

#### The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research

Strength through Collaboration

# **Overview of Handling of PK Data in CDISC Standards**

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# Agenda

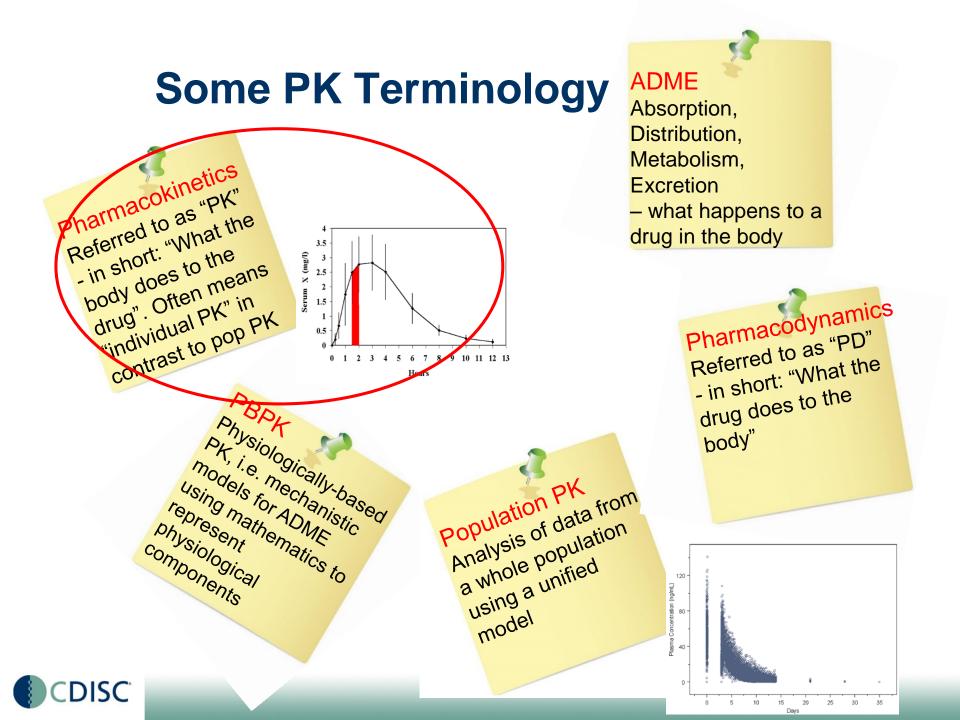
- Some PK Terminology and Concepts
- PK Data and CDISC
- Specific Considerations
  - Relationship Records
- What's next?

