

SECURE DATA OFFICE: AN INDEPENDENT TEAM THAT CAN COME TO THE RESCUE IN BLINDED TRIALS

Annelies Van Zeveren, PhD

Project Manager Biometrics and Medical Affairs

SGS Life Science – Clinical Research

PhUSE US Connect 2018

WHEN YOU NEED TO BE SURE



- Introduction
- Secure Data Office tasks
 - Randomisation Data
 - The Pharmacokinetic (PK) Data flow
 - Other unblinding data streams
 - Cleaning of unblinding data
 - Deliver blinded result transfers
 - Deliver data to unblinded teams
- Conclusion

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■ Double blind study:

- Subject and investigator are unaware of treatment status
- Parties without access to unblinding data: subjects, investigators, Data Management, Statistics, PK analysts, sponsor
- Parties with access to unblinding data: pharmacists, bio-analytical lab, unblinded CRA

■ Unblinding data:

- Any data that can unblind the study
 - Treatment information, Pharmacokinetic & Immunogenicity data
 - Biomarkers.....

■ Downside:

- Unblinding data is not cleaned
- Delay in clinical database lock or unblinding data are not included in lock
- Crunched timelines for some parts of the analysis

Who should handle randomisation data and other unblinding data (e.g. PK, biomarker, immunogenicity data)?



WHEN YOU NEED TO BE SURE

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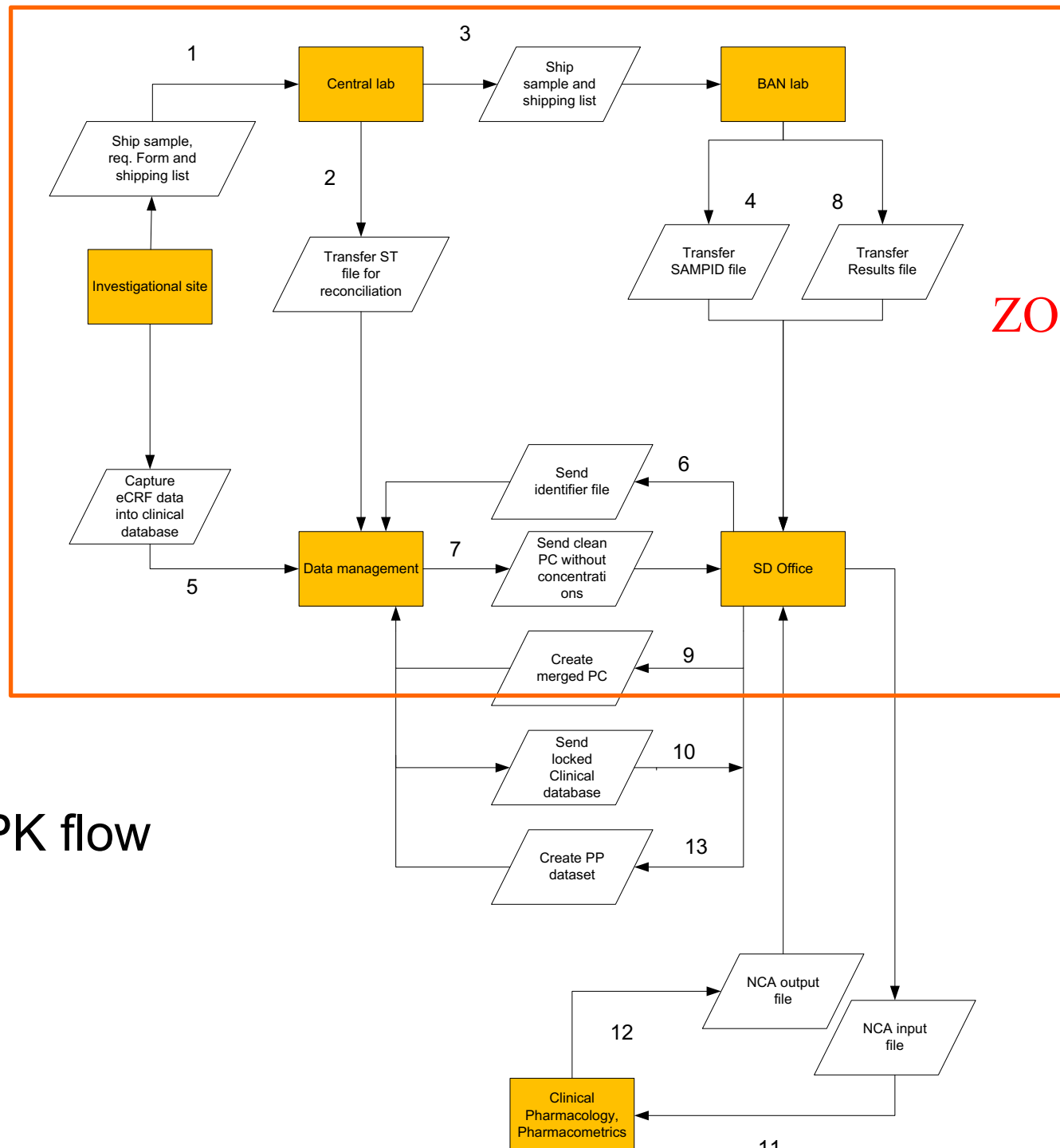
- Dedicated team, physically separated from other study team members
- Separate databases and secure server locations
- Clearly defined processes in SOPs and WIs



