

DATA MANAGEMENT • BIOSTATISTICS • PROGRAMMING • MEDICAL WRITING • PHARMACOVIGILANCE



Quanticate

A PASSION FOR EXCELLENCE



Demystify Adam PC and PP

---by Hema Krishnamoorthy

Global Solutions from the World's
Largest Data-Dedicated CRO

Disclaimer



All opinions discussed in this presentation are my personal views, and do not reflect the views or opinions of my company

Agenda



- **Introduction**
- **PK Process Flow**
- **CDISC PK datasets VS Non-CDISC PK datasets**
- **Creation of ADPC**
 ADPC Variables
- **Creation of ADPP**
 ADPP Variables

Introduction



Submission of Pharmacokinetic (PK) data

SDTM domains

Extends to all collected data which includes:

PC Domain – for Pharmacokinetic Concentrations

PP Domain – for Pharmacokinetic Parameters (derived from PC records)

ADAM Datasets

Respective analysis-ready datasets based upon the Basic Data Structure (BDS) of the CDISC ADaM

ADaM is reserved for the subsequent manipulation/interrogation of the data

ADPC - for PK Concentrations

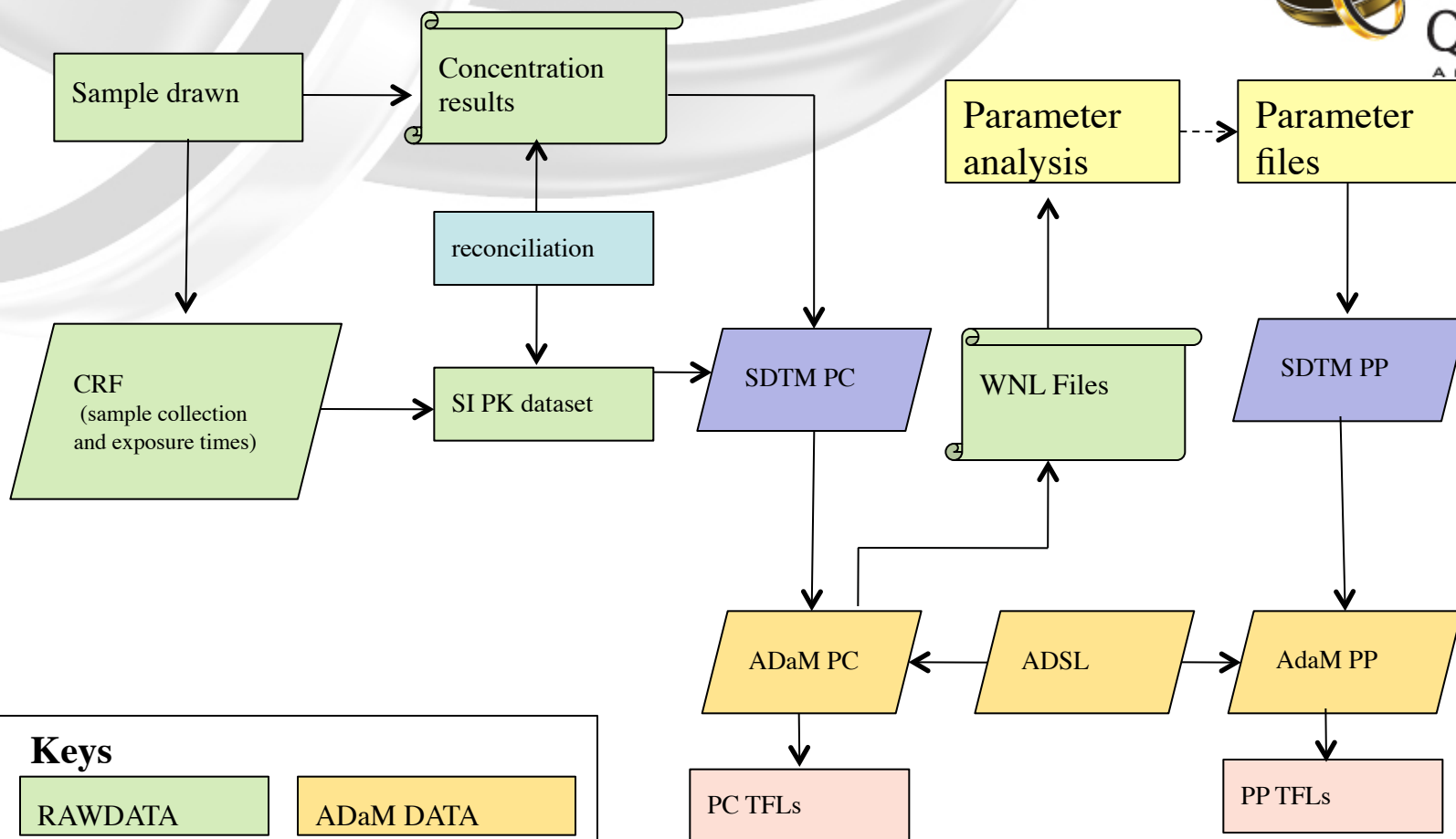
ADPP - for PK Parameters

ADPC and ADPP are used for the PK analysis, the statistical analysis on PK parameters and the generation of Tables, Listings and Figures (TLF)

