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The NIH STTR Program

May 1, 2015

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Topics

- Size of NIH/HHS program
- Set-asides & spending
- Research Institutions and Universities in STTR
- Discretionary Technical Assistance and STTR
- Switching between SBIR and STTR
- Proof-of-Concept Pilot (Kurt Marek, NHLBI)

NIH SBIR/STTR Website

http://sbir.nih.gov

HHS Program Funding

2015 Budget	SBIR	STTR
NIH	$691M	$95M
CDC	$7M	N/A
ACL (NIDILRR)	$2.7M	N/A
FDA	$1.45M	N/A
ACF	$88K	N/A

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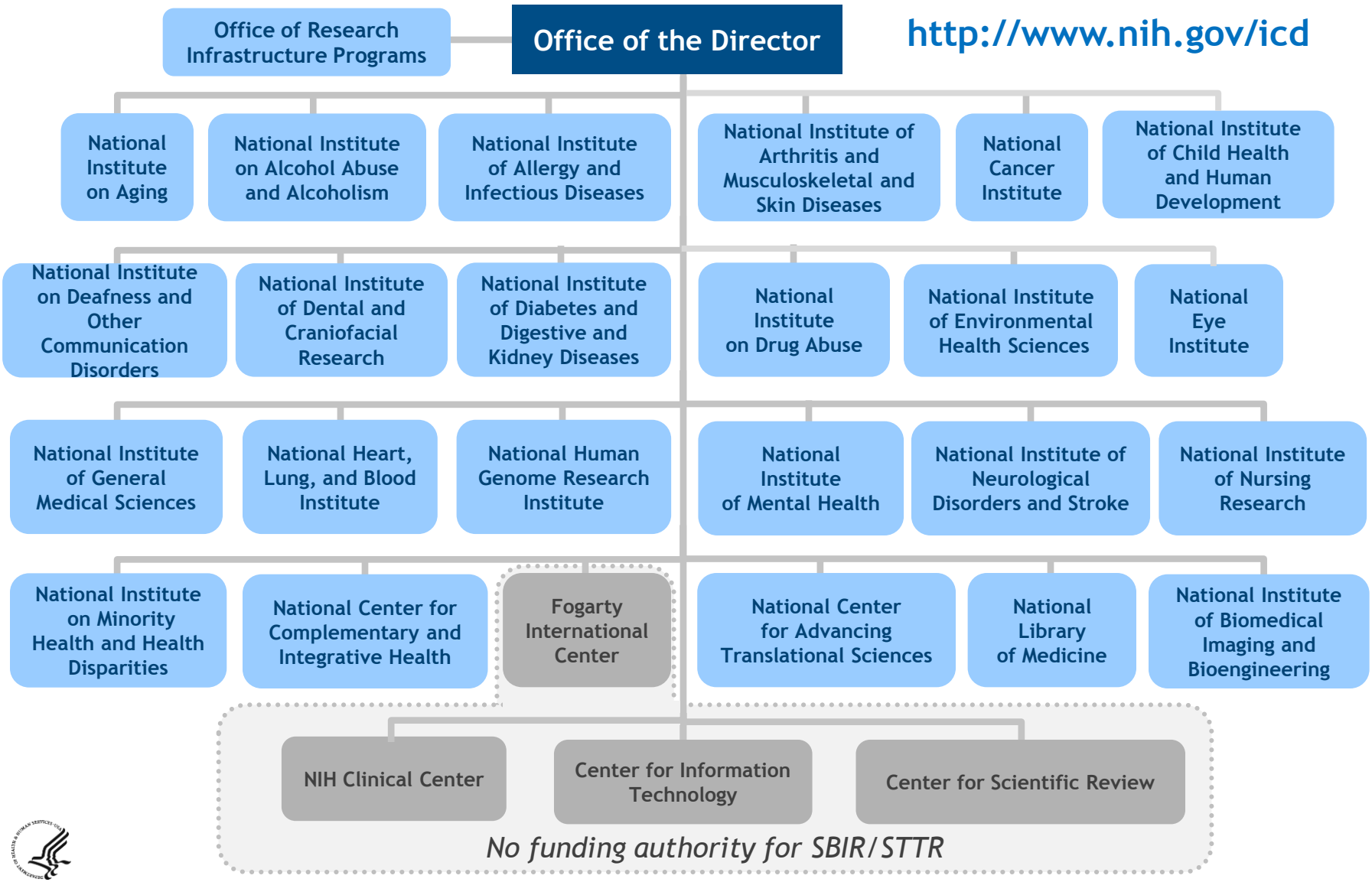
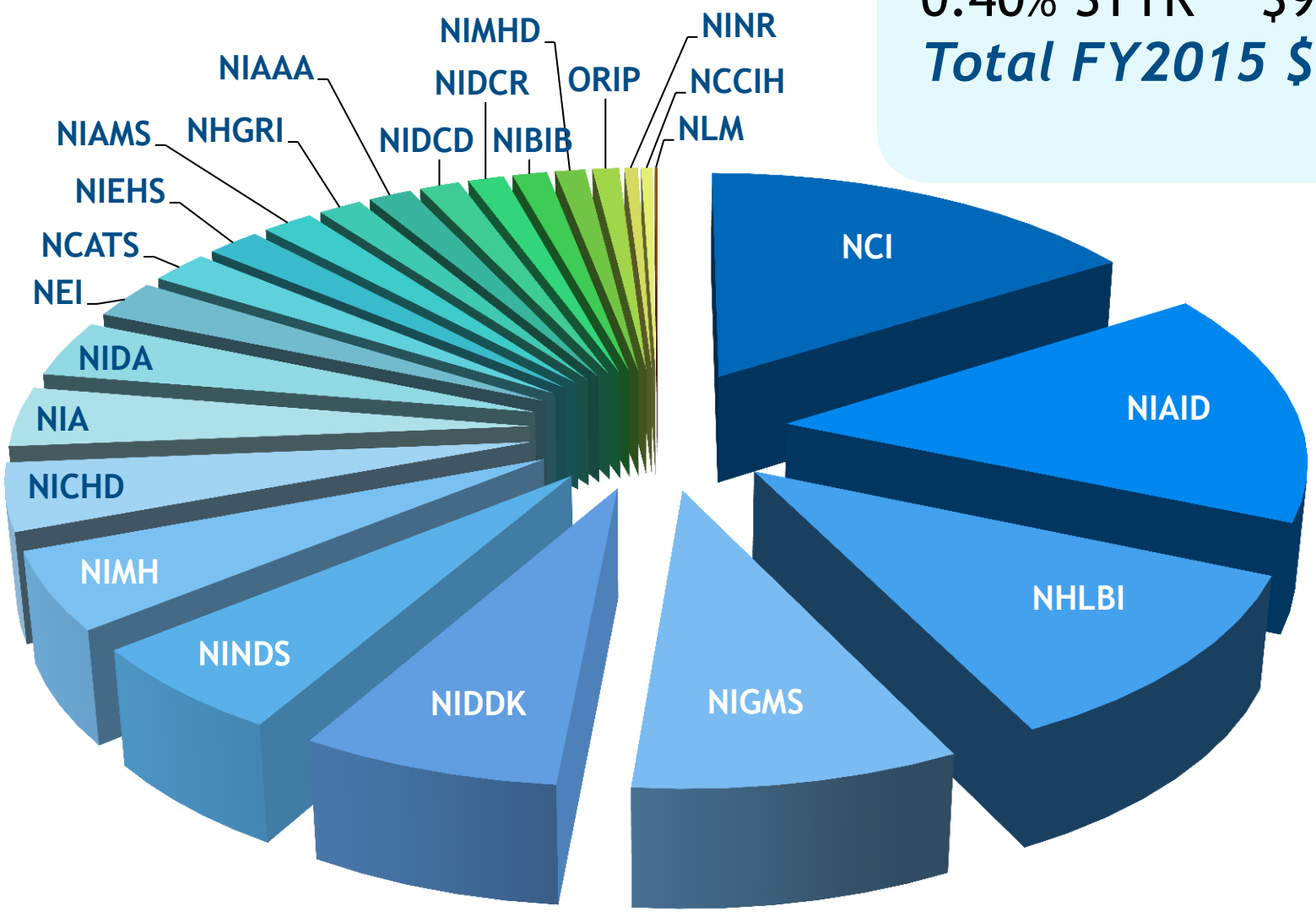
http://www.nih.gov/icd



NIH SBIR/STTR Budget Allocations FY2015

2.9% SBIR $691M
0.40% STTR $95M
Total FY2015 $786M



HHS SBIR Expenditures

- HHS found compliant by GAO by meeting or exceeding STTR set-aside in FY2006-2013.
- HHS exceeded STTR set-aside in FY14.