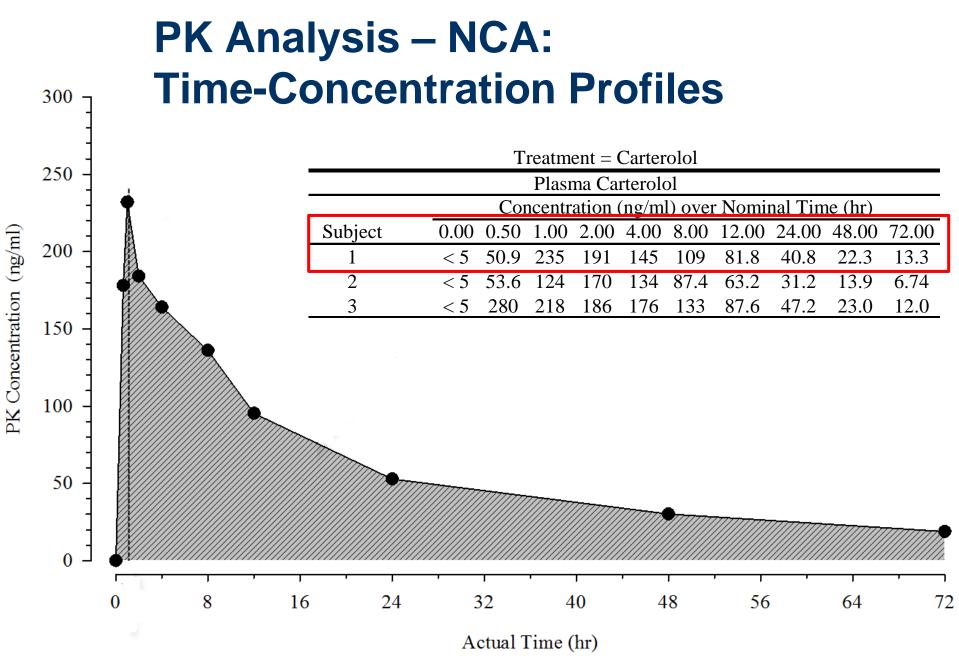


# Some of my Sources

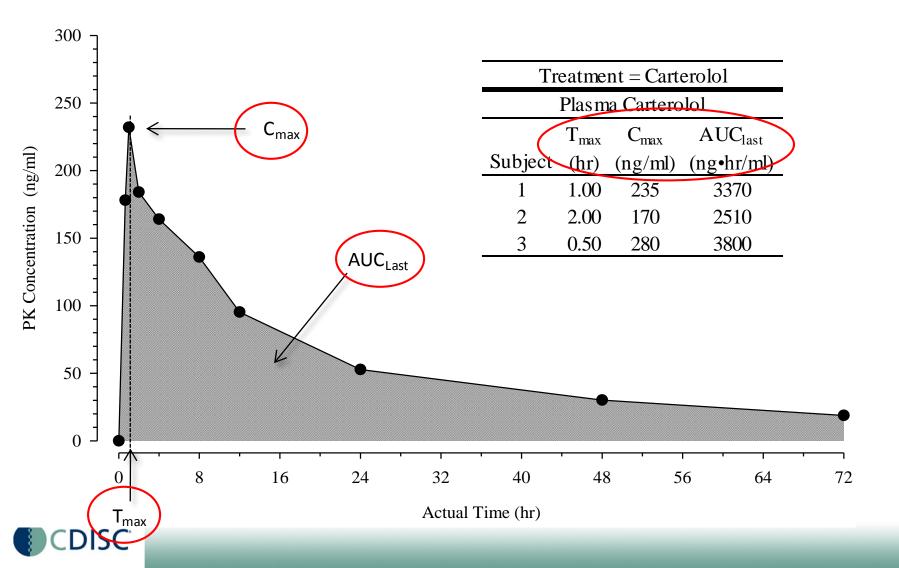
- Considerations in Submitting PK Data in an SDTM-Compliant Format
  - F. Wood, P. Schaefer, R. Lewis, PharmaSUG 2012
- Considerations in the Use of Timing Variables in Submitting SDTM-Compliant Datasets
  - J. Salyers, R. Lewis, F. Wood, PharmaSUG 2013
- Implementation of CDISC ADaM in the Pharmacokinetics Department
  - J. Magielse, CDISC Interchange 2014
- Phoenix Connect Users Guide, 2014
- ... and of course the various standards documents







#### PK Analysis Results: Some PK Parameters



# Variables for PK Analysis

- Observations: Set of variables to identify unique time-concentration profiles ('key' variables such as subject, treatment, study id, ...).
- Dosing: Same 'key' variables + dose value and time point
- Additional subject data: Per subject demographics (such as age, race, etc.) and additional findings (such as weight, alcohol usage, smoking habits, etc.)
- Depending on the analysis program the data can be in one dataset or in separate datasets, like observation and dosing worksheets

# Example for PK Analysis Datasets – Observation and Dosing Worksheet

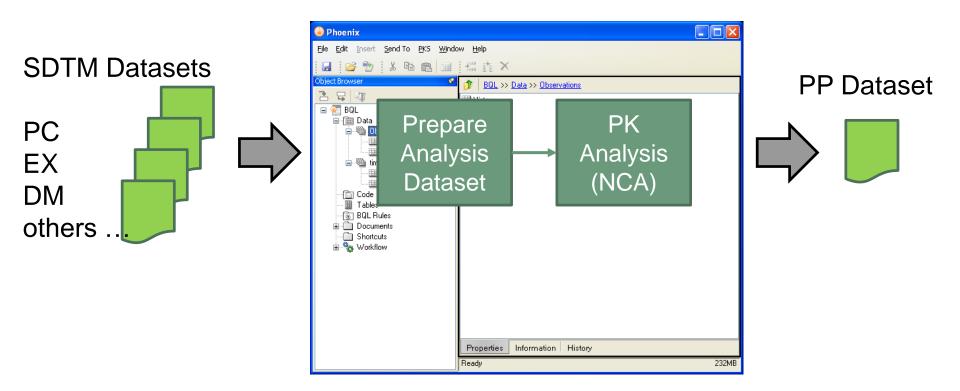
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# **PK Data in SDTM**

- Specific pharmacokinetics domains based on General Observation class were introduced in SDTMIG v. 3.1.2
  - PC Pharmacokinetics Concentration for timeconcentration profiles
  - PP Pharmacokinetics Parameters for PK results
- Dosing information, like treatment and dose amount are in EX domain
- Some subject data (like AGE, SEX, RACE) are in DM domain
- Additional subject data (like weight, height, smoking, ...) are in SC, VS, and maybe other finding domains.
   For PK analysis typically baseline values are relevant.



# The PK Analysis Workflow based on CDISC Data



What if your tool does not create an analysis-ready dataset?



