



EXPERTISE

SAFETY

SOLUTIONS

## Sofie Stynen

- Clinical Data Manager Coordinator at SGS
- 11 years experience in clinical trials
- Started at Clinical Pharmacology Unit (CPU) as Clinical Trial Assistant
- Things I like: urban exploration, travelling and a combination of those two

WHEN YOU NEED TO BE SURE

SGS



EXPERTISE

SAFETY

SOLUTIONS

# RESOURCE ARISING: CLINICAL DATA AUTOMATION POSSIBILITIES BEYOND DATA CAPTURE

Sofie Stynen – Clinical Data Manager Coordinator, SGS

Annelies Van Zeveren – Project Director Biometrics and Medical Affairs, SGS

Phuse Connect US 2020 – Orlando Florida | March 8th -11th 2020

WHEN YOU NEED TO BE SURE

SGS

## DISCLAIMER AND DISCLOSURES

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the opinions of PhUSE members, respective companies or organizations.*

## AGENDA

- eSource in clinical trials
- Trial set-up in an eSource system
- Conversion to SDTM
- Access to real-time-data
- Query management
- Importance of roles, rights and restrictions
- Future explorations
- Conclusion

## eSource in clinical trials



## INTRODUCTION - ESOURCE IN CLINICAL TRIALS

- Electronic data capture system
- Replaces paper source data
- Digital interface
- (e)CRF no longer needed
- Easy access to real-time data
- eSource integrates data capture, site automation, sample management, data flow facilitation, data visualization and data management

## ESOURCE IN CLINICAL TRIALS

- In 2012 SGS started implementing 1st eSource system
- End-to-end support for 1st eSource system will be terminated
- Search for new system to keep up with complexity of trials and handling of more data
- In September 2019 started with first case study with 2nd eSource system
  - First trial locked in February 2020

- Benefits 1st generation eSource system
  - Eliminates data entry in (e)CRF
  - Easy access to real-time data
  - Set-up library: forms can be re-used
  - Reduces error rate
  - Reduces missing fields
  - Automated barcode drive sample management
  - Data from devices are captured directly
  - Lab data are uploaded into eSource
  - Remote data monitoring
  - Re-use of SDTM annotations and data conversions

### ■ Benefits 1st generation eSource system

- Eliminates data entry in (e)CRF
- Easy access to real-time data
- Set-up library: forms can be re-used
- Reduces error rate
- Reduces missing fields
- Automated barcode driven sample management
- Data from devices are captured directly
- Lab data are uploaded into eSource
- Remote data monitoring
- Re-use of SDTM annotations and data conversions

# ESOURCE IN CLINICAL TRIALS

## ■ eSource user requirements per user group

| Site                                                                                                                                                                              |  |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| <ul style="list-style-type: none"> <li>• Subject recruitment</li> <li>• Trial setup</li> <li>• Data collection</li> <li>• Sample management</li> <li>• Data assessment</li> </ul> |  |  |  |  |

# ESOURCE IN CLINICAL TRIALS

■ eSource user requirements per user group

| Site                                                                                                                                                                              | Data Management                                                                                                                                           |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| <ul style="list-style-type: none"> <li>• Subject recruitment</li> <li>• Trial setup</li> <li>• Data collection</li> <li>• Sample management</li> <li>• Data assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Converting data to SDTM</li> <li>• Cleaning: queries</li> <li>• Create dummy data to setup conversion</li> </ul> |  |  |  |

## ESOURCE IN CLINICAL TRIALS

### ■ eSource user requirements per user group

| Site                                                                                                                                                                              | Data Management                                                                                                                                           | CRA's                                                                                                                                          |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| <ul style="list-style-type: none"> <li>• Subject recruitment</li> <li>• Trial setup</li> <li>• Data collection</li> <li>• Sample management</li> <li>• Data assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Converting data to SDTM</li> <li>• Cleaning: queries</li> <li>• Create dummy data to setup conversion</li> </ul> | <ul style="list-style-type: none"> <li>• Site managment</li> <li>• Source Data verification: queries</li> <li>• View real-time data</li> </ul> |  |  |

