NIH Collaboratory

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Writing a Compelling Grant Application

Marcel Salive, MD, MPH
National Institute on Aging

Essentials of Embedded Pragmatic Clinical Trials

Learning goals

- Identify elements of a compelling ePCT application
- Tips on NIH matchmaking

Important things to know

- Online resources are available for the development of pragmatic trial grant applications
- NIH has new policies and forms related to clinical trial grant applications
- Some things, such as milestones and safety monitoring, may be negotiable around the time of an award

National Institutes of Health

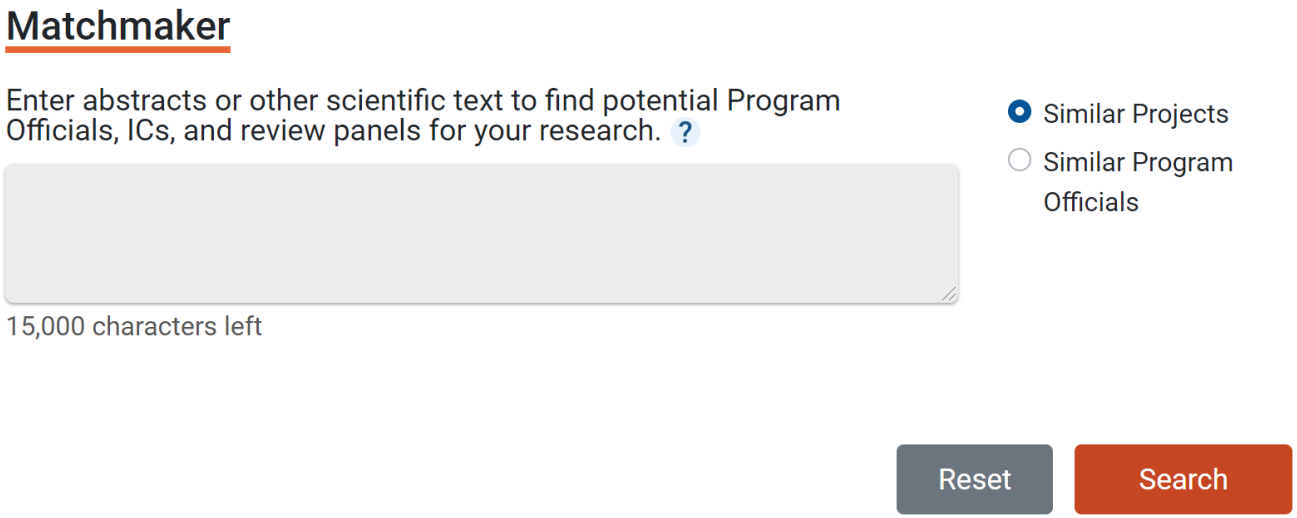
- NIH is made up of 27 institutes and centers, or ICs
- ICs award >80% of the NIH budget each year
- Each IC has a budget and a director, and typically their own review for large trials

Find the right NIH program official

IC mission and priorities:

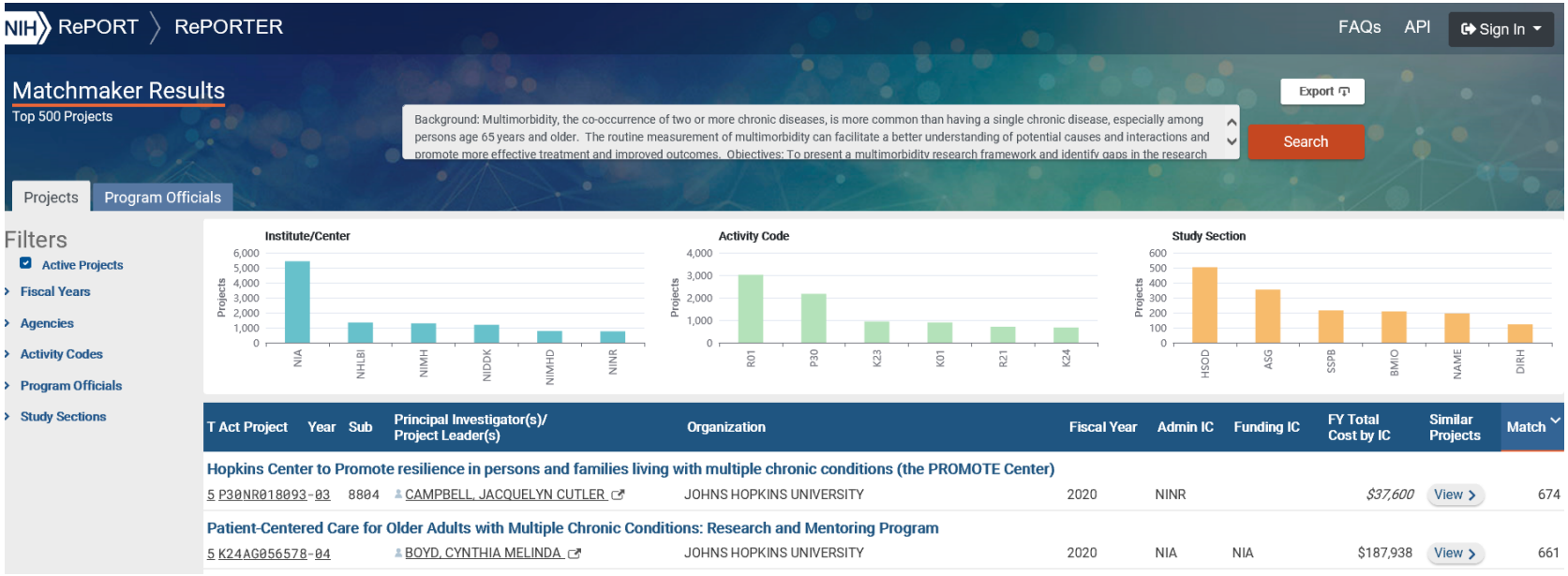
- Focus on a specific disease area, organ system, or stage of life
- Use Matchmaker tool in NIH RePORTER for suggestions
- Talk to program officials
- Consult your mentor and colleagues

