

DH02 - THE SECURE DATA OFFICE CONCEPT

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SGS Life Science – Secure Data Office

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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-analysis lab, unblinded CRA
- Unblinding data:
 - Any data that can unblind the study
 - Treatment information
 - Pharmacokinetic data
 - 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)?

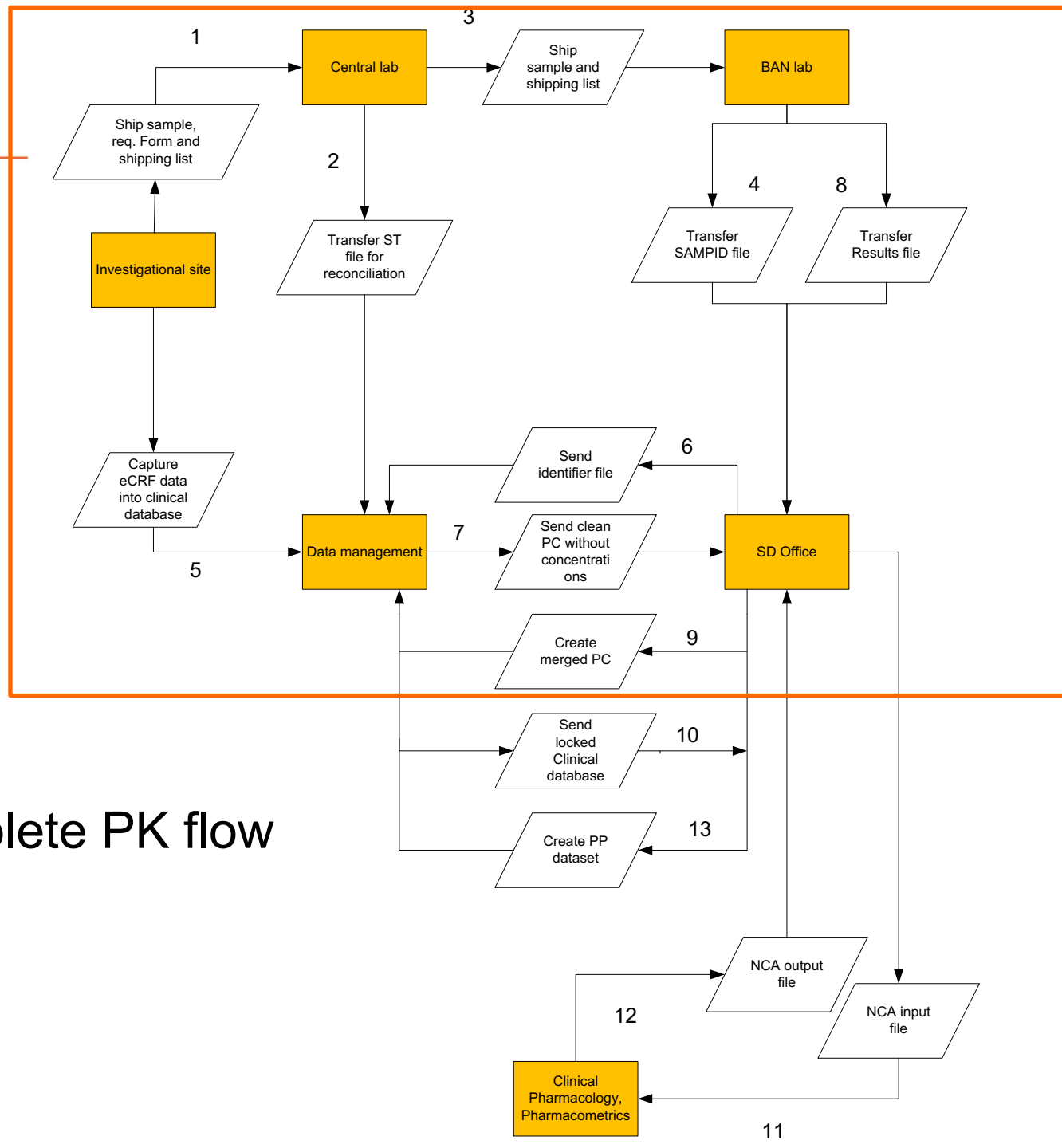
- Dedicated team, physically separated from other study team members
- Secure server locations and separate databases
- Clearly defined processes in SOPs and WIs

