

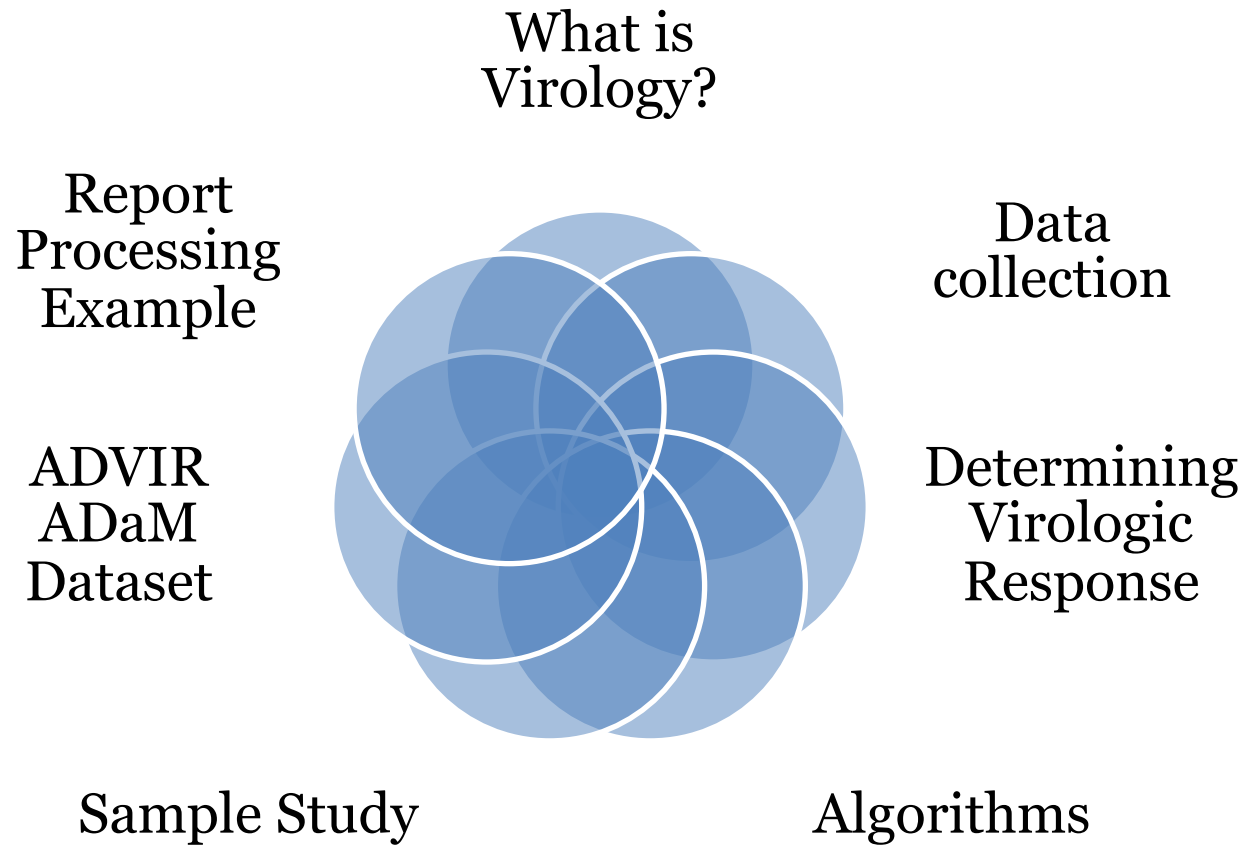


Creating Virologic Response ADaM Dataset

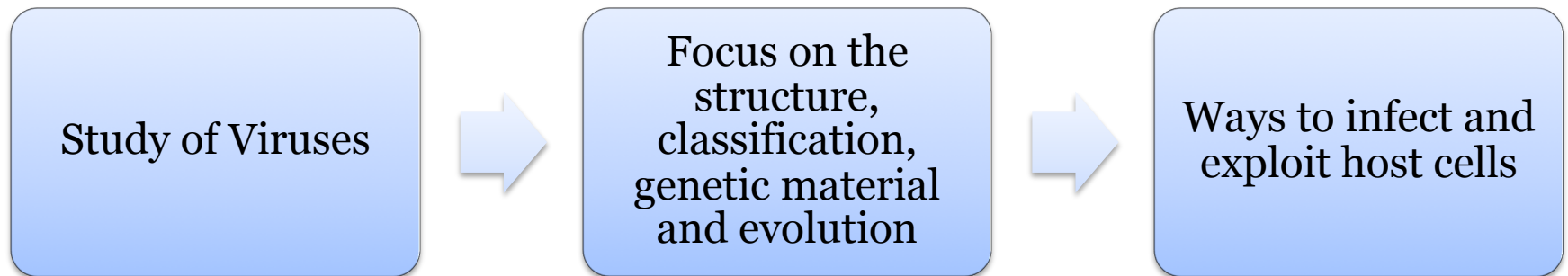
Manjusha Alapati

25-Feb-2019

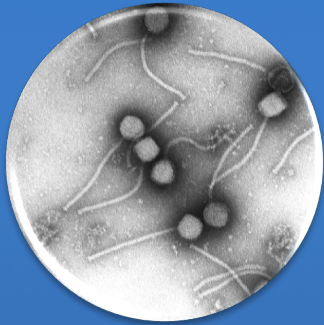
Agenda



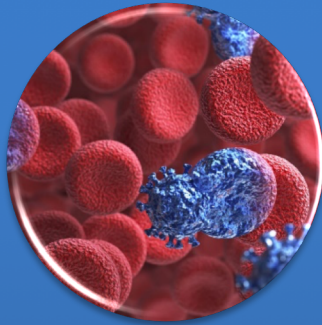
What is Virology?



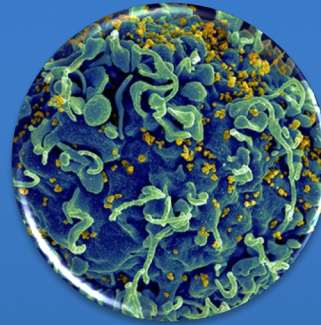
Data Collection



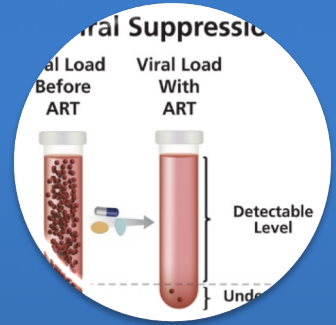
Collected from
host and
infecting virus
to know the
association