#### From Here ...

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12       SEX       Character       1       1       15       PCREASND       Character       1       3       USUBJID       Character       21       US         13       RACE       Character       25       16       PCNAM       Character       1       4       EXSEQ       Numeric       8       BEST12.       EX       1       1       PCSPEC       Character       1       1       PCSPECND       Character       1       1       I       IS       PCSPESND       IS       IS       PCSPESND       Character       1       IS       IS       PCSOSU       Character       2       IS       PCSPESND       IS       IS	ater       1       1       15       PCREASND       Character       3       USUBJID       Character       21       USUBJID         ater       25       116       PCNAM       Character       4       EXSEQ       Numeric       8       BEST12.       EXDOSF         ater       3       10       118       PCSPCCND       Character       0       6       EXDOSE       Numeric       8       BEST12.       EXDOSF         ater       10       10       20       VISIT       Character       0       20       VISIT       Character         21       VISITDY       Numeric       21       VISITDY       Numeric       8       EXDOSFRM       Character       2       EXDOSFRQ         22       PCDTC       Character       2       PCDTC       Character       3       8       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       2       PCDY       Numeric       8       BEST12.       EXDOST         24       PCDY       Numeric       2       PCTPTT       Character       11       EXROUTE       13       EXENDTC       Character       14       EXSTDT       13											2 DOMAIN	Character	2		DOMAIN
13       RACE       Character       25       16       PCNAM       Character       4       EXSEQ       Numeric       8       BEST12.       EX         14       ARMCD       Character       5       Character       17       PCSPEC       Character       5       EXTRT       Character       8       BEST12.       EX         16       COUNTRY       Character       10       19       PCLLQQ       Numeric       6       EXDOSFRM       Character       2       0       EX         17       DMDC       Character       10       20       VISIT       Character       8       EXDOSFRM       Character       6       EXDOSFRQ       Character       2       0       EX         18       DMDY       Numeric       8       BEST12.       2       10       10       EXDOSFRM       Character       6       EX       2       0       10       EX         18       DMDY       Numeric       8       BEST12.       10       10       EX       8       BEST12.       10       10       10       EX       10       10       10       10       10       10       10       10       10       10       10       <	ter       25       17       PCSPEC       Character       5       EXTRT       Character       8       EXTRT         ter       7       18       PCSPCCND       Character       6       EXDOSE       Numeric       8       BEST12.       EXDOSE         ter       10       20       VISIT       Character       7       EXDOSFRM       Character       2       EXDOSFRM         10       20       VISIT       Character       6       EXDOSFRM       Character       6       EXDOSFRM         11       VISITDY       Numeric       2       PCDTC       Character       9       EXDOSFRQ       Character       4       EXDOSFRQ         10       EXDOS       PCDTC       Character       10       EXDOSTOT       Numeric       8       BEST12.       EXDOSTOT         11       EXROUTE       Character       10       EXDOSTOT       Numeric       8       BEST12.       EXDOSTOT         12       EXSTDTC       Character       11       EXROUTE       Character       16       EXENDTC         13       EXENDT       Character       16       EXENDT       13       EXENDY       Numeric       8       BEST12.       EXENDY							Character				3 USUBJID	Character	21		USUBJID
14       ARMCD       Character       5       17       PCSPEC       Character       5       EXTRT       Character       8       EX       EX         15       ARM       Character       7       18       PCSPCCND       Character       6       EXOSE       Numeric       8       EST12.       19       PCLLQQ       Numeric       7       EXOSU       Character       6       EXOSFRQ       Character       6       EXOSFRQ       Character       6       EXOSFRQ       Character       6       EX       EX         18       DMDY       Numeric       8       BEST12.       10       VISIT       Character       7       EX       6       EXOSFRQ       Character       6       EX       EX         18       DMDY       Numeric       8       BEST12.       10       VISIT       Character       7       EX       10       EXOSFRQ       Character       6       EX       EX         11       Italizing       22       PCDTC       Character       11       EXOSTOT       Numeric       8       EX       EX         12       EXSTRT       Character       16       EX       EX       11       EXOSTOT       Numeric	ter       5       17       PCSPEC       Character       5       EXTRT       Character       8       EXTRT         ter       7       18       PCSPCCND       Character       6       EXDOSE       Numeric       8       BEST12.       EXDOS         ter       10       20       VISIT       Character       7       EXDOSFRM       Character       2       EXDOSFRM         10       20       VISIT       Character       10       8       EXDOSFRM       Character       2       EXDOSFRM         22       PCDTC       Character       10       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       10       EXDOSTOT       Numeric       8       BEST12.       EXDOSTOT         24       PCDY       Numeric       11       EXROUTE       Character       4       EXSTDTC         25       PCTPT       Character       12       EXSTDTC       Character       16       EXSTDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXENDTC         27       PCELTM       Character       15       EXENDY       Numeric			Character	25	16	PCNAM	Character				4 EXSEQ	Numeric	8	BEST12.	EXSEQ
13       Arkin       Character       7       CAUSE       Numeric       8       BEST12.       EX       EX       EX         16       COUNTRY       Character       10       11       PCLLOQ       Numeric       7       EXDOSE       Numeric       2       EX         18       DMDY       Numeric       8       BEST12.       21       VISIT       Character       8       EXDOSE       Numeric       6       EX       8       EXDOSE       Numeric       8       EXDOSE       Numeric       6       EXDOSE       Numeric       8       EXDOSE       Numeric       10       EXDOSE       Numeric       10       EXDOSE       Numeric       11       EXDOSE       Numeric       12       EXDOSTO       Numeric       12       EXDOSTO       Numeric       12       EXSTDTC       Character       13       EXENDTC       Character       13       EXENDTC       Character       14       EXSTDY       Numeric	Add       /		14 ARMCD	Character	5	17	PCSPEC	Character				5 EXTRT	Character	8		EXTRT
