



# How to write an ADaM specification PP06 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

## SDTM

Model version  
Implementation Guide version  
Sponsor Implementation  
aCRF

## ADaM

Model version  
Implementation Guide version  
OCCDS Implementation Guide  
Sponsor Implementation

Other Standards Inputs  
Controlled Terminology  
Sponsor Terminology  
Define.xml  
SDRG, ADRG

## Statistical Analysis Plan

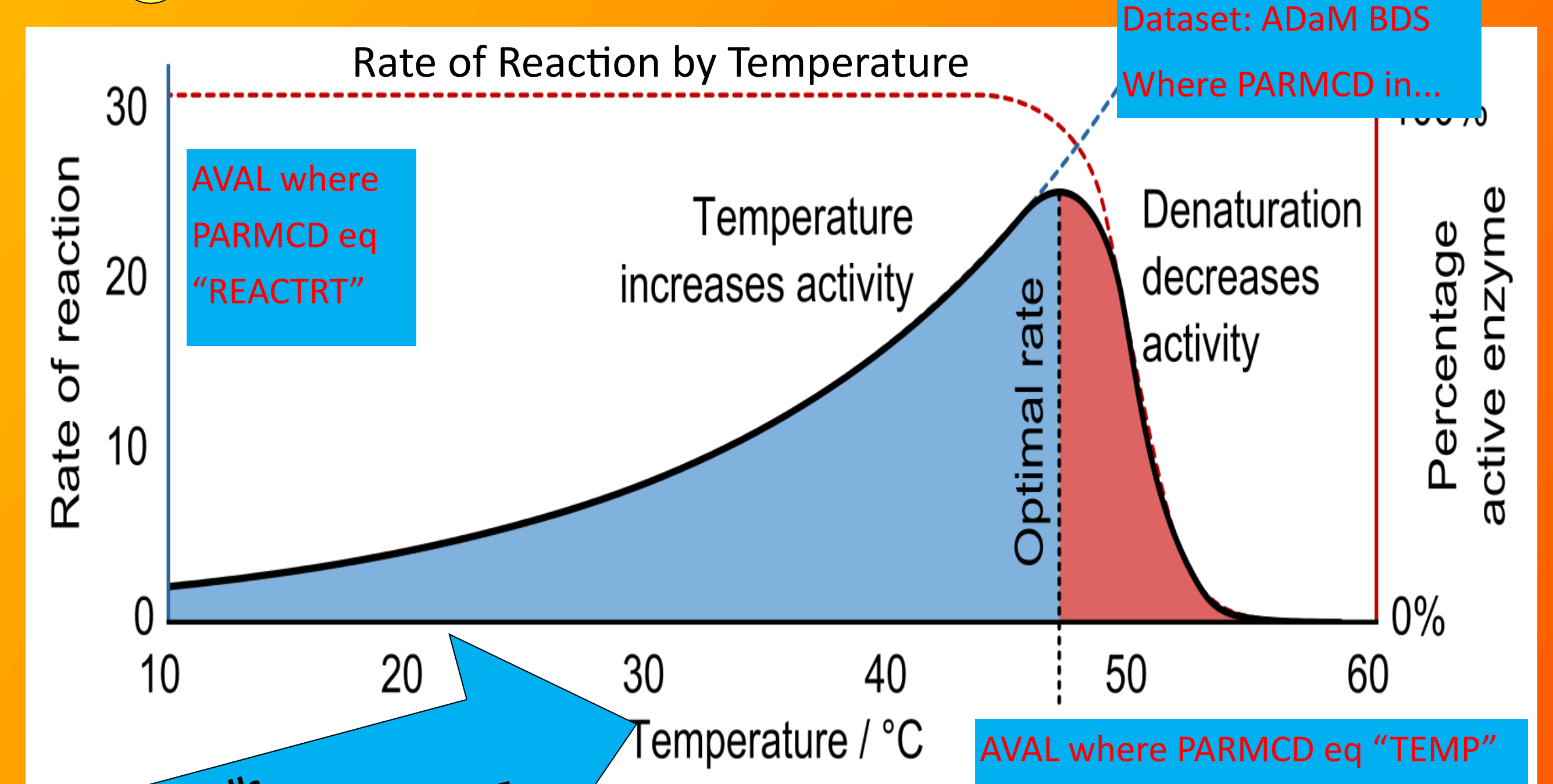
- \* Efficacy
  - \* Models
  - \* Statistical measures
  - \* Summaries
  - \* Plots
  - \* Covariates
  - \* Baseline definition
- \* Time to Event
  - \* How many parameters?
  - \* Input data?
  - \* Summary (e.g Kaplan-Meier)
- \* Patient Reported Outcomes
  - \* Including diary data?
- \* Imputations
  - \* 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 con-meds, for example?
- \* Exploratory
  - \* Extension of efficacy analysis?
  - \* Sensitivity analysis?
  - \* Which dataset should this be in?
- \* Subject Characteristics
- \* Baseline Values
- \* Analysis visits and flags

## TFL Shell checklist

- Footnotes
- Model Statements
- Programming Notes
- Table / Plot Layout



When creating ADaM specifications, if there are gaps in the SAP or anything needs to be clarified, feedback to the Statistician ASAP.

## ADaM Specification

### Datasets

ADSL  
BDS  
OCCDS  
Other

### OCCDS

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

### ADSL

Population Flags  
Baseline Values  
Subject Characteristics  
Treatment allocation  
Important dates  
Analysis Periods

### 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

Annotated TFL shells  
Aid ADaM design and programming

