

Academic Careers in Clinical Research

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University of California, San Francisco

August 7, 2014

Building a Career in Clinical Research

Date	Speaker	Topic
7/31	Shlipak	Getting Started
8/7	Whooley	Academic Clinical Research
8/14	Katz	Public Health
8/21	Schroeder	Foundations & Public Policy
8/28	Barron	Biotechnology Industry
9/4	Saint	Securing a Job
9/11	Whooley	Work/Life Balance

Before Next Week's Session

Readings:

- Holmes 2009 (Manuscript preparation)
- Demaria 2011 (Manuscript revision)
- Demaria 2013 (Manuscript review)
- Garfield 2006 (Journal Impact Factors)

Manuscript Preparation and Publication

David R. Holmes, Jr, MD; Patricia K. Hodgson, BA; Rick A. Nishimura, MD; Robert D. Simari, MD

Circulation 2009;120:906-913

 COMMENTARY

The History and Meaning of the Journal Impact Factor

Eugene Garfield, PhD

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However, it ma

JAMA 2006; 295:90-93

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EDITOR'S PAGE

Manuscript Revision



**Anthony DeMaria,
MD, MACC**

*Editor-in-Chief, Journal
of the American College
of Cardiology*

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EDITOR'S PAGE

What Constitutes a Great Review?

Anthony N. DeMaria, MD, MACC

Editor-in-Chief, *Journal of the American College of Cardiology*

Before Next Week's Session

Readings:

- Holmes 2009 (Manuscript preparation)
- Demaria 2011 (Manuscript revision)
- Demaria 2013 (Manuscript review)
- Garfield 2006 (Journal Impact Factors)

Assignment:

1. Identify 4 different grants (1 intramural, 1 government, 1 industry, and 1 foundation) for which you are eligible
2. Develop a realistic timeline for submitting 1 of these grants

COURSE FINAL ASSIGNMENT

For you to receive credit for the course, your mentor must send an email to Olivia@epi.ucsf.edu by 5PM on 9/26/14 stating that s/he has met with you to review your:

1) UCSF-formatted CV

2) Career plan

Olivia will reply to your mentor confirming that this email has been received. Please note that the CV and career plan themselves need not be turned in. However, it is the student's responsibility to make sure that the mentor has emailed (and received confirmation from) Olivia by 9/26/14.

<http://academicaffairs.ucsf.edu/advance/cv.php>

University of California, San Francisco

CURRICULUM VITAE

Name: This section does not import; it is populated with data from the campus payroll system and employee database

The information below is based on the 2005 UCSF CV Guidelines defined by CAP (the Committee on Academic Personnel). Most of the text is entered into tables that are navigated through by using the tab key. To add more lines to a table tab through to the end and tab again

EDUCATION:

Date range	Institution	Degree	Department
------------	-------------	--------	------------

LICENSES, CERTIFICATION:

Year	Description
------	-------------

PRINCIPAL POSITIONS HELD:

Date range	Institution	Position	Department
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Example Career Plan Outline

The goal of the career plan exercise is to help you articulate your goals and make a plan for achieving them. The career plan should be 1 to 2 pages. Ask yourself what you would like to be doing in 2 years, and then develop a strategy to get there. An example outline for post-doctoral fellows and junior faculty is provided below. **However, medical students, residents and other scholars who are not currently post-doctoral fellows should feel free to use whatever outline and format is most helpful for their career development.**

- A. Goals: Write down 1 to 3 career goals, and draft a chronology beginning with your current position and the major career steps you would like to take, including the position(s) you would like to occupy in the next 5 years. Draft an ideal job description, including percent of time doing research, clinical work, teaching and administrative tasks. Be as specific and realistic as possible.
- B. Specific objectives: Now, thinking just about the next 2 years,
 - For each year, list what, specifically, how you will spend your time
 - Percent research
 - Percent coursework
 - Percent clinical (subdivide by inpatient/outpatient, etc.)
 - Percent teaching (subdivide as appropriate)
 - List specific mentors and other colleagues you would like to work with, with specific roles for each mentor

- C. Meet with your mentor to discuss this 1 to 2 page career plan along with your academic-format curriculum vitae.
- D. Verify that your mentor has sent an email to Olivia@epi.ucsf.edu by **5PM on September 26, 2014**, stating that s/he has reviewed your CV and written career plan with you. Olivia will reply to your mentor confirming that this email has been received. The CV and career plan themselves need not be turned in, but it is the student's responsibility to make sure that the mentor has emailed (and received confirmation from) Olivia.