Collection of
taxonomic
identification
and genetic
sequencing of
infecting virus



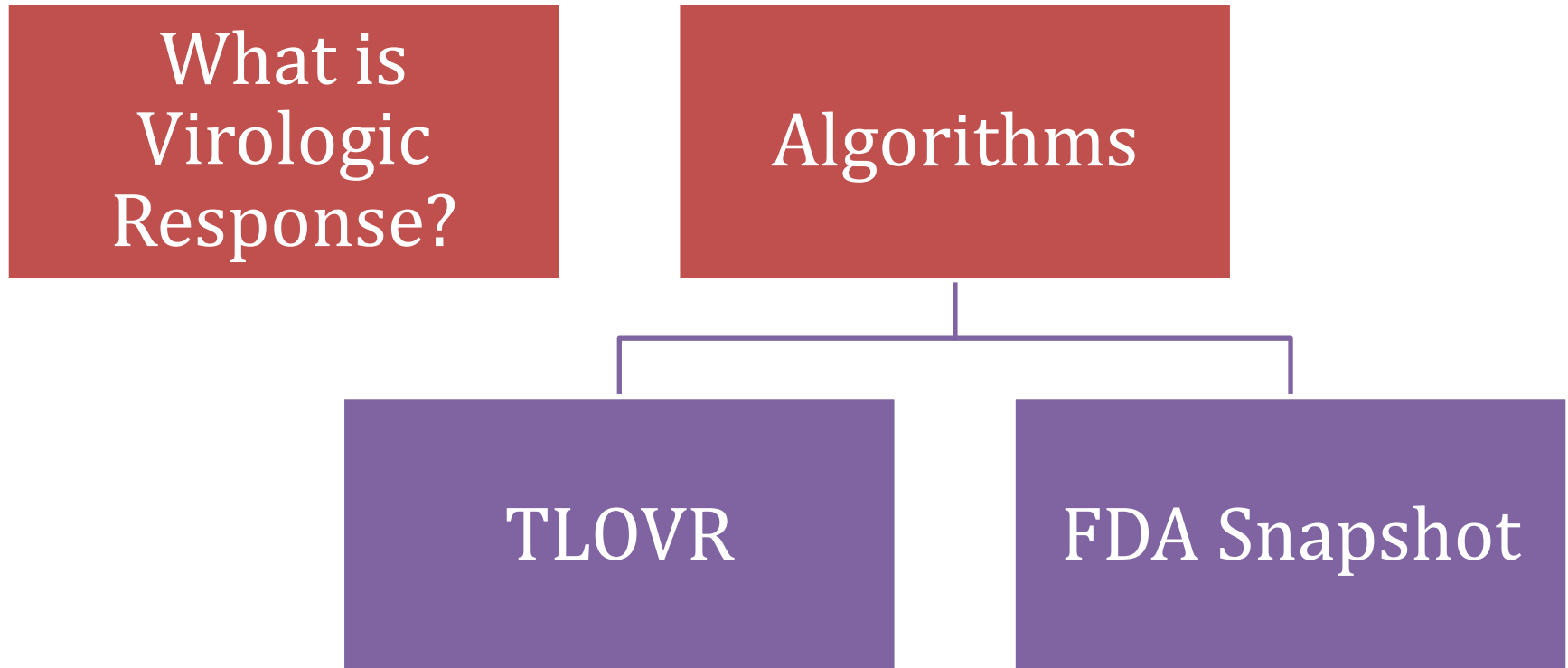
Classification of
type of virus



Measurement
of Viral Load



Determining Virologic Response



Algorithms

HIV-1 RNA

- Collected at different time points

Frequency of Viral Load

- Analysis of data

Handling missing data

- Imputation Methods

Virologic Success