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- Generation of randomisation lists
 - Documented randomisation list specifications
 - By SAS programmers with statistical background
 - Distribution to required recipients

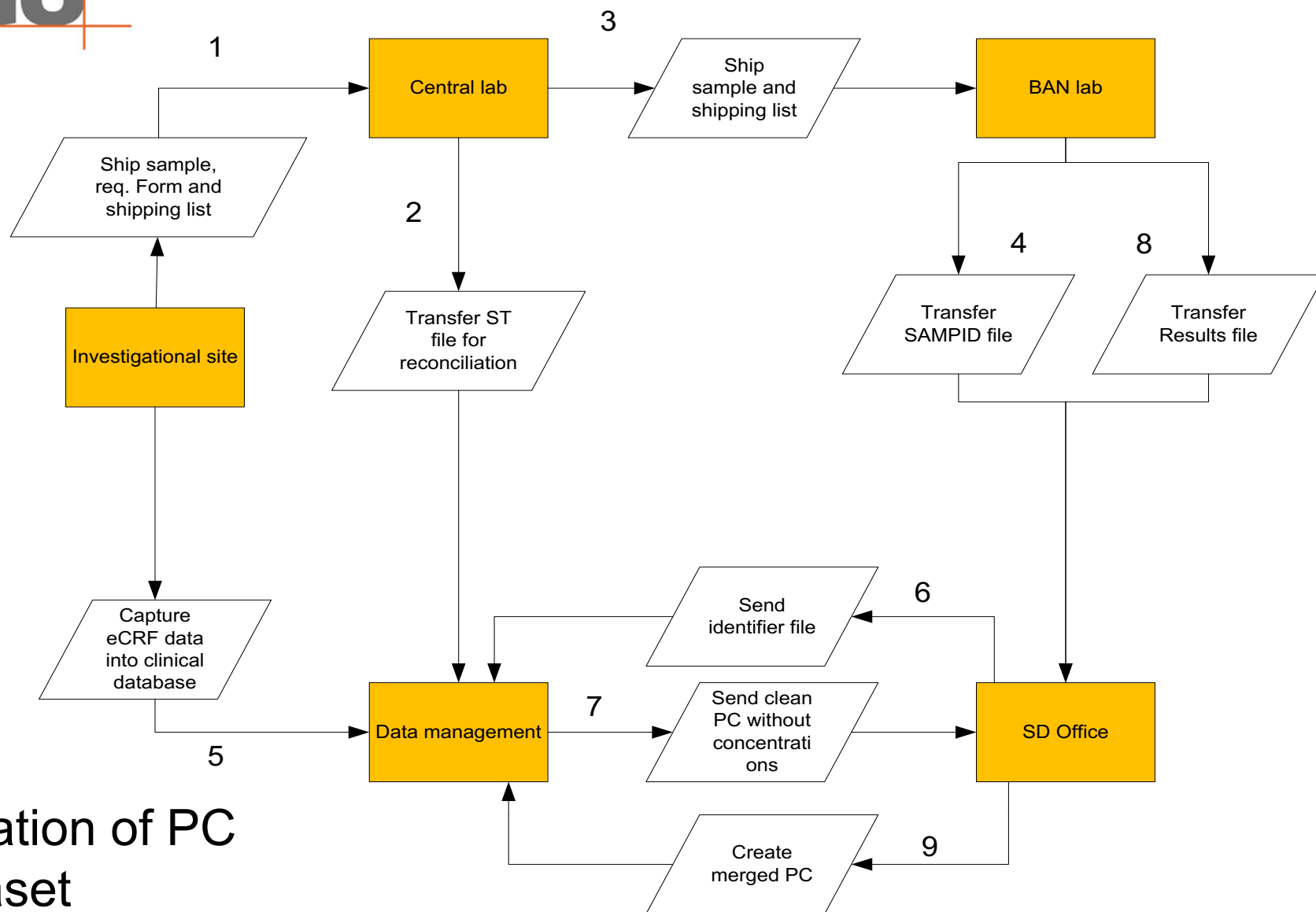
- Creation of SDTM datasets containing randomisation information based on following input
 - Receive randomisation information: from external vendor or internally created
 - Subject information: from data management