PK process flow



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Keys

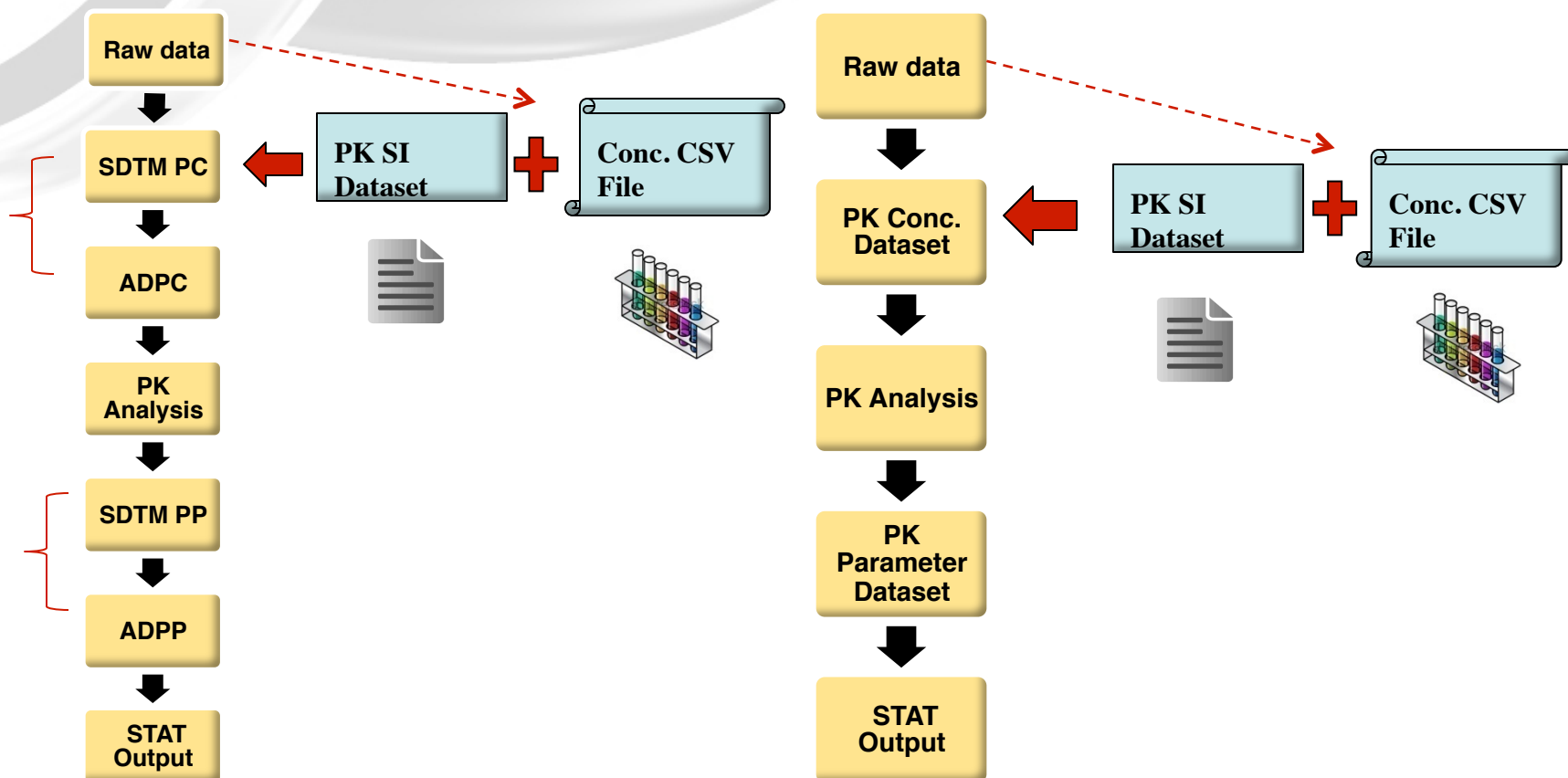
RAWDATA

ADaM DATA

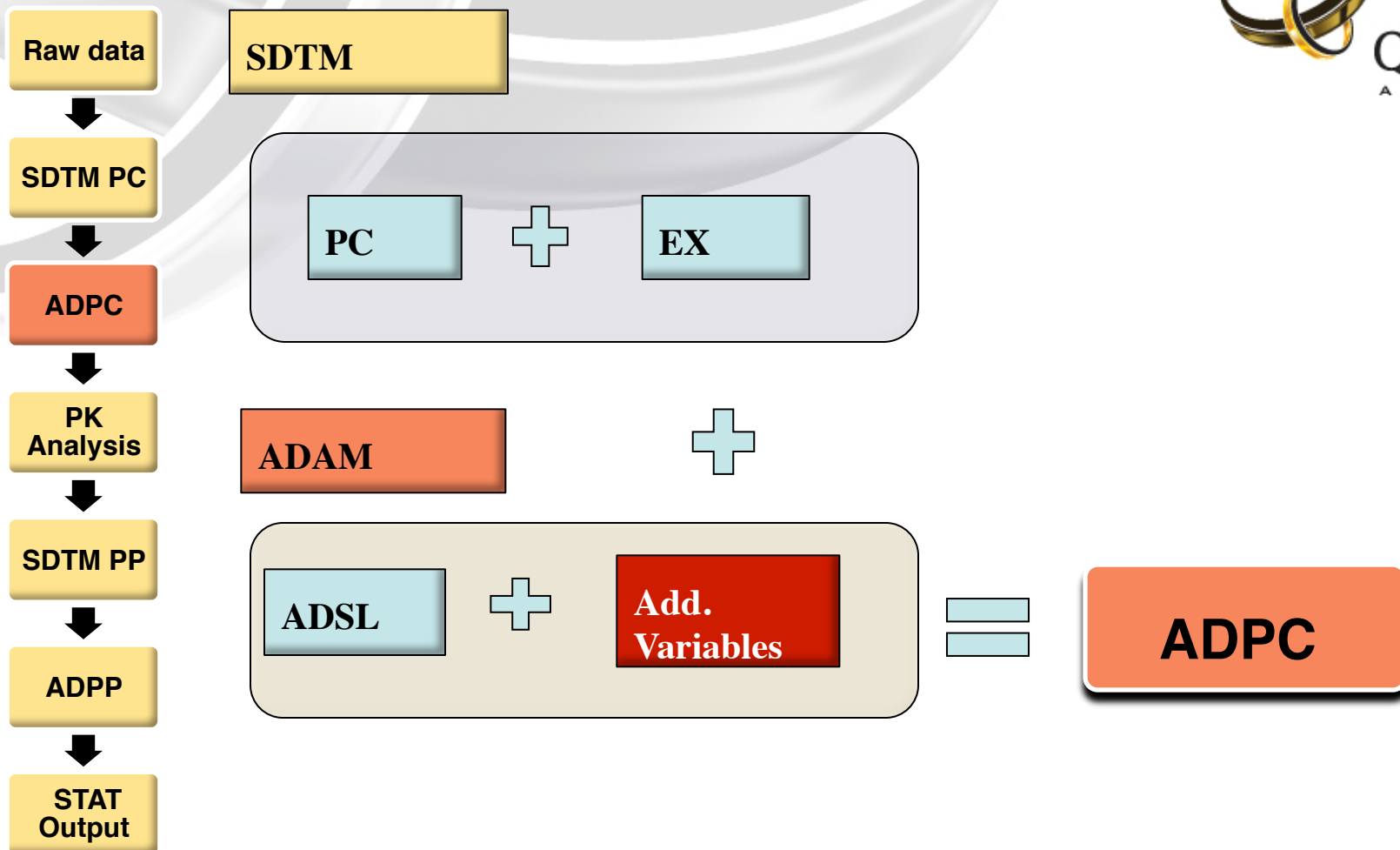
SDTM DATA

Analysis DATA

Creation of CDISC PK datasets vs Non-CDISC PK datasets



Creation of ADPC



ADPC



- Basic Data Structure:**

One record per subject per parameter per analysis timepoint

USUBJID	TRTA	VISIT NUM	VISIT	PCTPTNUM	PCTPT	AVISITN	AVISIT	ADY	ATPTN	ATPT
ex1000.00001	1	20	Day1	PREDOSE	10	20	Day1	1	10	PREDOSE
ex1000.00001	1	20	Day1	1 HR	20	20	Day1	1	20	1 HR
ex1000.00001	1	20	Day1	2 HR	30	20	Day1	1	30	2 HR
ex1000.00001	1	30	Day3	PREDOSE	10	30	Day3	3	10	PREDOSE
ex1000.00001	1	30	Day3	1 HR	20	30	Day3	3	20	1 HR
ex1000.00001	1	30	Day3	2 HR	30	30	Day3	3	30	2 HR

