SUCCESSFUL GRANT WRITING STRATEGIES FOR AN R AWARD

Ian de Boer, MD, MS ITHS April 29, 2016







Institute of Translational Health Sciences Accelerating Research. Improving Health. Institute of Translational Health Sciences

CAREER DEVELOPMENT SERIES



We love to hear from you!

Please connect anytime.



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ITHS Institute of Translational Health Sciences Accelerating Research. Improving Health.

Our Focus

- Speeding science to the clinic for the benefit of patients and communities throughout WWAMI
- We promote the translation of scientific discovery to practice by:
 - □ Fostering innovative research
 - Cultivating multi-disciplinary research partnerships
 - Ensuring a pipeline of next-generation researchers through robust education and career development programs



lan de Boer, MD, MS



Associate Professor of Medicine, Division of Nephrology

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Dr. Ian De Boer is Associate Professor of Medicine, Division of Nephrology and Adjunct Associate Professor, Epidemiology at the University of Washington. He received his medical degree from Oregon Health & Science University School of Medicine and has been in practice for 16 years. Dr. de Boer's research interests include prevention and early identification of chronic kidney disease, diabetic kidney disease, and vitamin D deficiency and kidney disease.

Successful grant writing strategies for an R award

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"Sex R awards"



?



Dr. de Boer

Dr. Ruth

"Sex R awards"

- "I didn't know you were a sex researcher."
- "Wow I did not know you did research on sex!"
- "I am impressed with your "sex" Rois. All this time, I thought you were writing on diabetes and vitamin D!"
- "I had to read this item several times, trying to understand what it means to have sex-specific grant applications"
- "I know that the new "rigor" and "reproducibility" requirement is supposed to make sure we take sex into account, but..."
- "For a minute I thought you were writing Ro1s in "my" area!"

Successful grant writing strategies for an R award

- For which award should I apply?
- How will my application be reviewed?
- When and how should I plan my application?
- How should I organize and write my application?

Good resources

http://grants.nih.gov/grants/oer.htm

http://www.niaid.nih.gov/researchfunding/grant/pag es/default.aspx

http://public.csr.nih.gov/Pages/default.aspx



My KL₂ mentors









John Brunzell Endocrinology

Bryan Kestenbaum Nephrology

Noel Weiss Epidemiology Jeff Probstfield Cardiology

My KL2 goals

- Learn scientific content
- Learn research skills
 - Epi & biostats: advanced courses & application
 - Managing a research team
- Develop a track record
 - Publications
 - Small grants: pilot & feasibility award
- Focus on topics/skills needed in future

Vitamin D & cardiovascular disease

Vitamin D & kidney disease

Insulin resistance & kidney disease

For which award should I apply?

- Funding Opportunity Announcement (FOA)
 - Program Announcement (PA)
 - PAR: special receipt, referral, and/or review considerations
 - PAS: includes specific set-aside funds
 - Request for Applications (RFA)
- Grant mechanism
 - Ro1, R21, Ro3, R34, ...
 - K23, KL2, T32, U01, ...

For which award should I apply?

Research Grants (R series)



Should I apply for an R21?

The NIH Exploratory/Developmental Grant supports exploratory and developmental research projects by providing support for the early and conceptual stages of these projects. These studies may involve considerable <u>risk</u> but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.

Should I apply for an R21?

	Roi	R21	
Title	Research project grant	Exploratory/developmental grant	
Purpose	To support a discrete, specified, circumscribed project	To introduce novel scientific ideas, model systems, tools, targets, and technologies	
Maximum duration	5 years	2 years	
Standard budget cap (total direct costs)	\$2,500,000	\$275,000	
Renewable?	Yes	No	
Preliminary data	Expected	Not required, but still expected	
Success rate (FY 2015)	16.0%	14.4%	

http://www.niaid.nih.gov/researchfunding/grant/strategy/

https://report.nih.gov/success_rates/

My R21 experience

"Dr. de Boer is a junior investigator with excellent training ... He does not have experience in clinical trial design or participation mentioned in preliminary data..."

"...lack of any evidence that diabetics with significant proteinuria will even respond to 2000 IU of cholecalciferol per day..."

