



# **IMPLEMENTING LSAF**

## **THE DANONE NUTRICIA JOURNEY**

Paul Vervuren

Jean-Marc Ferran

Paper DH04

PHUSE EU Connect 2019



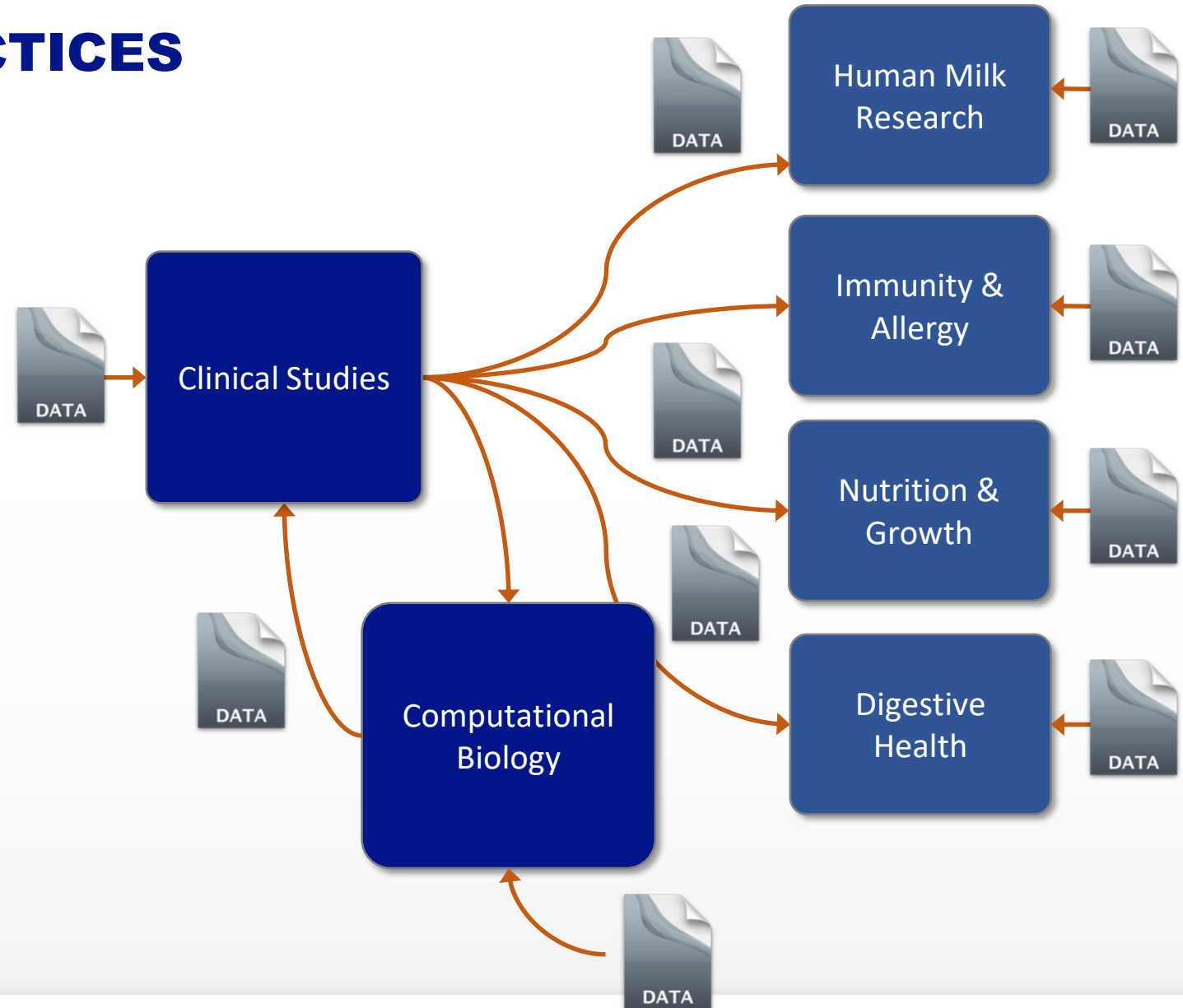
# AGENDA

- Introduction
- Project phasing
- High-level Architecture
- Piloting & Risk Based Approach
- Automation of Tasks and Use of LSAF APIs
- Support Process
- Summary

