

SBIR Grant Application

Lessons learned by a novice

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Cloudbreak Therapeutics

Introduction

- Where I come from
 - Biochemistry and molecular biology Ph.D. and cancer research Postdoc
 - Ophthalmology and dermatology drug development research in the Biology Dept at Allergan-until 2015
 - Ophthalmology drug development at Cloudbreak Therapeutics-now
- SBIR experiences
 - First application submitted on Sep. 5, 2015, a direct to Phase II grant
 - Since then, we have submitted 3 Phase I and one Fast-track Phase I and II applications
- Today I will share what I learned about SBIR grant application
 - Hopefully to help shorten your learning curve if you want take this route
 - Nothing can substitute doing it yourself, so don't hesitate to get your feet wet

Topics

- What are SBIR and STTR?
- Who can apply?
- Why should you apply?
- How to apply?
- How is your application reviewed?
- What is important for a successful application?
- Questions and discussions.

What are SBIR and STTR?

- SBIR: Small Business Innovation Research
- STTR: Small Business Technology Transfer
- They are US federal seed money to bring science to market
 - Mission Statement: “To support Scientific Excellence and Technological Innovation through the investment of Federal research funds in critical American priorities to build a strong national economy... one small business at a time”
 - Stimulate technological innovation
 - Fund high-risk/high-return projects
 - Use small business to meet US federal R&D needs

SBIR

- Small business development act of 1982
- Set-aside program for small business to engage in Federal R&D with goal of commercialization
- 3.2% of the extramural research budget for agencies with a budget greater than \$100M per year
 - May increase to 6% by 2028
- Over 5,000 new awards every year
- **\$2.2 billion set-aside each year**