- HIV-1 RNA level < 50 copies/mL

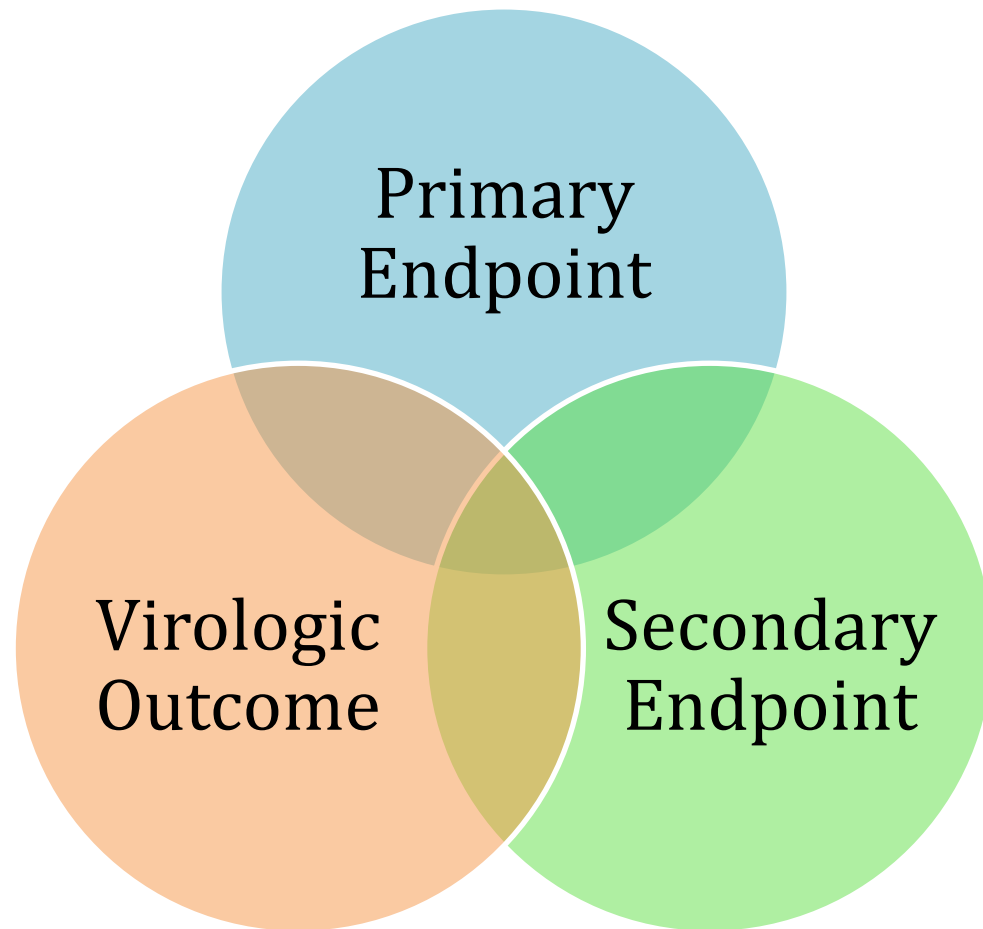
Virologic Failure

- HIV-1 RNA level ≥ 50 Copies/mL

No Virologic Data

- Missing Data at time point

Sample Study



ADVIR ADaM Dataset

Dataset Metadata

- Structure
- Key Variables
- Class of Dataset

Variable Metadata

- Analysis Visits Records
- Derived Results Records
- Additional Parameter Records
- Analysis Flag Variables

Contd..