# RETHINK DATA PRACTICES

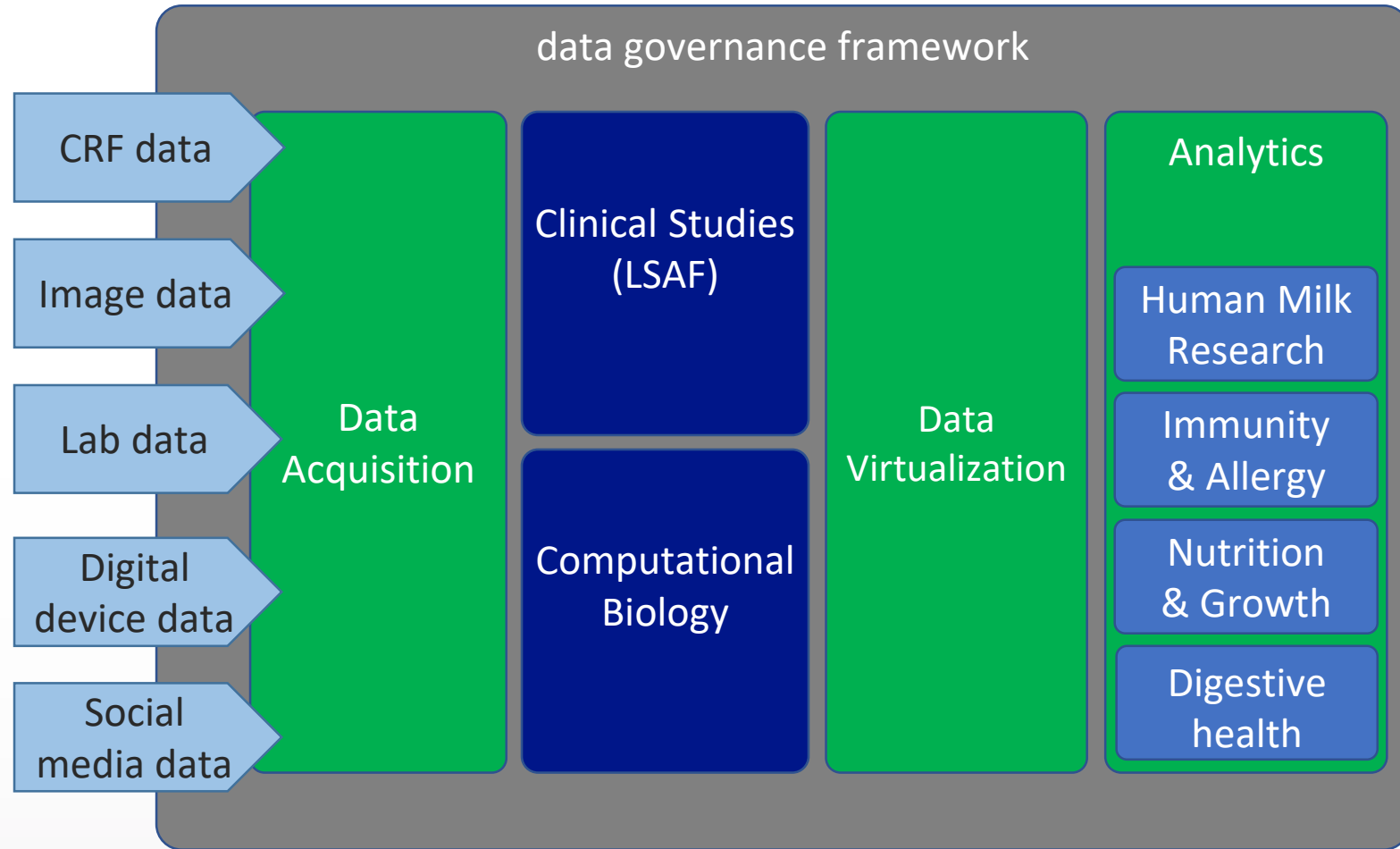
## Issues:

- Manual data exchange
- No clear oversight
- No shared standards
- No full data lineage
- No shared workspaces



# TARGET SITUATION

- Common principles, data policies and practices
- Shared data acquisition processes and data standards
- Responsible sharing of research data
- Collaboration spaces with advanced analytics capabilities
- Mature level of auditability, data lineage, reproducibility, and automation