17       DMDTC       Character       10         18       DMDY       Numeric       8       BEST12.         20       VISIT       Character       1         21       VISITOY       Numeric       1       8       EXDOSFRM       Character       6       EXA         21       VISITOY       Numeric       2       PCDTC       Character       1       8       EXDOSFRQ       Character       4       EXA         22       PCDTC       Character       2       PCDTC       Character       1       EXDOSFRQ       Character       4       EXA         23       PCENDTC       Character       2       PCDY       Numeric       1       EXROUTE       Character       4       EXA         11       EXROUTE       Character       2       PCDY       Numeric       1       EXENDTC       Character       1       EXENDTC       1<	addression       10       10       20       VISIT       Character       2       EXDOSU       Character       2       EXDOSU         ic       8       BEST12.       21       VISITDY       Numeric       8       EXDOSFRM       Character       6       EXDOSFRQ         22       PCDTC       Character       22       PCDTC       Character       9       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       24       PCDY       Numeric       8       BEST12.       EXDOSTOT         24       PCDY       Numeric       25       PCTPT       Character       11       EXROUTE       Character       16       EXSTDTC         25       PCTPTNUM       Numeric       28       PCTPTREF       Character       13       EXENDTC       Character       16       EXENDY         28       PCTPTREF       Character       29       PCRFTDTC       Character       16       EXTPT       16       EXTPT         30       PCEVLINT       Character       30       PCEVLINT       Character       9       EXTPTREF         30       PCEVLINT       Character       16       EXTPT       Character		15 ARM	Character	7	18	PCSPCCND	Character				6 EXDOSE	Numeric	8	BEST12.	EXDOSE
17       DMDTC       Character       10         18       DMDY       Numeric       8       BEST12.         20       VISIT       Character       9       EXDOSFRQ       Character       4       6 <t< td=""><td>ter       10       20       VISIT       Character       8       EXDOSFRM       Character       6       EXDOSFRM         ic       8       BEST12.       21       VISIT       Character       9       EXDOSFRQ       Character       4       EXDOSFRQ         22       PCDTC       Character       10       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       11       EXROUTE       Character       4       EXROUTE         24       PCDY       Numeric       11       EXROUTE       Character       4       EXROUTE         25       PCTPT       Character       12       EXSTDTC       Character       16       EXSTDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXSTDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         29       PCRFTDTC       Character       16       EXTPT       Character       17       EXTPT         30       PCEVINT       Character       10       PCRFTDTC       Character       17       EXTPT       17       EX</td><td></td><td>16 COUNTRY</td><td>Character</td><td>3</td><td>19</td><td>PCLLOQ</td><td>Numeric</td><td></td><td></td><td></td><td>7 EXDOSU</td><td>Character</td><td>2</td><td></td><td>EXDOSU</td></t<>	ter       10       20       VISIT       Character       8       EXDOSFRM       Character       6       EXDOSFRM         ic       8       BEST12.       21       VISIT       Character       9       EXDOSFRQ       Character       4       EXDOSFRQ         22       PCDTC       Character       10       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       11       EXROUTE       Character       4       EXROUTE         24       PCDY       Numeric       11       EXROUTE       Character       4       EXROUTE         25       PCTPT       Character       12       EXSTDTC       Character       16       EXSTDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXSTDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         29       PCRFTDTC       Character       16       EXTPT       Character       17       EXTPT         30       PCEVINT       Character       10       PCRFTDTC       Character       17       EXTPT       17       EX		16 COUNTRY	Character	3	19	PCLLOQ	Numeric				7 EXDOSU	Character	2		EXDOSU
18 DMDY       Numeric       8 BEST12.       21 VISITDY       Numeric       9 EXDOSFRQ       Character       4       5         22 PCDTC       Character       23 PCENDTC       Character       10 EXDOSTOT       Numeric       8 BEST12.       5         23 PCENDTC       Character       24 PCDY       Numeric       11 EXROUTE       Character       4       6       5         24 PCDY       Numeric       25 PCTPT       Character       12 EXSTDTC       Character       16       5       5         25 PCTPT       Character       26 PCTPTNUM       Numeric       13 EXENDTC       Character       16       6       5         27 PCELTM       Character       28 PCTPTREF       Character       15 EXENDY       Numeric       8       8       5       5       5         28 PCTPTREF       Character       29 PCRFTDTC       Character       15 EXENDY       Numeric       8       8       5       5       5         29 PCRFUTC       Character       29 PCRFTDTC       Character       17       5       5       5       6       6       5       5         29 PCRFUTC       Character       29       PCEVUNT       Character       17       5       5 </td <td>ic       8       BEST12.       21       VISITDY       Numeric       9       EXDOSFRQ       Character       4       EXDOSFRQ         22       PCDTC       Character       10       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       24       PCDY       Numeric       11       EXROUTE       Character       4       EXDOSFRQ         24       PCDY       Numeric       25       PCTPT       Character       11       EXROUTE       Character       16       EXENDTC         26       PCTPTNUM       Numeric       28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         30       PCEVLINT       Character       17       EXTPTREF       Character       9       EXTPTREF</td> <td></td> <td>17 DMDTC</td> <td>Character</td> <td>10</td> <td>20</td> <td>VISIT</td> <td>Character</td> <td></td> <td></td> <td></td> <td></td> <td>Character</td> <td></td> <td></td> <td>EXDOSERM</td>	ic       8       BEST12.       21       VISITDY       Numeric       9       EXDOSFRQ       Character       4       EXDOSFRQ         22       PCDTC       Character       10       EXDOSFRQ       Character       4       EXDOSFRQ         23       PCENDTC       Character       24       PCDY       Numeric       11       EXROUTE       Character       4       EXDOSFRQ         24       PCDY       Numeric       25       PCTPT       Character       11       EXROUTE       Character       16       EXENDTC         26       PCTPTNUM       Numeric       28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         30       PCEVLINT       Character       17       EXTPTREF       Character       9       EXTPTREF		17 DMDTC	Character	10	20	VISIT	Character					Character			EXDOSERM
22       PCDTC       Character       10       EXDOSTOT       Numeric       8       BEST12.       EXAMPLE         11       EXROUTE       Character       11       EXROUTE       Character       4       EXAMPLE         12       EXSTDTC       Character       16       EXAMPLE         13       EXENDTC       Character       16       EXAMPLE         14       EXSTDTC       Character       16       EXAMPLE         14       EXSTDTC       Character       16       EXAMPLE         14       EXSTDTC       Character       16       EXAMPLE         15       EXENDY       Numeric       8       BEST12.       EXAMPLE         14       EXSTDY       Numeric       8       BEST12.       EXAMPLE         15       EXENDY       Numeric       8       BEST12.       EXAMPLE         15       EXENDY       Numeric       16       EXAMPLE       EXAMPLE         16       EXTPT       Character       17       EXTPTEF       Character       17       EXTPTEF	22       PCDTC       Character         23       PCENDTC       Character         24       PCDY       Numeric         25       PCTPT       Character         26       PCTPTNUM       Numeric         27       PCELTM       Character         28       PCTPTREF       Character         29       PCRFTDTC       Character         30       PCEVLINT       Character		18 DMDY	Numeric	8 BEST12.	21	VISITDY	Numeric			-					