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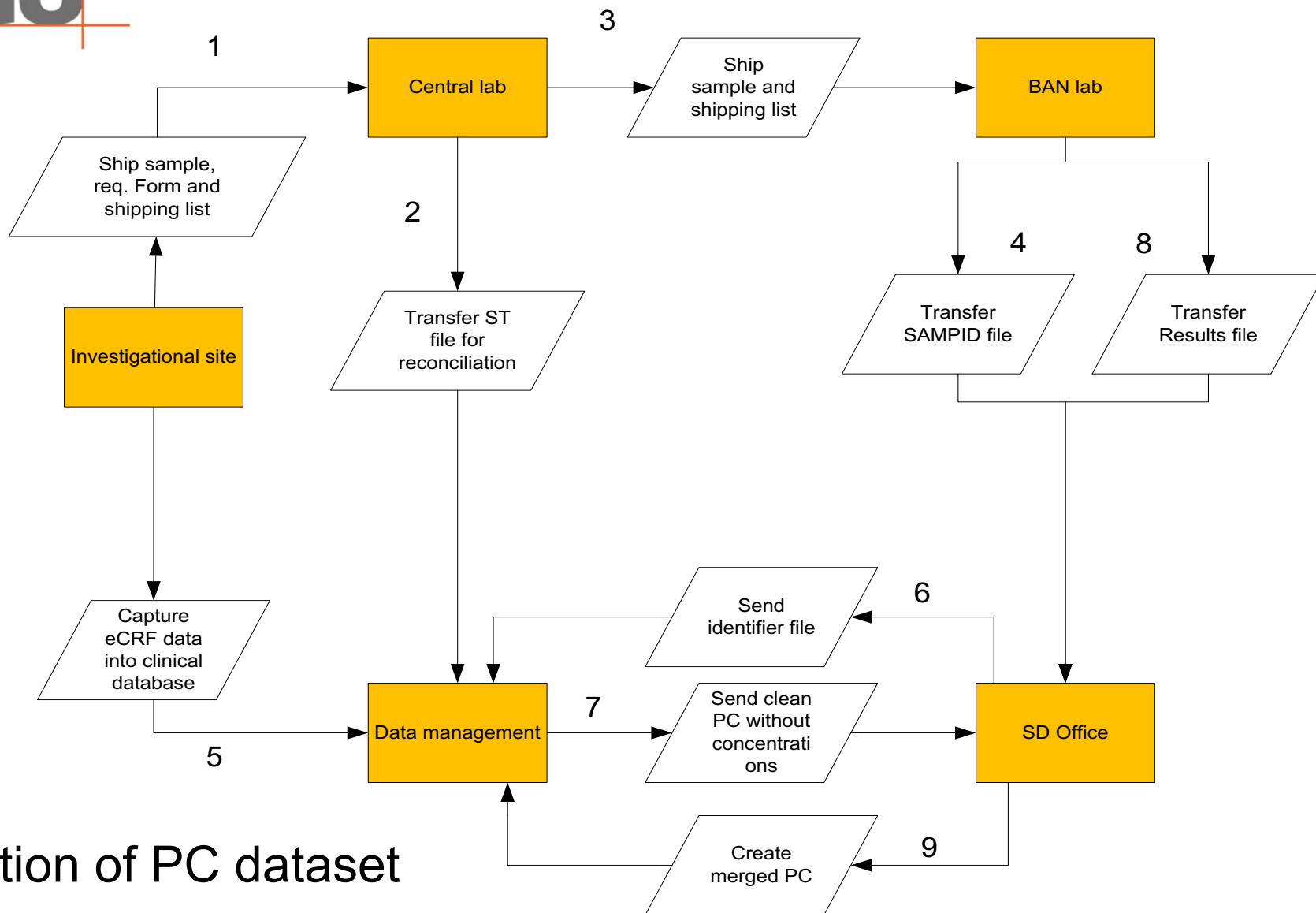
- Generation of randomisation lists
 - Documented randomisation list specifications
 - By SAS programmers with statistical background
 - Distribution to required recipients
- Support and handle of unblinding data in IWRS system
- Creation of SDTM dataset containing randomisation information based on following input
 - Subject information: from data management
 - Receive randomisation information: from external vendor or internally created

