

TOP 10 REASONS FOR GRANT FAILURE

Reason #10

NOT FEASIBLE

Reason #9

WRONG TEAM

Section 3

- Establishes **credibility** and **COMPETENCY** of the project PI and team
- Indicates the likely validity of the idea
- Give reassurance about **FEASIBILITY** of proposal
- Indicates empirical **basis for design choices**

Reason # 8

**TOO BURDENSOME (TIME,
COST, PATIENT BURDEN)**

Section 4: Methods

- Study Overview
- Matrix of events. (What/when?)
- Timelines, deliverables (GANT Chart)
- Recruitment
- Enrollment targets, retention estimates
- Selection of sample (why?)
- Selection of treatments (why A vs. B?)
- Selection of measures (why each? Why this many?)
- Quality control of interventions.
- Quality control of measurements.
- Data acquisition, management, compilation.
- Data analysis (one for each hypothesis)

Section 4: General Principles

- Take the reader through how you decided almost everything
- Detail key elements (e.g. sample definitions; assessments; findings; quality control of treatments, medication dosing, rescue medications)
- Anticipate obstacles and specify plans (e.g. missed appointments, missing data, protocol non-adherence, management of adverse effects, rescue medications)
- Discuss other designs/methods excluded (end of section 3)

Reason # 7

TOO COMPLICATED

Reason # 6

POORLY WRITTEN;

CANNOT FOLLOW

**Everything should be made
as simple as possible,
but not more so.**

Albert Einstein



Don't Bury the Lead

Begin with Your Conclusion:

Summary Lead
Elaboration of lead
details become
less and less
important
as the
story
ends

1. *CRUCIAL* information
2. *SUPPORTIVE* information
3. *REPETITIVE* information



The Inverted Pyramid

Eliminate words: Like an Abstract Writer

Consumers can ~~easily~~ lower ~~their~~ winter heating bills
By caulking and sealing, wearing warmer clothes, and
letting the sun in whenever possible.

Caulking and Sealing

Cold air can enter your house through ~~tiny~~ gaps around
windows, doors, exhaust fan outlets, or any ~~other~~ place
where the exterior surface of your home is penetrated.
In some older homes...

Language + Format - 1

- 1) AVOID compound sentences
- 2) Do not use different words to specify the same thing (e.g., subjects, participants, patients)
- 3) Use **bold** to highlight title of sections
- 4) Use introductory sentences (e.g., This section “will establish why studying X is important;” “how limited our knowledge is about;” why we believe that treatment B is very promising and now deserves a pivotal trial”

Language + Format - 2

- 5) Section titles can be statements or questions (e.g. "Depression is a devastating illness" vs "Why study depression?")
- 6) Summarize what you have said (e.g. In Section 2 at the end, "We have argued that X Y and Z are true, which establishes the need to study _____.") Should this project be successful, it will _____ (change , revise concepts, provide new methods to _____, etc.)
- 7) Use present tense (vs. future)?

Reason # 5

NO PILOT DATA

Reason #4

NO PRIMARY

HYPOTHESIS/OUTCOMES

Section 1: Aims and Hypotheses

- Introduction of Problem (what, why, how)
- Overall Aim - Ties everything together, unifies
- Specific Aims (each aim leads to a hypothesis)
- Primary Hypothesis (one)
 - Primary Endpoint Clear?
 - Sets Power/Sample Size
- Secondary Hypotheses (limit 3)
- Exploratory Analysis (limit 2)

The Ideal Primary Hypothesis

- Has the Who, How, When, Where, and the Key Metric
- Logically leads to design

Reason #3

**DISCONNECT BETWEEN
SPECIFIC AIMS, HYPOTHESES
AND ANALYSES**

Exemplar Hypothesis

We hypothesize that in the treatment of outpatients, ___ to ___ years old in GP practice with unstable Type II diabetes as defined by _____ Hg/Ac levels, treatment A (dose, frequency, duration, by whom) will be more effective than treatment B (dose, frequency, duration, by whom) as measured by the % of Ss who achieve Hb/Ac <7 for 3 consecutive months

Exemplar Hypothesis

We hypothesize for a representative group of conservative psychiatric clinic outpatients attending ___ practices, depression rating scale A will be of greater clinical utility by providing at least 10% greater sensitivity than scale B without losing more than 2% specificity in identifying patients with major depression vs patients without MDD as established by the Structured Clinical Interviews for DSM-IV

Reason #2

ARGUMENT FOR STUDY

SIGNIFICANCE FAILS



Section 2: Organization



- Present a step by step case logically (as a lawyer before a jury)
- Build the argument one step at a time
- Each sub-section should make a single point
- Each subsection title should state the point (or raise the question)
- The points taken together lead to the research question(s) which specific aim(s) → Hypotheses

Section 2: Significance

- Does the Question matter?
- Is the case persuasive?
- Why is this new knowledge important? (To whom?)
- Will results change practice? Change behavior?
- Will results change understanding? (Change minds?)
- Will results provide new methods?
- Is the investigator creative?

Reason #1

QUESTIONS ARE

NOT IMPACTFUL

Creating Ideas



Finding Ideas that Challenge Conventional Wisdom

- Literature review
- Observations (Routine, Accidental)
- Syntheses across fields
- Discussions with colleagues/patients
- Refine the question(s) by specifying knowledge and practice contexts, subjects; methods, primary outcomes (dependent; variables), study period (duration); cost
- Are the best targets of treatment established (i.e. which disorders, what biomarkers?)

The Quick Review

- (1) Will the Q be Answered Clearly?
- (2) Is the Q Significant?
- (3) Is the Protocol Feasible/Credible?
 - (Scope vs budgets)
 - (Investigator; Capacity + Credibility)
 - Preliminary findings?
- (4) Are Methods Adequate?(planful, detailed, feasible)
- (5) Is Protocol Safe/Ethical?

Top 10 Reasons For Grant Failure

1. Questions are not impactful
2. Argument for study fails
3. Disconnect between specific aims, hypotheses and analyses
4. No primary hypothesis/outcomes
5. No pilot data
6. Poorly written; cannot follow
7. Too complicated
8. Too burdensome (time, cost, patient burden)
9. Wrong team
10. Not feasible

**Do not go where the
path may lead. Go instead
where there is no path
and leave a trail.**

Ralph Waldo Emerson