23       PCENDTC       Character       11       EXECUTE       Character       4       EXECUTE         11       EXECUTE       Character       4       EXECUTE       11       EXECUTE       Character       4       EXECUTE         12       EXECUTE       Character       16       EXECUTE       16       EXECUTE         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXE         27       PCELTM       Character       14       EXENDTC       Character       16       EXE         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXE         29       PCETUTC       Character       16       EXENDY       Numeric       18       BEST12.       EXE         28       PCTPTREF       Character       16       EXENDY       Numeric       18       BEST12.       EXE         29       PCEVINIT       Character       16       EXTPT       Character       17       EXTPTREF       Character       9       EXE	23       PCENDTC       Character       11       EXROUTE       Character       4       EXROUTE         24       PCDY       Numeric       12       EXSTDTC       Character       16       EXSTDTC         25       PCTPT       Character       13       EXENDTC       Character       16       EXENDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXENDTC         27       PCELTM       Character       16       EXSTDY       15       EXENDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       16       EXTPT       Character       16       EXTPT       EXENDY         30       PCEVLINT       Character       17       EXTPTREF       Character       9       EXTPTREF	<	•			22	PCDTC	Character						· · · ·		
12       EXSTDTC       Character       16       EXSTDTC         13       EXENDTC       Character       16       EXSTDTC         14       EXSTDTC       Character       16       EXSTDTC         15       EXENDY       Numeric       15       EXENDY       Numeric         16       EXSTDTC       Character       16       EXSTDTC         17       EXENDY       Numeric       15       EXENDY       Numeric       16       EX         17       EXTPT       Character       16       EX       EX         18       EXENDY       Numeric       18       BEST12       EX         19       PCRFTDTC       Character       16       EX       EX         18       EXENDY       Numeric       18       BEST12       EX         19       PCRFTDTC       Character       16       EXTPT       Character       17         19       EXTPTREF       Character       17       EXTPTREF       Character       18       EX	24       PCDY       Numeric         25       PCTPT       Character         26       PCTPTNUM       Numeric         27       PCELTM       Character         28       PCTPTREF       Character         29       PCRFTDTC       Character         30       PCEVLINT       Character					23	PCENDTC	Character						-	BESTIZ.	
12       EXSTDTC       Character       16       EX         25       PCTPT       Character       13       EXENDTC       Character       16       EX         26       PCTPTNUM       Numeric       14       EXSTDY       Numeric       14       EXSTDY       Numeric       15       EXENDY       Numeric       16       EX         28       PCTPTREF       Character       15       EXENDY       Numeric       16       EX         29       PCRFTDTC       Character       16       EX       16       EX         16       EX       EX       16       EX       17       EXENDY       Numeric       18       BEST12       EX         29       PCRFTDTC       Character       16       EX       16       EXTPT       17       17       17       17       17       17       17       17       17       17 <t< td=""><td>25       PCTPT       Character       12       EXSTDTC       Character       16       EXSTDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXENDTC         27       PCELTM       Character       14       EXSTDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         16       EXTPT       Character       16       EXTPT       EXENDY         29       PCRFTDTC       Character       16       EXTPT       EXTPT         30       PCEVLINT       Character       17       EXTPTREF       Character       9       EXTPTREF</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>-</td><td></td><td></td><td></td><td></td><td></td></t<>	25       PCTPT       Character       12       EXSTDTC       Character       16       EXSTDTC         26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXENDTC         27       PCELTM       Character       14       EXSTDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         16       EXTPT       Character       16       EXTPT       EXENDY         29       PCRFTDTC       Character       16       EXTPT       EXTPT         30       PCEVLINT       Character       17       EXTPTREF       Character       9       EXTPTREF										-					
26PCTPTNUMNumeric13EXENDTCCharacter16EX27PCELTMCharacter14EXSTDYNumeric8BEST12.EX28PCTPTREFCharacter15EXENDYNumeric8BEST12.EX29PCRFTDTCCharacter16EXEX16EX30PCFUNITCharacter17EXTPTREFCharacter9EX	26       PCTPTNUM       Numeric       13       EXENDTC       Character       16       EXENDTC         27       PCELTM       Character       14       EXSTDY       Numeric       8       BEST12.       EXENDY         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EXENDY         29       PCRFTDTC       Character       16       EXTPT       Character       27       EXTPT         30       PCEVLINT       Character       Image: Character	tializing									-		Character			
27       PCELTM       Character       14       EXSTDY       Numeric       8       BEST12.       EX         28       PCTPTREF       Character       15       EXENDY       Numeric       8       BEST12.       EX         29       PCRFTDTC       Character       16       EXTPT       Character       27       EX         20       PCFULINT       Character       17       EXTPTREF       Character       9       EX	27       PCELTM       Character         28       PCTPTREF       Character         29       PCRFTDTC       Character         30       PCEVLINT       Character										1	3 EXENDTC	Character	16		EXENDTC
28         PCTPTREF         Character         15         EXENDY         Numeric         8         BEST12.         EX           29         PCRFTDTC         Character         16         EXTPT         Character         27         EX           30         PCFFULVE         Character         17         EXTPTREF         Character         9         EX	28       PCTPTREF       Character         29       PCRFTDTC       Character         30       PCEVLINT       Character										1	4 EXSTDY	Numeric	8	BEST12.	EXSTDY
29     PCRFTDTC     Character     16     EXTPT     Character     27     EX       29     PCRFTDTC     Character     17     EXTPTREF     Character     9     EX	29     PCRFTDTC     Character       30     PCEVLINT     Character										1	5 EXENDY	Numeric	8	BEST12.	EXENDY
20 DCENTINT Character 9 EX	30 PCEVLINT Character 9 EXTPTREF										1	6 EXTPT	Character	27		EXTPT
	30 PCEVLINT Character											7 EXTPTREF	Character	9		EXTPTREF
						30	PCEVLINT	Character		•						
data\local\temp\temp1_cdisc carterolol nca example	data) la cal\tama) taman 1 calica castavalal non avamala															

