

TT02

SAS Life Science Analytical Framework (LSAF) in a nutritional clinical research setting

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Agenda



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Introduction

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Initial Needs

3

Challenges and Solutions

4

Next Steps for Nestlé Clinical Development

Introduction



Nestlé Research Clinical Development Unit:

- Generates data based evidence
- Runs clinical trials
- About nutritional products

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Initial Needs



- Homogeneous ways of working
- Storage of clinical data
- Sharing data and programs
- Standardized data extraction from upstream environments

 Increase efficiency of DM and Stats

 Prepare for GDPR

What is LSAF?



LSAF = Life Science Analytical Framework

Repository	Programming
Audit Trail	SAS language
Access control	Automated
Linked to Medidata© Rave	
Web based	

What do we do in LSAF?



Data Managers

Data storage

Extraction from
Medidata© Rave

External data

Data Quality Review

Biostatisticians

Programming

→ share data/programs/documents

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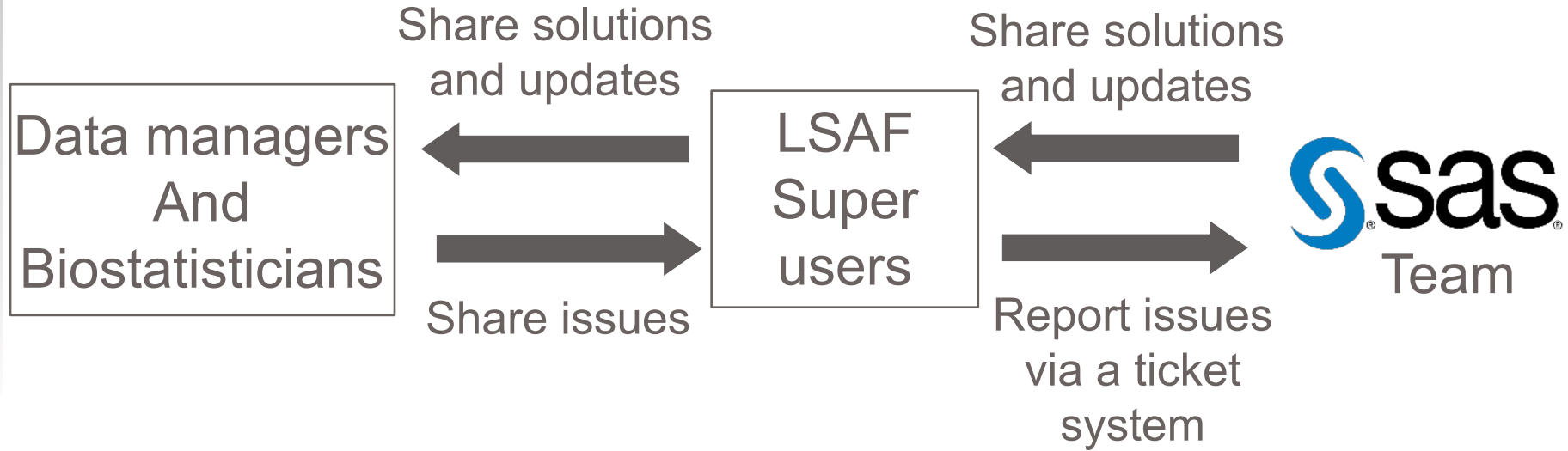
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Daily Routine



➡ Point of contact between BST/CDM and SAS

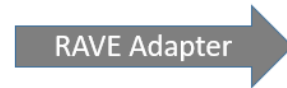
Documentation

- Define Roles and Responsibilities
- Guidance
 - ✓ How to create a trial in LSAF?
 - ✓ How to program in LSAF?
- Roll-out plan



Improvement of existing tools

- Adaptation to LSAF (revision of macros)
- Data extraction from Medidata©:



Automated data and
metadata extraction



LSAF Repository

- Data Quality Review process

Change Management



Users need to get out of their comfort zone...
... Strategy for a smooth transition:



- ✓ Planned in advance
- ✓ During the implementation: consult the users
- ✓ Training, communication, regular support +++

Performance



- On boarding phase challenging
- Data extraction process efficient
- Account management easy
- Web based

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Next Steps

- Still work to do:
 - ✓ Jobs Scheduling
 - ✓ Dashboarding
 - ✓ External Users
 - ✓ Other analytical software



Summary and conclusion



- Many **advantages**
- Must anticipate **challenges**
→ Change Management!!

Innovative solution → acceleration and strength

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