NIH RePORTER matchmaker tool



- Use draft of specific aims
- Email query to program official rather than call (we telework and attend meetings)

Matchmaker results (example)



- This can help to connect you with the most appropriate PO(s)
- Prepare agenda and questions, to productively interact!
- Program officer can recommend a study section or two

Find the right FOA

- Request for Application (RFA)
  - For specific areas of science where more research is needed, and applications are encouraged for investigator-initiated research in this specific area of science
- Notice of Special Interest (NOSI) and Program Announcement (PA, PAS, PAR)
  - For an area of scientific interest for one or more ICs where investigator-initiated research is needed

NIH scientific contacts

NCCIH	Robin Boineau	**NIDA**	Sarah Duffy
NCI	Erica Breslau	**NIDCR**	Dena Fischer
NHLBI	Larry Fine	**NIDDK**	Pamela Thornton
NIA	Marcel Salive	**NIMH**	Jane Pearson
NIAAA	Brett Hagman	**NINDS**	Robin Conwit
NIAID	Clayton Huntley	**NINR**	Jeri Miller
NIAMS	Chuck Washabaugh	**ODP**	Carrie Klabunde
NICHD	Sue Marden		

Tailor the application

Tailor your application to address all the FOA-specific instructions and review criteria

Application dos

- Justify the research
- Include pilot data
- Address potential overlaps
- Reduce complexity
- Ensure aims are capable of advancing the field
- Choose appropriately expert personnel for a multidisciplinary team
- Link data collection and analysis to aims
- Justify the use of multiple sites and sample size

Application don’ts

- Skip any steps (eg, literature review)
- Use dense or confusing writing style
- Include untestable aims
- Include non-relevant aims or fishing expeditions
- Assume that prior collaboration is irrelevant

Strategies for success

- Pose a clear research question
- Convince the reviewer your study is worth doing
- Sell your research plan–highlight the strengths
- Identify weaknesses and explain how you will deal with them
- Tailor your application to the funding agency
- Obtain feedback from your collaborators, consultants, and others

NIH online resources

https://researchmethodsresources.nih.gov/

- Research methods resources on designing pragmatic and group randomized trials
- NIH Grants Guide: finding FOAs
- NIH Guidance on Biosketches
- NIH Peer Review
- NIH General Application Guide
- NIH Inclusion Policies for research involving human subjects
- NIA Blog (subscribe for weekly posting)

Inside NIA A Blog for Researchers

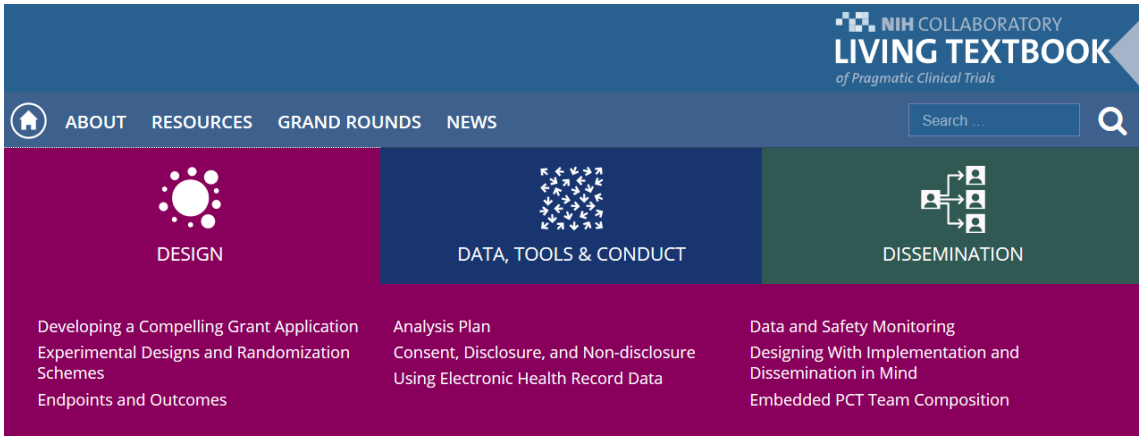
Get weekly updates on NIA funding policies and research priorities.

Subscribe

Important things to do

- Read relevant Funding Opportunity Announcement multiple times
- Identify program staff at your target NIH Institute/Center and review your Specific Aims and any questions about them
- Obtain adequate feedback on the Research Plan from the entire study team

Resource: The Living Textbook



Developing a Compelling Grant Application

- Introduction
- Find the Right Program Official
- Find the Right Funding Opportunity Announcement
- Write a Strong Proposal That Addresses Review Criteria
- Review Criteria
- Award Status
- Additional Resources