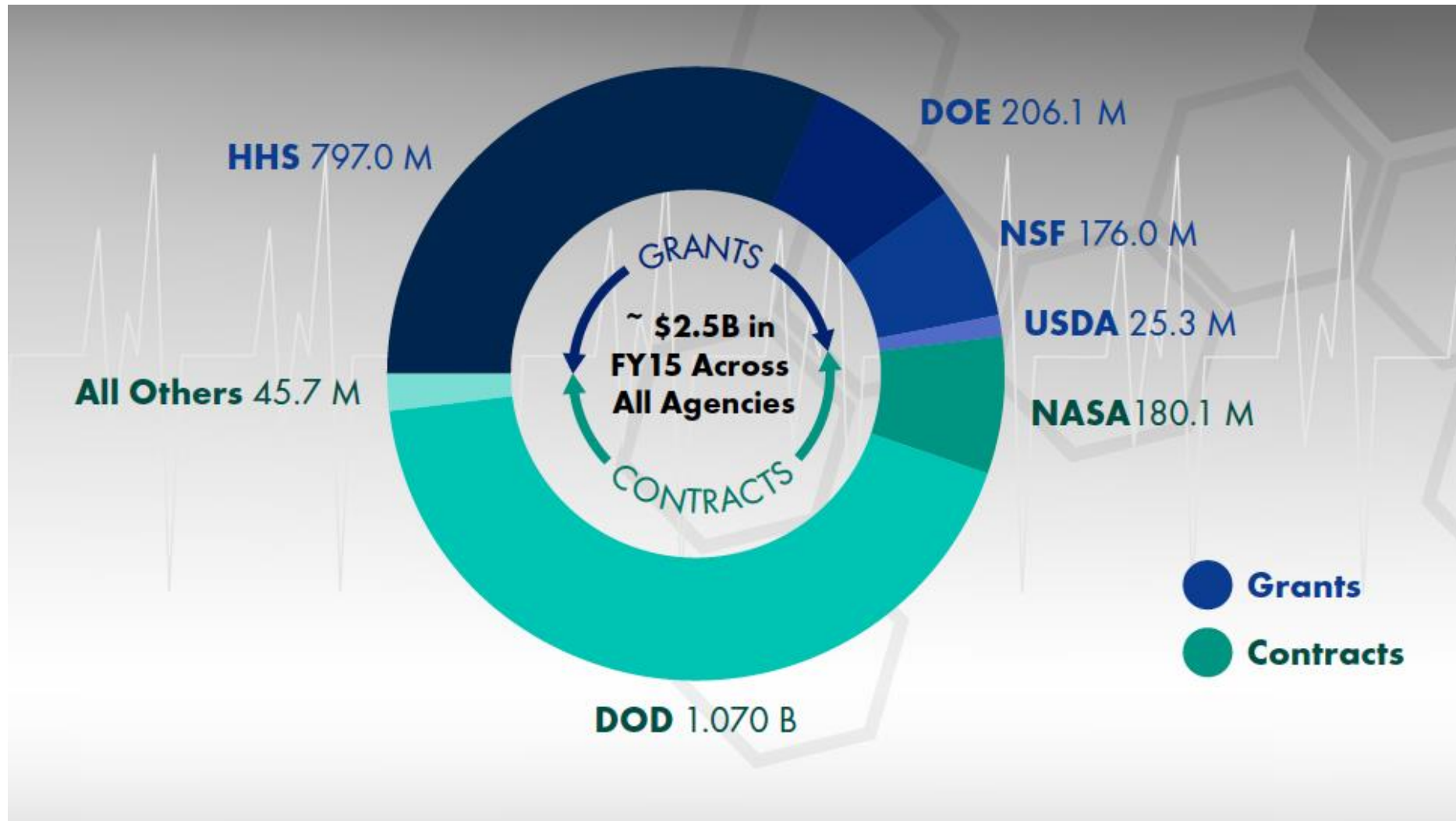
STTR

- Small business technology transfer act of 1992
- Parallel set-aside program which requires small businesses to subcontract with a U.S. research institution – with goal of commercialization
- 0.45% of the extramural research budget for agencies with a budget greater than \$1B per year
- **\$300 million set-aside each year**

Participating Federal Agencies



SBIR/STTR Budget by Agency, FY2015



Advantages

- Non-diluted capital
 - The government will not get any equity position or ownership of your firm
 - No repayment is required (it is not a loan)
- IP/data protection
 - Grantee retains all patent rights
 - The government can't share your report and data with anyone outside the government for 4 years during which you can apply for patents

SBIR can be very useful for early stage companies-a famous example is Qualcomm

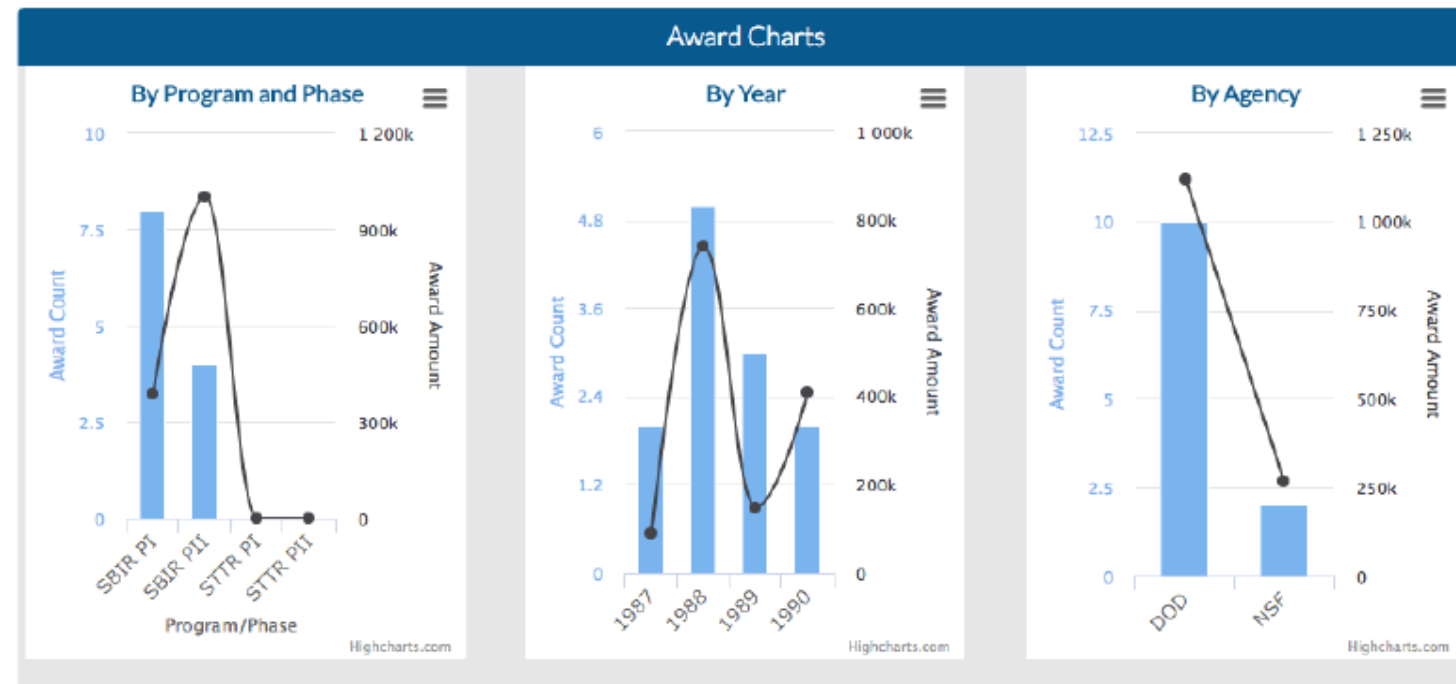
Qualcomm Inc.

