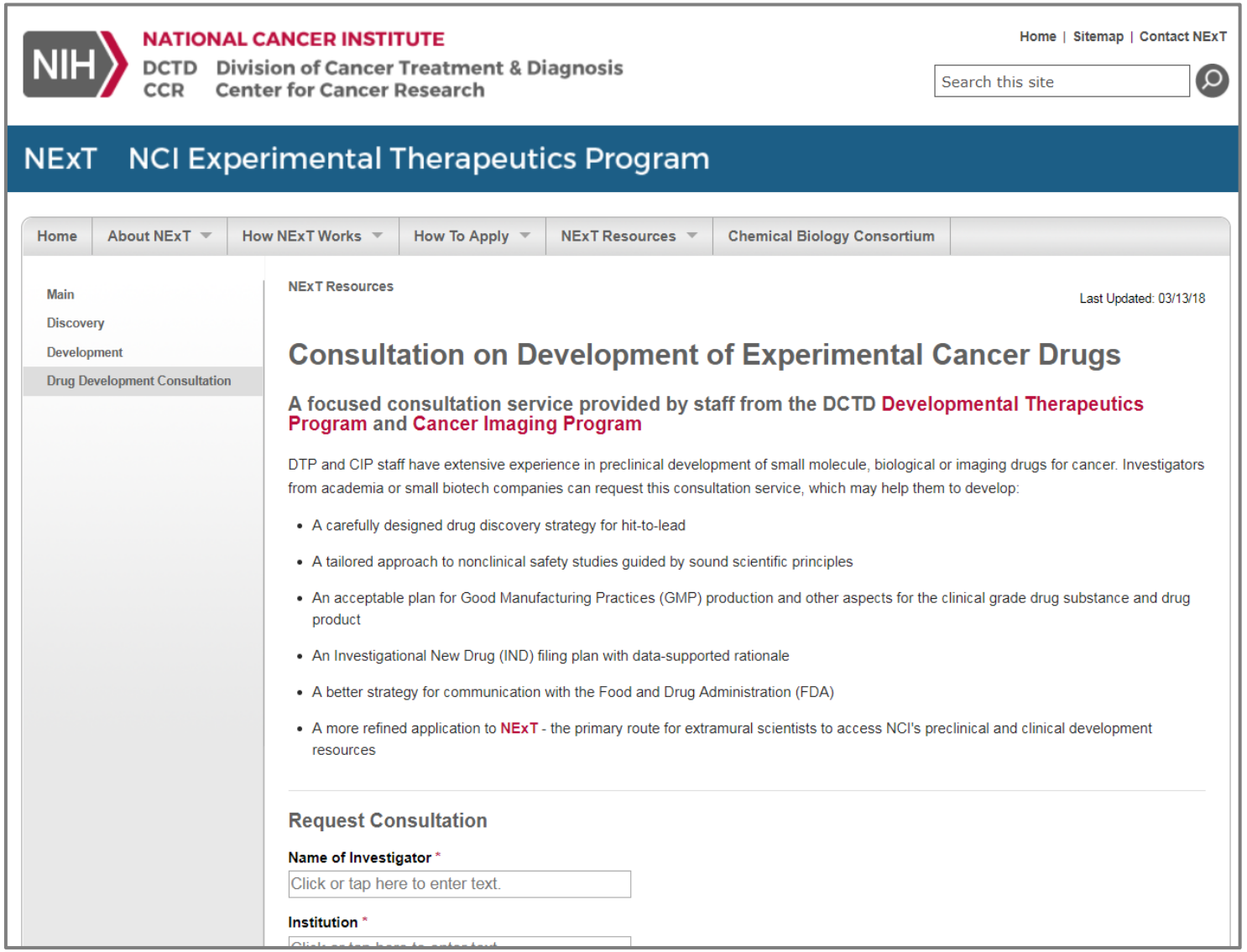
*will likely need a companion biomarker

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

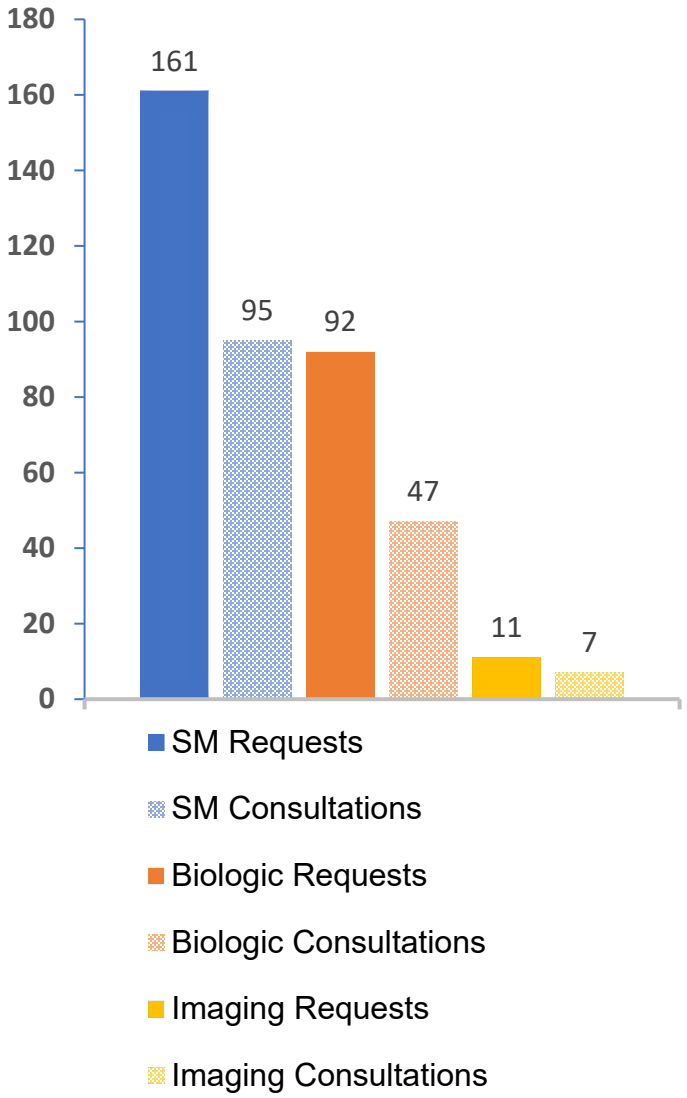
Coordinators:
Morgan O'Hayre– Small Molecules
Rachelle Salomon - Biologics



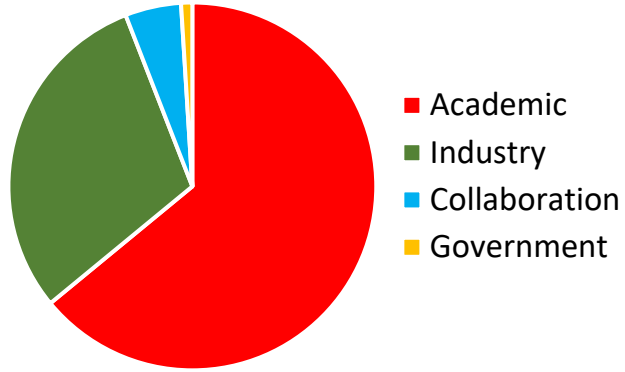
Product Development Consultation Service

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

Type of Product:



Institution Type:



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

NIH Funding Status:

Active grant = 125

Location:

33 states; 12 countries

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?