## ESOURCE IN CLINICAL TRIALS

### ■ eSource user requirements per user group

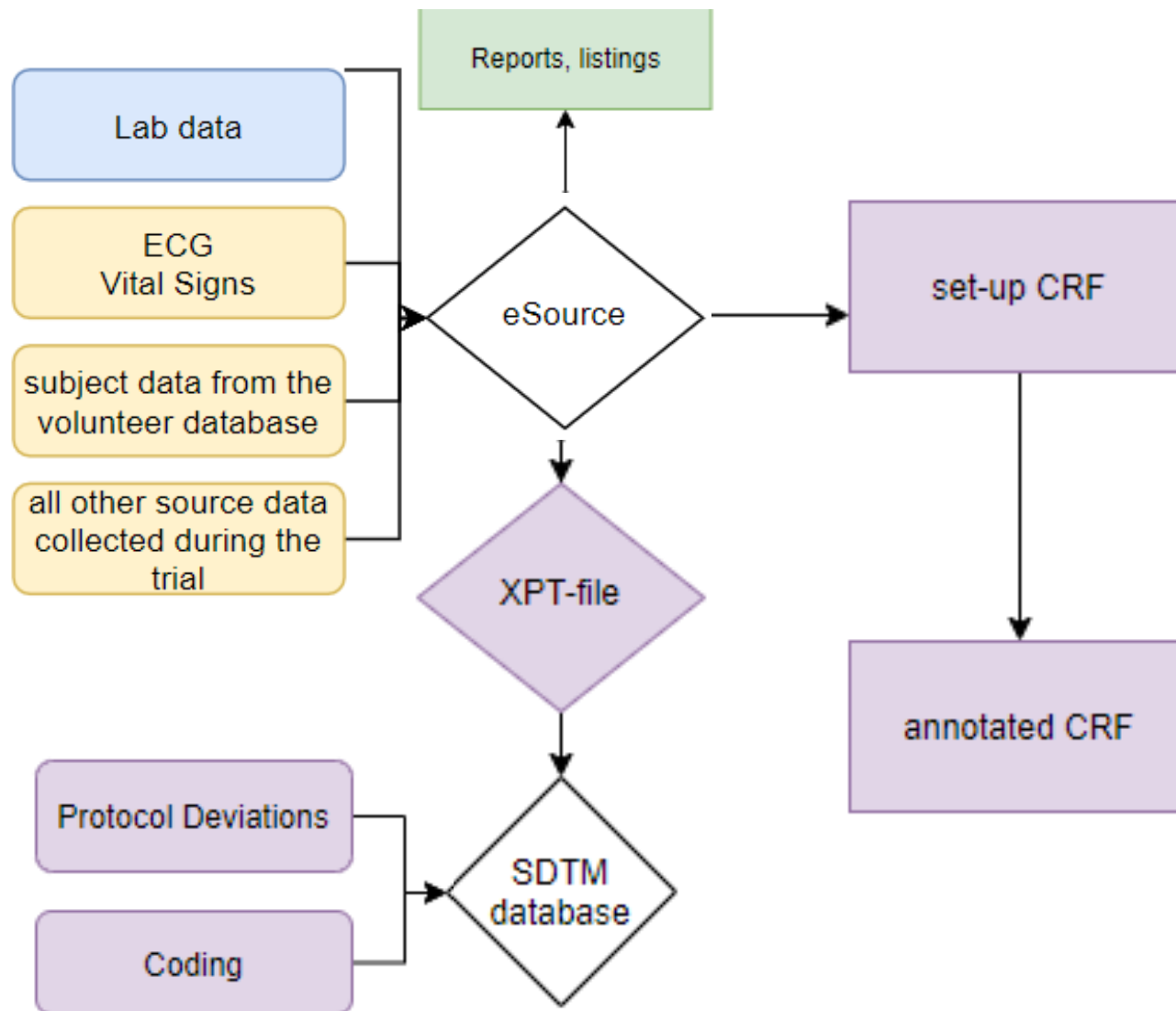
| Site                                                                                                                                                                              | Data Management                                                                                                                                           | CRA's                                                                                                                                           | Medical Monitor                                                                                                       |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--|
| <ul style="list-style-type: none"> <li>• Subject recruitment</li> <li>• Trial setup</li> <li>• Data collection</li> <li>• Sample management</li> <li>• Data assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Converting data to SDTM</li> <li>• Cleaning: queries</li> <li>• Create dummy data to setup conversion</li> </ul> | <ul style="list-style-type: none"> <li>• Site management</li> <li>• Source Data verification: queries</li> <li>• View real-time data</li> </ul> | <ul style="list-style-type: none"> <li>• <b>Medical Monitoring: queries</b></li> <li>• View real-time data</li> </ul> |  |

