

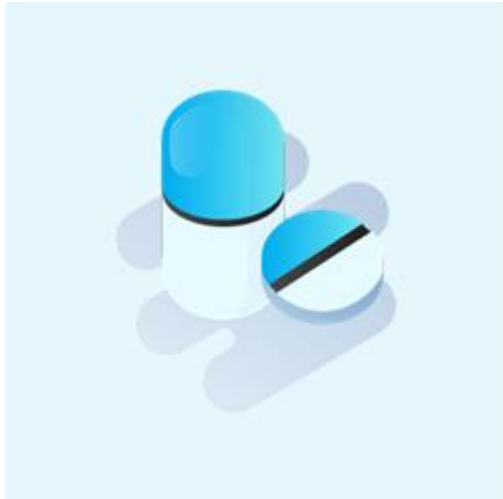


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YOUR Platform | YOUR Way

## Anju Adaptive Life Sciences Platform

Anju Clinical Suite



Anju Medical Affairs Suite



Anju Data Suite



YOUR Platform | YOUR Way

# The eClinical Product Suite



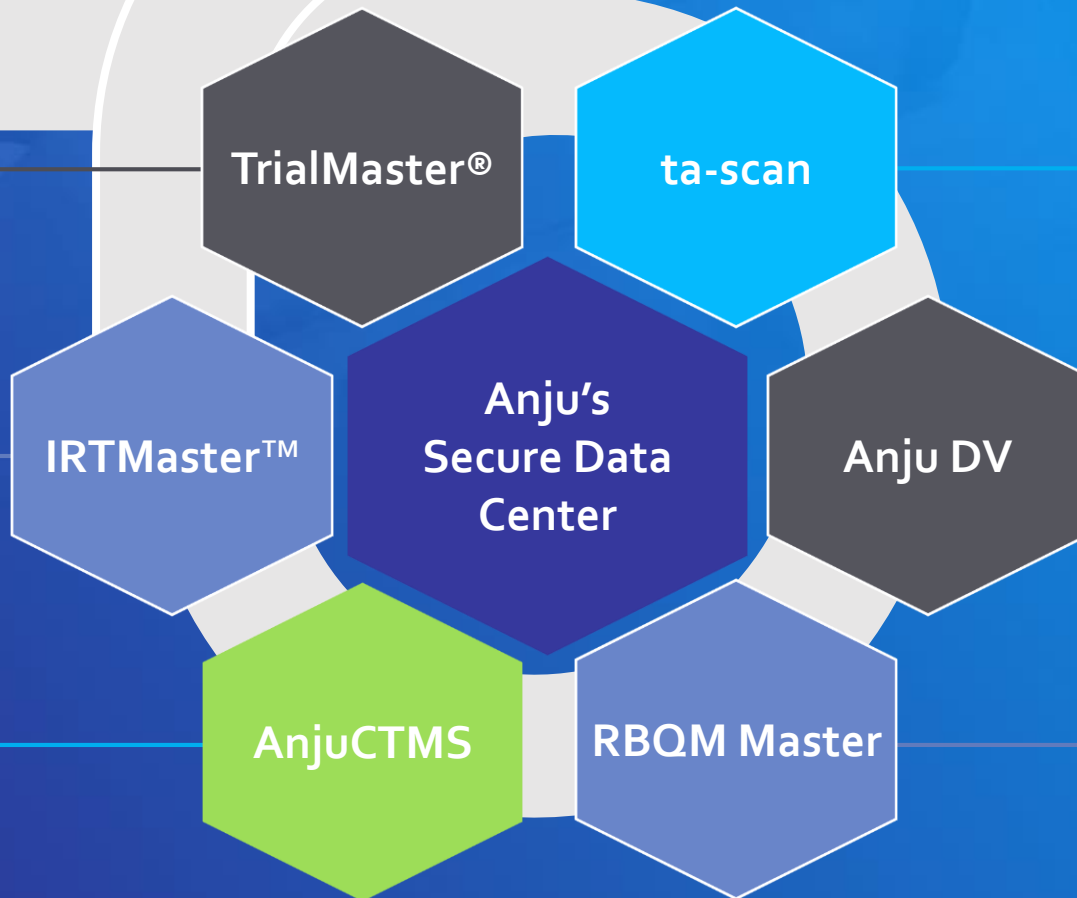
INNOVATION | QUALITY | PRODUCTIVITY | SCALABILITY

*Expanding the borders of clinical data*

- EDC with built-in ePRO
- Direct SDTM export, reporting tools
- Dynamic Monitoring
- Autoencoder data dictionaries

