SD Office

Secure Data Office: Saving time and preserving blinded trial status by utilizing independent programming

Elke Vansnick

Head Secure Data Office

SGS Life Science Services

SDE Phuse Beerse 08MAY2012

SD Office

Overview

- Introduction
  - Background
  - Need
- What is Secure Data Office?
- Requirements
- Case study
- Conclusion

SGS
SD Office

Introduction - Background

- Clinical teams under pressure
  - Time to deliver results ↓
    - As short as possible after database lock
  - Amount of data ↑
  - Requirements of regulatory agencies ↑

- Need for efficient ways to produce trial results
  - Planning
  - Standardisation
  - Preparation of analysis programs before database lock
    - But what with blinded data (not accessible before database lock)
      Use of mock data not always possible…

SD Office

Introduction - Need

- Companies are struggling with PK data
  - PK data can unblind the trial and should only be accessible after database lock
  - Consequence:
    - Data issues are only detected after lock
    - Programming of PK Input files can only start after database lock
      - » Example NONMEM files: Randomisation, exposure and PK data needed for programming, mock data can not help
      - » Creating NONMEM datasets-how to escape the nightmare Pharmaceutical Programming, Vol 3, N 2 December 2010 , pp. 80-83(4)

Delay in availability of PK analysis results

SD Office

Introduction - Need

- How can we make sure, that the PK results are sooner available after database lock?
  - Access to data earlier (before lock)
  - Start programming the PK input file before lock
  - Deliver PK input file close after database lock

SGS's answer: Secure Data Office

SD Office

What is Secure Data Office?

- Independent dedicated group within SGS LSS Biometrics
  - No link with Data Management or Statistics Department
- Staff:
  - Data Managers
  - SAS programmers
- Only manage unblinding data streams/programming, no other responsibilities within a project
  - => can be unblinded before database lock

SD Office

What is Secure Data Office?

- A secure IT environment
  - Separate database and server folders with only access by SD Office employees
  - Secure exchange medium

► Alternative for the ‘unblinded’ employees within Sponsor Company / CROs

SD Office

SD Office tasks

- All DM activities and SAS programming with data that can unblind a study can be handled within SD office
  - Handling of pharmacokinetic data
  - Handling of other blinded data (Laboratory data, Anti-body data,…)…
  - Programming of PK/PD input files (NCA, NONMEM, …)
  - …
- Randomization data
  - Creation of randomisation lists
  - Distribution/release of randomisation lists
  - Cleaning randomisation data
- Handling of 'limited' access data (e.g.. DNA results, linking of de-identified samples, de-identification of database…)
- ….

SD Office

Requirements

- Staff
  - Experienced/well-trained: Handling of sensitive data
  - Independent: Staff is working on an “Island” and is not involved in other steps of trial processing. Moreover staff should minimize interaction with the study team to avoid accidental unblinding
- Planning
  - Time critical
  - Small projects
  - Several Sponsors
- Agreements on derived data between SD Office and Sponsor Stats group
  - Safety/Efficacy data should be in sync with PK data
  - Share formulas, …

SD Office

Requirements

- Standarisation
  - CDISC standards
    - Easy translation of protocol information to datasets
    - Additional time (and cost!) can be saved by creating validated macros for merging the standardized data
    - Incoming data can be checked on quality and completeness via standard checks before programming starts
  - Internal processes
- Well documented specifications / transfer agreements
  - Communication is important
    - What does the sponsor expect from SD Office?

