How to write an ADaM specification like a NINJA

What documents do you need? What questions do you need to ask?

Protocol
- Endpoints
- Efficacy
- Time to Event
- Safety
- Exploratory
- Patient Reported Outcomes
- Covariates
- Subgroups
- Populations
- Visit Schedule

Statistical Analysis Plan
- Efficacy
- Models
- Statistical measures
- Summaries
- Plots
- Covariates
- Baseline definition
- Time to Event
- How many parameters?
- Input data?
- Summary (e.g. Kaplan-Meier)
- Patient Reported Outcomes
- Including diary data?
- Imputations
- Missing values
- Missing dates / times
- Responder flags / category

Statistical Analysis Plan
- Safety
- Data types (AE, Lab, ECG, etc)
- Summaries—same for data types such as ECGs, Labs, Vital Signs.
- Diary data required?
- Baseline—same for all safety analyses?
- Imputations
- Missing values
- Missing dates / times
- Is this the same for all data types?
- Or is it different for AEs than concomitants, for example?
- Exploratory
- Extension of efficacy analysis?
- Sensitivity analysis?
- Which dataset should this be in?
- Subject Characteristics
- Baseline Values
- Analysis visits and flags

ADaM Specification
- Datasets
  - ADSL
  - BDS
  - OCCDS
  - Other

ADaM
- Model version
- Implementation Guide version
- Sponsor Implementation

OCCDS
- Events
- Medical Interventions
- Coded Variables
- Pre-, Concomitant & Post-treatment flags
- Grouping Variables

Code lists
- Character variables
- Categories
- Groups

BDS
- Parameters
- Analysis Values
- Analysis Periods
- Analysis Visits
- Analysis Flags
- Analysis Categories

Other
- Sponsor defined
- Not BDS nor OCCDS
- E.g. Protocol Deviations

Computational Algorithms
- Complex derivations
- Derivations for variables in multiple datasets

Rate of Reaction by Temperature
- Temperature increases activity
- Denaturation decreases activity
- Optimal temperature
- Rate of reaction

Annotated TFL shells
- Aid ADaM design and programming

ADaM ADSL POP06
- AVAL where PARMCD eq "TEMP"
- AVAL where PARMCD eq "REACTRT"

AID
- AVAL where PARMCD in...

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