# LSAF @ Danone Nutricia Research

## Data Science & Biometrics team

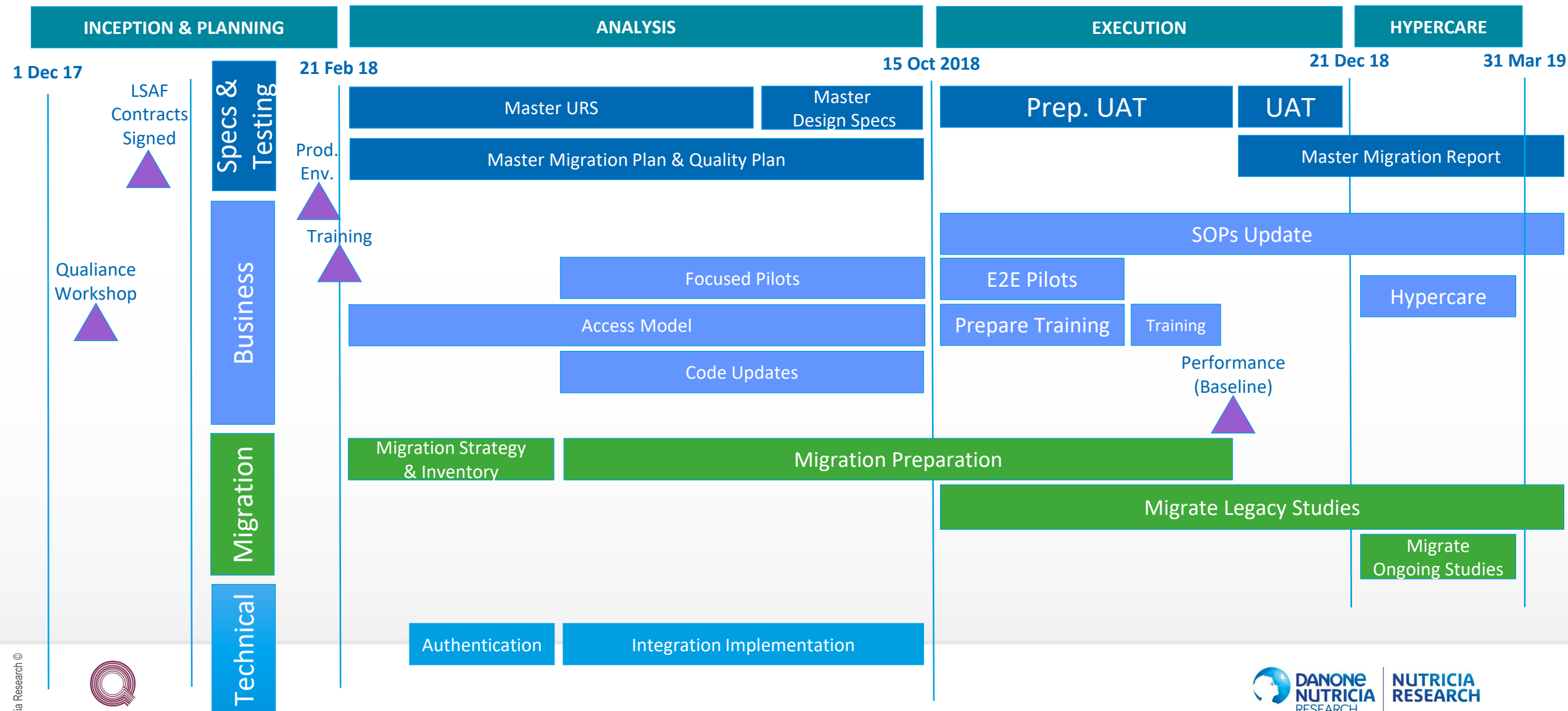
- Approx. 50 user in Data Management, Statistical Programming & Biostatistics (NL, SG)
- Legacy environment: local SAS server + file server
- Key needs: Performance, User management, Life cycle management, Automation, Global collaboration