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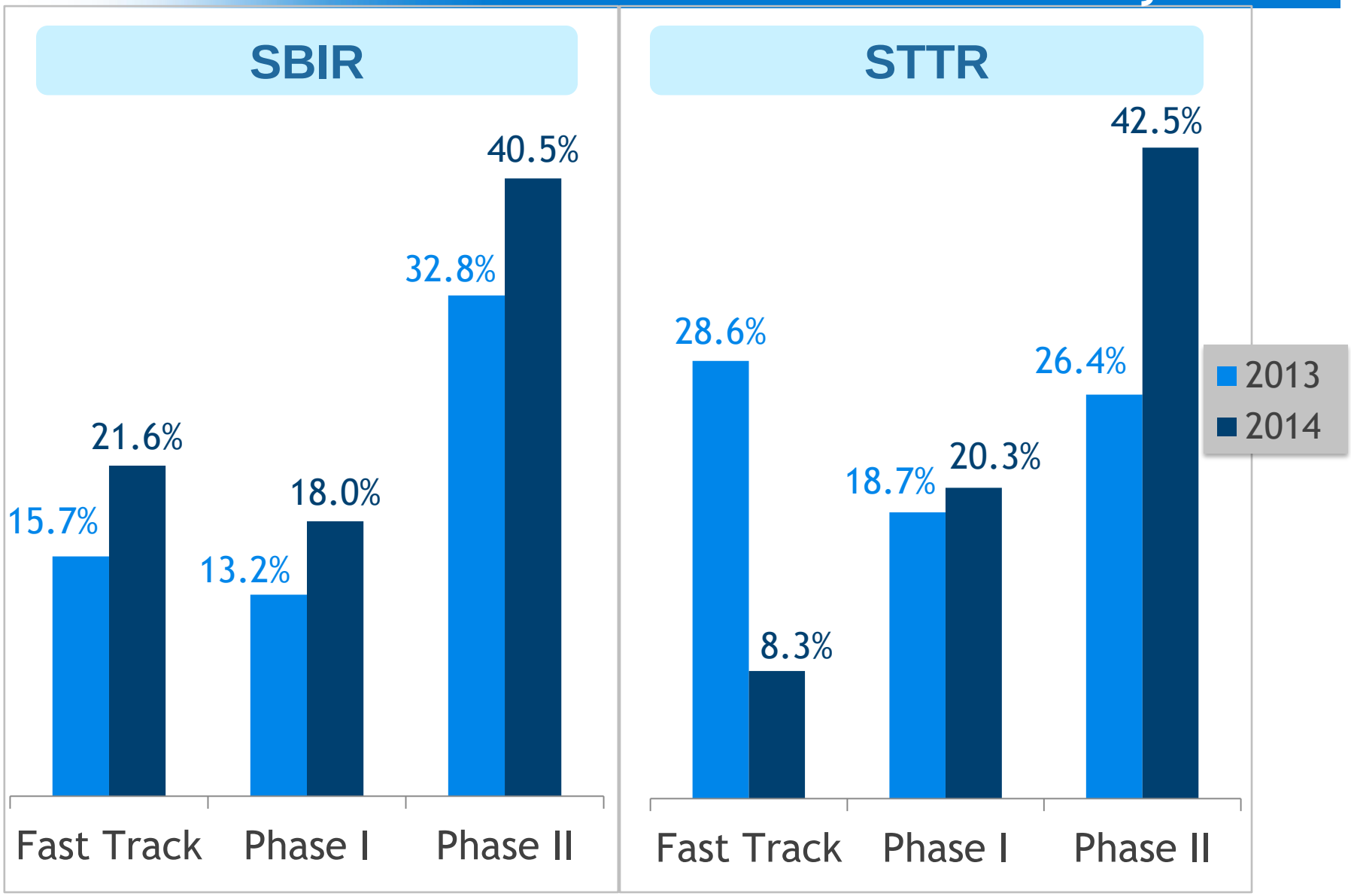
Success Rate of SBIR/STTR 2013 and 2014 by Phase