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### ... to Here: Merged PK Analysis Datasets

C Carterolo	ol with I	NCAs >> Workf	low >> CDISC Data Prepar	<u>/er</u>									
	Verific	cation											
		STUDYID	USUBJID	PCSCAT	P	CSPEC VI	SIT	VISITDY	PCDTC	PCDY	РСТРТ	PCTPTNUM	PCELT (hr)
ut Data	1	CART_001	CART_001-A01-Some_L7	ab NON-COMPA	RT PLA	SMA DAY	(1	1	11/26/2011 7:00:00	AM 7	1 PREDOSE	0	-0.08333
ose	2	CART_001					-	<u>_</u>			1 PREDOSE	0	-0.08333
ampie	3	CART_001			_	mnles		<u>.</u>			1 15MIN	0.25	
g I	4	 CART_001	CART_001-A01-Some_L7	ab NON-COMP		•		1	11/26/2011 8:21:00	AM 7	1 15MIN	0.25	
ettings	5	CART_001			RT PLA			<u>.</u>			1 30MIN	0.5	
<i>//</i>	6	CART_001						<u>.</u>				0.5	
/	7_	CART 001							<u> </u>			0.75	
DISC Cart	terolol												
·		/erification											
	<u>ال</u>		USUBJID ({	AGE ({YEAR5})	SEX	RACE		EXTRT	EXDOSFRM	EXDOSFRO	EXROUT	TE EXDOSE (mg)	EXDC
-		1 CART_00'	1-A01-Some_Lab	25 M		WHITE	1	Sydneyol	TABLET	Q24H	ORAL	1	1 mg
		2 CART_00	1-A01-Some_Lab	25 M		WHITE	1	Sydneyol	TABLET	Q24H	ORAL	1	1 mg
xtOutput			1-A02-Some_Lab	18 F			RI	Sydneyol	TABLET	Q24H	ORAL	1	1 mg
Log				18 F	· Dc	sing	RI S	Sydneyol		Q24H	ORAL		1 mg
Settings		-	_	23 F		WHITE		Sydneyol		Q24H	ORAL		1 mg
			-	23 F		WHITE		Sydneyol		Q24H	ORAL		1 mg
				23 F		WHITE		Sydneyol		-	ORAL		1 mg
			1 A02 Come Lab	22 5		WILTTE		Cudamed C		0040	0.004		1
	Results	Results Verific Results Verific t Data se mple Dutput g ttings 5 6 7 CDISC Carterolol v Results V Results V Results V Results V Log Settings 6 7 Conse Sample Sample Conse Sample Conse Sample Conse Sample Conse Sample Cons	Results       Verification         I       STUDYID         t Data       1       CART_001         se       2       CART_001         g       3       CART_001         g       3       CART_001         g       5       CART_001         g       CART_001       6         g       CART_001       6         g       CART_001       7         g       CART_001       1         conse       CART_001       1         conse       CART_001       2         g       I       CART_001         g       CART_001       3         conse       CART_001       3         g       CART_001       3         g       CART_001       5         g       CART_001       5         g       CART_001       6         g       CART_001       6         g       CAR	Results       Verification         Image:	Image: Structure         STUDYID         USUBJID         PCSCAT           t Data         1         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           se         2         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           2         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           3         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           4         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           5         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           6         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           6         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           7         CART 001         CART_001-A01-Some_Lab         NON-COMPAR           6         CART_001         CART_001-A01-Some_Lab         NON-COMPAR           7         CART_001-A01-Some_Lab         25         M           1         CART_001-A01-Some_Lab         25         M           1 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        NON-COMPART         PLASMA         DAY1         1         11/26/20118:21:00 AM         1         S0MIN         0.55           CCART_001-A01-Some_Lab         NON-COMPART         PLASMA         DAY1         1         11/26/20118:21:00 AM         1