## Implementation approach

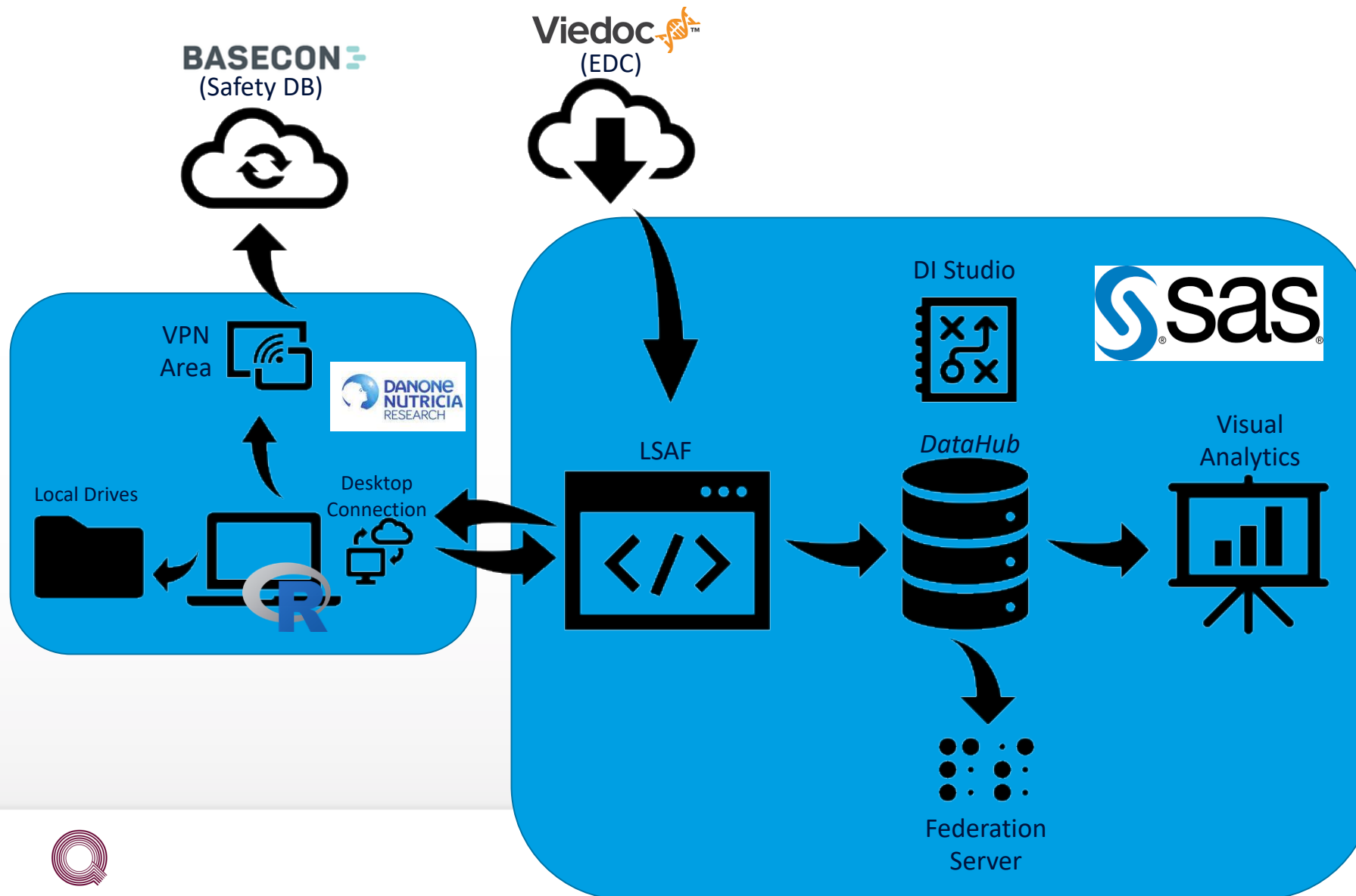
- Achieve go-live within a year (before end of 2018) and decommission legacy environment
- Selective migration of data
  - Approx. 60 'active' studies and some folders for pooled analyses
- Data virtualization and visualization capabilities developed in parallel project

