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STANDARDIZATION OF PRE-CLINICAL DATA AND METADATA USING SEND

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01 INTRODUCTION

CONTEXT

Each pre-clinical study in a silo

- Different structures
- Different semantics (age, gender, …)
- No traceability
- No database management

➔ Pooling and capitalization difficulties!

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NEEDS

- Growing need for preclinical data pooling
- Cross analysis with clinical studies and other data
- Business need to go faster to decision
- Ensure the quality of the data

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HOW

- Data Flow Quality Assessments
- Secure and regulate data transfers
- Standardize datasets
- Assure completeness and accuracy
- Data Management & Statistical Workflow

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02 GLOBAL PROCESS SETUP

OBJECTIVES

- Do not slow down the result delivery
- Control the data flow
- Assure the best quality possible
- Capture metadata
- Automated process

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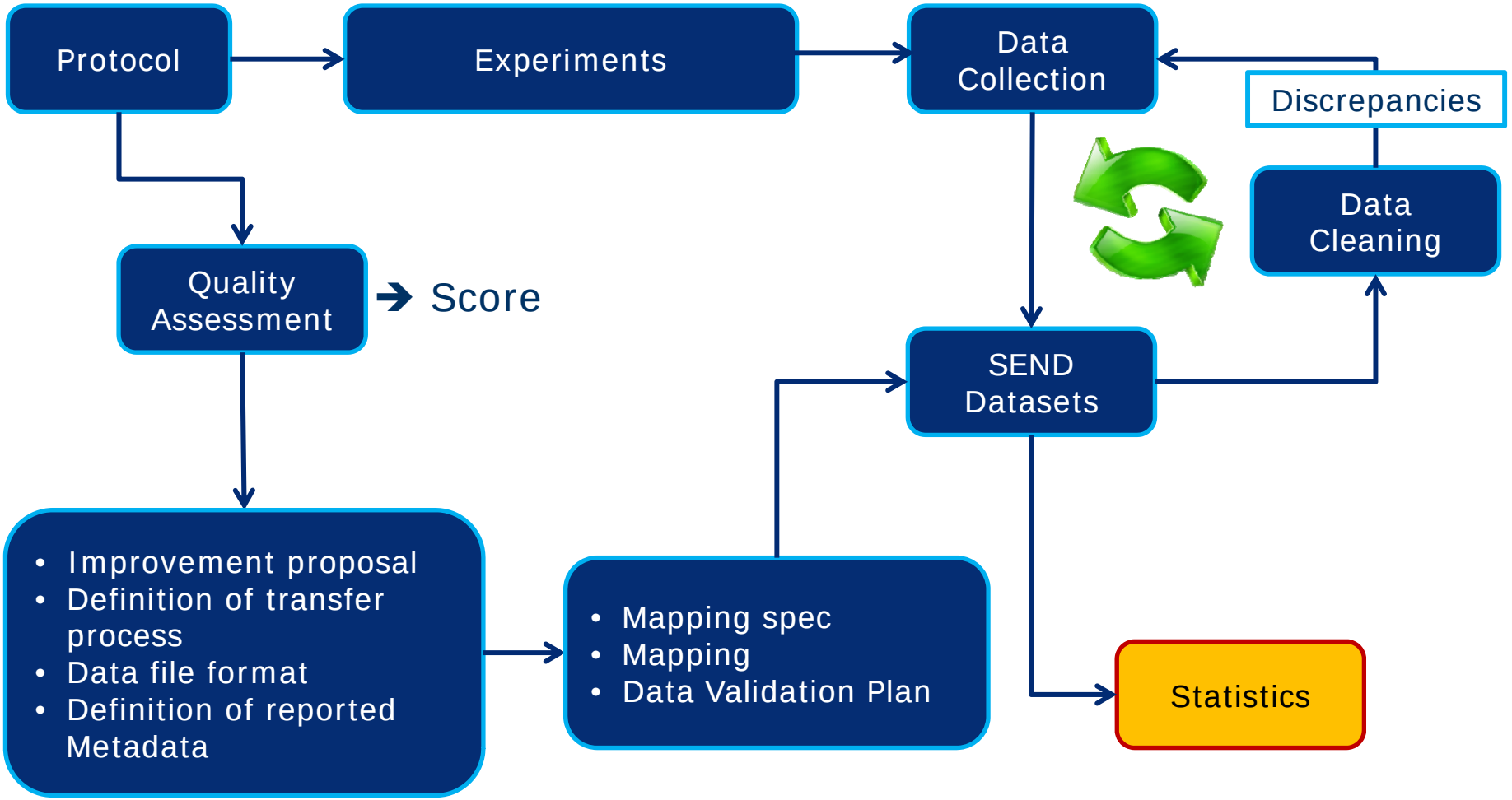
PROCESS OVERVIEW