"The timetable proposed for the study is unrealistic..."

"The recruitment plan is overambitious."

Should I respond to an RFA?

	NIH Parent Program Announcement (e.g. PA-16-160)	Institute-specific Program Announcement (e.g. PA-16-043)	Request for Applications (RFA) (e.g. PAR-13-128)
Initiator	Investigator	Investigator	Institute
Research focus	Broad	Intermediate	Narrow
Reviewers	Center for Scientific Review (CSR) study section	CSR or SEP	Special emphasis panel (SEP)
Funding metric	Percentile score	Percentile score	Impact score rank
Specific funding	No	No	Yes
New investigator bonus	Yes	Yes	No

Should I respond to an RFA?

- Sound confusing? It is.
- Consider the parent Ro1 your default FOA
- More specific PAs sometimes advantageous
 - May direct application to a specific institute
 - May lead to SEP review
- Be wary of RFAs
 - May be more competitive
 - May be geared to established investigators
 - Discuss with your mentor
 - Call the Program Officer

Successful grant writing strategies for an R award

- For which award should I apply?
- How will my application be reviewed?
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- How should I organize and write my application?

What happens to my application?



What happens in study section?

- Each application assigned to 3 reviewers
- Preliminary scores assigned by each reviewer independently
- Top 50% of scores discussed in study section
- Reviewers 1, 2, and 3 describe aim, strengths, weaknesses
- Discussion amongst full study section
- Each of 3 reviewers states final overall score
- Remaining members score silently
- Discussion summary prepared by chair

Who reviews my application?

CHAIRPERSON WAGENKNECHT, LYNNE E, DRPH PROFESSOR AND ASSOCIATE DIRECTOR DIVISION OF PUBLIC HEALTH SCIENCES SCHOOL OF MEDICINE WAKE FOREST UNIVERSITY WINSTON-SALEM, NC 27157

MEMBERS BACCARELLI, ANDREA, MD, PHD, MPH MARK AND CATHERINE WINKLER ASSOCIATE PROFESSOR OF ENVIRONMENTAL EPIGENETICS DEPARTMENTS OF ENVIRONMENTAL HEALTH AND EPIDEMIOLOGY SCHOOL OF PUBLIC HEALTH HARVARD UNIVERSITY BOSTON, MA 02215

BARNARD, JOHN, PHD (*) HEAD, SECTION OF STATISTICAL GENETICS AND BIOINFORMATICS DEPARTMENT OF QUANTITATIVE HEALTH SCIENCES CLEVELAND CLINIC CLEVELAND, OH 44195

BASU, SAONLI, PHD (*) ASSOCIATE PROFESSOR DIVISION OF BIOSTATISTICS UNIVERSITY OF MINNESTOA MINNEAPOLIS, MN 55455

BUTTE, NANCY F, PHD (*) PROFESSOR OF PEDIATRICS DEPARTMENT OF PEDIATRICS CHILDREN'S NUTRITION RESEARCH CENTER BAYLOR COLLEGE OF MEDICINE HOUSTON, TX 77030

 Cover letter can be used to direct your application to a standing CSR study section:

http://public.csr.nih.gov/StudySections/

- Useful if you are aware of a good fit
- Otherwise best to leave it to CSR!
- Can request a SEP, but these change
- Institute/Center assignment is based on PA/RFA (if issued by IC) or application subject material

Dear Committee:

Enclosed is our original research proposal entitled, "Phosphorous, vitamin D metabolism, and cardiovascular outcomes: the Multi-Ethnic Study of Atherosclerosis." We are submitting the proposal under the R01 mechanism. This is our initial submission of the proposal.

The general objective of our proposal is to evaluate relationships of disturbed phosphorous and vitamin D metabolism with subclinical and clinical cardiovascular disease. In the grant application, we propose to add new serum and urine markers of phosphorous and vitamin D metabolism to the Multi-Ethnic Study of Atherosclerosis, an NHLBI funded prospective study of cardiovascular disease.

We are suggesting the proposal be sent to the National Heart, Lung, and Blood Institute (NHLBI) for review by the Cardiovascular and Sleep Epidemiology (CASE) study section.

Thank you very much for consideration of our work.