# PROJECT PHASING

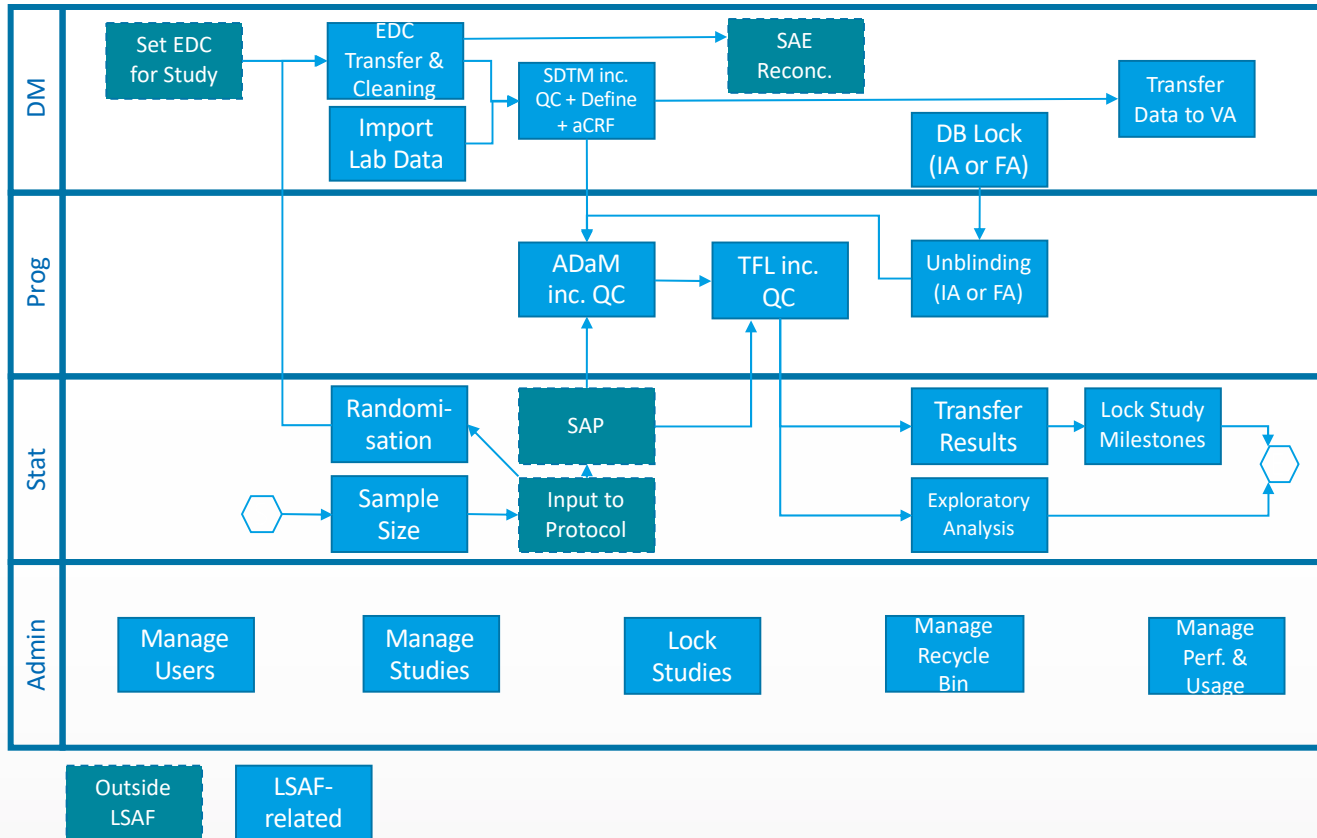
Technical  
Go-live



# LSAF+ HIGH-LEVEL ARCHITECTURE



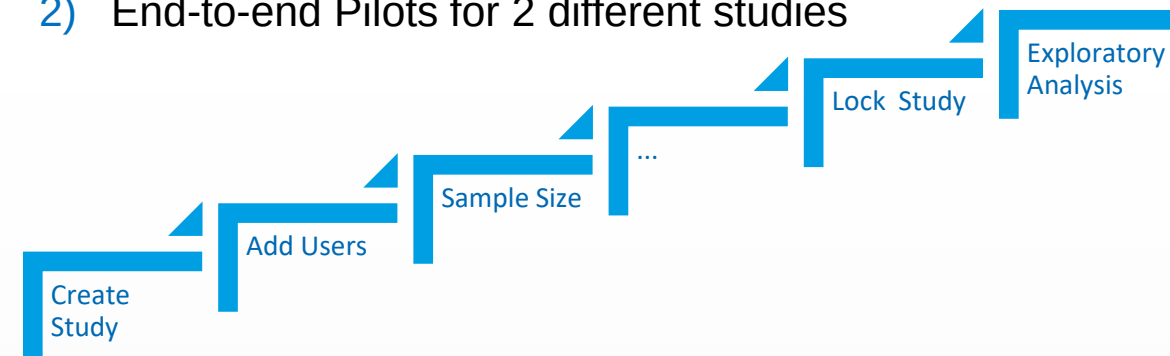
# PILOTING – FOCUSED & E2E PILOTS



## 1) Focused Piloting of each Process



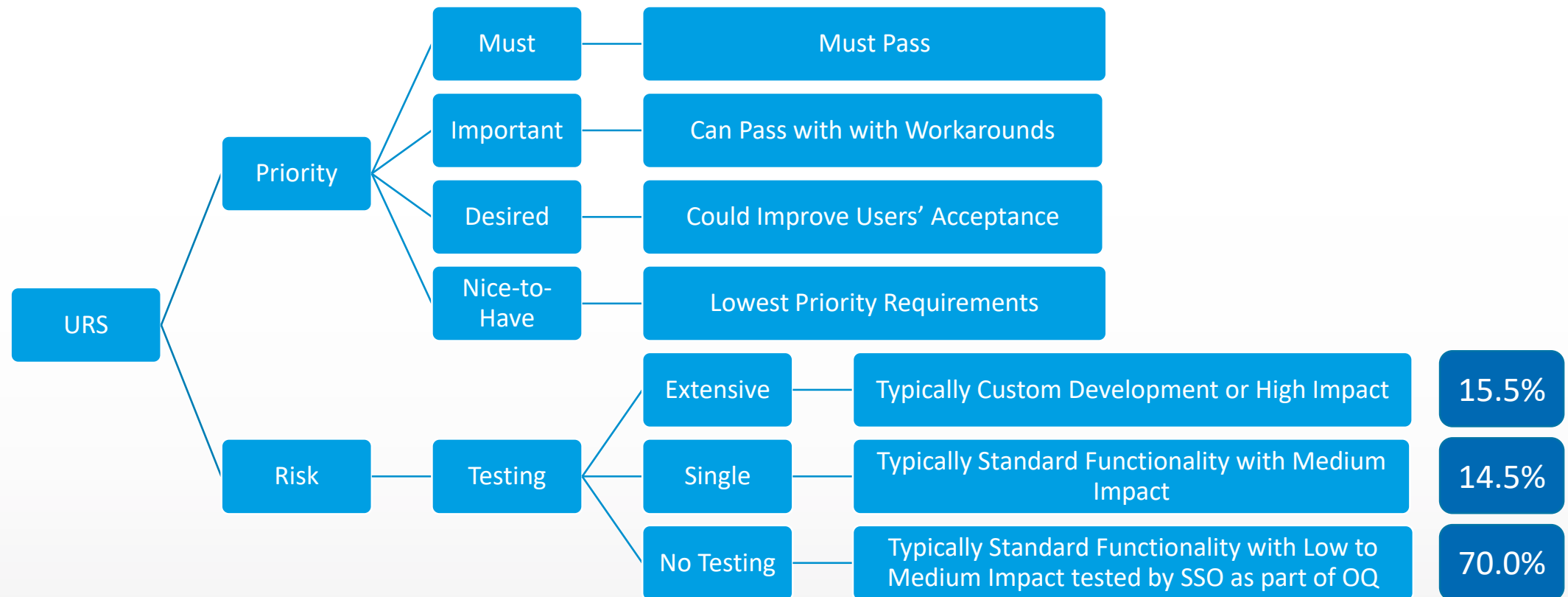
## 2) End-to-end Pilots for 2 different studies



## 3) Make final changes prior to UAT & Training

- Update Access Model & Design Specs
- Update & Re-Test Utilities
- Update Impact Analyses
- Re-run E2E Pilots

# RISK-BASED APPROACH TO TESTING



# AUTOMATION OF TASKS AND USE OF LSAF APIs



# DATA GOVERNANCE

*'Huge leap forward with regard to auditability, process control, and data protection'*

- version control
- e-signing
- Improved lineage
- access management
- audit trail