To: Olivia@epi.ucsf.edu

From: Your mentor

cc: Student (=you)

Subject: <Student's name> CV and written career plan

Dear Olivia,

I am writing to confirm that I have met with <name of student> to review and discuss his/her CV and written career plan for Epi 227 (Building a Career in Clinical Research).

Sincerely,

Name of mentor

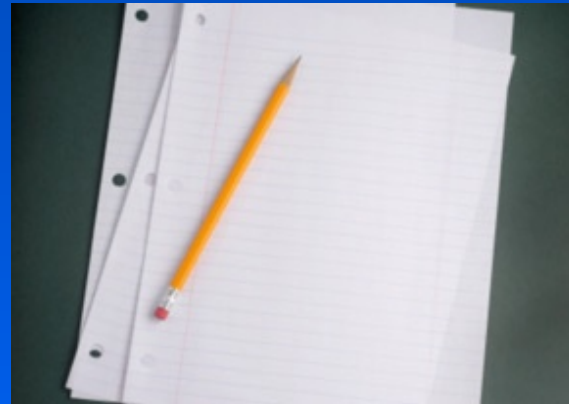
ACADEMIC CAREERS IN CLINICAL RESEARCH

Outline

- Writing papers
- Funding resources
- Tips for writing grants
- Dealing with rejection

Outline

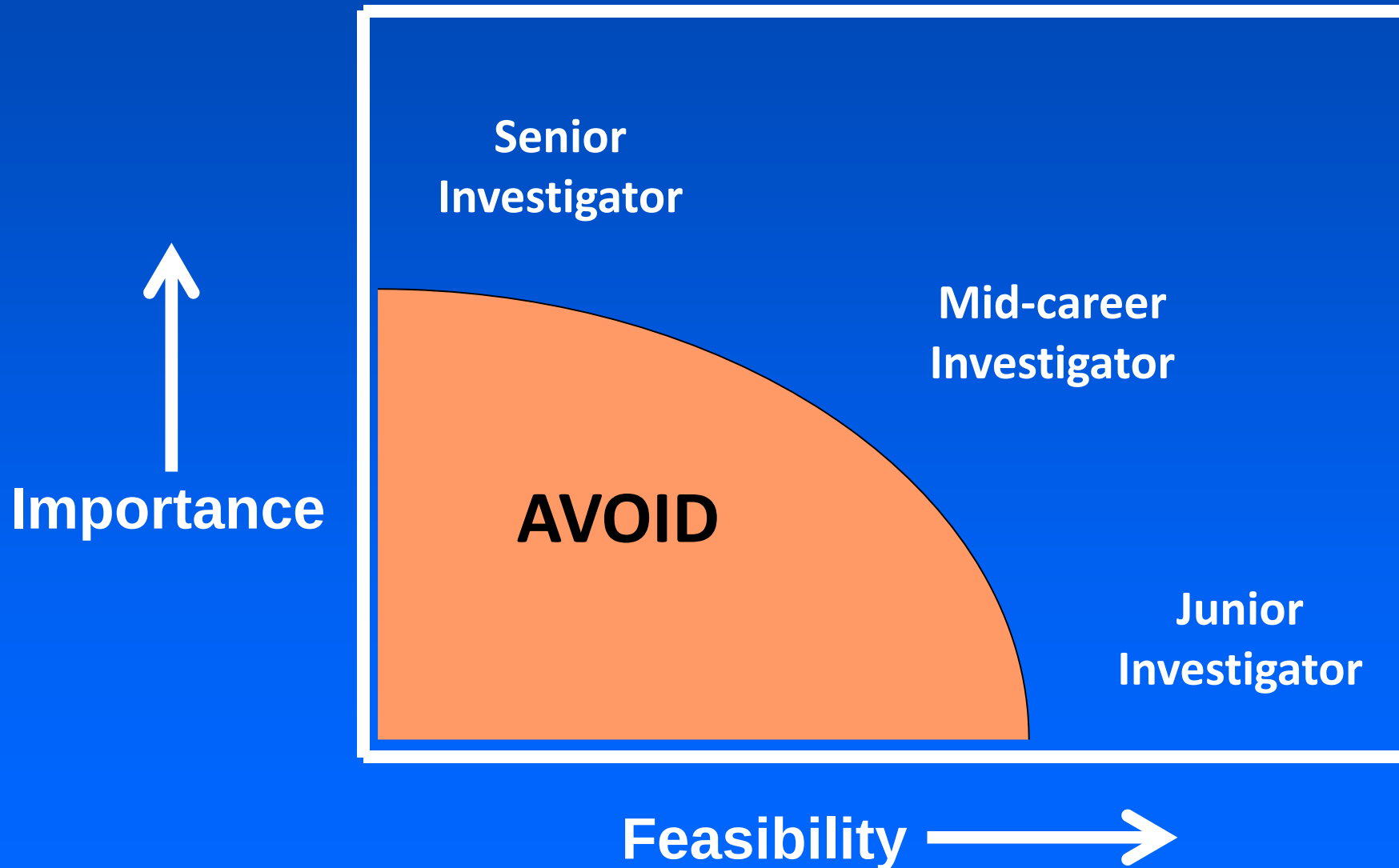
- Writing papers
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Steps for writing your first paper