FROM PC

FROM ADSL

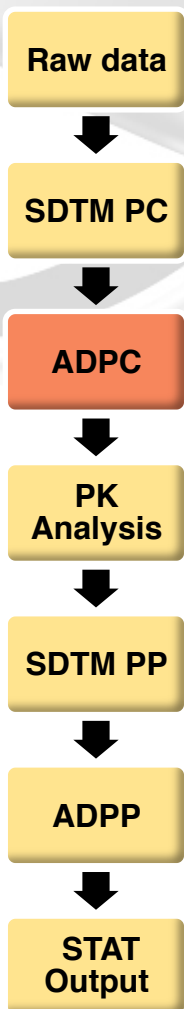
FROM EX

ADD. VARIABLES

ADPC

EXSTDTC	PCDTC	ADTM	ARELTM1	ARELTMU	PCSTRES C	PCSTRES N	AVAL C	AVAL	ANL01FL
2013-07-05T09:00	2013-07-05T08:55	05-07-2013:08:55:00	-0.0833	HOURS	<1	.	<1	0	Y
2013-07-05T09:00	2013-07-05T10:00	05-07-2013:10:00:00	1	HOURS	1511	1511	1511	1511	Y
2013-07-05T09:00	2013-07-05T11:00	05-07-2013:11:00:00	2	HOURS	1852	1852	1852	1852	Y
2013-07-08T09:00	2013-07-08T08:55	08-07-2013:08:55:00	-0.0833	HOURS	1360	1360	1360	1360	Y
2013-07-08T09:00	2013-07-08T10:00	08-07-2013:10:00:00	1	HOURS	1410	1410	1410	1410	Y
2013-07-08T09:00	2013-07-08T11:00	08-07-2013:11:00:00	2	HOURS	490	490	490	490	Y

Creation of ADPC



- **Additional/derived variables:**

PARAM, PARAMN, PARAMCD

ADTM, ASTDTM, AENDTM

AVISIT, AVISITN

ATPT, ATPTN

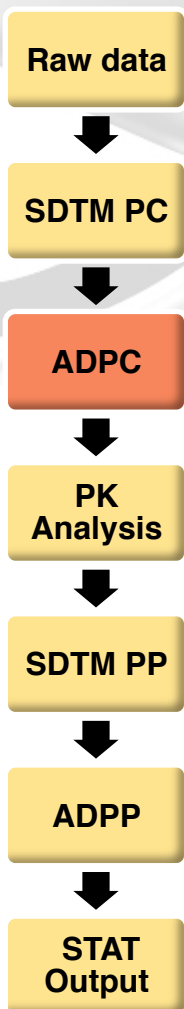
ARELTM, ARELTMU

ANLzzFL, ANLzzFD

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

Creation of ADPC



- **Additional/derived variables:**

PARAM, PARAMCD, PARAMN

ADTM, ASTDTM, AENDTM

AVISIT, AVISITN

ATPT, ATPTN

ARELTM, ARELTMU

ANLzzFL, ANLzzFD

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

PARAM :

Represents the analyzed compound with its unit (e.g. 'Compound X (ng/mL)');

PARAMCD:

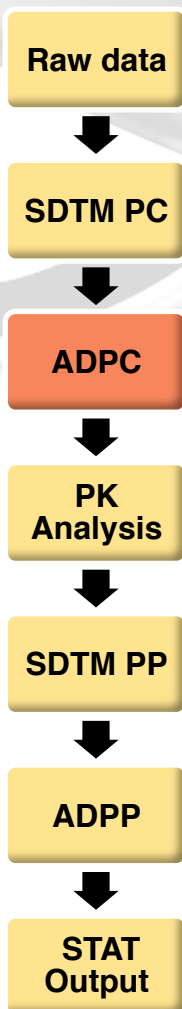
The abbreviation of the analyzed compound

PARAMN:

The numeric counterpart

.

Creation of ADPC



- **Additional/derived variables:**

PARAM, PARAMCD, PARAMN

ADTM, ASTDTM, AENDTM

AVISIT, AVISITN

ATPT, ATPTN

ARELTM, ARELTMU

ANLzzFL, ANLzzFD

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

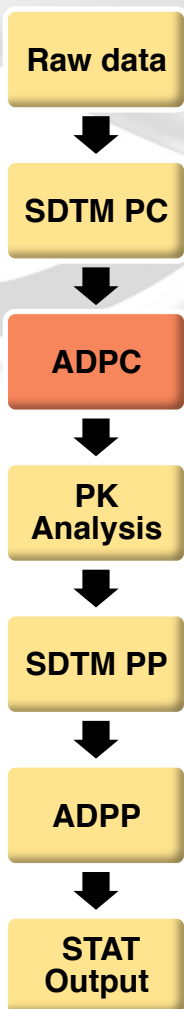
ADTM:

The Date/Time associated with the analysis value (AVAL)

ASTDTM and AENDTM:

The start and end time associated with of an analysis interval, e.g. for urine collection.

