



EXPERTISE

SAFETY

SOLUTIONS

DH05: eSource Arising: Clinical Data Automation Possibilities Beyond Data Capture

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WHEN YOU NEED TO BE SURE

SGS

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- 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

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



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ESOURCE IN CLINICAL TRIALS

- eSource user requirements per user group



Site				
• Subject recruitment • Trial setup • Data collection • Sample management • Data assessment				

ESOURCE IN CLINICAL TRIALS



- eSource user requirements per user group

Site	Data Management			
• Subject recruitment • Trial setup • Data collection • Sample management • Data assessment	• Converting data to SDTM • Cleaning: queries • Create dummy data to setup conversion			

ESOURCE IN CLINICAL TRIALS

■ eSource user requirements per user group



Site	Data Management	CRA's		
• Subject recruitment • Trial setup • Data collection • Sample management • Data assessment	• Converting data to SDTM • Cleaning: queries • Create dummy data to setup conversion	• Site managment • Source Data verification: queries • View real-time data		

ESOURCE IN CLINICAL TRIALS

■ eSource user requirements per user group



Site	Data Management	CRA's	Medical Monitor	
• Subject recruitment • Trial setup • Data collection • Sample management • Data assessment	• Converting data to SDTM • Cleaning: queries • Create dummy data to setup conversion	• Site managment • Source Data verification: queries • View real-time data	• Medical Monitoring: queries • View real-time data	