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NIH-wide SBIR/STTR Success Rates 2013-2014

Fiscal Year	SBIR[1]/STTR[2]	Phase[3]	Number of Applications Reviewed	Number of Applications Awarded	Success Rate[4]	Total Funding[5]
2013	SBIR	Fast Track	313	49	15.7%	$13,981,386
2013	SBIR	Phase I	3,738	495	13.2%	$114,040,157
2013	SBIR	Phase II	542	178	32.8%	$136,348,846
2013	STTR	Fast Track	42	12	28.6%	$2,542,128
2013	STTR	Phase I	583	109	18.7%	$24,138,629
2013	STTR	Phase II	72	19	26.4%	$10,985,373
2013	**FY TOTAL**		**5,290**	**862**	**16.3%**	**$302,036,519**
2014	SBIR	Fast Track	328	71	21.6%	$17,054,967
2014	SBIR	Phase I	3622	652	18.0%	$144,793,079
2014	SBIR	Phase II	566	229	40.5%	$170,387,226
2014	STTR	Fast Track	60	5	8.3%	$1,082,086
2014	STTR	Phase I	788	160	20.3%	$35,828,877
2014	STTR	Phase II	87	37	42.5%	$22,182,184
2014	**FY TOTAL**		**5,451**	**1,154**	**21.2%**	**$391,328,419**

Success Rates Posted Online: http://report.nih.gov/success_rates/index.aspx

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Research Institutions and STTR

	FY10	FY11	FY12	FY13	FY14
STTR Budget $M	74	73	85	81	97
Phase I % $ to SBC	55	56	53	56	54
Phase I %$ to Res. Inst.	45	43	47	44	46
Phase II % $ to SBC	58	59	56	59	59
Phase II %$ to Res. Inst.	40	38	41	41	41

Universities receive the large majority of STTR Research Institution Funds

	FY10	FY11	FY12	FY13	FY14
Univ. Phase I	118	81	123	114	130
FFRDC Phase I	0	0	2	0	1
Other Phase I	24	17	22	30	34
Univ. Phase II	94	73	74	28	35
FFRDC Phase II	0	0	0	0	0
Other Phase II	16	18	15	9	10

Number of organizations receiving STTR funds as non-profit research partner

Discretionary Technical Assistance

- NIH Provided programs – Opened to STTR in FY12 per P.L. 112-81
  - Phase I Niche Assessment Program – Foresight S&T
    - 59/273 (22%) STTR SBCs participated.
  - Phase II Commercialization Assistance Program – Larta Inc.
    - 14/139 (10%) STTR SBCs participated.
- Applicant requested Technical Assistance
  - 2 Phase II STTR SBCs in FY14

Switching between SBIR and STTR

- Applicants can switch between:
  - Phase I STTR awardees to Phase II SBIR & vice versa
  - Phase II STTR awardees to Phase IIB SBIR & vice versa
- NIH Institute and Center Program Managers use this authority manage budgets and the needs of the investigators to:
  - Switch Phase I STTR to SBIR pre-award & vice versa
  - Switch Phase II STTR to SBIR pre-award & vice versa

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Phase 0 POC: NCAI and REACH

Section 5127 of the SBIR/STTR Reauthorization Act of 2011

***Purpose**: To support proof-of-concept centers (Hubs) that facilitate and accelerate the translation of biomedical innovations into commercial products that improve patient care and enhance health*

***Long-term goals**: To foster commercialization success, economic development and culture change at the Hub institutions*

Program Background:

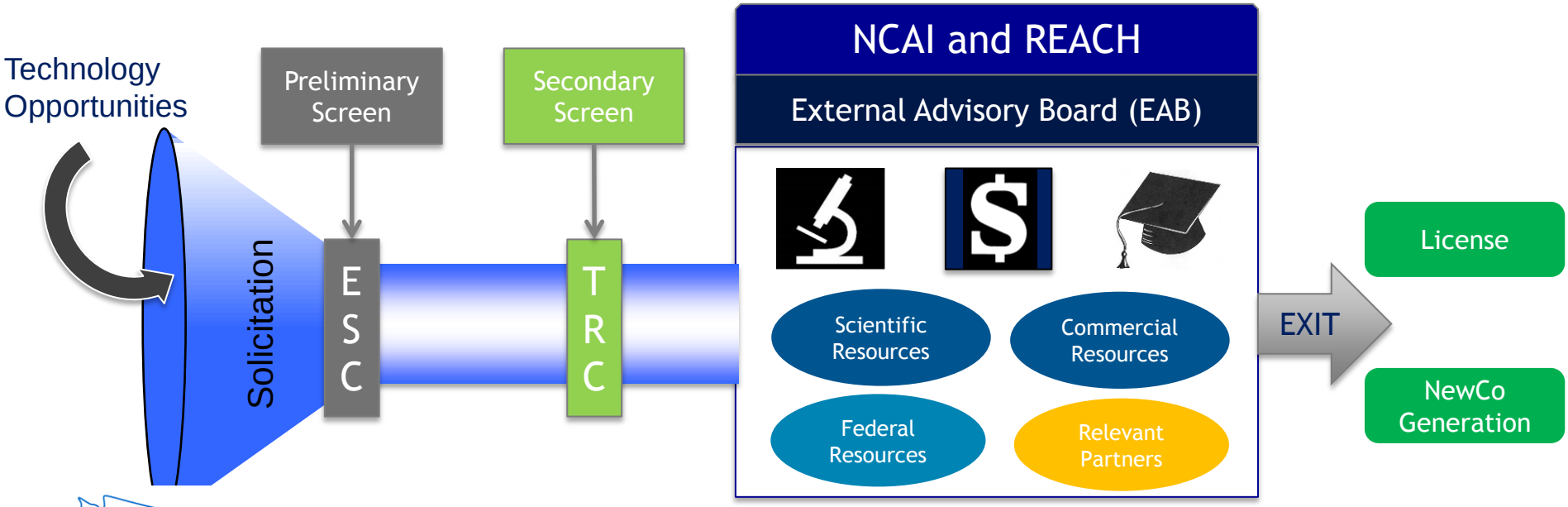
Barriers to translating technologies from academic labs to the market:

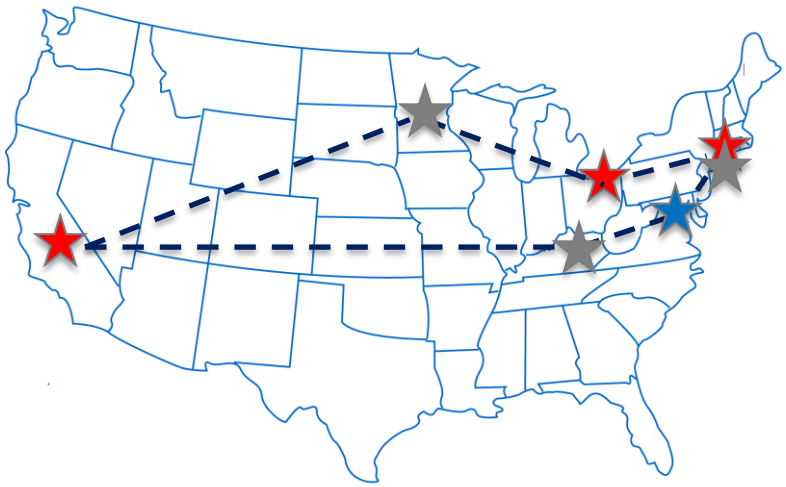
- **Funding gap** between basic research discoveries and scientific proof of feasibility/ validation studies
- **Lack of knowledge and understanding** by innovators about how technologies are brought to market
- **Lack of access** to sufficient technology development and commercialization resources that are required for early stage technology development.

Program Components:

1. **Infrastructure** for identifying the most promising technologies
2. **Funding** for product definition studies *(e.g. feasibility studies, prototype development or proof-of-concept studies)*
3. **Access** to expertise in areas required for early stage technology development (*scientific, regulatory, reimbursement, business, legal and project management)*
4. **Skills development** and hands-on experience in entrepreneurism

Commercially Relevant Technology Sourcing Followed by Milestone-Driven Development





NIH Centers for Accelerated Innovations: Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

Research Evaluation and Commercialization Hubs: University of Minnesota, Long Island Biomedical Hub, University of Louisville

National Institutes of Health: NSF, FDA, USPTO, CMS, Kaiser

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More Information

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