- PK data (Identifiers and results): Bio-analytical lab → SDO
- Blinded transfers: SDO → DM
- Cleaning is performed by DM
- DM delivers clean PC file to SDO
 - Contains CRF and sample tracking data
 - Without results
- SDO delivers clean PC file with results to include at time of database lock

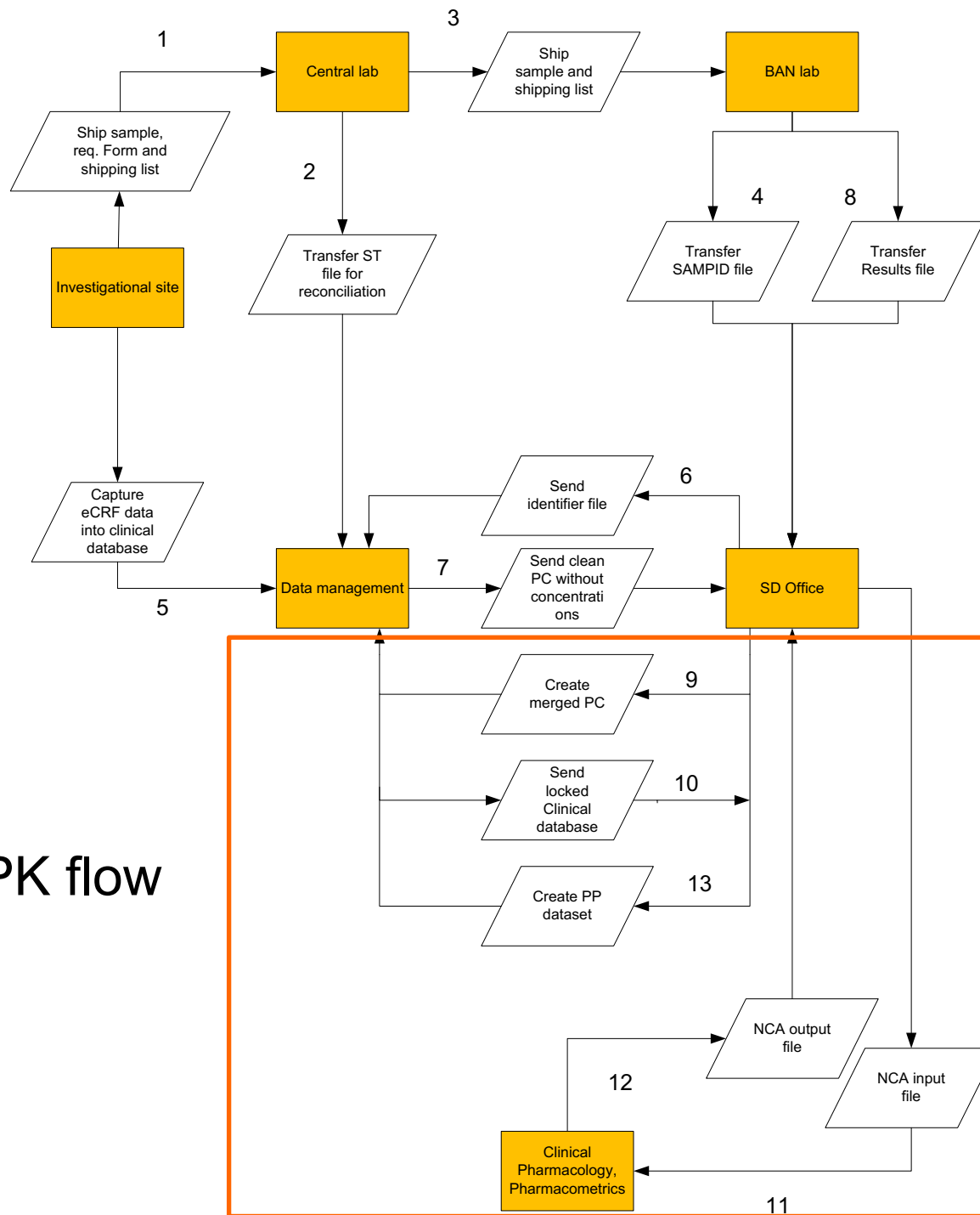


ZOOM 1

Complete PK flow



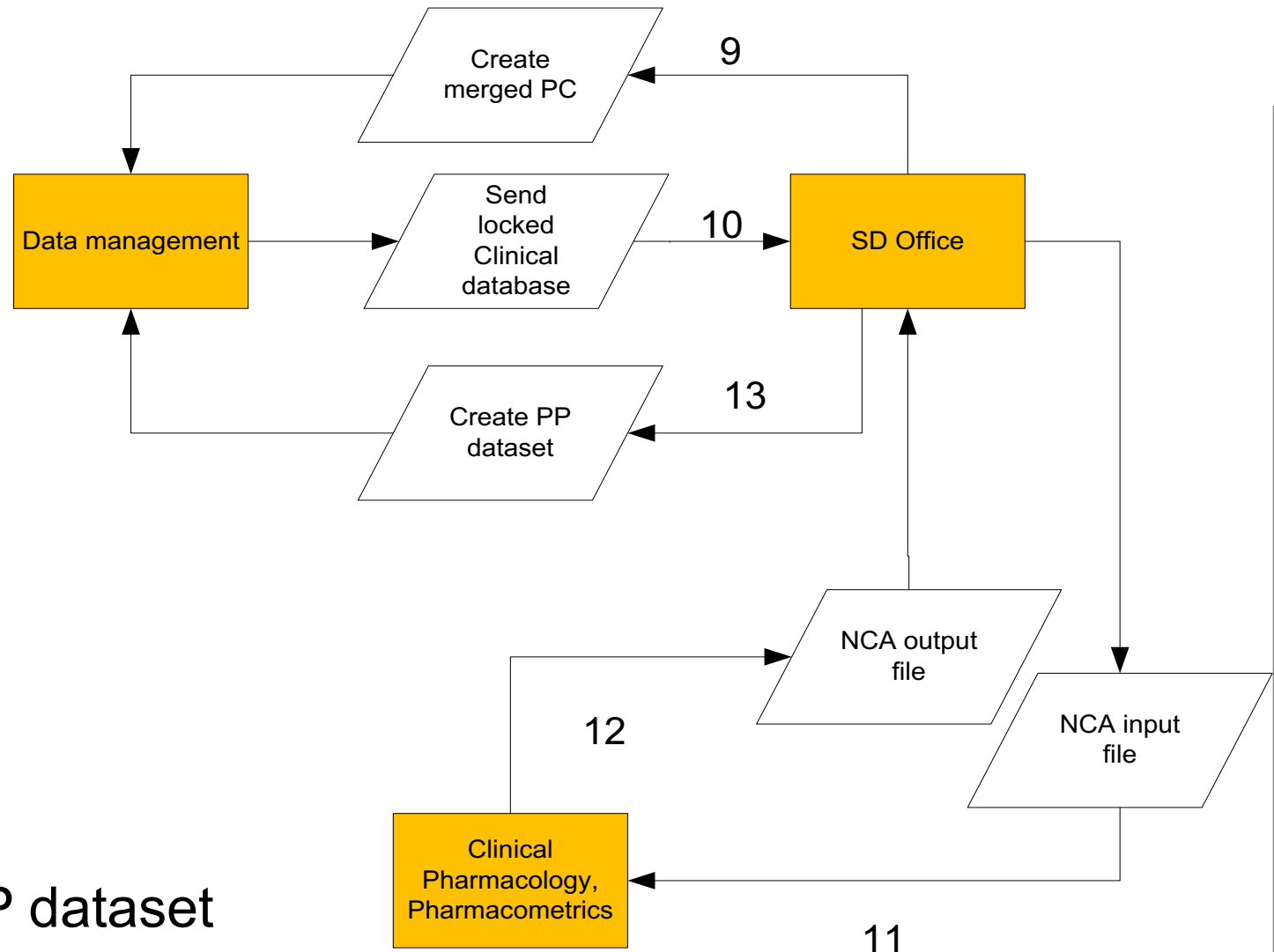
Creation of PC dataset



ZOOM 2

Complete PK flow

CREATION OF PK INPUT FILES AND PP DATASET

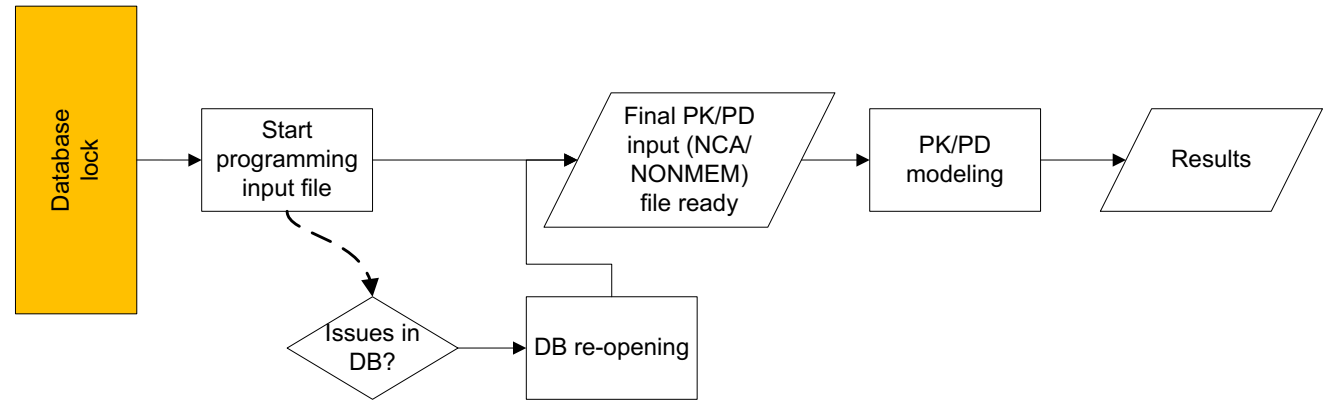


Creation of PP dataset

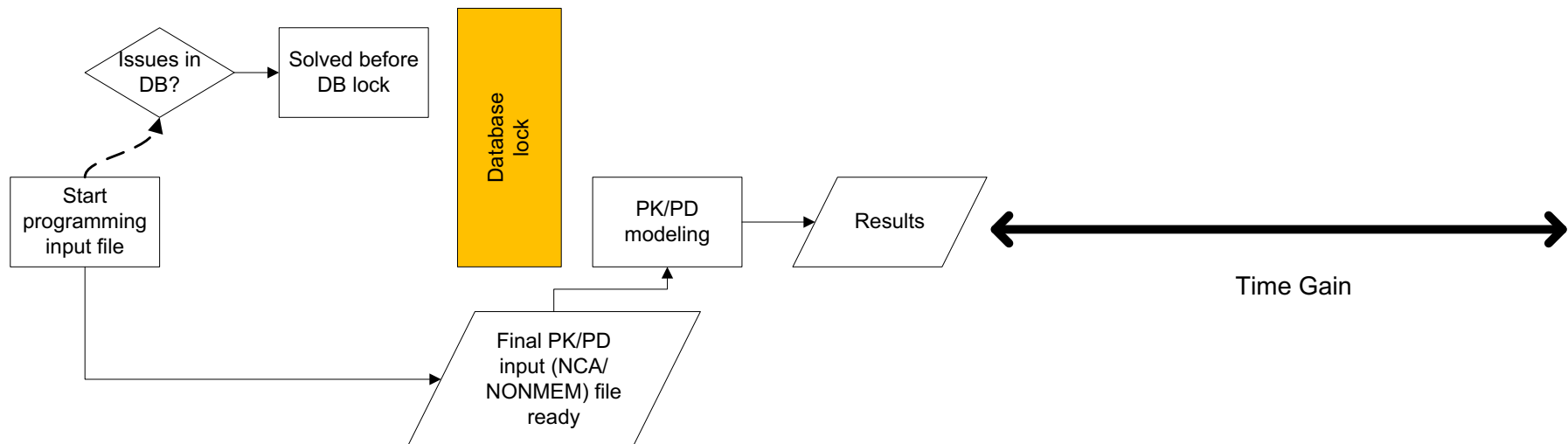


CREATION OF PK/PD INPUT FILES BY SDO

Without SD Office



With SD Office



OTHER UNBLINDING DATA STREAMS: LAB DATA

- Similar to PK data stream
- Only unblinding analytes via SDO
- SDTM domains: LB, PD, IS
- DM unblinded at release
 - Yes: combine LB parts by DM
 - No: combine LB parts and release by SDO