- PK data is always unblinding
- PK data (Identifiers and results): bio-analysis lab → SDO
- Blinded transfers: SDO → Data Management (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 DB lock



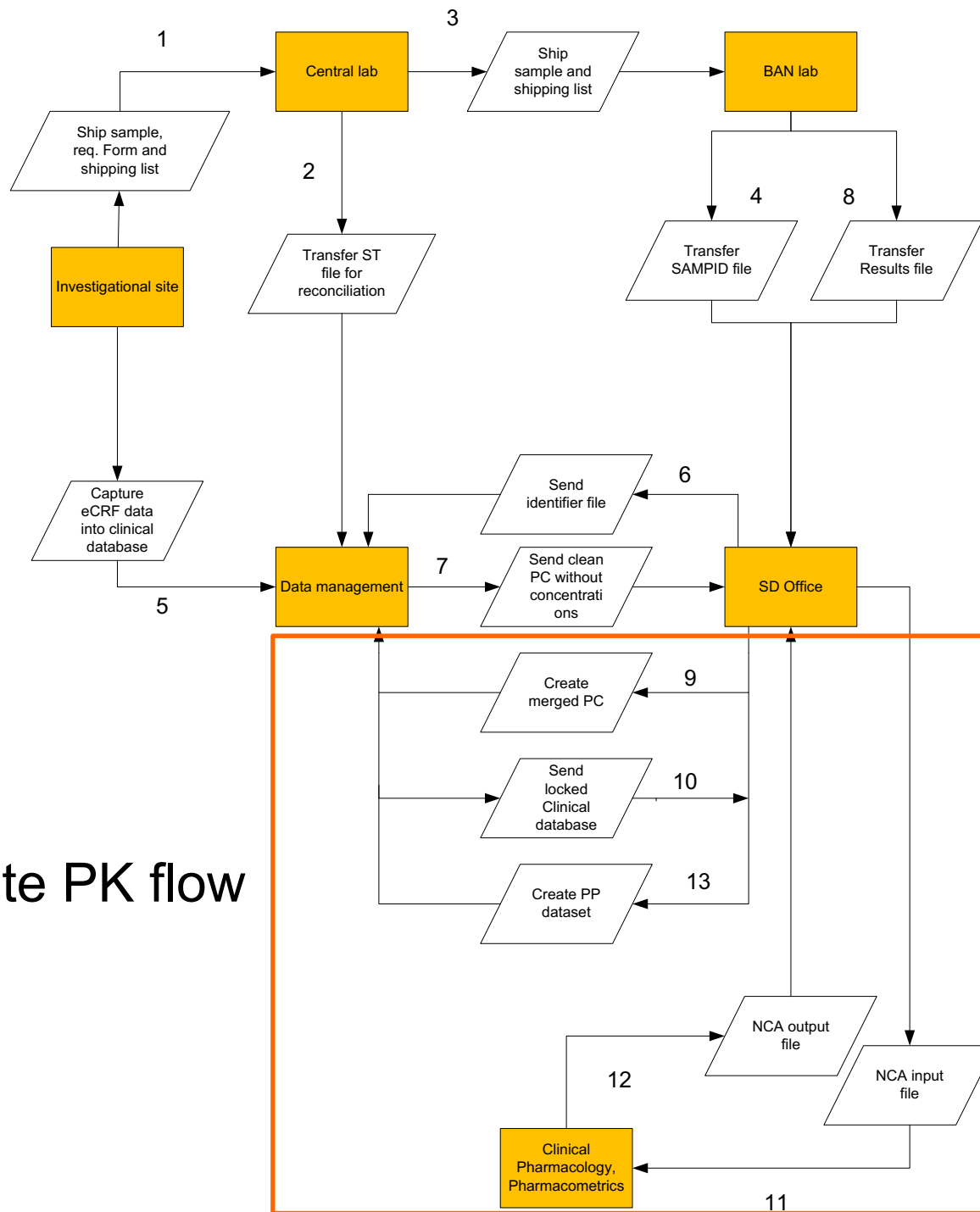