Sincerely,

Bya Ketertan

for de la

Bryan Kestenbaum, MD MS

lan de Boer, MD MS

We suggest the Kidney Nutrition Obesity and Diabeles (KNOD) study section at NIDDK review our application because KNOD has previously reviewed the proposal and we have responded to the reviewers specific concerns. The proposal is a metabolism study in humans with a substantial laboratory component, will emphasize epidemiology, and will examine whether kidney disease is an important determinant of mineral metabolism in the general population.

Thank you very much for consideration of our work.

Sincerely,

Bya Ketertan

for de to-

Bryan Kestenbaum, MD MS

lan de Boer, MD MS

Dear Committee:

Enclosed is a research proposal entitled "Randomized trial of vitamin D and omega-3 fatty acids for diabetic kidney disease." This is a new submission for competitive renewal of R01DK088762, of which I am PI.

Thank you very much for considering our work.

Sincerely,

for de tom

lan de Boer On behalf of the study investigators

Do new investigators get a break?

"<u>New investigators</u> are the innovators of the future they bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation."

Definition: "...has not previously competed successfully as PD/PI for a substantial NIH independent research award." (excludes Ro3, R21, R34, K/T/F awards)

grants.nih.gov/policy/new_investigators

Many institutes provide a favorable payline for early stage investigators

"An ESI, or Early Stage Investigator, is a *New Investigator* who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant."

Who funds secondary analyses of existing data, qualitative research?

- Methods work is valued
- New data sets are a generated resource!
- With increasing emphasis on "big data," comparative effectiveness, and clinical implementation, data-driven projects seem to be becoming more common
- If a question is significant and innovative and the best approach uses existing data or qualitative methods – go for it!

Successful grant writing strategies for an R award

- For which award should I apply?
- How will my application be reviewed?
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When I should I start an Ro1?



Deadlines! UW Policy

SEVEN BUSINESS DAYS

- eGC-1 routed with all final business elements:
 - Budget
 - Budget justification
 - Cost share commitments
 - Subawards
 - Conflicts of interest
- Elements describing scope of work, at least in draft form

THREE BUSINESS DAYS

 Final, complete proposal due to OSP at 5pm

https://www.washington.edu/research/osp/gim/gim19.html

Who should review my grant?

	Mentor	Peers	Collaborators	Anyone who will!
Brainstorming	\checkmark	\checkmark		
Aims page	\checkmark	\checkmark	\checkmark	\checkmark
Research plan, in process	\checkmark			
Research plan, full draft	\checkmark	\checkmark	\checkmark	
Other components	\checkmark			

Who should be on my grant?

- Think team science
 - Invite co-investigators to "cover the bases" for knowledge and skills
 - Investigators with redundant skills can be difficult to justify
- Should I include my mentor?
- Should I include a biostatistician?
- Name well-trained staff if you can

Should I have a Co-PI?



- Multiple PIs are increasingly common:
 - MPIs can bring complementary skills
 - All PIs receive recognition
- Detailed multiple PI plan required:
 - Rationale!
 - Leadership approach
 - Conflict resolution
- New investigator points only available if <u>all</u> MPIs qualify

Can international investigators apply for NIH grants?

- The institution is the official applicant
 - Usually higher education (UW!), nonprofits, small businesses, or governments
 - Foreign institutions are often allowed (announcementspecific)
- Any individual with necessary skills, knowledge, and resources may be PI
- Foreign organizations must be justified

How do I generate a budget?

Key resources:

- Department/Division administrator
- Mentor
- Early rough draft to ensure your plans are feasible for your proposed grant mechanism
- Personnel are the largest portion of most budgets
 - Staff effort frequently underestimated
 - Excess attention often paid to supplies

Do I have enough preliminary data?

- The answer is usually yes!
- What do preliminary data demonstrate?
 - Your topic is important
 - Your proposal is feasible
 - You (or your team) can recruit participants
 - You (or your team) has technical expertise
 - You can design and interpret studies logically
 - Your hypothesis has a good chance of panning out

Successful grant writing strategies for an R award

- For which award should I apply?
- How will my application be reviewed?
- When and how should I plan my application?
- How should I organize and write my application?

Where should I focus my efforts?

