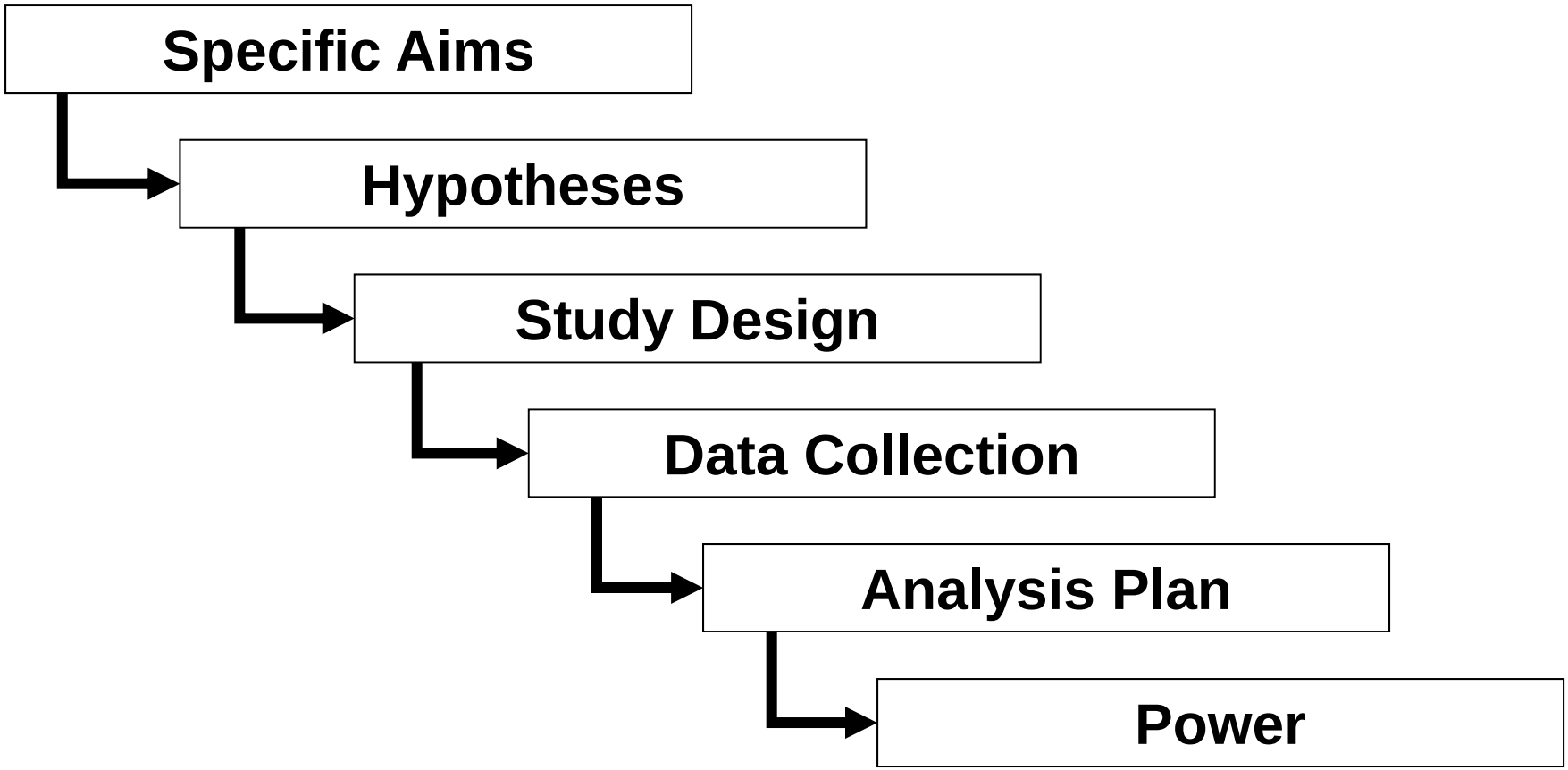
DATA ANALYSIS PLAN

1. *How it fits in*
2. *What it shows*
3. *Example*
4. *Tips and morals*

Henry Feldman
Clinical Research Center
Boston Children's Hospital

ANALYSIS PLAN: BIRD'S-EYE VIEW

A good analysis plan is the ultimate demonstration that your whole proposal is well formulated.



WHAT THE ANALYSIS PLAN SHOWS

You know what data you will collect.

- **Outcomes: single, composite, I^o, II^o, exploratory**
- **Independent variables: groups, exposures, predictors**
- **Covariates, confounders, mediators, modifiers**
- **Correlated clusters**

You thought about how the data will come out.

- **Yes/no data: how to classify**
- **Measured data: source and magnitude of variance**
- **Missing data**

WHAT THE ANALYSIS PLAN SHOWS CONT.

You thought about how to analyze the data.

- **Address hypotheses and aims**
- **Account for covariates, confounders, clusters**
- **Test interactions**
- **Express the design, do justice to the data**
- **Template useful at abstract and manuscript time**
- ***NOT* the Table of Contents of your biostatistics text**

WHAT THE ANALYSIS PLAN SHOWS CONT.

You assessed chances of an interesting finding.

- **Choice of sample size, what it gets you**
- **Precision for descriptive aims**
- **Power to detect clinically significant effect, if it's there**
- **Minimum interesting difference**

You have the resources to carry out your plan.

- **Software and hardware**
- **Consultants and collaborators**

ANALYSIS PLAN: EXAMPLE

- **The primary endpoint is free testosterone level, measured at baseline and after the diet intervention (6 mo).**
- **We expect the distribution of free T levels to be skewed and will log-transform the data for analysis. Values below the detectable limit for the assay will be imputed with one-half the limit.**
- **The primary analysis will be a comparison of 6-mo changes in free T between the two diet arms, using Student's independent t-test with two-sided $p<0.05$ as critical value.**
- **We will follow the intention-to-treat principle, analyzing each subject as randomly assigned regardless of compliance with diet.**
- **In secondary analyses we will use multiple regression to adjust for covariates including age, pubertal stage, insulin responsiveness.**
- **We will test for interactions, particularly for modification of the diet effect on free T by pubertal stage and insulin responsiveness.**

Analysis Plan: Example cont.

- Comparison of dichotomous outcomes (rash, nausea) will be made by Fisher exact test, then by logistic regression to adjust for covariates and test interactions.
- To test for biased dropout, we will compare baseline characteristics of those who completed to those who dropped out.
- SAS software version 9.3 will be used for all computations.
- The magnitude of detectable diet effect depends on (a) coefficient of variation of free T, estimated to be 2.3% inter-assay and 40% inter-subject [18]; (b) within-subject correlation, estimated at 0.6 [26].
- The planned sample of 30 provides 80% power to detect a 20-50% differential in free T change between diets.
- Literature suggests that this diet can produce such an effect, and any smaller effect would not be clinically significant.

ANALYSIS PLAN: TIPS & MORALS

- **Data are random numbers. Plan accordingly.**
- **Statistical analysis is the language of scientific inference. Expand your vocabulary.**
- **Statistical analysis is harder than it looks.**
- **Get help now, before you start writing.**
- **Get help while you are writing.**
- **Budget help for later.**
- **When in doubt, call statistician.**
- **When not in doubt, call statistician.**