- Randomization and supplies management
- Support for adaptive trials
- Study build through UI

- Document tracking with eTMF,
- Event tracking SVR toolkit,
- Finance module, inventory tracking, protocol deviations, issues, SAEs



- Market Intelligence
- KOL identification
- Feasibility reports
- Payment information

- Data analytics & visualizations
- Study risk management and monitoring
- Cross-study reporting

- Closed loop risk management
- Study risk management and monitoring
- Integrated reports and insights



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# SDTM Automation in EDC system

20 May 2021



# AGENDA

- Case Introduction
- Programming of SDTM data within EDC system - Benefits
- Programming of SDTM data within EDC system - Challenges
- Conclusion



#Data #DataDriven  
#DataStrategy #DataIntegration  
#DataViz #DataStandards  
#DataScience #Datagovernance  
#HealthCare #DataAnalysis  
#ClinicalTrials  
#ArtificialIntelligence  
#AdvancedAnalytics  
#MachineLearning #Digital  
#Chatbot #Biometrics #CRO  
#ClinicalData  
#LifeSciencesExperts  
#Whodrug #MedDRA  
#Pharmacovigilance  
#ClinicalResearchLifeCycle  
#MedicalWriting  
#MedicalInformation  
#MedicalReview #SDTM  
#ADaM #CDISC #Innovation  
#RegulatorySubmissions  
#Protocol #Coding

# CASE INTRODUCTION

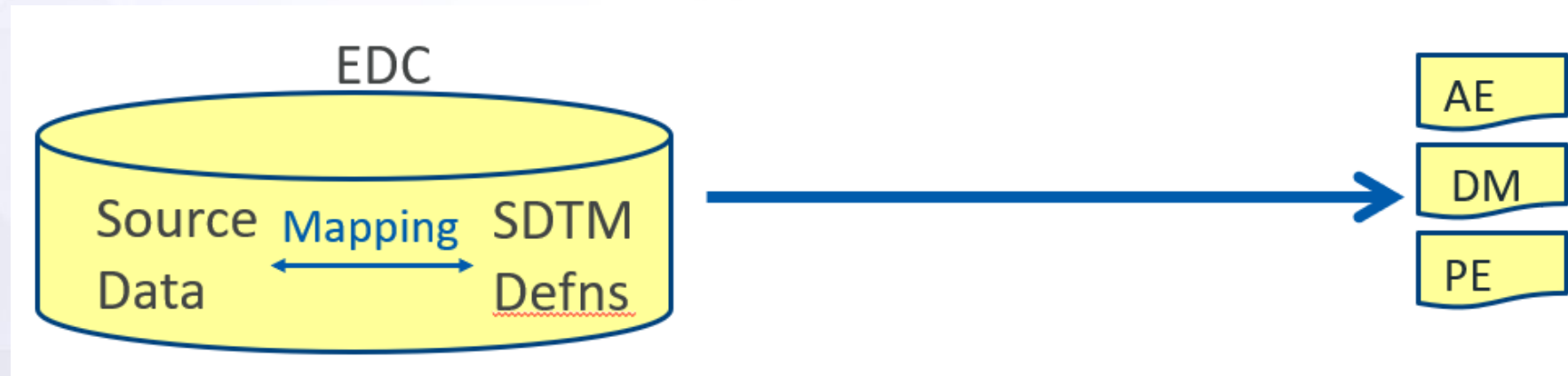
- Biometrics Study → from database build to statistical analysis
- SDTM data required for:
  - Data Monitoring - Visualization dashboards
  - SDTM Data available as quick as possible for different DSMB, SRC, and all other meetings
  - SDTM data available as quick as possible for statistical team for statistical analysis



SDTM build module available in Anju TrialMaster EDC

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM

- Training from Anju team + Certificate
- Programming done within a specific SDTM Module, using export template available
- Standard templates are available for all SDTM domains for programming
- The latest available mapping template is following the SDTMIG V3.2
- There is also the possibility to import standards library (if available) in ODM format
- SDTM Programming is done in parallel with study set-up, so SDTM Data can be available from the FPFV.





# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM

- Create a new Export Template:

The screenshot illustrates the steps to create a new export template in the EDC system. It shows three main windows:

- Export Templates Manager:** A table listing existing templates. The 'DOSING' template is highlighted. Below the table are buttons for 'Duplicate', 'New', 'Edit', 'Delete', 'Edit Mapping', and 'Rebuild All'. The 'New' button is circled in blue.
- Choose Standard:** A dialog box for selecting a standard. The 'SDTM 3.2' standard is selected in the dropdown menu and circled in blue. Below the dropdown is a list of aliases and descriptions, all of which are checked. At the bottom, the 'OK' button is circled in blue.
- Selected Domains:** A window for selecting domains. It has a table with columns for 'Domain Name', 'Alias', 'Type', and 'Items'. Below the table are buttons for 'Add All Forms', 'Add User Defined Domain', 'Add Standard Domains', 'Add All Groups', 'Delete', 'Save', 'Cancel', 'Next >', and 'Help'. The 'Add Standard Domains' button is circled in blue.

Red arrows indicate the flow of the process: from the 'Export Templates...' menu item in the 'TrialBuilder' window to the 'New' button in the 'Export Templates Manager' window, then to the 'Add Standard Domains' button in the 'Selected Domains' window, and finally to the 'OK' button in the 'Choose Standard' dialog box.

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – EXPORT TEMPLATE MODULE

Domain columns: SDTM.Laboratory Test Results-LB

**DataSources**

Trial: [REDACTED]

Object Hierarchy:

- TRIAL
  - SITE
    - Metric Data
    - Export Templates

**Columns**

Alias	Expression	Property	Type	Length	Format	Label
STUDYID	[STUDYID]	Expression	char			Study Identifier
DOMAIN	'LB'	Expression	char			Domain Abbreviation
USUBJID	[USUBJID]	Expression	char			Unique Subject Identifier
LBSEQ	SEQ_NUMBER(PARTITI...	Expression	num	8	8	Sequence Number
LBTESTCD	[LBTESTCD]	Expression	char			Lab Test or Examination Short Name
LBTEST	[LBTEST]	Expression	char			Lab Test or Examination Name
LBCAT	[LBCAT]	Expression	char			Category for Lab Test
LBORRES	[LBORRES]	Expression	char			Result or Finding in Original Units
LBORRESU	[LBORRESU]	Expression	char			Original Units
LBORNRO	case when [LBSTAT]...	Expression	char			Reference Range Lower Limit in Orig Unit
LBORNRI	case when [LBSTAT]...	Expression	char			Reference Range Upper Limit in Orig Unit
LBSTRESC	case when [LBCAT]=...	Expression	char			Character Result/Finding in Std Format
LBSTRESN	case when [LBCAT]=...	Expression	num	8	8	Numeric Result/Finding in Standard Units
LBSTRESU	[LBSTRESU]	Expression	char			Standard Units
LBSTNRLO	case when [LBCAT]=...	Expression	num	8	8	Reference Range Lower Limit-Std Units
LBSTNRHI	case when [LBCAT]=...	Expression	num	8	8	Reference Range Upper Limit-Std Units

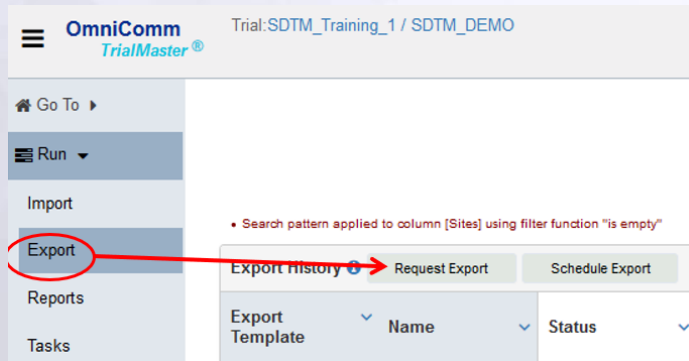
Add Delete Add Union Up Down Required Expected