- Aims!
- Research plan
 - Approach!
- Your biosketch
- Abstract & narrative
- Make sure you read the PA or RFA and talk with your administrator to outline all of the little things, too...

Specific Aims: key points

- Significance should be stated succinctly
 - Public health importance
 - Gaps in knowledge
- Overall goals of your proposal and broader research plan should be clearly stated
- Hypotheses should be testable, unambiguous
 - Statistical methods (approach) should map exactly to hypotheses on aims page
- Emphasize feasibility

How many aims should I have?

SPECIFIC AIM 1. To test the hypotheses that biomarkers of phosphorous excess are associated with incident cardiovascular events and subclinical cardiovascular disease.

1a. We hypothesize that higher concentrations of fibroblast growth factor-23, urine phosphorous, and serum phosphorous are associated with clinical disease: incident cardiovascular events, incident hypertension, and incident chronic kidney disease.

1b. We hypothesize that higher concentrations of serum fibroblast growth factor-23, urine phosphorous, and serum phosphorous are associated with subclinical CVD: incident aortic calcification, arterial stiffness, and an increase in left ventricular mass over time.

SPECIFIC AIM 2. To test the hypotheses that biomarkers of vitamin D insufficiency are associated with incident cardiovascular events and subclinical cardiovascular disease.

2a. We hypothesize that lower 25-hydroxyvitamin D concentrations are associated with clinical disease: incident cardiovascular events, incident hypertension, and incident chronic kidney disease.

2b. We hypothesize that lower 25-hydroxyvitamin D concentrations are associated with subclinical CVD: incident coronary artery calcification, arterial stiffness, and change in left ventricular mass over time.

2c. We hypothesize that associations of 25-hydroxyvitamin D concentrations with cardiovascular outcomes are stronger in the setting of elevated serum parathyroid hormone concentrations.

Write your approach next

- Start with an overview:
 - Summary
 - Outline to your subsequent organization
 - Highlight strengths
- Follow a logical order (design, population, exposure/intervention, outcomes, covariates, analysis, power)
- Include anticipated hurdles, potential fixes, limitations, and next steps

Example: approach overview

D1. Overview of proposed methods. We propose an ancillary study to the NIH-funded *VIT*amin D and OmegA-3 Tria*L* (*VITAL*), an NIH-funded 2x2 factorial randomized, double-blind, placebo-controlled trial. The overall goal of the proposed ancillary study is to determine whether cholecaliferol and/or ω -3 FA supplementation prevents the development and progression of DKD. To enact this VITAL DKD ancillary study, we will identify and recruit a sub-cohort of 1,500 VITAL participants with diabetes at baseline. Among this group, we will test whether the randomly assigned VITAL cholecalciferol and ω -3 FA interventions slow progression of albuminuria and reduce loss of estimated GFR. We will collect urine and blood samples at baseline (prior to randomization) and 4 years later to measure urine ACR and plasma creatinine and cystatin C (to calculate eGFR), along with important covariates. The proposed studies efficiently build on the established infrastructure of the parent VITAL trial, which is already funded to recruit the parent study population, provide participants with randomly assigned active or placebo medications, and obtain relevant baseline and follow-up data. Sample size for the proposed ancillary study is planned to provide high power to detect modest differences in study outcomes. We anticipate that the proposed studies will provide the highest quality evidence to date evaluating effects of vitamin D and ω -3 FA supplementation on DKD in humans.

D2. The parent VITAL trial. In Section D2, we describe characteristics of the funded parent VITAL study which are directly relevant to our proposed VITAL DKD ancillary study.

D2a. <u>Overview.</u> VITAL will be a randomized, double-blind, placebo-controlled trial of the benefits and risks of cholecalciferol (vitamin D₃, 1600 IU/d) and marine ω-3 FA (1 g/d; EPA to DHA ratio, 1:1) in the primary prevention of CVD and cancer. 20,000 participants (men ages ≥ 60 years, women ages ≥ 65 years) will be enrolled. Using a well-tested methodology developed by VITAL investigators at the BWH Division of

Where do I put my preliminary data?