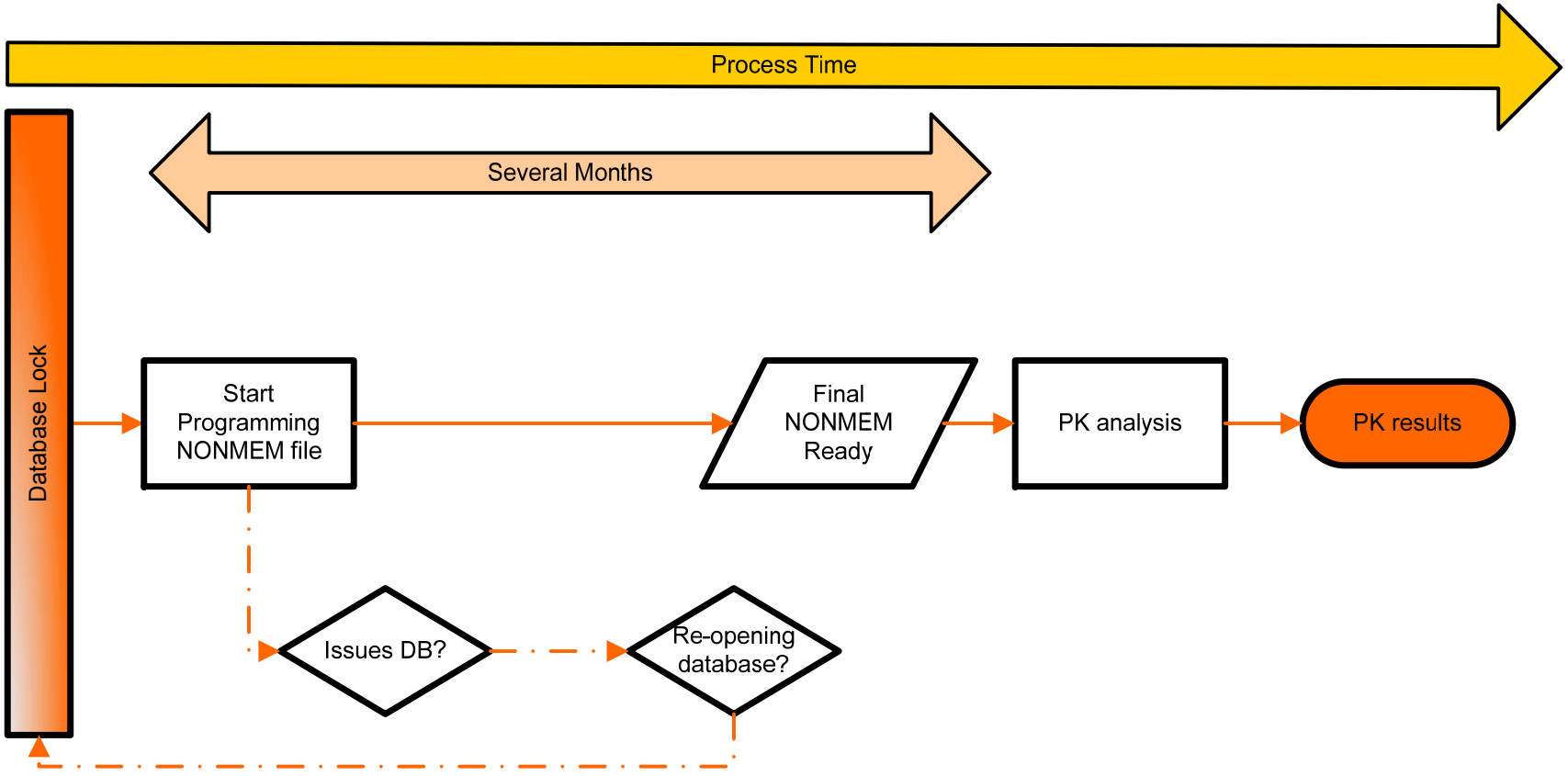
SGS
SD Office

Case Study

- Sponsor heading to a FDA submission for compound: Very strict timelines
- Deadline for Final PK report: 4 weeks after database lock of two phase III studies
- PK analysis: Modeling
  - Creation of input file (NONMEM)
  - PK analysis
  - PK report
- If the process starts after database lock, timelines cannot be reached!

SD Office

If programming starts after DB lock



SD Office

SD Office solution for the sponsor

- SD Office as “unblinded partner”
- Start project 6 months before database lock
- 1 month to create the specifications
  - Meetings, back and forward reviews of specifications
- Start SAS Programming 5 months before database lock
- First delivery of NONMEM file 3 months before lock
  - Blinded NONMEM file
    - Fake subjectID, no covariates
  - PK group prepared the PK analysis in ‘blinded’ way

