

Introduction to the ADNCA ADaM

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Abstract

Pharmacokinetics (PK) is an integral part of drug development as it is the process of analyzing the movement of drugs within the body. In order to describe, characterize, and quantify this effect, PK parameters are required to be calculated. This poster will provide an overview of the ADNCA (Data for Non-Compartmental Analysis) ADaM Dataset and how it is an effective way of generating a dataset that will contain the required data for calculating the PK Parameters. It will compare the ADNCA method to older processes used to aid PK Parameter derivation, and how it will improve efficiency during a study.

Overview of key variables

- With guidance from the Pharmacokineticist, relevant analysis information such as Trailing BLQs and Positive Predose records can be identified with derived flagging variables. This is similar to the existing expectations for analysis flags in the standard set of ADaM datasets.
- The ADNCA dataset follows the Basic Data Structure (BDS) as described in the ADaM IG. The standard variables expected in BDS ADaM datasets are applicable for the ADNCA, including those provided by ADSL.
- The ADNCA follows its own IG (Analysis Data Model Implementation Guide for Non-compartmental Analysis Input Data) which means it contains additional required variables (*) in comparison to a standard BDS ADaM. Further details on these variables are available below.

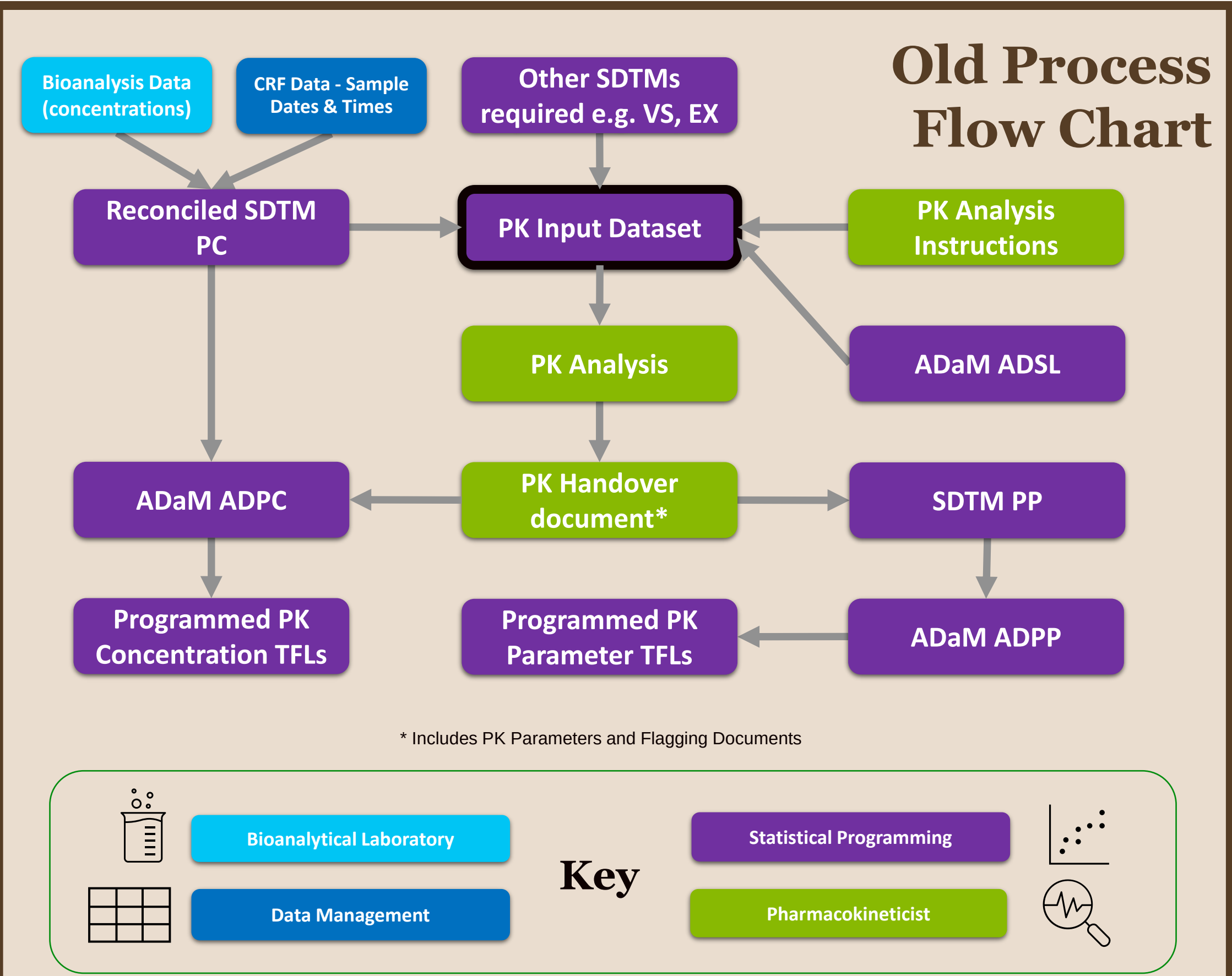
Comparisons of Process

PK Input Data	ADNCA
Instructions from PK department required	
Creation of PK Input Data dataset with information its own specification	Creation of ADNCA dataset with information in ADaM specification
PK Handover with PK Parameters and PK flagging provided	
PK SDTM datasets PC and PP created, with analysis result flagging variables presented in SUPPPC and SUPPPP	PK SDTM datasets PC and PP created, without analysis result flagging variables presented at this level
PK ADaMs datasets ADPC and ADPP; both with analysis result flagging variables presented within the main dataset using SDTM variables	PK ADaM dataset ADPP created, and PK ADaM ADNCA updated; both with analysis result flagging variables presented within the main dataset using PK Handover
Creation of PK TFLs	