Address
10555 Sorrento Valley Rd San Diego, CA, 92121

Information
DUNS:
of Employees: 10

Ownership Information	
Hubzone Owned:	N
Socially and Economically Disadvantaged:	Y
Woman Owned:	N

\$1.4 million SBIR support in its early years
When it had only 10 persons



Disadvantages

- Very hard work to apply
 - Registration with multiple government agencies and maintenance to keep up to date
 - Preparation of 15-20 documents for each application and more if awarded
 - Frequent communications with funding agencies
- Highly competitive with no guarantee that you will get any funding
 - About 15% success rate for Phase I
 - The glorious idea you came up with may not shine as brightly in front of the reviewers (the good news is that it may be easier than convincing investors if the idea is novel but risky)
- The time frame you planned may be thrown out of the window completely
 - You may have to apply multiple times to get funding
 - The government may be shut down (The two shut downs in 2017 delayed us 9 months)

Who can apply SBIR?

- Organized as for-profit U.S. business
- < 500 employees including affiliates
- Work **must** be done in the U.S.
- Greater than 50% U.S.-owned by individuals and independently operated
- PI does not have to be PhD or MD but has to be > 50% employed by the business
- STTR is a little different
 - Requires IP and cooperation agreements in place

SBIR and STTR comparison

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business (check solicitation)
Work Requirement	Guidelines: May outsource up to 33% (Phase I), 50% (Phase II)	Minimum Work Requirements: 40% Small Business 30% Research Institution Partner
Program Size	3.2% (FY15 - \$2.25B)	0.45% (FY15 - \$296M)
Majority VC ownership	Allowed (multiple VCs)(only some agencies)	Not allowed
Participating Agencies	11 agencies (extramural R&D budget > \$100M)	5 agencies (extramural R&D budget > \$1B)

The small business is always the applicant and awardee

Before you apply

WWW. SBIR.GOV

**Personnel/time
commitment**

Assess Fit

- Check Eligibility
- Review Agency topics
- Attend SBIR/STTR conference
- Speak with agency PMs
- Subscribe to agency notices
- Align internal/external resources
- Align letters of Support

Resources

- Federal sites
 - WWW.sbir.gov/tutorials has good on-line tutorials
 - SF424 SBIR/STTR Guide has detailed instructions for NIH grant application-a must read
 - Successful examples can also be found on sbir site
- UCI Applied Innovation sponsored presentations (free)
<http://innovation.uci.edu/the-cove/ecosystem/>
- SBIR/STTR road show at local Universities (UCI, UCLA, and others)
 - Talks by funding agencies about current funding interests and focuses
 - You can book one on one meetings with the funding agency officer ahead of time
 - University grant administrator talks about the success and failure experiences of the small businesses incubated on campus or spun off from their labs
 - LA city official talks about city support for small business to get federal grants
 - Register early if you want to go to the one at UCI
- Grant Agency presentations at professional conferences
 - For example, NEI grant officers presented at the 2018 ARVO