- 1) Obtain and learn Endnote (online or library tutorial)
- 2) Formulate a research question
- 3) Identify an already collected dataset
- 4) Look through data dictionary for variables of interest
- 5) Revise / refine research question as necessary

Carefully Choose Your Research Topic

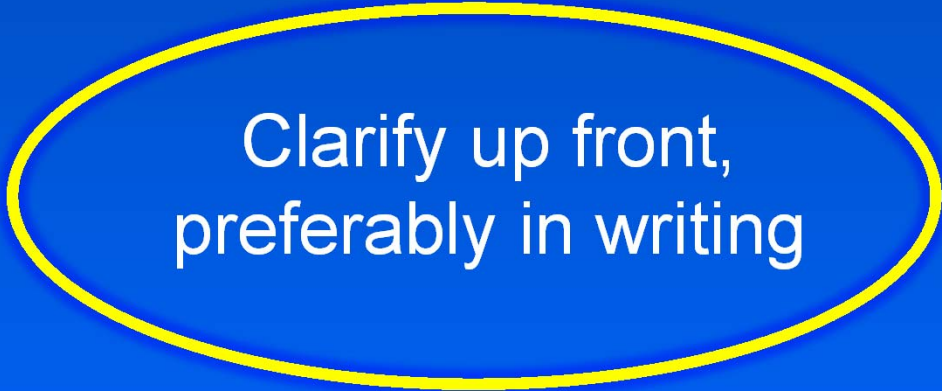


How to find datasets for analysis

- <http://www.epibiostat.ucsf.edu/courses/RoadmapK12/PublicDataSetResources/>
- <http://ctsi.ucsf.edu/research/celdac>
- <http://www.sgim.org/index.cfm?pageId=876>
- <http://www.cdc.gov/nchs/surveys.htm>
- <https://biolincc.nhlbi.nih.gov/>
- <http://www.icpsr.umich.edu/NACDA/>
- <http://www.adni-info.org/>
- <http://healthdata.gov/>
- Contact principal investigator of relevant study

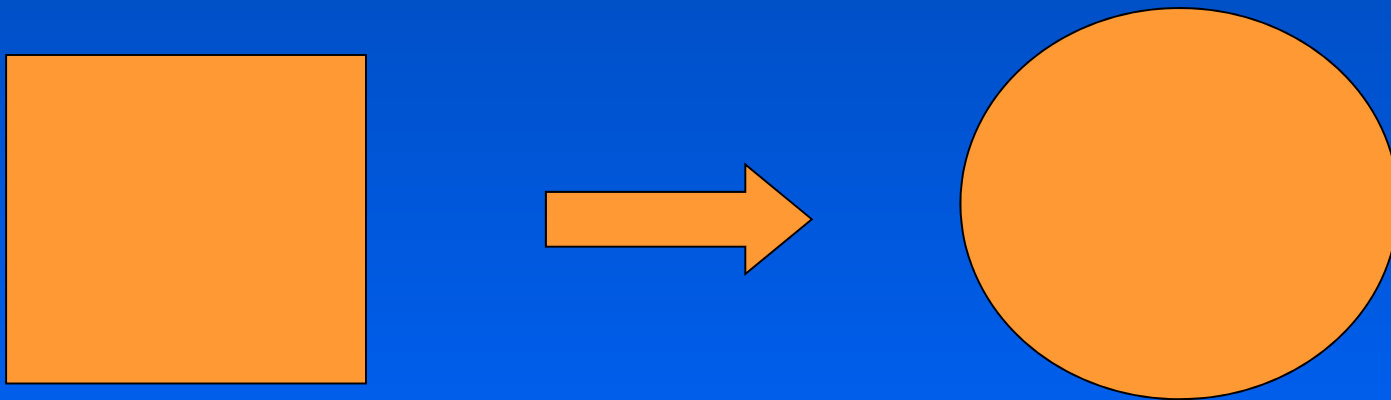
Authorship (order of importance)

1. First author
2. Last author
3. Second author
4. Penultimate author
5. Middle authors



Clarify up front,
preferably in writing

Successful papers, grants, careers . . .



. . . tell a story others want to hear.