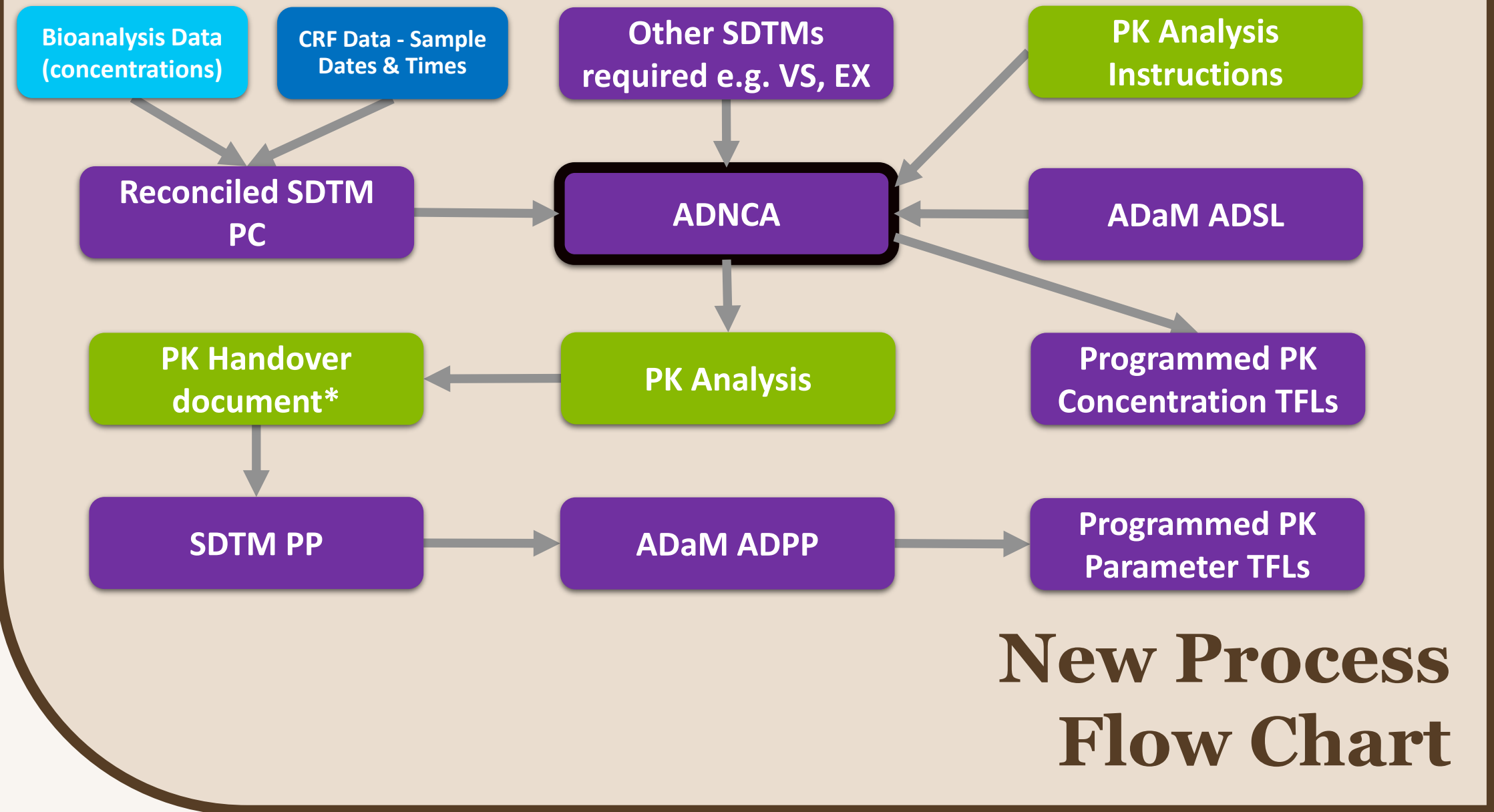
Benefits of using the ADNCA

- Improves Traceability** due to the ADNCA ADaM dataset being within the ADaM Case Report Tabulation (CRT) package. Therefore, the source and method derivation details will be present in the Define.xml further details such as explanations of flags and data issues can be provided in the Analysis Data Reviewers Guide (ADRG).
- Increases efficiency** by requiring only a single dataset, instead of the previous need to duplicate derivations in the PK Input Dataset and the ADaM ADPC. In turn, this helps reduce the timelines following the release of the unblinded PK data.
- Reduces inconsistencies** especially for complex studies where there is a high risk of discrepancies between duplicate derivations within the PK Input Dataset which is used for analysis, and ADPC which is used for the PK TFLs.
- Minimizes documentation** since all relevant data will be in a single dataset. There is not a need for a separate specification files because all data mapping and derivations are available in the ADaM specification.
- Further validation** available with the support of Pinnacle21. While the PK Input Dataset cannot be checked using formal standardized validation software, there are validation rules relating to the ADNCA available in the latest version of Pinnacle21.

Old Process Flow Chart



New Process Flow Chart



ADSL VARIABLES

STUDYID
USUBJID
SUBJID
SITEID
COMPFL
AGE
AGEU
RACE
ETHNIC

BDS CORE VARIABLES

PARAM
PARAMCD
PARAMN
AVISIT*
AVISITN
ATPT
ATPTN
ADT
ATM
AVAL
AVALU*
DTYPE
TRTP
TRTA

REQUIRED VARIABLES

DOSEA
DOSEU
PCRFTDT
PCRFTTM
PCRTFDTM
NRRLT
ARRLT
RRLTU