✓ Inspired from clinical studies domain

✓ Simplified

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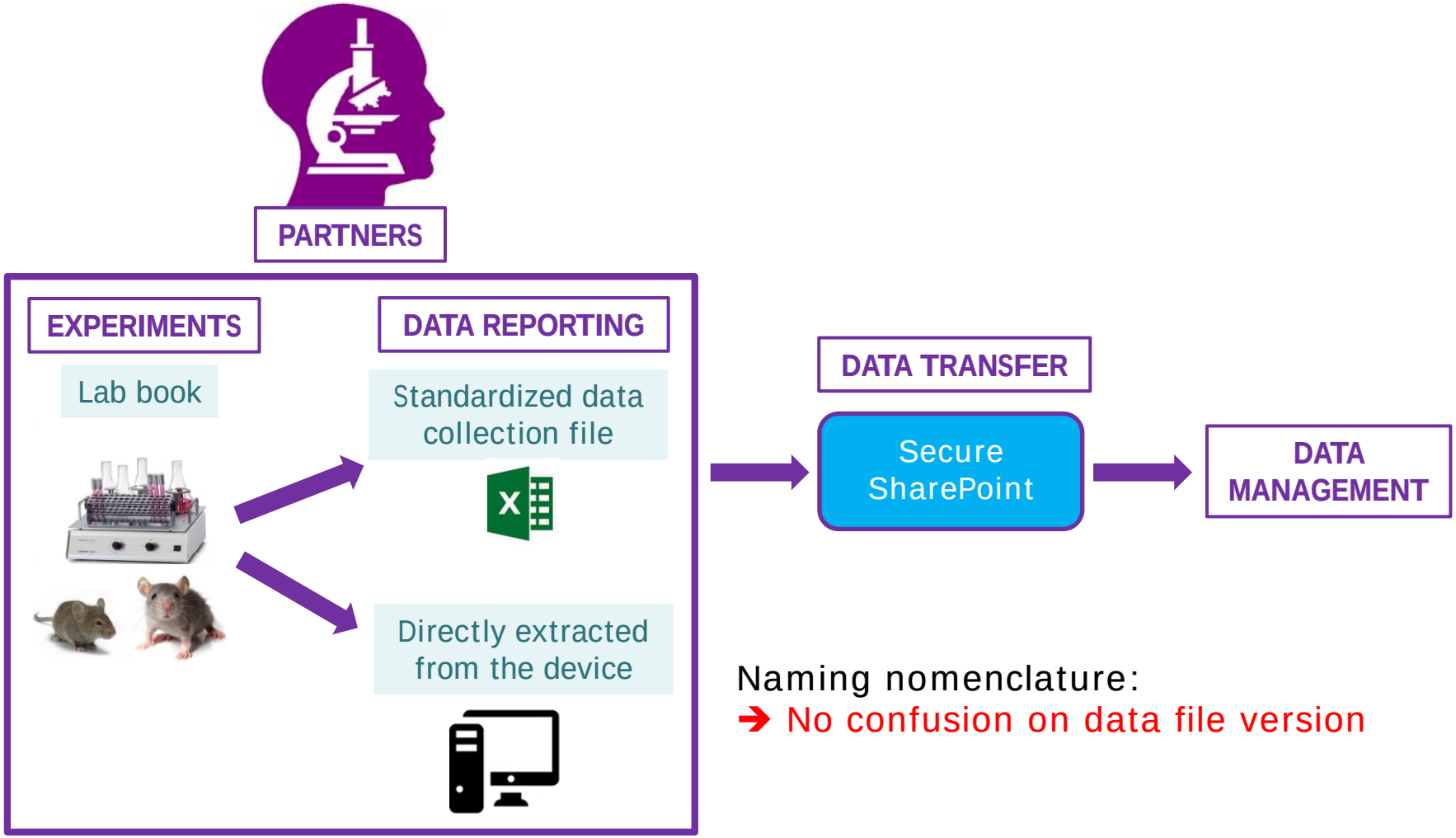
A SINGLE DATA FLOW