Data Source	Alias
[Template][SDTM 3.2 Export Template][dataLB][LBSTNRLO]	LBSTNRLO
[Template][SDTM 3.2 Export Template][dataLB][LBCAT]	LBCAT
[Template][SDTM 3.2 Export Template][dataLB][USUBJID]	USUBJID
[Template][SDTM 3.2 Export Template][dataLB][VISIT]	VISIT
[Template][SDTM 3.2 Export Template][dataLB][LBORNRO]	LBORNRO
[Template][SDTM 3.2 Export Template][dataLB][LBTESTCD]	LBTESTCD
[Template][SDTM 3.2 Export Template][dataLB][LBORRESU]	LBORRESU

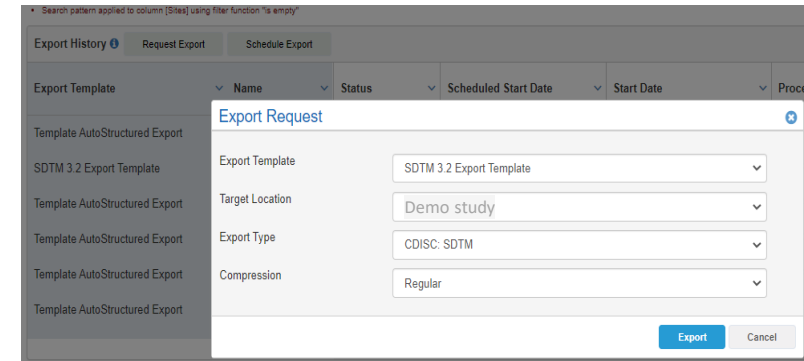
Rebuild View SQL OK Save Help

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS

- Easy to use for end-users
- How to extract your data in SDTM:
  - Request an export



wait for .... few minutes



Export Template	Name	Status
SDTM Export	Run once at 7/6/...	Completed



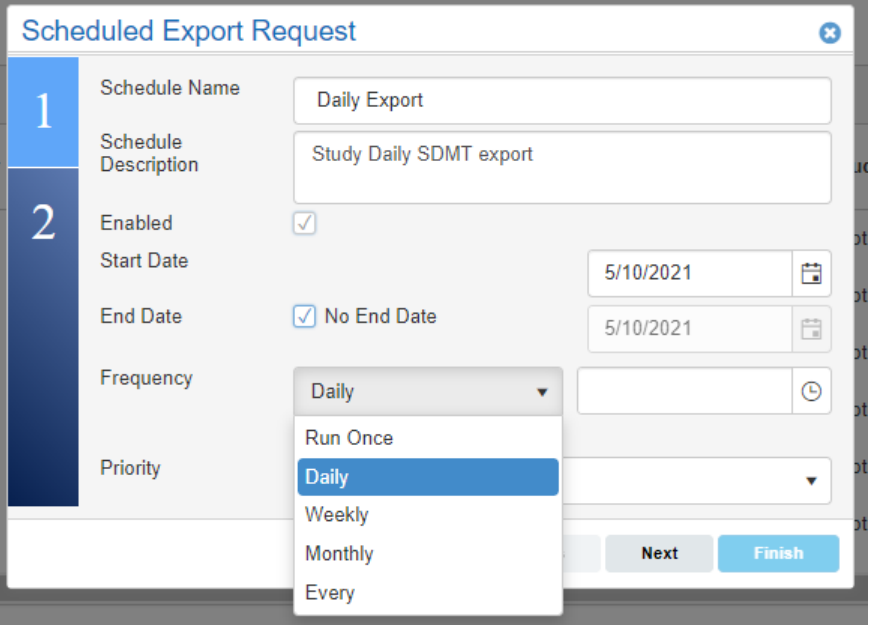
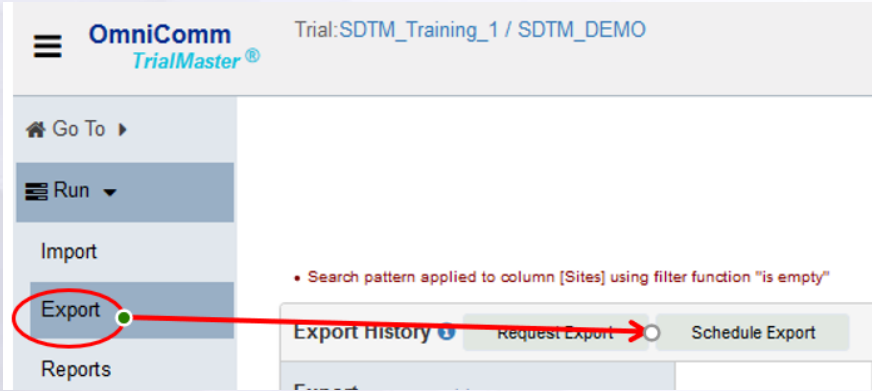
download a zip file (in .xpt format)