Creation of ADPC



- **Additional/derived variables:**
PARAM, PARAMCD, PARAMN
ADTM, ASTDTM, AENDTM
AVISIT, AVISITN
ATPT, ATPTN
ARELTM, ARELTMU
ANLzzFL, ANLzzFD
AVAL, AVALC
CRITy, CRITyFL, CRITyFN

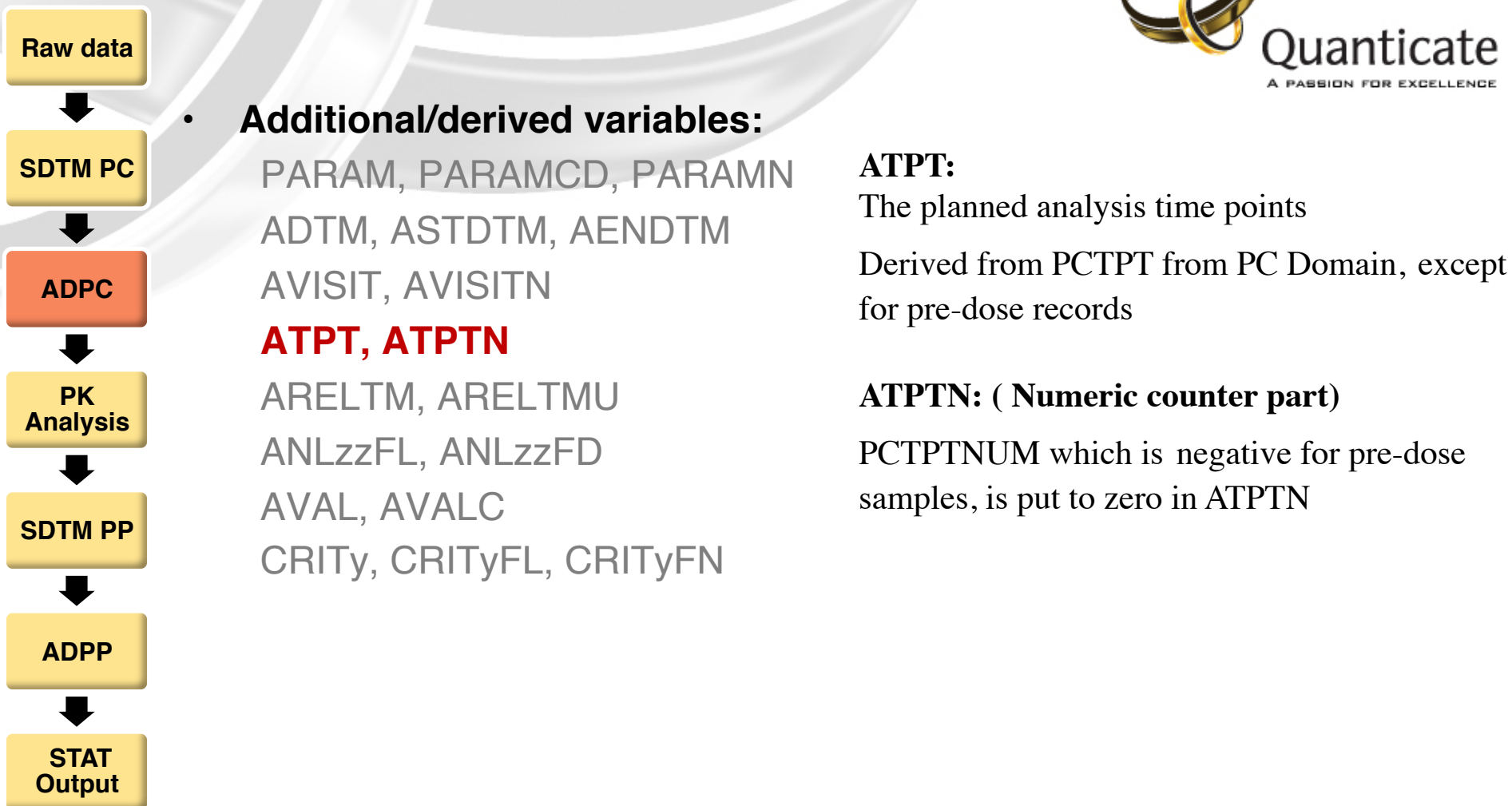
AVISIT:

derived from the variable VISIT
from the PC domain.

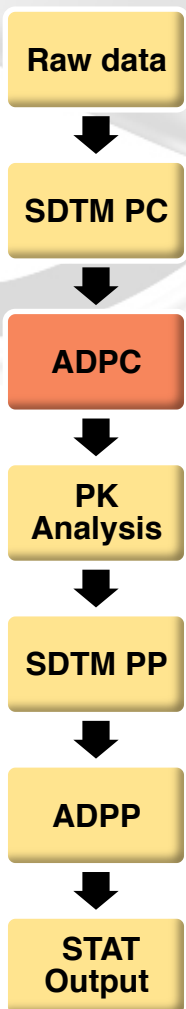
AVISITN: (Numeric counter part)

derived from the variable VISITNUM
from the PC domain.