INTRODUCTION (funnel)

Importance of general topic



Significance of specific area



Questions answered so far



Key questions not answered
in prior studies



**How I will answer these
critical questions**

DISCUSSION (reverse funnel)

What we found

What findings mean

How findings add to
what was already known

Why findings might have occurred

Study limitations

Conclusion

How to choose a journal

- Ask your mentor
- Look at journal to see whether they have published anything similar or relevant (if no, probably not interested)
- Look at impact factors in JCR (Journal Citation Reports)
- Cite work of authors who have papers in target journal
- Cover letter: 3-4 sentences on why this is an important NEW finding that is relevant to readers of that journal

Journal Citation Reports

- <https://vpn.ucsf.edu/> → <http://www.library.ucsf.edu/>
Collections and resources → Databases → Journal Citation Reports
- Journal's Impact factor = average number of times in a year that papers from prior 2 years have been cited
- Journal's Eigenfactor score (ranks total importance to the broader scientific community) – not as relevant for us
- A scholar's *h* index is the number of papers (*N*) by this scholar that have been cited *N* or more times

Suggesting Reviewers

- First or last authors of papers published in that journal
- Authors from references included in your paper
- Your mentor's colleagues
- Investigators whom you have met at conferences
- Friends from your professional training

Reviewing Papers

- Is it new?

- What is already known?
- What does this study add?

- Is it true?

- Are predictor and outcome measurements valid?
- Do the number of outcomes justify the conclusions?
- Is the statistical analysis appropriate?

Responding to reviewers (remember – they are volunteering their time)

- We thank the reviewer for this comment.
- The reviewer makes an excellent point.
- We agree with the reviewer.
- We appreciate this suggestion.
- Thank you for this helpful comment.
- This is a great idea.
- This is a very important point.
- We apologize for the confusion.

Etiquette (for abstracts and papers)

- E-mail coauthors a copy of submitted version
- Forward any decision letters regarding journal submissions or abstract presentations to all coauthors
- Offer coauthors the opportunity to review your responses to reviewers and the revised manuscript
- Once final version is published, email all coauthors with final citation (including page numbers) and attach a pdf copy of the accepted manuscript. For example:

- *I'm pleased to report that our manuscript has been accepted for publication! Here is the in press citation for your CVs:*

Smith J, Doe J, Jones S. Title of paper.
Name of Journal. Year; Volume: In press.

- Forward page proofs to last, first and corresponding authors
- Once final version is published, email all coauthors with final citation (including page numbers) and attach a pdf copy of the final manuscript. For example:
- *I'm pleased to let you know that our manuscript has now been published. Here is the final citation.*

Smith J, Doe J, Jones S. Title of paper.
Name of Journal. Year; Volume: Page numbers.

Outline

- Writing papers
- Funding resources
- Tips for writing grants
- Dealing with rejection



Rigorously peer-reviewed grants demonstrate investigator independence and recognition

1. US government research grants (NIH, DOD, VA)
2. Foundation or society grants (e.g., American Cancer Society, American Heart Association)
3. Investigator-initiated research funded by industry
4. Industry-sponsored research funded by industry

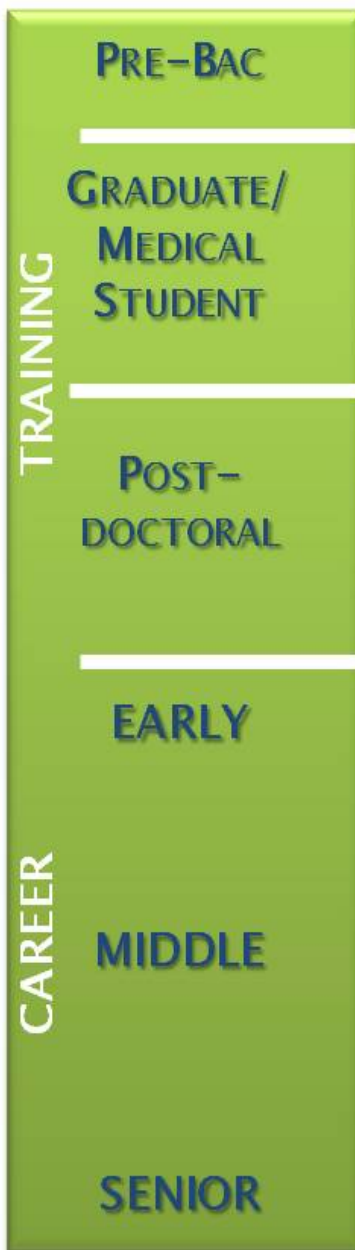
NIH Grants

National Institutes of Health

Small Grant (R03)

Research Project Grant (R01)