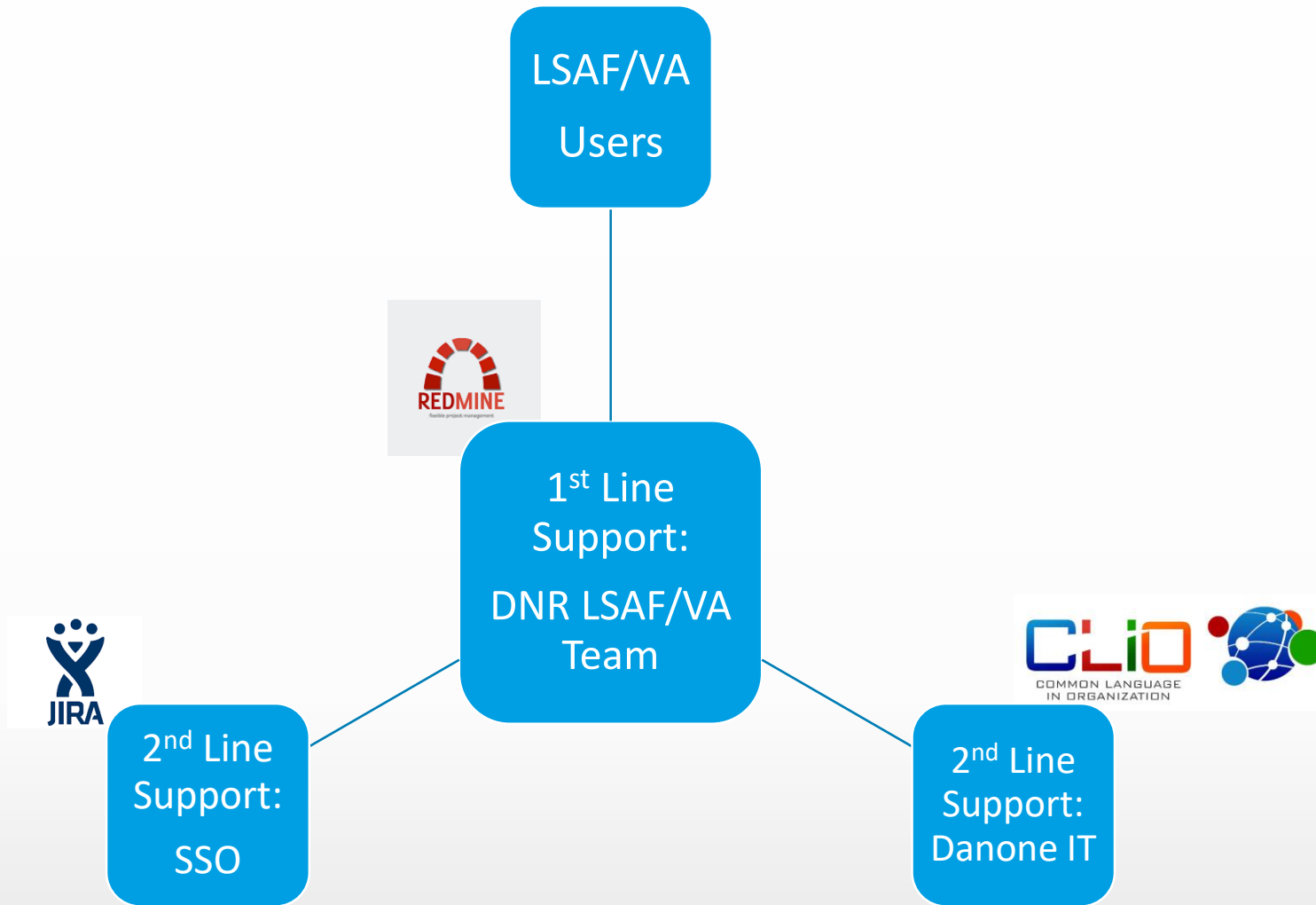
## Audit trail report

| Name                                                                                                                                                                                            | Date      | Time     | LSAF_TopLevel  | ORG_DM         | user1          | user2          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------|----------------|----------------|----------------|----------------|
| Project "StudyXYZ" created on 31MAY2018 07:41:26, #1, Deleted 10SEP2018 09:38:31                                                                                                                |           |          |                |                |                |                |
| MEMBER                                                                                                                                                                                          | 31MAY2018 | 07:41:26 | x-x-x          | x-x-x          | x-x-x          | x-x-x          |
| MEMBER                                                                                                                                                                                          | 31MAY2018 | 07:41:40 | Start [admin1] | x-x-x          | x-x-x          | x-x-x          |
| Project "StudyXYX" recreated 09JAN2019 06:06:10, #2                                                                                                                                             |           |          |                |                |                |                |
| MEMBER                                                                                                                                                                                          | 09JAN2019 | 06:06:10 | x-x-x          | x-x-x          | x-x-x          | x-x-x          |
| MEMBER                                                                                                                                                                                          | 09JAN2019 | 06:06:27 | x-x-x          | x-x-x          | x-x-x          | x-x-x          |
| MEMBER                                                                                                                                                                                          | 09JAN2019 | 06:06:29 | x-x-x          | x-x-x          | Start [admin1] | x-x-x          |
| MEMBER                                                                                                                                                                                          | 10JAN2019 | 10:28:17 | Start [admin2] | x-x-x          |                | x-x-x          |
| MEMBER                                                                                                                                                                                          | 11JAN2019 | 08:54:44 | End [admin2]   | x-x-x          |                | x-x-x          |
| MEMBER                                                                                                                                                                                          | 11JAN2019 | 10:01:41 | xxxxxx         | x-x-x          |                | x-x-x          |
| MEMBER                                                                                                                                                                                          | 11JAN2019 | 13:28:00 | xxxxxx         | x-x-x          |                | x-x-x          |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 07:23:40 | xxxxxx         | x-x-x          |                | x-x-x          |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 07:44:59 | xxxxxx         | Start [admin3] |                | Start [admin3] |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 07:45:14 | xxxxxx         |                | End [admin3]   |                |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 07:49:10 | xxxxxx         |                | xxxxxx         |                |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 08:40:16 | Start [admin3] |                | xxxxxx         |                |
| MEMBER                                                                                                                                                                                          | 28MAR2019 | 08:40:35 |                | End [admin3]   | xxxxxx         |                |