Creation of ADPC



Creation of ADPC



- **Additional/derived variables:**
PARAM, PARAMCD, PARAMN
ADTM, ASTDTM, AENDTM
AVISIT, AVISITN
ATPT, ATPTN
ARELTM, ARELTMU
ANLzzFL, ANLzzFD
AVAL, AVALC
CRITy, CRITyFL, CRITyFN

ARELTM:

Reference time with respect to different variables as:

PCRFTDTC (Date/Time of reference intake in PC domain)

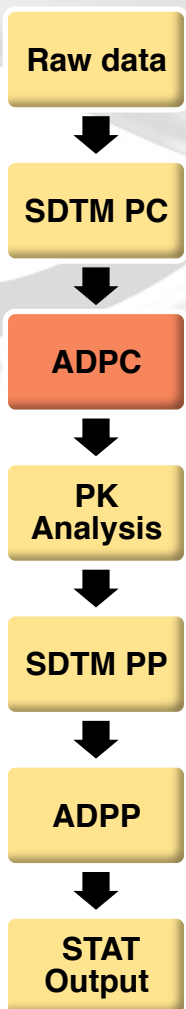
TRTSDTM (Datetime of First Exposure to Treatment, from ADSL)

EXSTDTC (start Date/Time of treatment in EX domain).

ARELTMU:

Relative time unit

Creation of ADPC



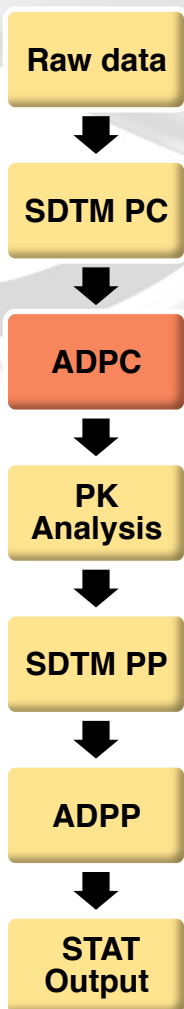
- **Additional/derived variables:**
PARAM, PARAMCD, PARAMN
ADTM, ASTDTM, AENDTM
AVISIT, AVISITN
ATPT, ATPTN
ARELTM, ARELTMU
ANLzzFL
AVAL, AVALC
CRITy, CRITyFL, CRITyFN

ANLzzFL:

to select a set of records for one or more analyses

“zz” represents an index for a record selection algorithm, and will be replaced with 01-99.

Creation of ADPC



- **Additional/derived variables:**
PARAM, PARAMCD, PARAMN
ADTM, ASTDTM, AENDTM
AVISIT, AVISITN
ATPT, ATPTN
ARELTM, ARELTMU
ANLzzFL
AVAL, AVALC
CRITy, CRITyFL, CRITyFN

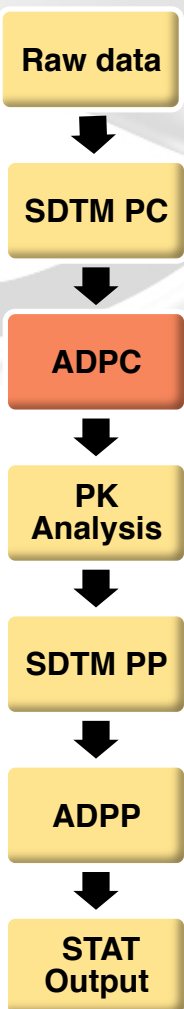
AVAL:

The analysis value equal to PCSTRESN, the numeric result in standard unit from PC Domain.

AVALC:

The character counterpart

Creation of ADPC



- **Additional/derived variables:**
PARAM, PARAMCD, PARAMN
ADTM, ASTDTM, AENDTM
AVISIT, AVISITN
ATPT, ATPTN
ARELTM, ARELTMU
ANLzzFL
AVAL, AVALC
CRITy, CRITyFL, CRITyFN