Exploratory/
Developmental Grant (R21)



- ← Institutional Training Grant (T34)
- ← Institutional Training Grant (T32)
- ← Individual NRSA Fellowship (F31, F30)
- ← Institutional Training Grant (T32)
- ← Individual NRSA Fellowship (F32)
- ← Pathway to Independence Award (K99/R00)
- ← Mentored Research Scientist Development Award (K01)
- ← Mentored Clinical Scientist Development Award (K08)
- ← Mentored Patient-Oriented RCDA (K23)
- ← Mentored Quantitative RCDA (K25)
- ← Independent Scientist Award (K02)
- ← Midcareer Investigator Award in Patient-Oriented Research (K24)
- ← Senior Scientist Award (K05)

Graphic represents a small sample of NIH funding mechanisms available.

General Funding Resources

- Pivot – set up automated funding search for your interests
- Foundations – www.fdncenter.org www.cof.org
- Federal government opportunities – www.grants.gov
- Grantmakers in health – www.gih.org
- Grateful patients (via development office)
- NIH Guide Listserve –
<http://grants.nih.gov/grants/guide/listserv.htm>

UCSF Office of Sponsored Research

<http://osr.ucsf.edu/>

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We help researchers build collaborative research teams, pursue funding opportunities, deliver effective proposals & administer awards

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Research Development Office



The Research Development Office (RDO) fosters scientific collaborations between internal and external research teams and facilitates proposal development for large, multi-investigator project grants. The RDO is also home to the Resource Allocation Program and the Limited Submission Program.

[Learn more →](#)

Research Management Services



Research Management Services (RMS) provides expert administrative support to all researchers, from pre-award through the award process on all grant mechanisms. RMS teams collaborate with the Principal Investigator (PI), his/her department and our sponsors so that PIs may be successful in their research grants.

[Learn more →](#)

Government and Business Contracts



Government and Business Contracts (GBC) provides negotiation, acceptance and award setup for City/County, State and Federal contracts, business contracts, and incoming subcontracts where the prime source of funding is a contract.

[Learn more →](#)

Grants administration

Pre-award

- Budgeting
- Letters of support
- Paperwork/signatures
- Biosketches and other support pages
- Uploading documents

Post-award

- Hiring and purchasing
- Budget projections
- Progress reports
- Agency correspondence

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Lingo

- RFA = Request for Applications
- RFP = Request for Proposals
- PA = Program Announcement

Types of grants

- Fellowship grants – salary support for post-doctoral fellows
- Career Development Grants – salary support for junior faculty
- NIH Loan repayment grants
- Research grants – support for research expenses, may also include salary support

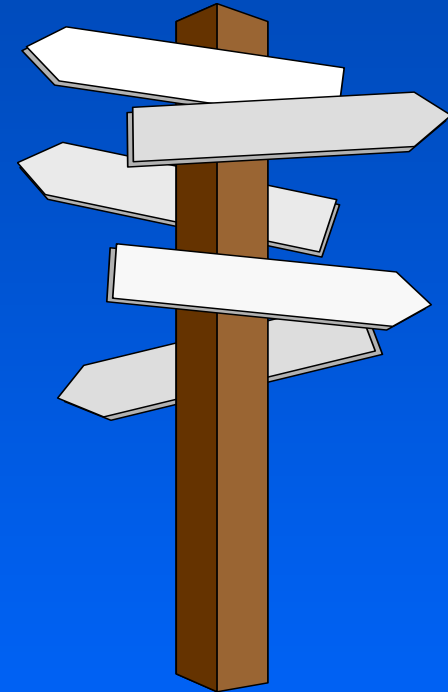
Should I do an additional year of fellowship?

- Advantages:

- complete projects
- find the right job
- educational experience

- Disadvantages:

- salary at fellowship level
- loss of momentum
- can often obtain similar experience on faculty



Fellowship funding opportunities

- National Institute of Health (e.g., F32)
- Societies (e.g., American Cancer Society)
- Foundations (e.g., Robert Wood Johnson)
- Pharmaceutical or biotech company grant
- Intramural grants (e.g., <http://rap.ucsf.edu/grants/>)

Deadlines - NIH Fellowship Grants

<i>Due date</i>	<i>Review</i>	<i>Notified</i>	<i>Award</i>
April 8	June	September	December
August 8	October	January	April
December 8	February	May	July

See “F Kiosk” for detailed information:
http://grants.nih.gov/training/F_files_nrsa.htm

Career Development Grant Sources (Salary support for junior faculty)

- UCSF programs:
<http://accelerate.ucsf.edu/funding/career-development-awards>
- NIH (K awards, Minority or R01 Supplements)
- VA Career Development Awards
- NIH Minority or R01 Supplement
- Foundations: www.fdncenter.org www.cof.org
- Professional societies