If it "sets the stage" – Significance

- Scope of the problem
- Provides rationale for your question
- If it demonstrates feasibility Approach
 - Recruiting record
 - Laboratory methods
 - Methodologic expertise
- Wherever it goes, call it "preliminary data" and highlight it!

Example: preliminary data in Significance

B. SIGNIFICANCE

 DKD is a large and growing public health burden. Diabetic kidney disease (DKD) is defined as albuminuria, reduced glomerular filtration rate (GFR), or both that is clinically attributable to diabetes.¹⁻³ Over the last 2-3 decades, the prevalence of DKD in the US has increased in direct proportion to the prevalence of diabetes itself, with an estimate of 6.9 million people in 2005-2008 (Figure 1).⁴ The prevalence of DKD is likely to continue to increase over the next 15 years as the number of diabetes cases worldwide doubles. Intensive glucose control helps prevent DKD, and reninangiotensin-aldosterone system (RAAS) antagonists help slow DKD progression.5-15 However, residual risks of DKD development and progression are high, and no new treatments targeting DKD have successfully been introduced in the last two decades.^{1-3,16} As a result, more than 50,000 patients now progress from DKD to end stage renal disease in the US each year.¹⁷ Moreover, patients with DKD are at markedly increased risk of cardiovascular disease (CVD) and mortality.¹⁸⁻²⁰ In fact, provocative recent studies suggest that the increased morbidity and mortality of type 1 diabetes, and



perhaps type 2 diabetes (Figure 2), are concentrated among patients with kidney disease.²¹⁻²³ To mitigate the growing public health burden of DKD, new approaches are needed to prevent DKD as well as its progression and CVD sequelae. Ideally, such approaches should be sufficiently accessible, inexpensive, safe, and effective to apply to the large at-risk diabetes population.

2. Vitamin D is a promising therapeutic intervention for DKD prevention and treatment. While vitamin D has long been used to enhance bone health in selected populations, pleiotropic effects of vitamin D on other

Example: preliminary data in Approach

NHANES III (3.15), was 48%. Interestingly, fasting insulin concentration (Figure 8), fasting glucose concentration, and HOMA-IR score did not differ by estimated GFR. These data suggest (a) that abnormalities of glucose and insulin metabolism are highly prevalent in our CKD population, and (b) that more sensitive and specific methods of assessing insulin resistance, and/or application of validated estimating equations to larger CKD populations, are required to further define the relationship of GFR with insulin resistance, which may not be linear.

Low serum vitamin D concentrations C5. are associated with diabetes mellitus and impaired fasting glucose in moderatesevere CKD. We assessed whether low circulating vitamin D concentrations are associated with clinical abnormalities in glucose metabolism among CKD patients in the SKS. First, we tested whether serum 25hydroxyvitamin D (25(OH)D) concentrations and calcitriol concentrations are associated with clinical diabetes mellitus in 268 SKS participants for whom these labs were obtained as part of standard evaluation. Diabetes was defined as use of hypoglycemic medications. self-report of diabetes, fasting glucose ≥ 126 mg/dL, or random glucose ≥ 200 mg/dL. 25(OH)D concentration reflects intake of vitamin D from both dietary and cutaneous



among nondiabetic participants in the Seattle Kidney Study

How detailed should my statistical methods be?

- Statistical methods must match hypotheses presented in Aims (consider restating here)
- Explicitly state models, approaches to confounding (including covariates), and interpretation of results
- Provide clear power calculations, including assumptions, ideally providing enough information for these to be reproduced
- Consult a Biostatistician!

How long should my Significance section be?

- Usually 2-3 pages
- "Tell a story"
- Use section headings as topic sentences
- Consider a summary paragraph at the end
- The goal is to convince reviewers that your proposal is an important and logical next step for research

Example: Significance

B1. CKD is a common, important public health problem. CKD is defined as impaired GFR or the presence of albuminuria and is prevalent in up to 13% of the United States population.^{1, 2} Though kidney disease research has historically focused on end stage renal disease (ESRD - dialysis and kidney transplantation), the bulk of kidney disease from a population health perspective consists of earlier stages of