## ESOURCE IN CLINICAL TRIALS

### ■ eSource user requirements per user group

| Site                                                                                                                                                                              | Data Management                                                                                                                                           | CRA's                                                                                                                                          | Medical Monitor                                                                                                | Client                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Subject recruitment</li> <li>• Trial setup</li> <li>• Data collection</li> <li>• Sample management</li> <li>• Data assessment</li> </ul> | <ul style="list-style-type: none"> <li>• Converting data to SDTM</li> <li>• Cleaning: queries</li> <li>• Create dummy data to setup conversion</li> </ul> | <ul style="list-style-type: none"> <li>• Site managment</li> <li>• Source Data verification: queries</li> <li>• View real-time data</li> </ul> | <ul style="list-style-type: none"> <li>• Medical Monitoring: queries</li> <li>• View real-time data</li> </ul> | <ul style="list-style-type: none"> <li>• <b>Trial overview: dashboards</b></li> <li>• View real-time data</li> </ul> |

## E-SOURCE IN CLINICAL TRIALS



## Trial set-up in an eSource system



## TRIAL SET-UP IN AN ESOURCE SYSTEM



- Set-up eSource by dedicated Clinical Pharmacology Unit (CPU) staff
- Set-up CRF (sCRF) → data to be captured in SDTM
  - Time and Event Schedule
  - Forms

### 1st eSource system

External software solution program:

Updates eSource  
→ sCRF and subject CRF template to be updated

### 2nd eSource system

CRFs extracted from within eSource system:

Updates eSource  
→ Automatically updated in sCRF and subject CRF

## Blood (screening)

|       | Name                               | Result | Unit | Normal Range | Sex    |
|-------|------------------------------------|--------|------|--------------|--------|
|       | Alanine Transferase (ALT, GPT)     |        |      |              | Both   |
|       | Albumin                            |        |      |              | Both   |
| BLO   | Alkaline Phosphatase               |        |      |              | Both   |
| LB_B  | Aspartaat transferase (AST, GOT)   |        |      |              | Both   |
|       | Basophils (%)                      |        |      |              | Both   |
|       | Basophils                          |        |      |              | Both   |
|       | Blood Urea Nitrogen (BUN)          |        |      |              | Both   |
| LB_ST | CK-MB Mass                         |        |      |              | Both   |
|       | Calcium                            |        |      |              | Both   |
|       | Calcium Corrected for albumin      |        |      |              | Both   |
|       | Chloride                           |        |      |              | Both   |
| LB_RE | Cholesterol                        |        |      |              | Both   |
|       | Creatinin Kinase (CK)              |        |      |              | Both   |
|       | Creatinine                         |        |      |              | Both   |
|       | Direct Bilirubin                   |        |      |              | Both   |
| LB_FA | Eosinophils (%)                    |        |      |              | Both   |
|       | Eosinophils                        |        |      |              | Both   |
|       | Follicle Stimulating Hormone (FSH) |        |      |              | Female |
|       | Gamma Glutamyltransferase (GGT)    |        |      |              | Both   |
|       | Glucose                            |        |      |              | Both   |
| LB_SA | HDL-Cholesterol                    |        |      |              | Both   |
|       | HIV 1/2 anti body                  |        |      |              | Both   |
|       | Hematocrit                         |        |      |              | Both   |
|       | Hemoglobin                         |        |      |              | Both   |
|       | Hepatitis B surface Antigen        |        |      |              | Both   |
|       | Hepatitis C virus Antibody         |        |      |              | Both   |
|       | Indirect Bilirubin                 |        |      |              | Both   |