NIH Career Development Awards

<i>Due date</i>	<i>Review</i>	<i>Notified</i>	<i>Award</i>
February 12	June	September	December
June 12	October	January	April
October 12	February	May	July

See “K Kiosk” for detailed information

<http://grants.nih.gov/training/careerdevelopmentawards.htm>

VA Career Development Awards (2 cycles per year)

<i>Letter of Intent</i>	<i>Application due</i>	<i>Reviewed</i>
8 months prior to start date	6 months prior to start date	4 months prior to start date

<http://www.research.va.gov/funding/CDP.cfm>

NIH Eligibility

Must be U.S. citizen
or permanent resident

U.S. or non-U.S.
organization can apply

- K23
- NIH loan repayment
- R01 minority supplement

K99/R00

- R01
- R21
- R03

www.niaid.nih.gov/researchfunding/grant/pages/newpiportal.aspx

NIH Pathway to Independence Award (K99/R00)

- Kangaroo: 2 years fellowship + 3 years faculty support
- Non-US citizens eligible to apply from a US institution
- Foreign institutions not eligible to apply
- <http://grants.nih.gov/grants/guide/pa-files/PA-11-197.html>

NIH Definition of Minority (may vary by program):

Underrepresented minority students and investigators are defined as individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical, behavioral, clinical or social sciences.

NIH Loan Repayment Program

http://www.lrp.nih.gov/about_the_programs/index.aspx

- Repays \$35,000/year in educational loans for 1 or 2 years
- Half of applications funded (1/3 of new, 2/3 of renewals)
- Must be a US citizen or permanent resident
- Must have a health professional doctoral degree
- Must spend at least 50 percent time doing clinical research
- Educational debt must be at least 20 percent of your salary
- Employed by a nonprofit institution or government entity

Five NIH Loan Repayment Programs

http://www.lrp.nih.gov/about_the_programs/index.aspx

- Clinical Research
- Pediatric Research
- Health Disparities Research
- Contraception and Infertility Research
- Clinical Research for Individuals from Disadvantaged (Low Income) Backgrounds

Other research grants

- Federal government opportunities – www.grants.gov
- DOD – <http://cdmrp.army.mil/funding/reftable.shtml>
- HRSA – <http://www.hrsa.gov/grants/index.html>
- [Patient-Centered Outcomes Research Institute](http://www.pcORI.org) (PCORI)
- Agency for Health-Care Research and Quality (AHRQ)
- Industry (Investigator-Initiated Research programs)
- Grantmakers in health – www.gih.org
- Foundations – <http://foundationcenter.org>

Outline

- Writing papers
- Funding resources
- Tips for writing grants
- Dealing with rejection



Preparing grant applications

- Specific Aims page: brief summary of background with 2 to 4 very clear, specific, concrete objectives (and associated hypotheses)
- Budget (defining study objectives and coming up with budget an iterative process); aim for max
- Look at successful proposals
- Get feedback early and often

Grant Writing Guidance

Examples of successful research proposals and expert advice on how to navigate and write grant applications.

- Writing NIH Mentored K Award Applications ?
- How to Write a PCORI Grant ?
- K Proposal Library (K08, K23, K24, K99) ?
- T32 Proposal Library ?
- Diversity Supplement Proposal Library ?
- Data Safety Monitoring Protocol Library ?
- PCORI Proposal Library ?
- All Grant Writing Resources ?

Explore: <http://accelerate.ucsf.edu/funding?/career-development-awards>

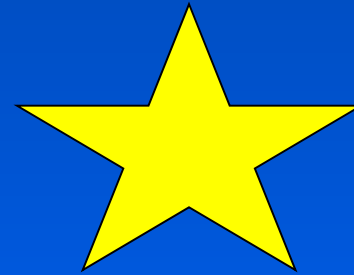
Tips for writing a successful proposal



- Read and re-read instructions
- Make a time-line
- CTSI consult: <http://accelerate.ucsf.edu/consult>
- Complete forms early (cover page, other support, etc.)
- Review other successful applications
- Find out who is on review committee:
<http://www.csr.nih.gov/Committees/rosterindex.asp>
- Contact program officer at target NIH Institute

Supporting letters

- Select strong mentors
 - well known in field
 - expertise in your area
- Ask for letters at least 1 month before due date
 - attach your CV and proposal outline
 - offer to provide draft of letter
 - let them know outcome of application