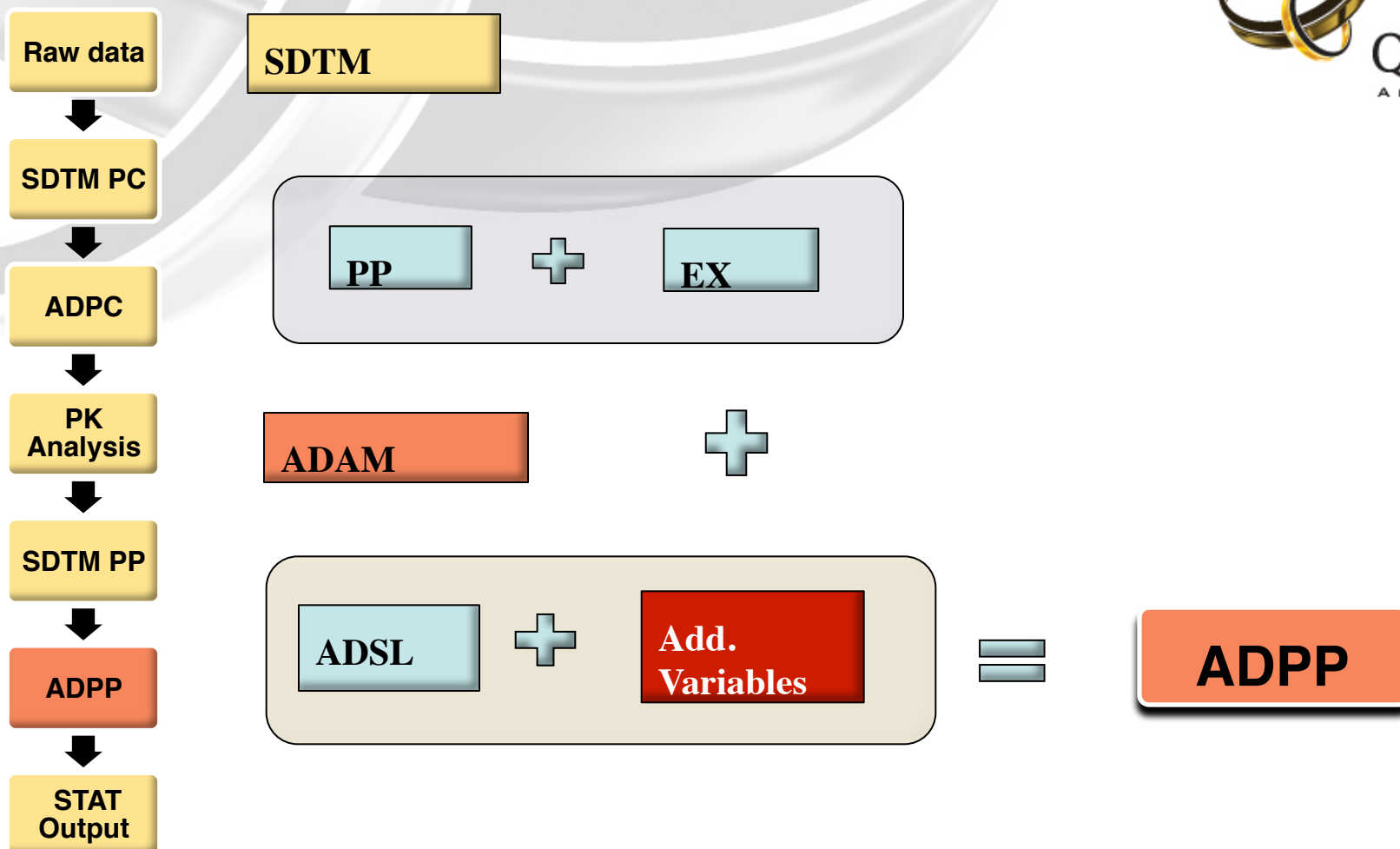
CRITy:

Analysis criteria are evaluated in CRITy
“y” is used to categorize the different criteria
and will be replaced with a
single digit: 0-9.

CRITyFL, CRITyFN:

The outcome of the analysis criteria

Creation of ADPP



ADPP



- **Basic Data Structure:**
- One record per subject per parameter

USUBJID	TRTA	Pptest CD	Pptest	VISIT NUM	VISIT	AVISITN	AVISIT	PPSTR ESC	PPSTRES N	PPSTRES U
ex1000.00001	1	AUCPEO	AUC %Extrapolation Ob	20	Day1	20	Day1	0.215	0.215	%
ex1000.00001	1	AUCIFO	AUC Infinity Obs	20	Day1	20	Day1	4.208	4.208	h*ug/mL
ex1000.00001	1	AUCLST	AUC to Last Nonzero Conc	20	Day1	20	Day1	1.852	1.852	h*ug/mL
ex1000.00001	1	CMAx	Max Conc	20	Day1	30	Day1	3.062	3.062	ug/mL
ex1000.00001	1	LAMZHL	Half-Life Lambda z	20	Day1	30	Day1	0.226	0.226	h
ex1000.00001	1	LAMZ	Lambda z	20	Day1	30	Day1	1	1	h

FROM PC

FROM ADSL

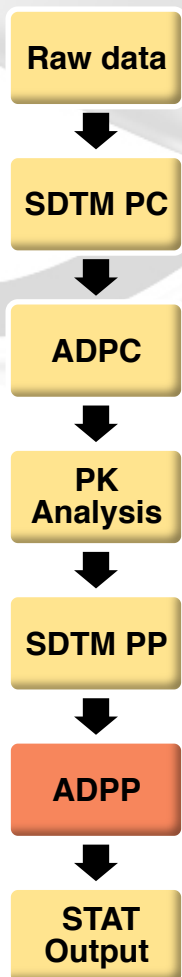
FROM EX

ADD. VARIABLES

ADPP

USUBJID	PARAMCD	PARAM	AVALC	AVAL	EXDOSE	LDOSE	ANL01FL
ex1000.00001	AUCPEO	AUC % Extrapolation Ob (%)	0.215	0.215	25	1.3979	Y
ex1000.00001	AUCIFO	AUC Infinity Obs (h*ug/mL)	4.208	4.208	25	1.3979	Y
ex1000.00001	AUCLST	AUC to Last Nonzero Conc (h^ug/mL)	1.852	1.852	25	1.3979	Y
ex1000.00001	CMAX	Max Conc (ug/ mL)	3.062	3.062	25	1.3979	Y
ex1000.00001	LAMZHL	Half-Life Lambda z (h)	0.226	0.226	25	1.3979	Y
ex1000.00001	LAMZ	Lambda z (h)	1	1	25	1.3979	Y
ex1000.00001	TMAX	Time of CMAX (h)	0.215	0.215	25	1.3979	Y