| MEMBER                                                                                                                                                                                          | 03APR2019 | 14:56:15 |                | xxxxxx         | xxxxxx         |                |
| MEMBER                                                                                                                                                                                          | 15APR2019 | 11:56:19 |                | xxxxxx         | xxxxxx         |                |
| Report created at 14MAY2019 09:14, Request path: "/StudyXYZ"                                                                                                                                    |           |          |                |                |                |                |
| <div> <div>&lt; &gt;</div> <div>Current Members</div> <div>MEMBER</div> <div>LSAF_TopLevel</div> <div>ORG_DM</div> <div>DM</div> <div>PI ...</div> <div>+</div> <div>:</div> <div></div> </div> |           |          |                |                |                |                |

| Source                                                                                                                                                                                                        | File name    | Version | E-signed      | User ID | Role associated with | Reason for sign | Comment entered a     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---------|---------------|---------|----------------------|-----------------|-----------------------|
| TASK 1                                                                                                                                                                                                        | 010_ADSL.sas | 1       | 14MAR19:09:29 | user1   | Clinical Programmer  | Approve         | Approved after adapta |
| INPUT                                                                                                                                                                                                         | ae.sas7bdat  |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | an.sas7bdat  |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | chk.sas7bdat |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | dm.sas7bdat  |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | eos.sas7bdat |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | ex.sas7bdat  |         |               |         |                      |                 |                       |
| INPUT                                                                                                                                                                                                         | f.sas7bdat   |         |               |         |                      |                 |                       |
| <div> <div>&lt; &gt;</div> <div>Manifest</div> <div>Job</div> <div>E-Signatures</div> <div>Task(s)</div> <div>Input</div> <div>Output</div> <div>Input Other</div> <div>Log-Listing</div> <div>+</div> </div> |              |         |               |         |                      |                 |                       |

## Manifest report

# SUPPORT PROCESS



## SUPPORT PROCESS FOR:

### Bugs:

- System Unavailability
- Performance Issues
- Data Transfer Issues
- Permission/Privilege Issues
- DNR LSAF Utilities
- Code Issues

### Administration:

- Study Creation Request
- User Access Request
  - Add/Remove Permissions
- Lock/Unlock Accounts
- Lock/Unlock Study Milestones

### New Features:

- New LSAF functionalities
- New Utilities
- New Integration Capabilities

# SUMMARY

- Successful project!
- Success factors: preparations, LSAF expertise, project team
- Connection with Visual Analytics environment made data come alive
- Important benefits realized:
  - Access Control, Traceability of Actions, Standard Folder Structure, Better Data Flow, Better Support
- Next steps: QC process, R, LSAF 5.x



# THANK YOU

## CONTACT INFORMATION

Paul Vervuren  
Danone Nutricia Research  
[paul.vervuren@danone.com](mailto:paul.vervuren@danone.com)  
[www.danone.com](http://www.danone.com)  
[www.nutriciaresearch.com](http://www.nutriciaresearch.com)

Jean-Marc Ferran  
Qualiance ApS  
[jmf@qualiance.dk](mailto:jmf@qualiance.dk)  
[www.qualiance.dk](http://www.qualiance.dk)