ZOOM 1

Complete PK flow



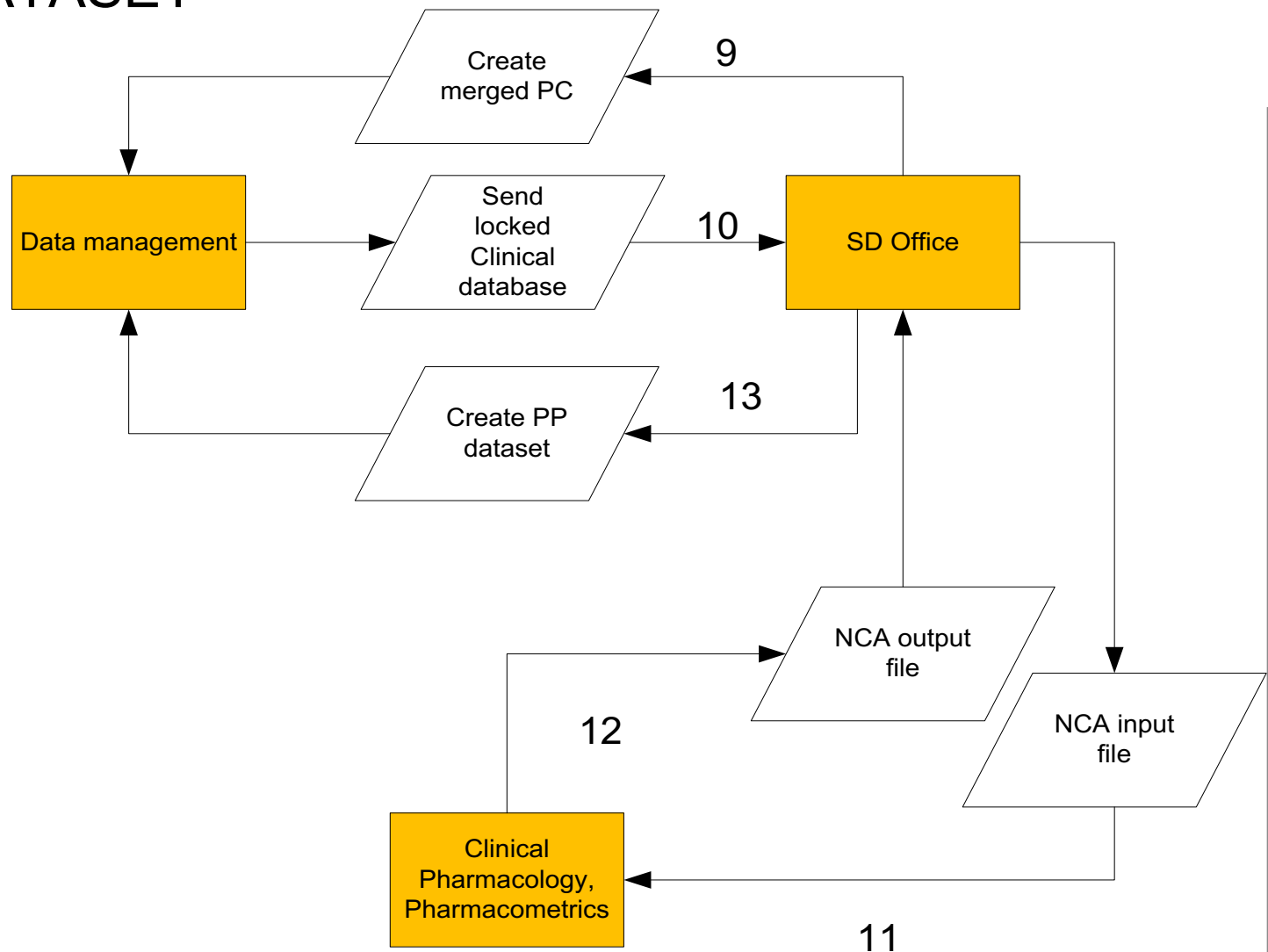
Creation of PC dataset

Complete PK flow



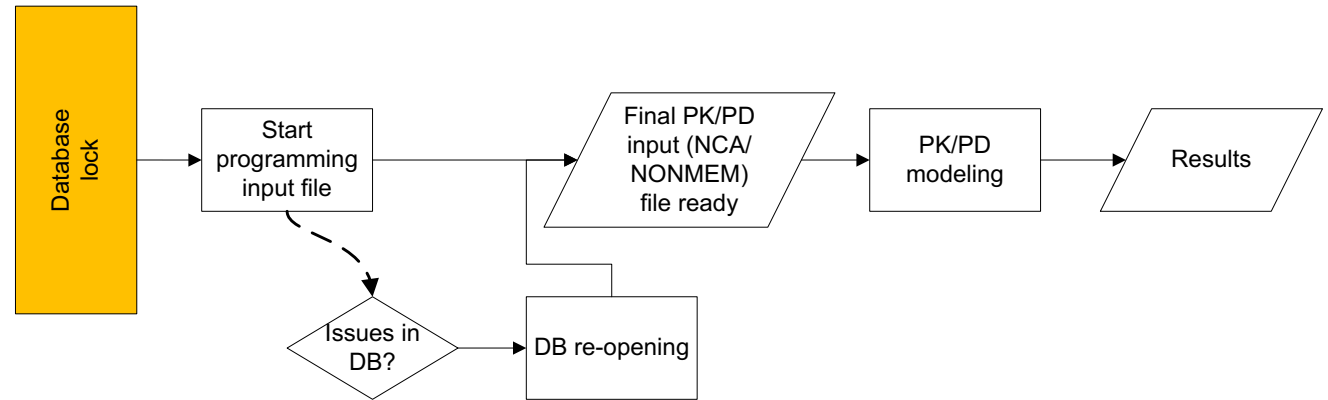
ZOOM 2

CREATION OF PK INPUT FILES AND PP DATASET

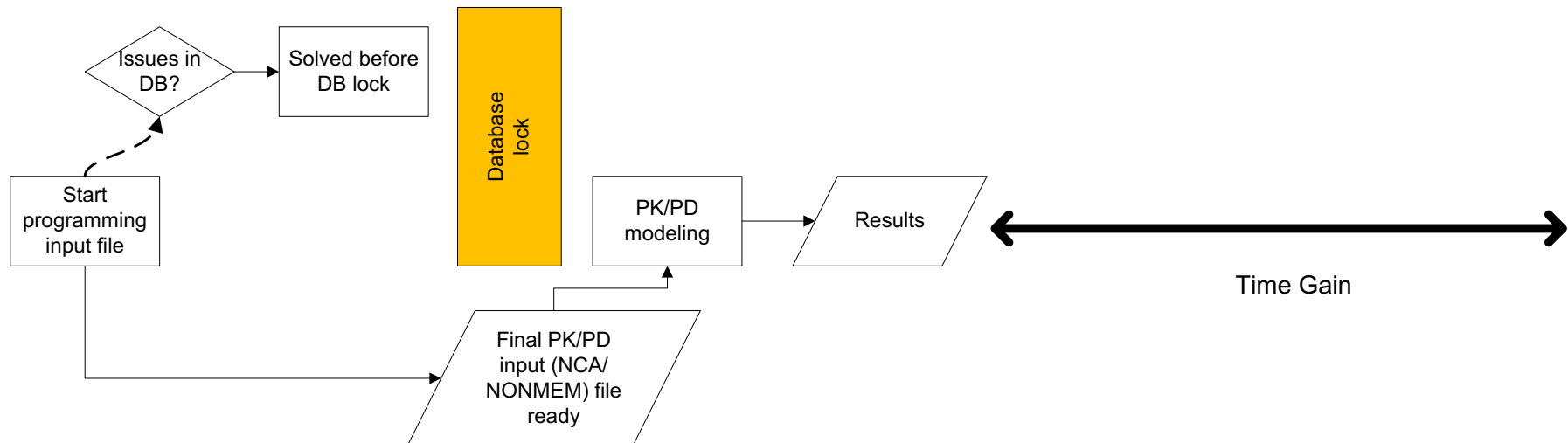


CREATION OF PK/PD INPUT FILES BY SDO

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

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



THANK YOU FOR YOUR ATTENTION

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