You need to register with these government agencies

- Do it early, can take 6-8 weeks
 1. Get a DUNS number
<http://fedgov.dnb.com/webform/displayHomePage.do;jsessionid=81407B1F03F2BDB123DD47D19158B75F>)
 2. Register on WWW.SAM.GOV
 3. Register on SBA www.sbir.gov/registration
 4. Register on www.grants.gov
 5. Register on eRA commons for NIH grant applications
<https://era.nih.gov/erahelp/commons/default.htm#cshid=1026>

Application process

Gated Process - Three Phases

Phase I

Concept Development
6 months – 1 year
~ \$150,000

Phase II

Prototype Development
24 months
~ \$1,000,000

Phase III

Commercialization
No SBIR funding

Solicitation to Award Process

Find
Solicitation

Proposal
Submission

Evaluation

Award Phase I

UCLA Clinical and Translational Science Institute -grant application facilitation process



Large Multidisciplinary Mechanisms



NEW
FOA



EXPERTISE
IDENTIFIED



BRAINSTORMING



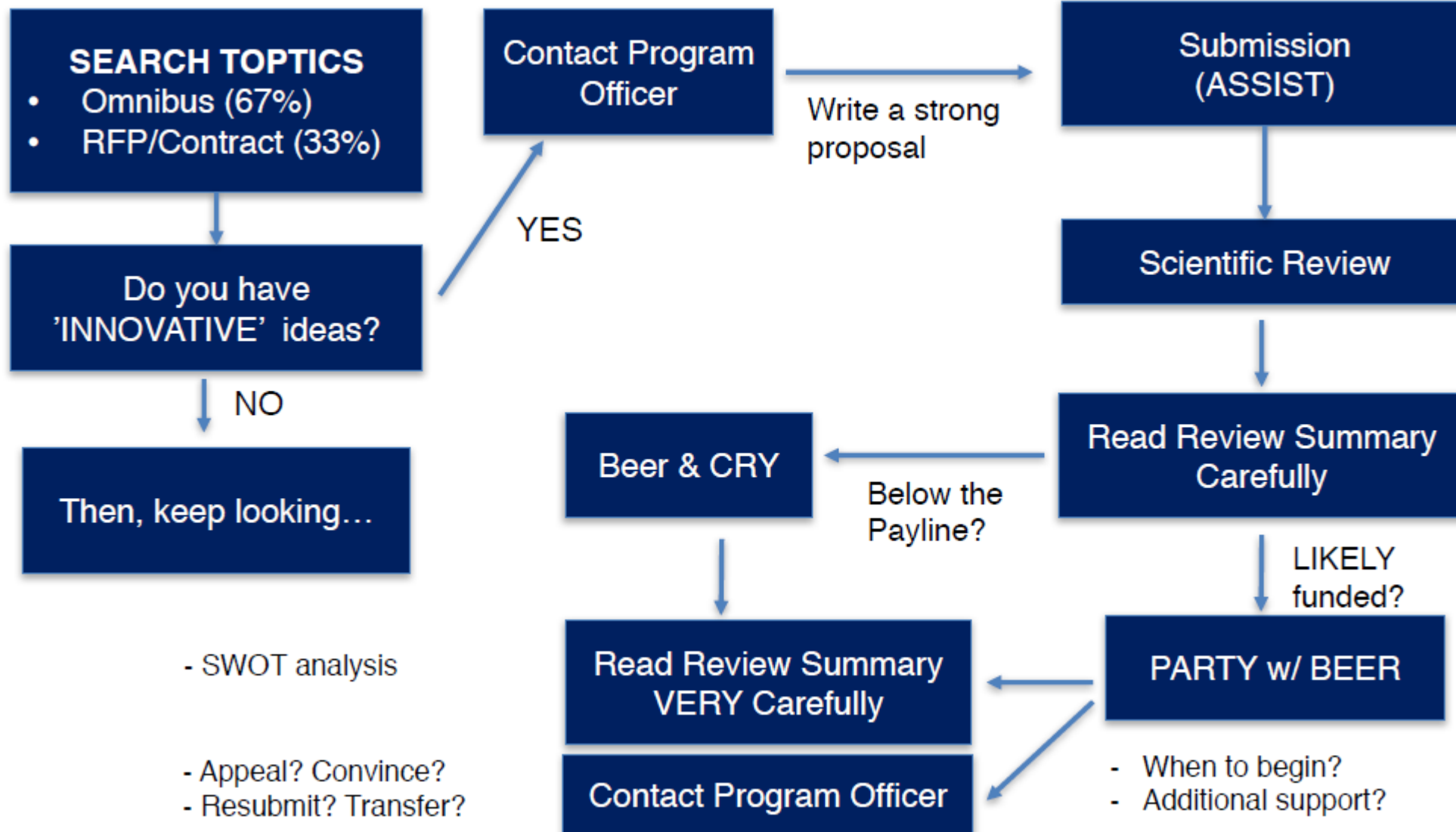
PROPOSAL
DEVELOPMENT



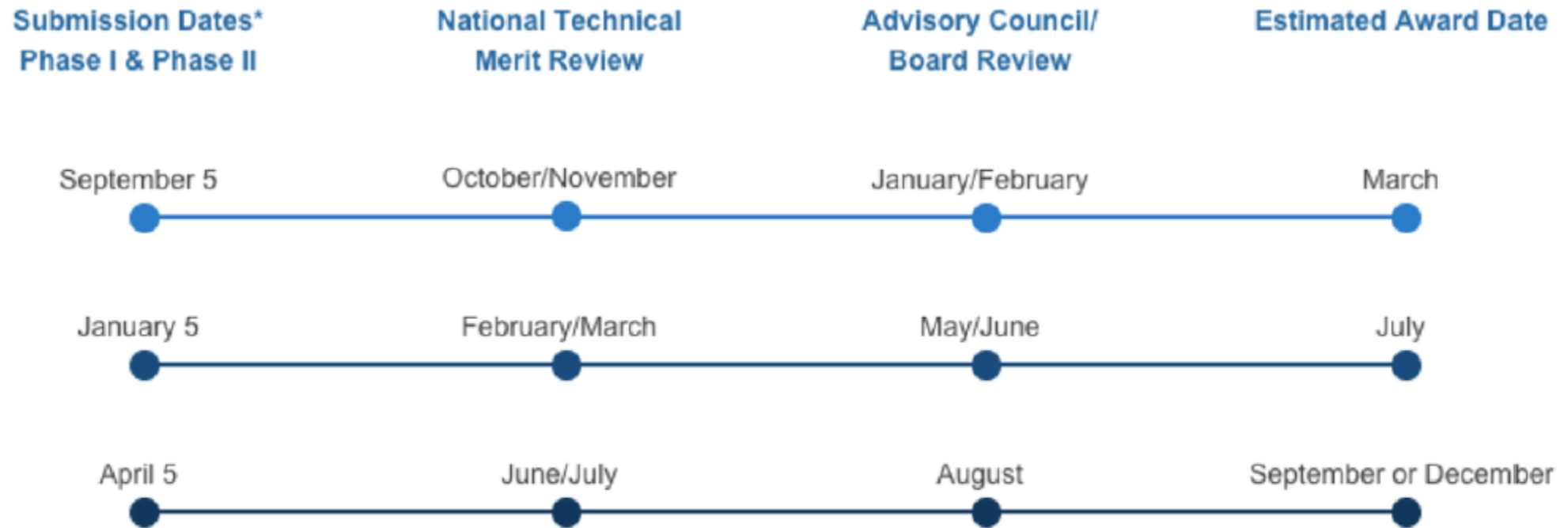
SUBMISSION

- 193 PCORI, DOD, NIH, etc. receive facilitation; 40 awarded
- \$212M in new grant funding

A typical application journey



Submission dates



~ **6 Months** from application to award

Key elements for application

- A problem and a solution
 - Fits the mission of the funding Agency
 - Clearly presented
- Important documents
 - Title (will the project fits the Agency interest?)
 - Narrative/Abstract (3 sentences)
 - Specific Aims (one page)
 - Research Strategy (6 pages for Phase I and 12 pages for Phase II)
 - Facilities
 - Biographies