gin: CRF

main: LB

Variable name  
in XPT-fileFormat  
restriction

H:mm:ss

SCREENING  
ationPanel  
attached  
with tests  
to be  
performed

2<sup>nd</sup> eSource system:

- Set-up: easier to review
- Inefficiencies detected during setup-phase
- Coding lists were added: more standardized data
- Variable names → aligned to SDTM



Conversion to SDTM



**LBREASND**

Conditionally Visible

## LBFAST

### Conditionally Visible

**LBDTC**

*Requires Barcode Verification*



## CONVERSION TO SDTM

domains in extract  
from 2nd eSource  
system

|                     |                             |                          |                      |
|---------------------|-----------------------------|--------------------------|----------------------|
| LPS_AE              | VWDATAEVENT_SGS             | VWLIBRARYSAMPLETYPE      | VWSETUPSTUDYPART     |
| LPS_AE_QUES         | VWDATAFORMANSWER            | VWLIBRARYTEST            | VWSETUPSUBJECT       |
| LPS_CM              | VWDATAFORMLINK              | VWLIBRARYVESSELTYPE      | VWSETUPTEST          |
| LPS_CM_MISSING      | VWDATAOBSERVATIONMEDICATION | VWSCHEDULEEVENT          | VWSETUPTREATMENT     |
| LPS_COMMENTS_TRANS  | VWDATAPARTICIPANT           | VWSCHEDULEGROUP          | VWSETUPTREATMENTSEQU |
| LPS_DM              | VWDATAPARTICIPANTADDDLEMO   | VWSCHEDULEPANEL          |                      |
| LPS_DMEXTRA         | VWDATAPARTICIPANTHISTORY    | VWSCHEDULETEST_SGS       |                      |
| LPS_EVENTS          | VWDATAPARTICIPANT_SGS       | VWSCHEDULEVOLUNTEERSTUDY |                      |
| LPS_IE              | VWDATAQUERY                 | VWSETUPCANDIDATE         |                      |
| LPS_METADATA        | VWDATA TESTRESULT           | VWSETUPCANDIDATESUBJECT  |                      |
| LPS_MH              | VWDATA TESTRESULT2          | VWSETUPCLINICALVISIT     |                      |
| LPS_PK_UNSCH        | VWLIBRARYCODELIST           | VWSETUPEVENT             |                      |
| LPS_QUES            | VWLIBRARYCOMMENT            | VWSETUPEVENTPANEL        |                      |
| LPS_SV              | VWLIBRARYEVENTCATEGORY      | VWSETUPEVENTPLAN         |                      |
| LPS_TESTS           | VWLIBRARYFACILITY           | VWSETUPFORM              |                      |
| LPS_TESTS_TRANS     | VWLIBRARYFORM               | VWSETUPFORMQUESTION      |                      |
| VWCTSTUDYSEQUENCES  | VWLIBRARYFORMQUESTION       | VWSETUPGROUP             |                      |
| VWCTSTUDYTREATMENTS | VWLIBRARYINSTRUMENT         | VWSETUPPANEL             |                      |
| VWDATAADVERSEFORM   | VWLIBRARYMEDICALTERM        | VWSETUPSEQUENCE          |                      |
| VWDATACHANGELOG_SGS | VWLIBRARYPANEL              | VWSETUPSTUDY             |                      |
| VWDATAEVENT         | VWLIBRARYREASON             | VWSETUPSTUDYCODELIST     |                      |