CKD (**Figure 1**).² Specifically, approximately 15 million Americans have moderate-severe CKD (stage 3-4, defined by estimated GFR 15-59 mL/min/1.73m²), of which the majority (71-82%, depending on age) have neither diagnosed nor undiagnosed diabetes.^{2, 3} Moderate-severe CKD has a clear impact on public health: persons with this degree of kidney disease are at markedly increased risk of poor health outcomes (**Figure 2**).⁴ In particular, persons with CKD suffer high rates of cardiovascular events and cardiovascular disease death, including ischemic heart disease, stroke, peripheral artery disease, and sudden death.⁵

B2. CKD amplifies cardiovascular disease risk. CKD is now recognized as a strong independent risk factor for cardiovascular disease (CVD) and death. Persons with CKD have an increased prevalence of traditional CVD risk factors, particularly age, diabetes, and hypertension. However, CVD remains markedly elevated after accounting for traditional risk factors (e.g. Figure

2).^{4, 6} Moreover, interventions which improve CVD outcomes in the general population, e.g. statins, have not been efficacious in advanced CKD.⁷ <u>Together, these observations suggest that individuals with CKD have important "non-traditional" risk factors for cardiovascular disease which are not adequately addressed by risk reduction strategies developed for the general population.</u> These non-traditional risk factors may relate to

Does the innovation section matter?

- Innovation is one of the five main scoring categories
- Reviewers must comment specifically on innovation
- Bullet the innovative aspects of your study to make it easy for reviewers!
- But don't exaggerate!

Does the innovation section matter?

C. INNOVATION

 New interventions for DKD. No new therapies for DKD prevention or treatment have been established in the last two decades, despite the increasing public health impact of this condition. Clinical trials have established that tight glycemic control can help prevent DKD and perhaps its progression and that RAAS inhibitors can reduce the risk of renal progression in established DKD.⁵⁻¹⁵ However, RAAS inhibitors do not prevent the development of DKD,¹²⁸ and dual RAAS blockade and new agents targeting DKD progression have failed in phase 3 clinical trials.¹²⁹⁻¹³³ This study evaluates two potential new therapies for DKD.

• Evaluation of interventions suitable for wide-spread application in prevention and treatment. Most trials targeting DKD have enrolled participants with advanced disease characterized by substantial albuminuria and reduced GFR. Studying this DKD sub-population, which is at high risk of renal progression, fills an important need and is a logical approach for therapies directed at late-stage fibrotic processes. However, patients with advanced disease constitute a minority of the DKD population, and an even smaller proportion of the overall diabetes population at risk of DKD. This study evaluates relatively inexpensive and safe agents that may be suitable for broad application to prevent DKD and reduce its public health burden on a large scale.

• Efficient leveraging of an ongoing, high-quality randomized clinical trial with a community-based approach to data collection. Clinical trials evaluating DKD progression require long-term follow-up and usually involve frequent in-person study visits. As a result, these trials are usually extremely costly and often enroll a highly selected group of participants who are able to accommodate substantial study burden. We will leverage an ongoing, high-quality NIH-funded clinical trial (the parent VITAL trial) and our established DKD ancillary study to efficiently evaluate promising interventions over long-term follow-up. Our approach requires no additional funding for study medications, collection of routine data (or a for covariates and adherence), or

Abstract & narrative

Abstract:

- Summary of rationale, goals, & methods
- Available on eReporter if funded
- Narrative: public health relevance
- Pair together, shouldn't repeat each other
- Abstract & narrative will logically repeat key elements of Aims, Significance, & Approach

How many tables & figures should I include?

- Lots! Ideally 1-2 for each page
- Advantages:
 - Makes skimming & reading less painful
 - Allows reviewers to glean key information quickly
 - They're memorable
- Use captions and titles to make sure each "stands alone"
- Avoid "tombstone pages" that are solid text

Should I repeat myself?

- Yes for key concepts. Emphasize these in:
 - Specific Aims
 - Overview of Approach
 - Abstract & narrative
- No for everything else
 - Don't repeat population descriptions, methods, etc
 - Refer to other parts of your grant

Some take home points

- Ro1 awards are usually your best target
- Build on your own work
- Think ahead, start early
- Keep it simple
- Leave time to revise Aims and Approach over, and over, and over...
- Solicit LOTS of feedback

Thank You



Questions?



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