Naming nomenclature:

➔ No confusion on data file version

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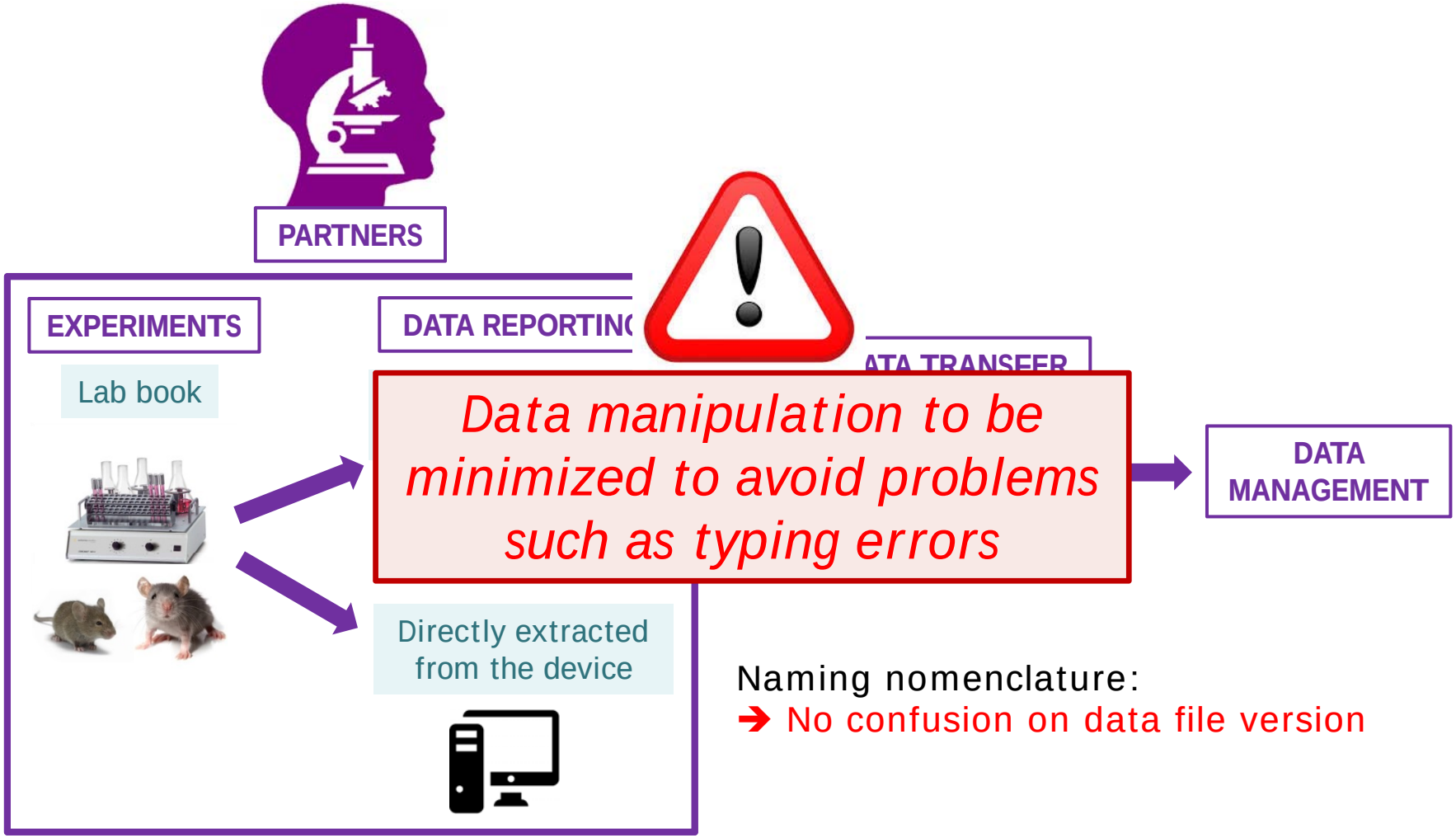