OTHER UNBLINDING DATA STREAMS: PROTOCOL DEVIATIONS

- Identification of unblinding protocol deviations (usually medication kit errors)

		Protocol deviation defined as	
		Any medication kit misallocation	Only treatment misallocations
Medication kit number unblinding?	Y	SD Office involved	SD Office involved
	N	Detection of medication kit misallocations by data management	SD Office involved

OTHER UNBLINDING DATA STREAMS: PROTOCOL DEVIATIONS

- Assigned medkit = planned data
- Dispensed medkit = actual data
- Reconciliation of planned and actual data by SDO
- SDO creates part of the DV domain:
 - Deviations related to medkit or treatment misallocations

CLEANING OF UNBLINDING DATA

- Only if cleaning of the unblinding content is required
- Cleaning requirements: in secure data handling plan
- Cleaning Checks are:
 - Defined
 - Documented
 - Programmed
 - Validated
 - Ran
- Review output of checks
- Write and follow up queries: blinded/unblinded

DELIVER BLINDED RESULT TRANSFERS TO BLINDED TEAMS

- PK data (Identifiers and results), other unblinding data: external vendor → SDO
- Blinded transfers: SDO → Data Management (DM)
- Cleaning is performed by DM
- Results transfer with dummy identifiers/scrambled: SDO → Statistics, PK analysts: dry runs

DELIVER DATA TO UNBLINDED TEAMS

- PK data (Identifiers and results), other unblinding data:
external vendor → SDO
- Blinded transfers: SDO → Data Management (DM)
- Cleaning is performed by DM
- Results transfer with real production data: SDO
→ Safety committee, DRC, Statistical Support Group (SSG)

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■ Role of SD Office

- Create randomisation lists and datasets
- Clean data before database lock
 - PK data
 - Medication kit misallocations
 - Other unblinding data
- Prepare input files for PK/PD analysis upfront -> analysis can start earlier

■ Results

- Time gain after database lock
- Higher quality
- Unblinded data available before database lock for DRC, SSG, dry runs
- Off the critical path and key results can be met



THANK YOU FOR YOUR ATTENTION



Meet us at the SGS booth 5

CONTACT US

clinicalresearch@sgs.com

EUROPE: +32 15 27 32 45

AMERICAS: + 877 677 2667

WWW.SGS.COM/CRO



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Agriculture, Food and Life Clinical Research

Annelies Van Zeveren

Project Director Biometrics and
Medical Affairs

SGS Belgium NV

Life Science
Generaal De Wittelaan 19a bus 5
2800 Mechelen
Belgium

Phone: + 32 15 40 49 89
Fax: +32 15 29 93 02
E-mail : annelies.vanzeveren@sgs.com
Web : www.sgs.com/ICRO

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CONTACT US

clinicalresearch@sgs.com

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