### Steps for Merging SDTM Datasets into PK Analysis Datasets

- The list of all subjects is derived from the DM domain. Carry STUDYID in case there are multiple studies in the dataset.
- The samples per subject are derived from the PC domain.
  - Typically, the reference time point (PCRFDTC) is matched to the dosing start time (EXSTDTC). Time variables (PCELTM, PCDTC, PCENDTC) are used to calculate nominal and actual sample times.
  - For distinct values of PCTESTCD decide whether data are stacked (narrow dataset) or pivoted (wide dataset).
  - Need to decide which result value to use (typically, PSTRESN, but consider PCSTRESC and PCORRES as well). Add unit to column header or keep in separate column.
  - Urine volume observations (PCTESTCD=VOLUME) will typically go on the same row as the corresponding concentration observation.
- Get unique treatment from EX domain (typically, subset of EXTRT, EXDOSFRM, EXROUTE, and EXDOSFRQ) and extract dosing time and amount.
  - If creating separate datasets for samples and dosing, add treatment information also to the sample dataset

#### **Observation Worksheet**

Name	derived from	Name	derived from
STUDYID	DM	EXTRT	EX
USUBJID	DM	EXDOSFRM	EX
PCSCAT	PC	EXDOSFRQ	EX
PCSPEC	PC	EXROUTE	EX
PCSPCCND	PC	EXSTDY	EX
VISIT	DM	EXENDY	EX
VISITDY	DM	EXTPT	EX
PCDTC	PC	EXTPTREF	EX
PCDY	PC	PCORRES	PC
PCTPT	PC	PCORRESU	PC
PCTPTNUM	PC	PCSTRESC	PC
PCELTM	PC	PCSTRESN	PC
PCTPTREF	PC	PCSTRESU	PC
PCENDTC	PC	PCLLOQ	PC
PCRFTDTC	PC	PCSEQ	PC
PCTESTCD	PC	VOLUME_PCORRES	PC
AGE	DM	VOLUME_PCSTRESC	PC
SEX	DM	VOLUME_PCSTRESN	PC
RACE	DM	VOLUME_PCLLOQ	PC
		VOLUME_PCSEQ	PC
		Relative_Actual_Time	Derived from PCRFDTC and PCDTC
		Relative_Nominal_Time	PCELTM
		Relative_Actual_End_Time	Derived from PCRFDTC and PCDTC
		Relative_Nominal_End_Time	PCELTM

### **Dosing Worksheet**

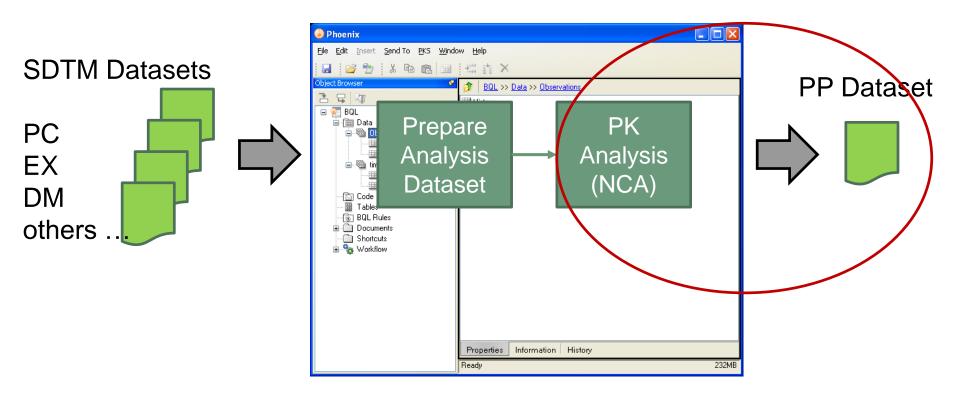
Name	derived from
STUDYID	DM
USUBJID	DM
AGE	DM
SEX	DM
RACE	DM
EXTRT	EX
EXDOSFRM	EX
EXDOSFRQ	EX
EXROUTE	EX
EXDOSE	EX
EXDOSU	EX
EXSTDY	EX
EXENDY	EX
EXTPT	EX
EXTPTREF	EX
EXENDTC	EX
EXSTDTC	EX
Relative_Actual_Time	Derived from PCRFDTC and PCDTC
Relative_Nominal_Time	PCELTM