Creation of ADPP



- **Additional/derived variables: Basic Data Structure**

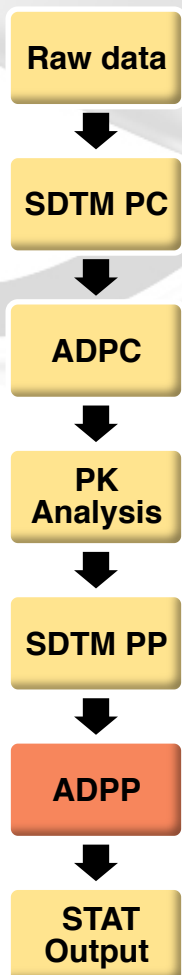
PARAM, PARAMN, PARAMCD

ANLzzFL, ANLzzFD

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

Creation of ADPP



- Additional/derived variables

PARAM, PARAMN, PARAMCD

ANLzzFL

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

PARAM:

PK parameter with its unit (e.g. 'Cmax (ng/mL)')

abbreviation of the PK parameter

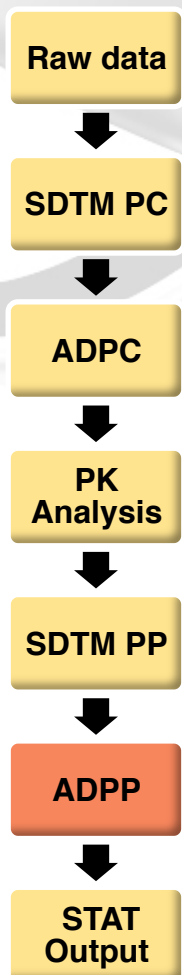
PARAMCD:

The abbreviation of the PK parameter

PARAMN:

The numeric counterpart

Creation of ADPP



- Additional/derived variables

PARAM, PARAMN, PARAMCD

ANLzzFL

AVAL, AVALC

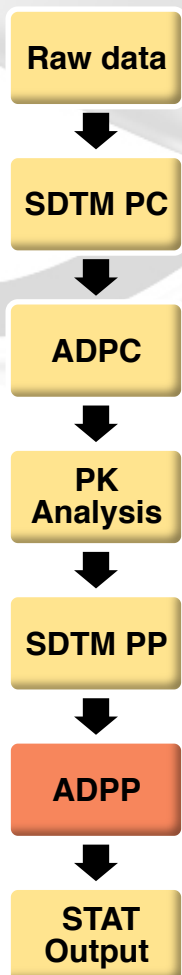
CRITy, CRITyFL, CRITyFN

ANLzzFL:

to select a set of records for one or more analyses

“zz” represents an index for a record selection algorithm, and will be replaced with 01-99.

Creation of ADPP



- Additional/derived variables

PARAM, PARAMN, PARAMCD

ANLzzFL

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

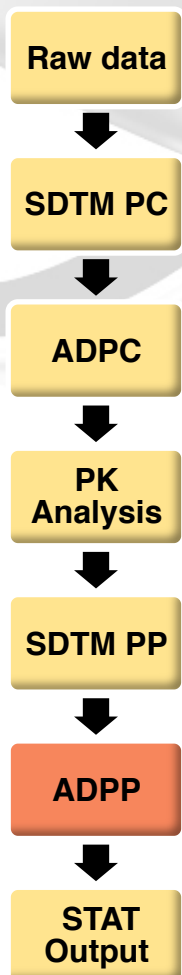
AVAL:

The analysis value equal to PPSTRESN, the numeric result in standard unit from PP Domain.

AVALC:

The character counterpart

Creation of ADPP



- Additional/derived variables

PARAM, PARAMN, PARAMCD

ANLzzFL, ANLzzFD

AVAL, AVALC

CRITy, CRITyFL, CRITyFN

CRITy:

Analysis criteria are evaluated in CRITy
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and will be replaced with a
single digit: 0-9.

CRITyFL, CRITyFN:

The outcome of the analysis criteria



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Any Questions ???

References:



<http://www.phusewiki.org/docs/Conference%202014%20CD%20%20Papers/CD06.pdf>

CDISC ADaM Implementation Guide

CDISC SDTM Implementation Guide

Many thanks to Mark Baird

- Contact information
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