Other extremely useful grant-writing resources

- <http://grants.nih.gov/training/resources.htm>
- <http://www.niaid.nih.gov/researchfunding/Pages/default.aspx>
- http://grants.nih.gov/grants/grant_basics.htm
- http://grants.nih.gov/grants/grant_tips.htm
- <http://grants.nih.gov/grants/oer.htm>
- <http://grants.nih.gov/grants/sitemap.htm>
- http://grants.nih.gov/grants/useful_links.htm

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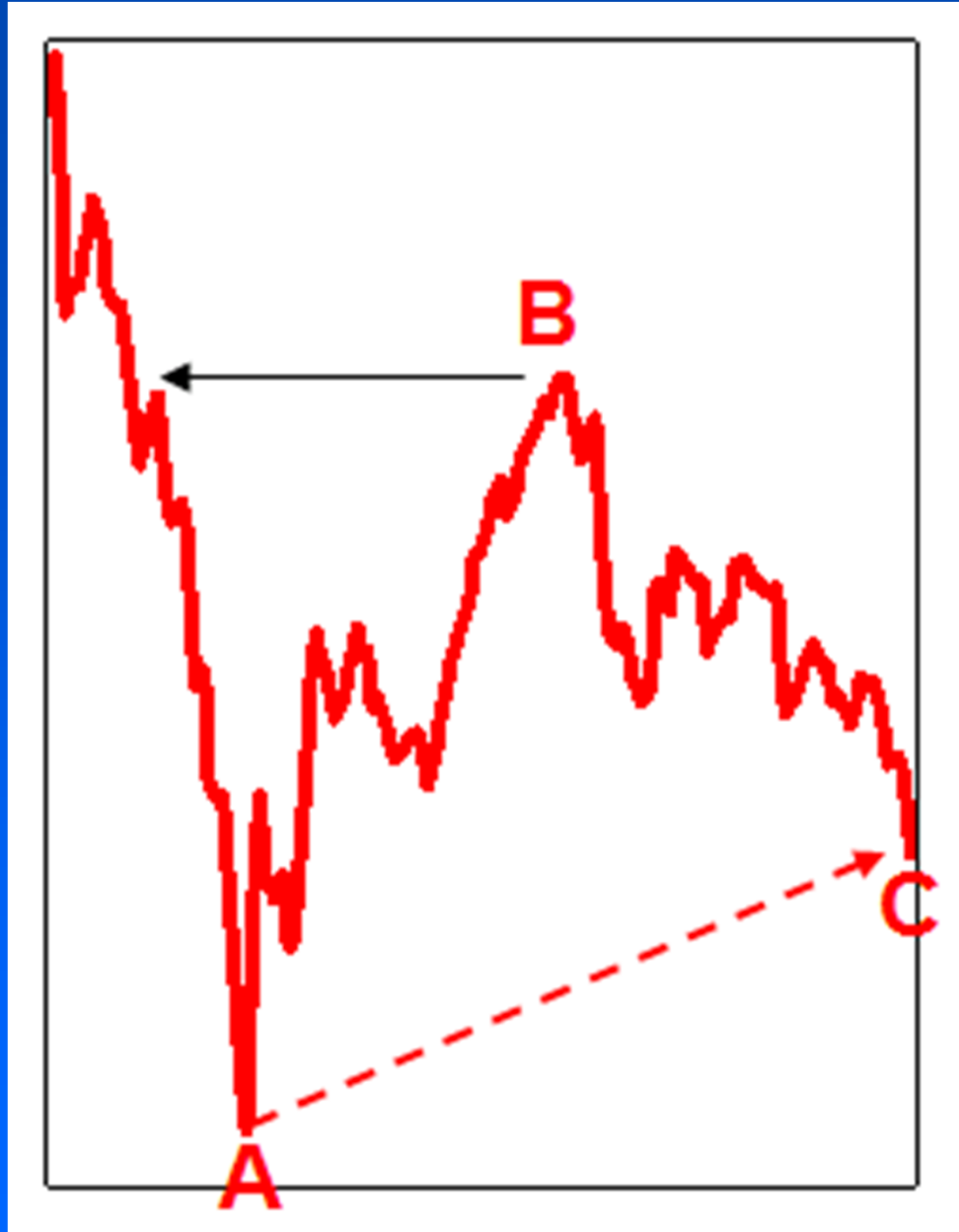