SD Office

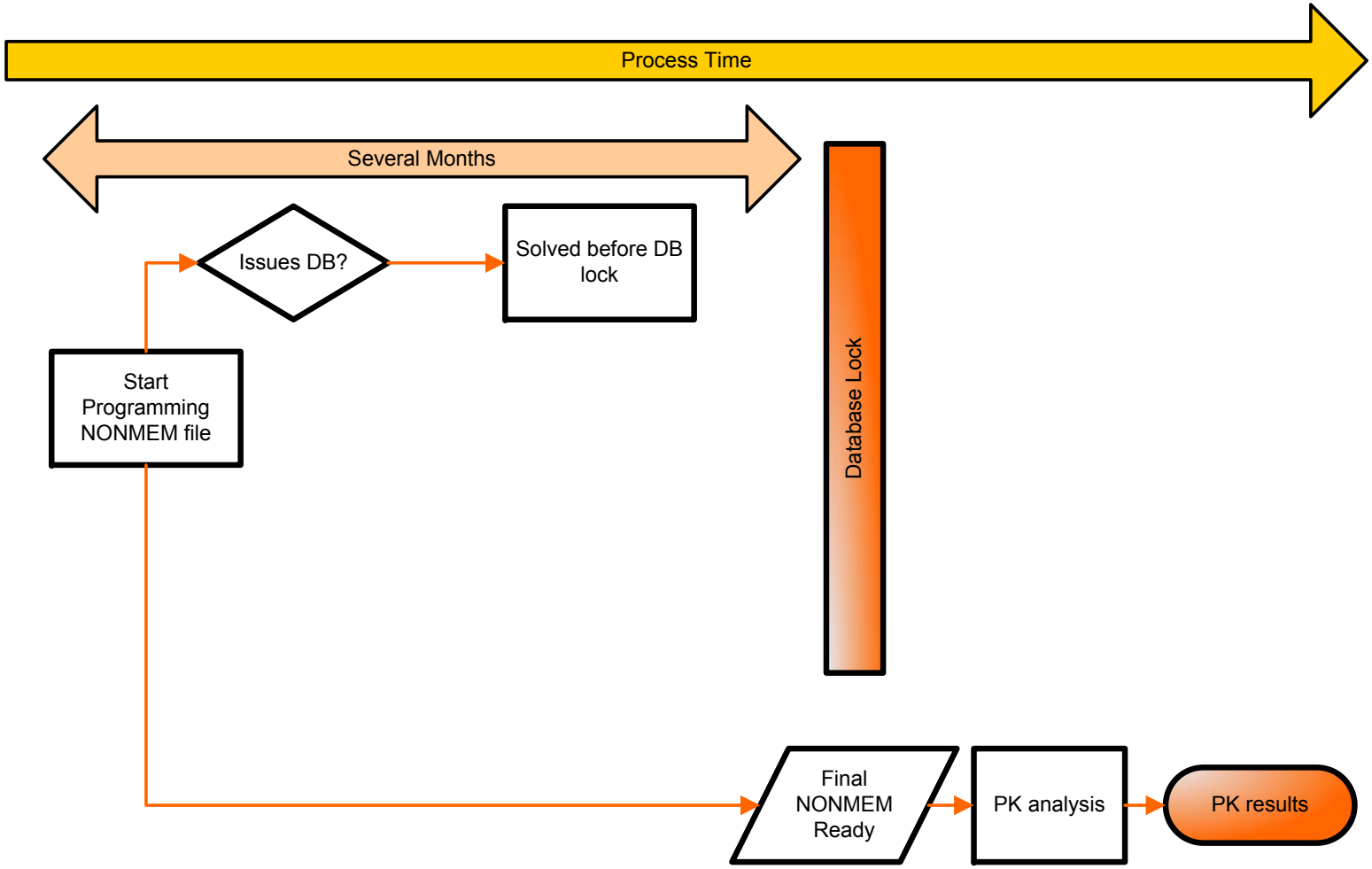
SD Office Solution

- After Database lock
  - Final locked database transferred to SD Office
  - Re-run of the NONMEM programs on final data
  - Release of NONMEM file within 5 days after receipt of source data
- PK analysis could be performed 1 week after database lock
- PK report could be written

► Submission timelines were reached

SD Office

SD Office solution



SD Office

What SD Office learned of this project

- Communication was important
  - Several stakeholders involved
    - Bio-analysis laboratory (PK concentrations)
    - Data Management (Source data (as clean as possible))
    - Statistics (Derivations)
    - PK groups (PK analysis)
  - Work-out timelines in detail
    - What is expected when and by whom?
- Training
  - New process, not clear for all departments
  - Confusion

SD Office

What SD Office learned of this project

- Start as soon as possible
  - NONMEM programming can indeed be a nightmare for phase III trials
- Quality gain at final lock
  - Feedback of data issues to DM
    - Resolved by database lock

SD Office

Conclusion: Advantages of using SD Office

- Blinded data can be handled and controlled without unblinding the sponsor team
  - No surprise at DB lock
- Standarisation and expertise
- Time gain:
  - The programming of files can start before database lock

SD Office

Contact details

Elke Vansnick - Head Secure Data Office

SGS Life Science Services

Generaal de Wittelaan 19A b5

B-2800 Mechelen

Phone: +32(0)15 440 156

Mobile: +32(0)471 95 02 71

E-mail : elke.vansnick@sgs.com

WHERE EXPERIENCE MEETS SPEED