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DATA MANAGEMENT EARLY INVOLVEMENT TO …

- Discuss the data management process with the external data provider
- Perform data quality risk assessment ➔ objective score
- Improvements implemented before the beginning of experiments
- Educate and raise awareness of our needs
- Define data transfer modality
- Discuss with the scientist what is important to be captured
- Define the data file template

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TRANSFORMATION TO STANDARDIZED DATASET

- Using SAS®
- Captures as much data as possible in the data file
- Additional data can be caught from the protocol (hard coding)

- Date format to be respected
- LoD /LoQ data entry convention to be defined

- Transformation according to SEND IG 3.0

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EXAMPLES OF DOMAINS USED

- DM: Demographics
- BW: Body Weights
- EX: Exposure
- CL: Clinical Observation
- DD: Death Diagnosis
- FW: Food and Water consumption
- LB: Laboratory Tests
- VS: Vital Signs

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BASIC DATA CLEANING

- Controls on:
  - Missing data (importance to justify any missing data)
  - Out of range data (ranges defined with the scientist)
    ➔ Avoid any obvious data entry error
  - Dates compared to the timepoints defined in the protocol
  - Evolution of weights
- Findings compiled in a discrepancy file
- Until all findings resolved

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03 WHY STANDARDIZATION?

WHY WE STANDARDIZE

- Efficiency via automation
  - ➔ Non added value tasks minimized
  - ➔ Quicker to decision
  - ➔ Constant quality

- Use SEND-in visualization tools

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WHY WE STANDARDIZE

- Standardized data collection template

  ➔ Maximize the automation of data mapping

- Standardized datasets

  ➔ Re-use of edit-check programs

  ➔ Outlier detection integrated to cleaning process

  ➔ Basic statistics automated

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VISUALIZATION TOOL

- SEND-in tool

  - Facilitate access to results as soon as the data are available

  - Custom reports

  - Dynamic / Easy navigation functionalities

➔ Anticipate statistic results and may save time on decision making process

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04 DIFFICULTIES – KEY LEARNINGS

CHANGE HABITS !

- Data Management involvement at an early stage
- People enrollment (internally + external partner)
- Fundamental work of education and pedagogy to provide a clear picture of our needs and objectives
- Support of the Quality Management System

Make people believe in it is the key for success!

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05 CONCLUSION

CONCLUSION

- Key points for success
  - ➔ Persuade the scientist and partners
  - ➔ Early involvement of data management
- Benefits
  - ➔ Standardization using SEND model brings us quality, traceability and homogeneity of our database (EFSA submission)
  - ➔ Ability to capitalize and pool our data
  - ➔ Efficacy and conviviality of results reading thanks to visualization tools
  - ➔ Efficacy and time saving to capitalize and pool our data

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THANKS

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