domains in extra  
from 1st eSource  
system

AE  
CM  
DM  
DS  
EC  
EG  
IE  
LAB\_DATA  
LB  
MH  
ML  
PC  
PE  
PM  
SU  
SUPPE  
VS  
X1

AE\_SAS SUPPLB\_SAS  
CM\_SAS SUPPE\_SAS  
CO\_SAS SUPPVS\_SAS  
DM\_SAS SU\_SAS  
DS\_SAS SV\_SAS  
DV\_SAS TA\_SAS  
EC\_SAS TE\_SAS  
EG\_SAS TI\_SAS  
EX\_SAS TS\_SAS  
IE\_SAS TV\_SAS  
LB\_SAS VS\_SAS  
MH\_SAS X1\_SAS  
ML\_SAS ZR\_SAS  
PC\_SAS  
PE\_SAS  
RELREC\_SAS  
SE\_SAS  
SUPPAE\_SAS  
SUPPCM\_SAS  
SUPPDM\_SAS  
SUPPDS\_SAS  
SUPPEG\_SAS

domains in  
SDTM  
database

## CONVERSION TO SDTM

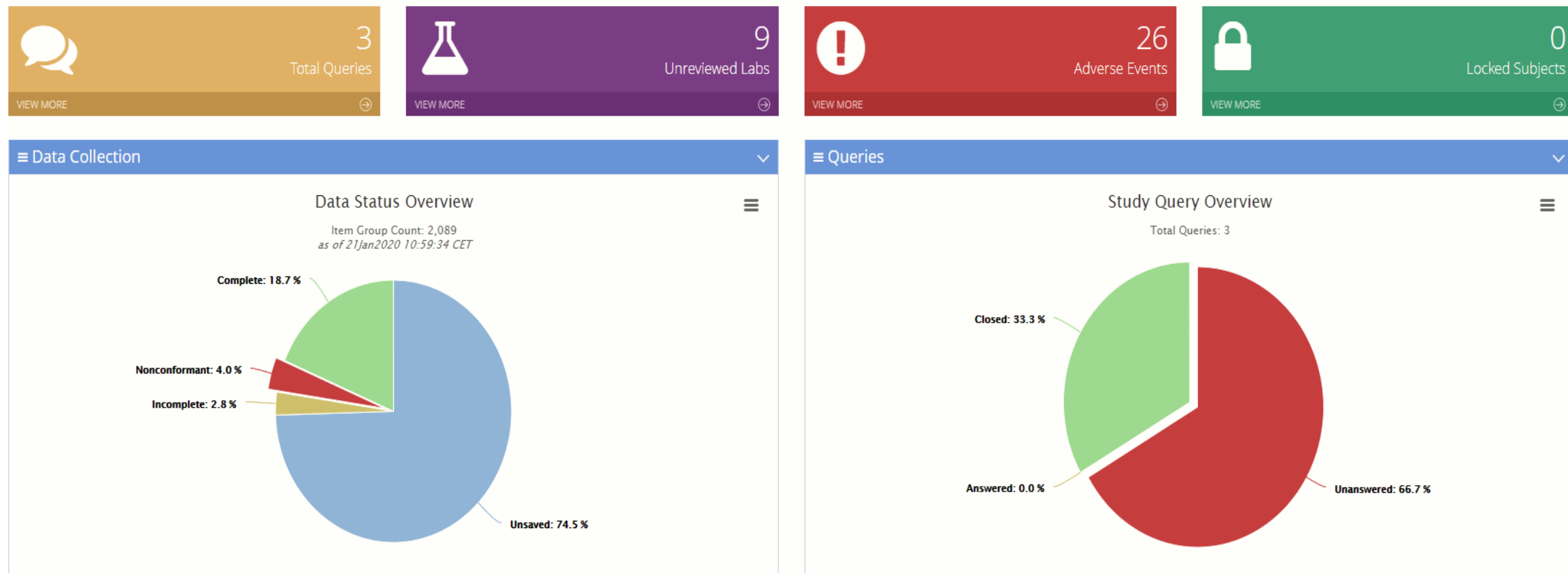
- Conversion is set up by using test data
- 2 environments: MAIN and TEST