- Illustration of Analysis Visit

STUDYID	USUBJID	TRTP	PARAMCD	VISIT	AVISIT	AVISITN
XXXXXX01	101-101	ABC	HIVRNA	Day 1	Baseline	1
XXXXXX01	101-101	ABC	HIVRNA	Day 7	Week 4	4
XXXXXX01	101-101	ABC	HIVRNA	Day 14	Week 4	4
XXXXXX01	101-101	ABC	HIVRNA	Day 21	Week 4	4
XXXXXX01	101-101	ABC	HIVRNA	Day 28	Week 4	4
XXXXXX01	101-101	ABC	HIVRNA	Day 35	Week 4	4
XXXXXX01	101-101	ABC	HIVRNA	Day 42	Week 8	8
XXXXXX01	101-101	ABC	HIVRNA	Day 48	Week 8	8
XXXXXX01	101-101	ABC	HIVRNA	Day 56	Week 8	8

Contd..

- Illustration of Derived Result

STUDYID	USUBJID	PARAMCD	VISIT	AVISIT	AVISITN	LBSTRESN	AVAL	DTYPE
XXXXXX01	101-101	HIVRNA	Day 1	Baseline	1	46	46	
XXXXXX01	101-101	HIVRNA	Day 7	Week 4	4	48	48	
XXXXXX01	101-101	HIVRNA	Day 14	Week 4	4	43	43	
XXXXXX01	101-101	HIVRNA	Day 21	Week 4	4	44	44	
XXXXXX01	101-101	HIVRNA	Day 28	Week 4	4	46	46	
XXXXXX01	101-101	HIVRNA	Day 35	Week 4	4		46	LOCF
XXXXXX01	101-101	HIVRNA	Day 42	Week 8	8	46	46	
XXXXXX01	101-101	HIVRNA	Day 48	Week 8	8	48	48	
XXXXXX01	101-101	HIVRNA	Day 56	Week 8	8		48	LOCF

Contd..

- Illustration of Additional Parameter

STUDYID	USUBJID	PARAMCD	VISIT	AVISIT	AVAL	DTYPE	PARAMTYP
XXXXXX01	101-101	HIV1 RNA	Day 1	Baseline	46		
XXXXXX01	101-101	HIV1 RNA	Day 7	Week 4	48		
XXXXXX01	101-101	HIV1 RNA	Day 14	Week 4	51		
XXXXXX01	101-101	HIV1 RNA	Day 21	Week 4	44		
XXXXXX01	101-101	HIV1 RNA	Day 28	Week 4	46		
XXXXXX01	101-101	HIV1 RNA	Day 35	Week 4	46	LOCF	
XXXXXX01	101-101	HIV1 RNA	Endpoint	Week 4	46		DERIVED
XXXXXX01	101-101	HIV1 RNA	Day 42	Week 8	54		
XXXXXX01	101-101	HIV1 RNA	Day 48	Week 8	48		
XXXXXX01	101-101	HIV1 RNA	Day 56	Week 8	48	LOCF	

Contd..

- Illustration of Derived Flag Variables

STUDYID	USUBJID	PARAMCD	VISIT	AVISIT	AVAL	DTYPE	CRIT1	CRIT1FL
XXXXXX01	101-101	HIV1 RNA	Day 1	Baseline	46		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 7	Week 4	48		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 14	Week 4	51		<50 copies/mL	
XXXXXX01	101-101	HIV1 RNA	Day 21	Week 4	44		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 28	Week 4	46		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 35	Week 4	46	LOCF	<50 copies/mL	Y
XXXXXX01	101-101	FINVALUE		Week 4	46		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 42	Week 8	54		<50 copies/mL	
XXXXXX01	101-101	HIV1 RNA	Day 48	Week 8	48		<50 copies/mL	Y
XXXXXX01	101-101	HIV1 RNA	Day 56	Week 8	48	LOCF	<50 copies/mL	Y

Report Processing Example

HIV-1 RNA Percent Change from Baseline at Week 48 (ITT Population, LOCF Data, ANCOVA Model)						
	%Change from Baseline			Treatment Difference		
	n	LSMEAN*	95% CI*	LSMEAN*	95% CI*	p-value*
Drug A (N=)						
Placebo (N=)						
N=ITT population; n=number of subjects with non-missing percentage change from baseline at week48; CI=confidence Interval; LS=Least Squares; *Based on ANCOVA model						





THANK YOU