#### **Some Specific Aspects**

- For volume sampling (urine samples) need to create start and end time of sampling interval
- For volume sampling need to place volume and concentration in one row for PK analysis
- Harmonize units and add units as properties to columns
  - If there are multiple units in one column, create multiple ("pivoted" not stacked) columns
- Handling of LOQ values for analysis and summary statistics
- Negative pre-dose sampling times are typically set to zero for PK analysis

# The PK Analysis Workflow based on CDISC Data





### **PK Analysis Results Dataset**

- A set of PK parameter values for each unique time-concentration profile (i.e. per subject, per treatment, ...)
- Organization of data can be
  - 'narrow' (aka 'CDISC-like' i.e. PK Parameter / Value pair per row)
  - or 'wide' (aka 'pivoted', i.e. there is a column for each PK Parameter and one row per profile)

#### Example for PK Results – Narrow and Wide Data Format

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Dc	Output Data	1	1	Carterolol	Rsq		0.96795142		29.31	1.808	No	Female		Hispanic		
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BQL Rules ⊕⊡ Document	Final Parameters	3	1	Carterolol	Corr_XY		-0.98384522	44	29.31	1.808	No	Female	157.5	Hispanic		
		4	1	Carterolol	No_points_lambda_z		3	44	29.31	1.808	No	Female	157.5	Hispanic		
- Shortcuts	Final Parameters Pivoted	4														
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		4 5 6	1		Lambda_z Lambda_z_lower	1/h h	0.090324573 2	44 44	29.31 29.31	1.808 1.808		Female Female		Hispanic Hispanic		

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Shortcuts	🕮 Final Parame		4	2 Carterolol + Rifampin	0.99797065	0.9959413	-0.99898481	3	0.028077174	24	72	2
Workflow	Partial Areas Plot Titles		5	3 Carterolol	0.99933452	0.99866905	-0.99966721	3	0.028385347	23.75	72	2
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# Mapping of PK Results to PP Domain

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# Mapping of PK Results to PP Domain

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But there are 2 rows per subject because there were 2 profiles per subject ...

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### **Connect PP & PC Records**

- Very often, there is more than one timeconcentration profile per subject, so the set of PK parameters (rows in PP) must be connected to the right profile (rows in PC).
- A straight forward way is to making sure that the PCRFTDTC for the set of PC records matches the PPRFTDTC in the PP records
- In some cases (exclusions of specific observations, multiple analytes per profile) this won't be powerful enough:
  - Then use RELREC records



# **Relationship Records – RELREC**

- RELREC is a special-purpose dataset that is used to describe relationships between records for a subject or relationships between datasets
- How relationships are recorded:
  - Each RELREC record points to one or more records in another dataset or domain
  - The relationship is expressed by the same relationship ID in the related RELREC records
- This can be used to connect the PP records to the corresponding PC records, i.e. to indicate which rows from PC (in other words which timeconcentration profile) was used to calculate the PK parameter in a specific row in PP (see example on next slide)



#### **RELREC Structure**

Variable Name	Variable Label	What it means
STUDYID	Study Identifier	
RDOMAIN	Related Domain Abbreviation	Identifies the domain of the record
USUBJID	Unique Subject Identifier	
IDVAR	Identifying Variable	Defines which variable in the domain is used to identify the record
IDVARVAL	Identifying Variable Value	Defines which value of the variable IDVAR is used
RELTYPE	Relationship Type	Ignore for relating subjects
RELID	Relationship Identifier	Unique value to mark the RELREC records that define a relationship

# **RELREC** for **Dataset to Dataset Relationships**

- All the records in MB domain are being related to all of the records in MS domain, so both USUBJID and IDVARVAL are null.
- Variables with sponsor-defined values (like -GRPID, --SPID, - -REFID) are good candidates for identifying related records: Same value -> The records are related.
  - Note that -SEQ can't be used (has not meaning across datasets)
- Meaning of RELTYPE

- ONE / ONE: only one record from each dataset
- ONE / MANY: One record from one dataset is related to multiple records of the other dataset
- MANY / MANY: Multiple records from one dataset are related to multiple records in the other dataset.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID								
EFC1234	MB		MBGRPID		ONE	А								
EFC1234	MS		MSGRPID		MANY	А								
	CDISC © CDISC 2014 Example from SDTMIG 3.1.2													

# **RELREC for PP and PC Relationship**

 Each PP record is related to all PC records of the profile by a number of RELREC records

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TST_S	ST_2A	F	°C	S	UBJ-00	2	PCSE	Q	20				REL_1		
TST_S	ST_2A	F	PC	S	UBJ-00	2	PCSE	Q	21				REL_1		
TST_S	ST_2A	F	°C	S	UBJ-00	2	PCSE	Q	23	5			REL_1	J	
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		© CDIS	C 2014												

### **Some Final Remarks**

- The described approach does not use ADaM datasets (like ADSL) instead transforms SDTM directly into an analysis-ready dataset.
- Note that a subgroup of the ADaM team is working on a data structure for a PK analysis dataset – this will provide a standard supporting individual PK analysis
- Some users are discussing what would be required for population PK datasets and results
- The PK Controlled Terminology team is constantly updating PK parameter terms and units. Keep watching ...





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