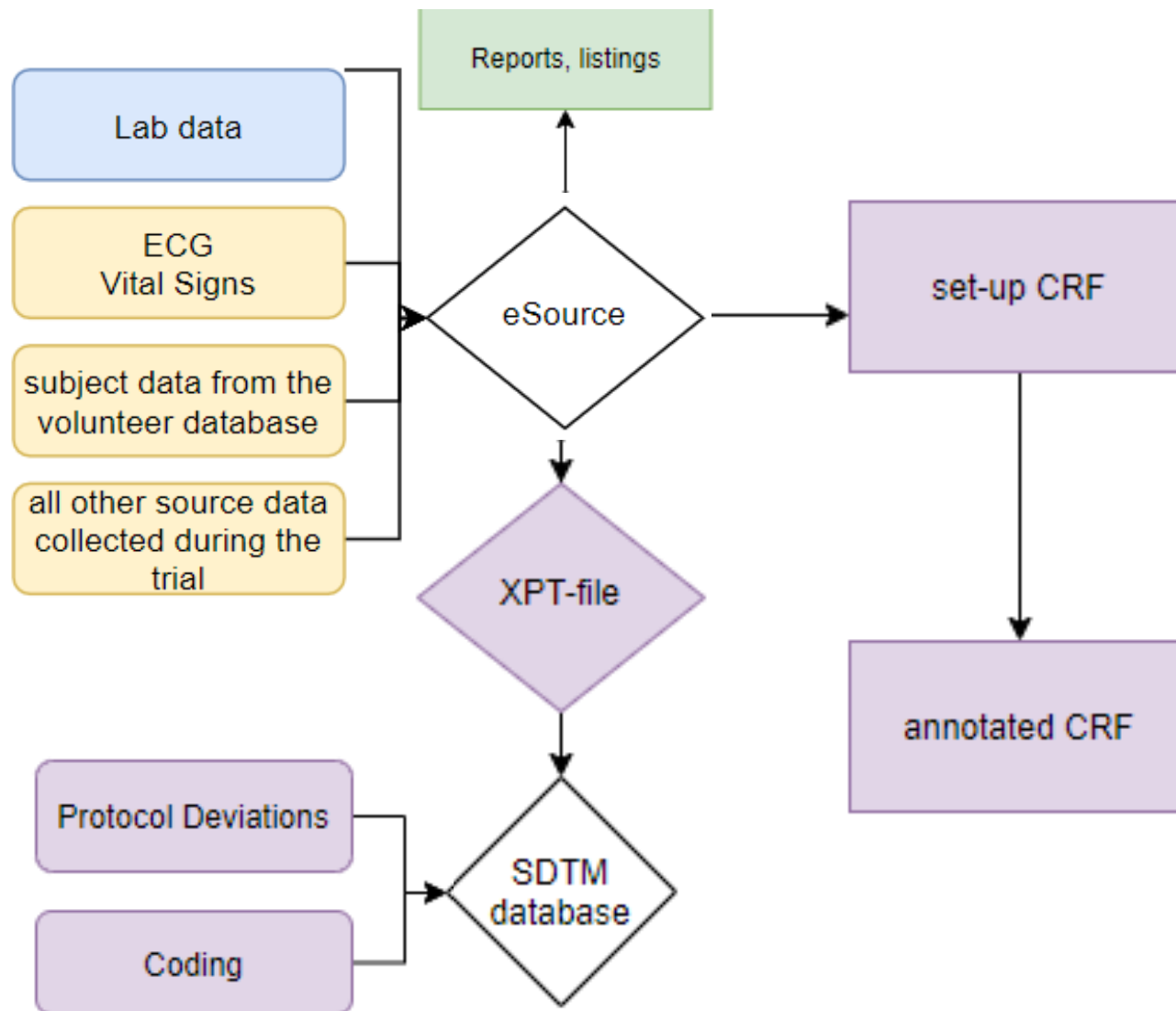
ESOURCE IN CLINICAL TRIALS

■ eSource user requirements per user group



Site	Data Management	CRA's	Medical Monitor	Client
• Subject recruitment • Trial setup • Data collection • Sample management • Data assessment	• Converting data to SDTM • Cleaning: queries • Create dummy data to setup conversion	• Site managment • Source Data verification: queries • View real-time data	• Medical Monitoring: queries • View real-time data	• Trial overview: dashboards • View real-time data

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-file

Format
restriction

Panel
attached
with tests
to be
performed

TRIAL SET-UP IN AN ESOURCE SYSTEM

2nd eSource system:

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



eSource

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



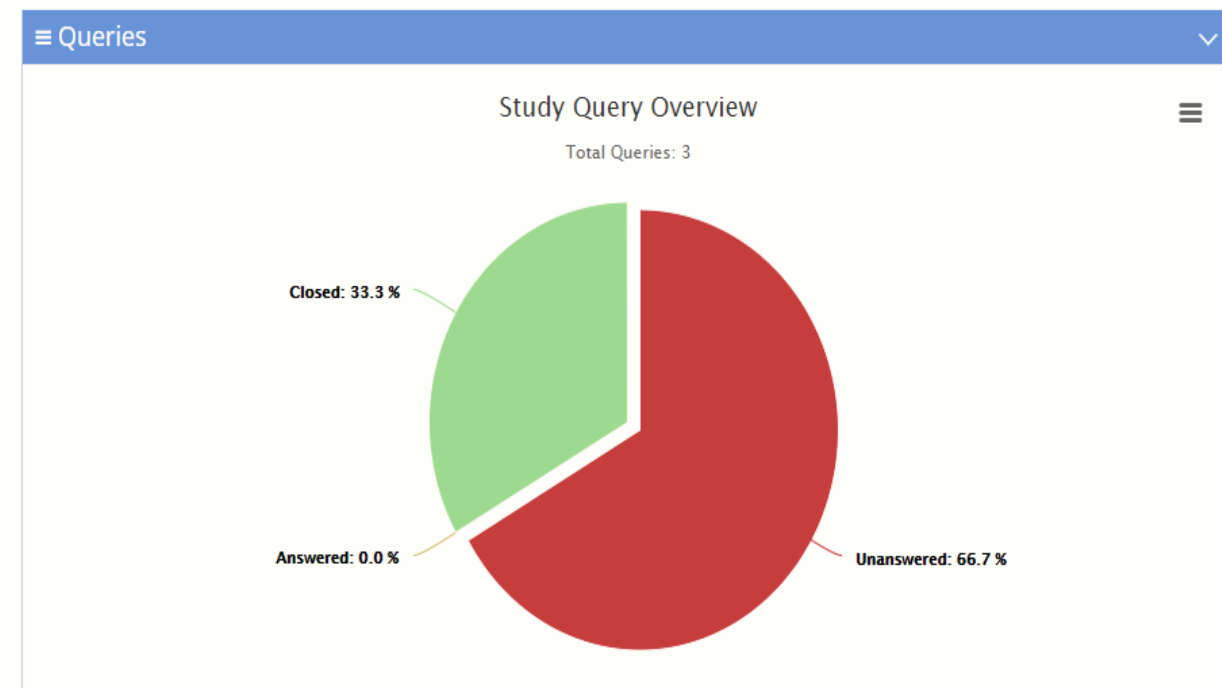
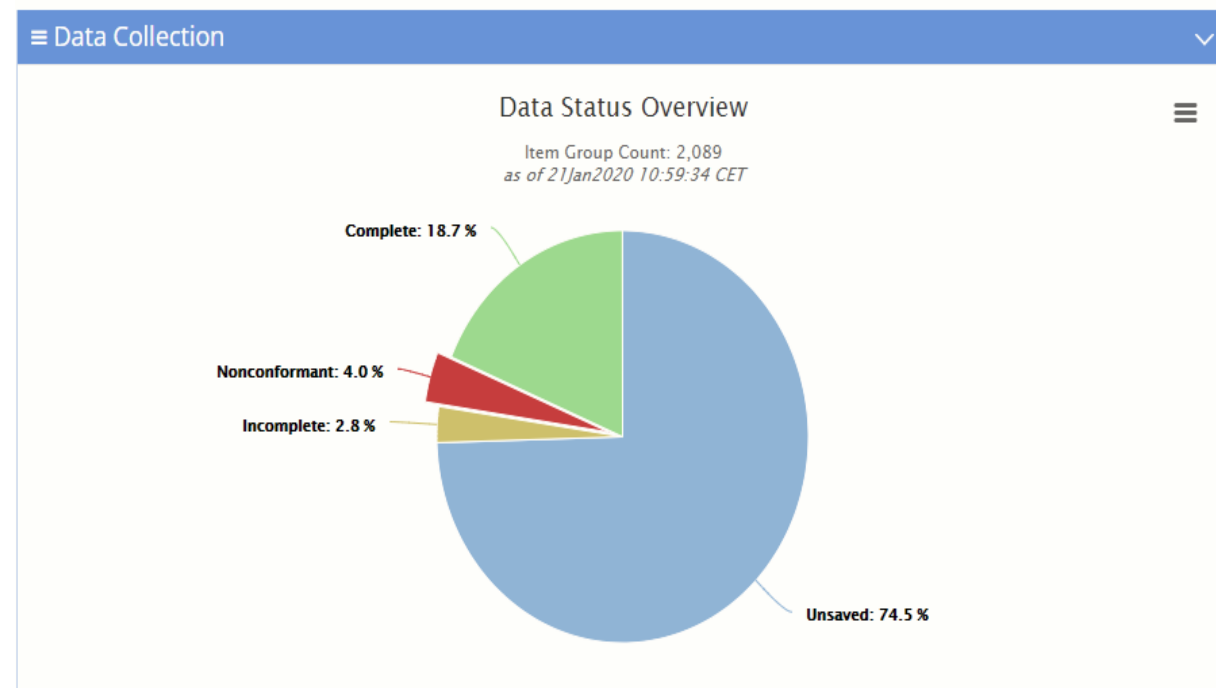
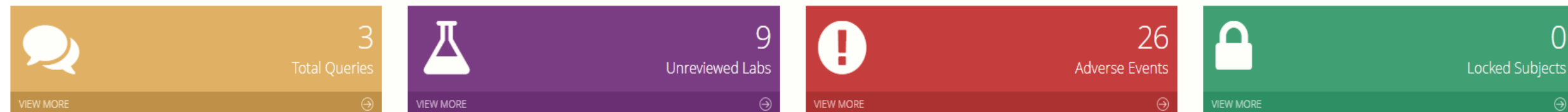
- Conversion is set up by using test data
- 2 environments: MAIN and TEST

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

eSource

Access to real-time-data

Dashboard visualizing study progress and status



Reporting exporting study data

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)

Data Status

narrow to item groups with status

Show Item Name?

Display Item name or Item prompt.

Output Type

Generate ↗

eSource

Query management



1 st eSource system at CPU	2 nd 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



eSource

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



eSource

Future explorations

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



eSource

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





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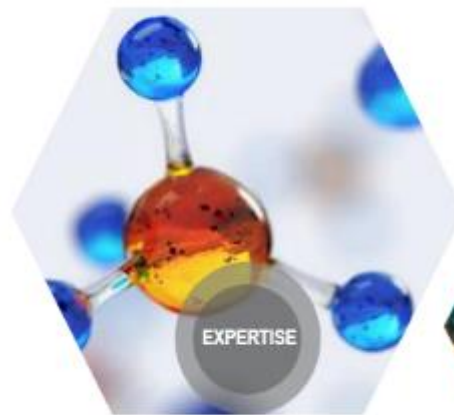
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