| 1st eSource system                            | 2nd eSource system                                                                                      |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Test data entered in main environment by site | Test data entered in test environment by data management<br><br>→ Easier in case of protocol amendments |

## Access to real-time-data



Dashboard visualizing study progress and status



Reports

Results



### Clinical Data

Generate reports encapsulating clinical data. If no fields are chosen, all will be included.

Subject(s)

Study Event(s)

Form(s)

\* ADVERSE EVENT / CONCOMITANT MEDICATION

Data Status

All ▼

narrow to item groups with status

Show Item Name?

Name ▼

Display Item name or Item prompt.

Output Type

Excel ▼

Generate ➞

Query management



| 1st eSource system at CPU                                        | 2nd eSource system at CPU                     |
|------------------------------------------------------------------|-----------------------------------------------|
| Different views (modules) for query creators and query resolvers | Same view for all                             |
| Not user-friendly, slow                                          | User friendly, fast                           |
| Interference DM needed for Medical Review-queries                | Medical monitor can easily create own queries |
| Elaborate GRD (Global Rulings Document) needed                   | Limited GRD                                   |

## The importance of roles, rights and restrictions



## THE IMPORTANCE OF ROLES, RIGHTS AND RESTRICTIONS

- General Data Protection Regulation (GDPR)
- Main and test environment allow for different roles, rights and restrictions
  - possibility for DM to enter dummy data in test
  - subject data only available in main environment
  - no personal data can be exposed

Future explorations





- Recruitment
  - reach large groups of subjects from within eSource system
- Provide data access for blinded trials
- Coding module
- Capture all subject data electronically (questionnaires, diaries)
  - ePro (electronic patient reporting outcome)
  - eSource module accessible for subjects

## 33



## CONCLUSION

- 2nd generation eSource system
  - More reusable forms
  - More standard data
  - Better alignment to SDTM
  - Work is facilitated for all user groups
- Challenges ahead
  - Explore boundaries eSource system
  - Reduce timelines in setup, conversion to SDTM and data cleaning
  - Explore possibilities for future improvement



# ADVANCED **CLINICAL** **RESEARCH** SOLUTIONS

LIFE INSPIRED, QUALITY DRIVEN

## CONTACT **US**



[clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)



EUROPE: +32 15 27 32 45  
AMERICAS: +1 877 677 2667



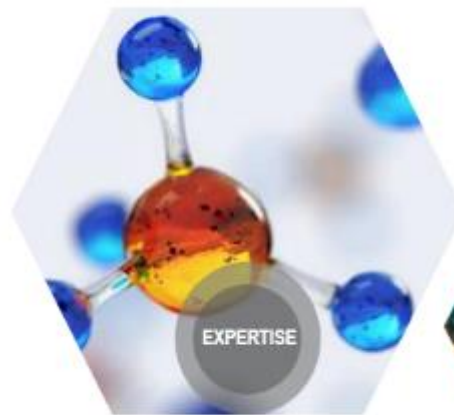
[www.sgs.com/cro](http://www.sgs.com/cro)

JOIN US at the **SGS BOOTH 31**



JOIN THE **SCIENTIFIC** COMMUNITY

Discover R&D market news and events  
[www.sgs.com/LinkedIn-Life](http://www.sgs.com/LinkedIn-Life)



**WWW.SGS.COM**

**WHEN YOU NEED TO BE SURE**

**SGS**