Reviewers

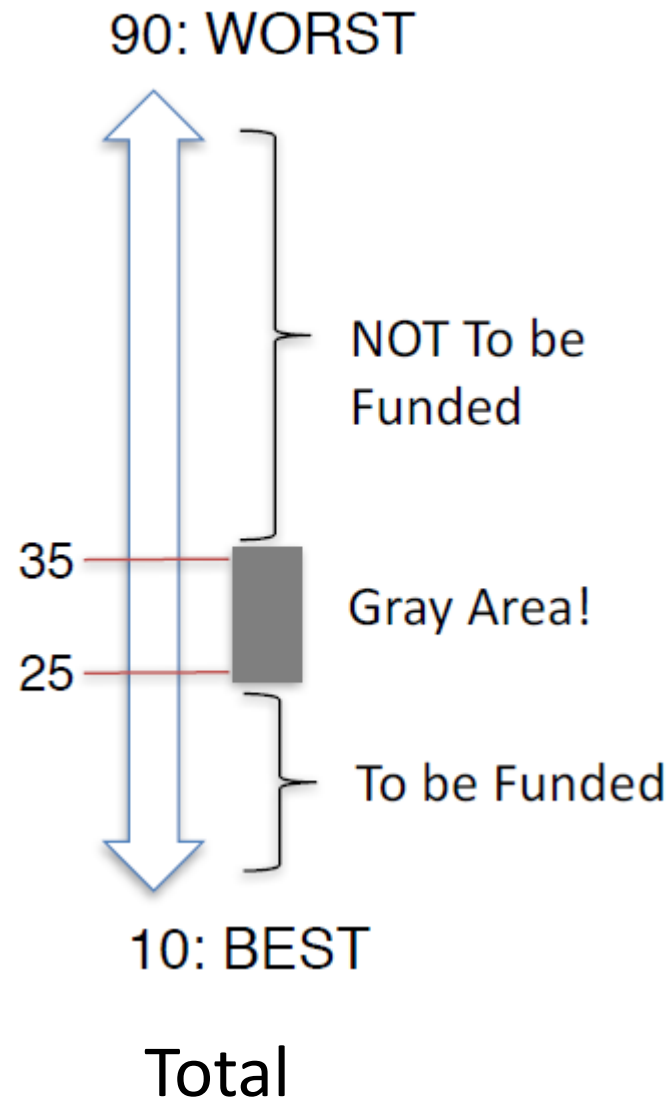
- At least 3 technical Reviewers
- For Phase II, there will also be 1 Reviewer for the commercialization plan
- What do they look at
 - The strength of the science
 - The ability to carry out the project
 - The potential impact

Review Criteria at NIH

- Review Criteria
 1. Significance
 2. Investigators
 3. Innovation
 4. Approach
 5. Environment
- A quick review followed by more detailed review
- Top half gets discussed in study sessions and scored
 - You will get a written feedback called Summary Statement
- Bottom half doesn't get discussed and you won't get any written feedback

The meanings of individual and total scores

Overall Impact or Criterion Strength	Score	Description
	1	Exceptional
High	2	Outstanding
	3	Excellent
	4	Very Good
Medium	5	Good
	6	Satisfactory
	7	Fair
Low	8	Marginal
	9	Poor



Our own examples

CRITIQUE 1 of a successful grant

Significance: 1
 Investigator(s): 1
 Innovation: 2
 Approach: 1
 Environment: 1

CRITIQUE 1 of a Failed grant

Significance: 4
 Investigator(s): 3
 Innovation: 3
 Approach: 6
 Environment: 2

Feedback from funding Agencies

- If you are in the upper half and got discussed in the Study Section discussion
 - You will get a Summary Statement which will have the score, the summary of overall impact and detailed discussions of strength and weakness by each reviewer
- If you are in the bottom half and did get to the Study Section discussion
 - You need to talk to your Program Officer to learn where the problems are
- Resubmission is a given
 - Almost nobody can get funded the first time.
 - When resubmitting, you need to address all the critiques by the reviewers if you have a Summary Statement
 - You need to make major changes based on your Program Officer's feedback if your grant didn't get discussed the first time

My 2-cents

- Do you have a good idea within the area of interest at a Federal Agency?
 - Science driven with reasonable risk (chance of success)
 - Novelty
 - Importance to the field
- Does the team have the expertise to do it?
- Clear presentation/writing is important
 - Make it understandable by scientists outside the field
 - Study Sections could be very diverse
- Communicate with your Institute Program Officer all the time
 - Before and after
 - Establish a good relationship
- Discuss with experienced applicants and have them review and critique your application if possible

Questions and Discussions

Thank you