Whooley – Rejected Grants and Manuscripts

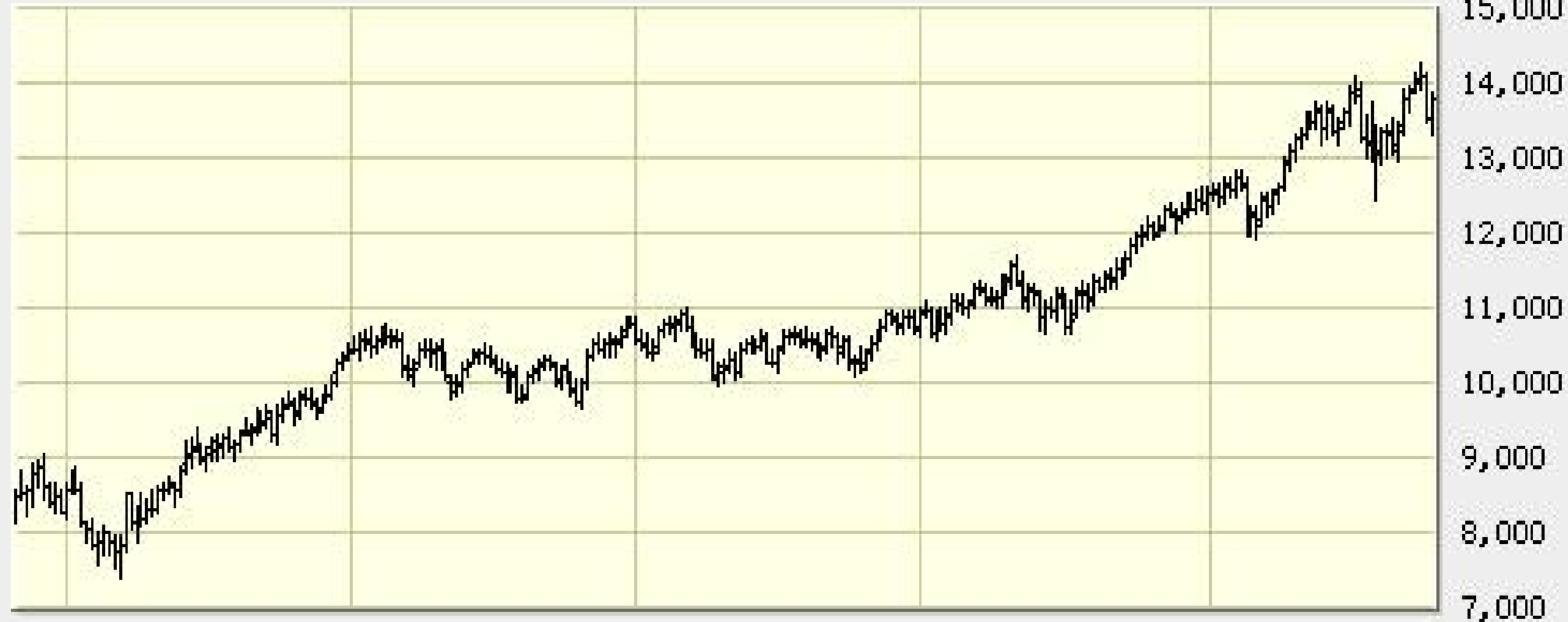
TNTC

(Too numerous to count)



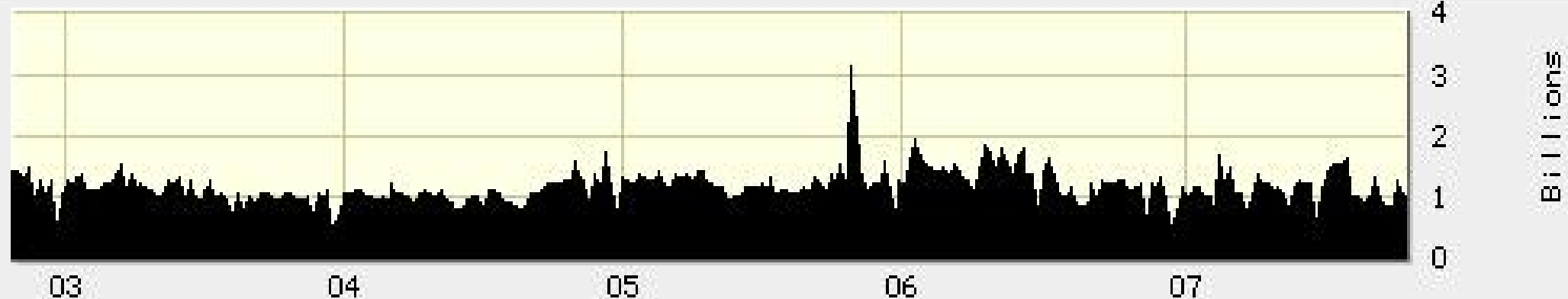
DJIA Weekly —

10/26/07



Volume —

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Dealing with rejection

- Expect 2 to 3 submissions for every paper / grant
- Politely respond to reviewers concerns
- Be persistent
- Remember: it's the numerator that counts