_SDTM_3.2_Export_Template_CDISC_SDTM_2021_04_07_14_41.zip					
Name	Type	Compressed size	Password protected	Size	Ratio
Errors	File folder				
ae.xpt	XPT File	38 KB	Yes	409 KB	91%
ce.xpt	XPT File	10 KB	Yes	114 KB	92%
cm.xpt	XPT File	65 KB	Yes	942 KB	94%

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS

- SDTM Data can also be exported on demand by the end user or by scheduling tasks to run on the server at a predetermined time and frequency

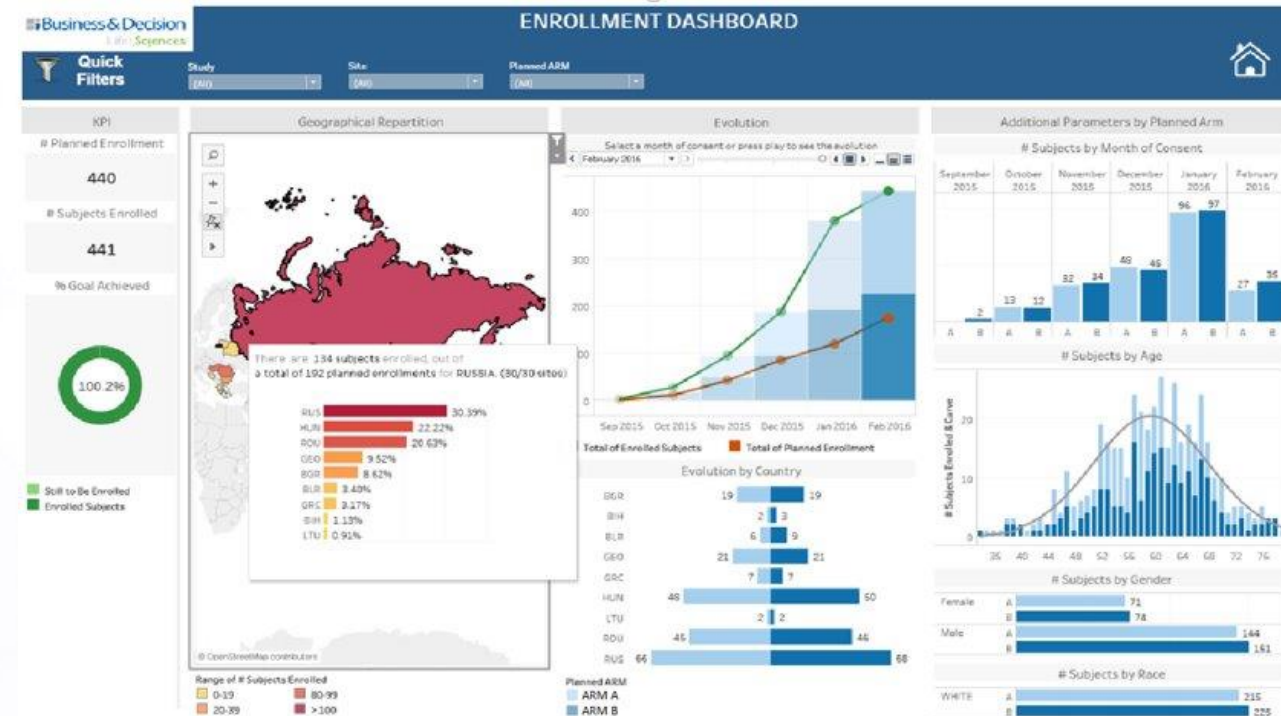
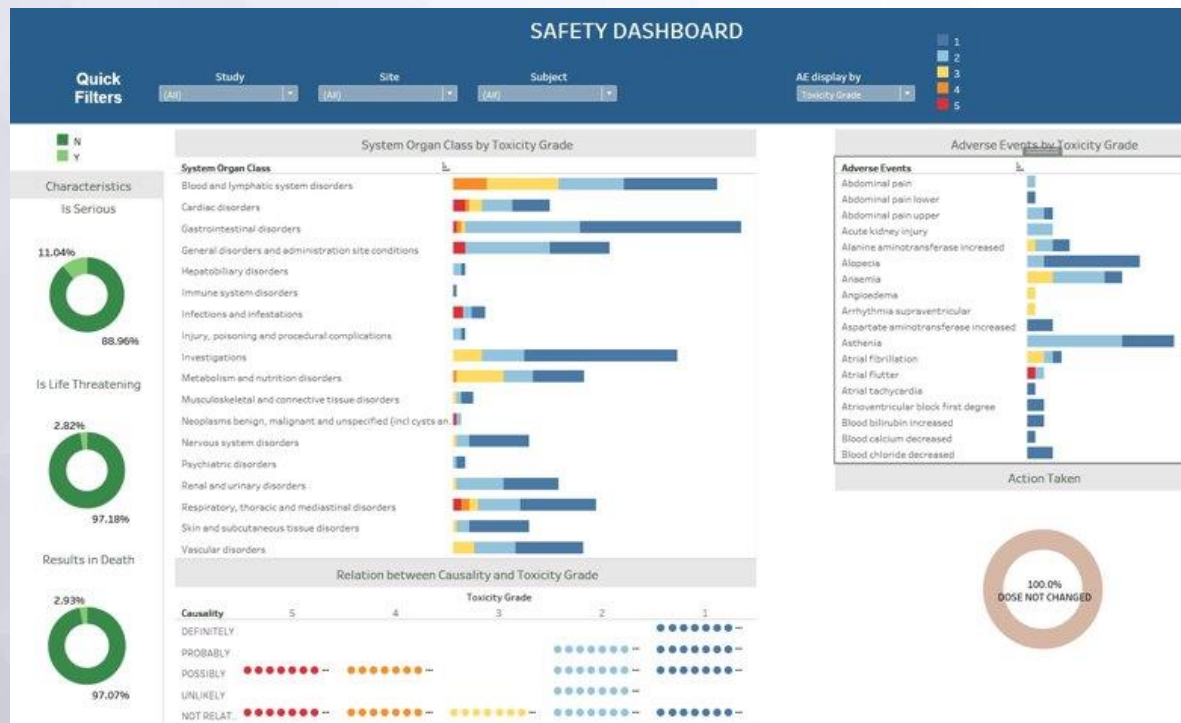


Scheduled Exports ⓘ	
<input type="checkbox"/> Name ↑	Owner
<input type="checkbox"/> Daily Export	pyouinou
<input type="checkbox"/> Run once at 8/19/2020 7:23:48 AM RT	sjonas

Delete

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM - BENEFITS (I)

- Real time SDTM extraction allows building Data Visualization dashboards enabling data monitoring in real time. NOTE: Visualization Dashboards are created outside EDC system by BDLs team using Tableau



# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – BENEFITS (II) – PATIENT PROFILE

Business & Decision Life Sciences

Select a subject to view the Patient Profile

STUDY-AB01/1102/11

Current Selection : STUDY-AB01/1102/11

Subject's Characteristics

Site	Age	Race	Sex	Arm
1102	54	WHITE	♂	ACTIVE DRUG

Baseline Characteristics

Characteristic	Value	Unit
Weight	73.0	kg
Height	175.0	cm
Body Surface Area	1.9	m <sup>2</sup>
Body Mass Index	23.8	kg/m <sup>2</sup>
ECOG	Grade 1	

Disposition

Event	Date
Randomization date	2016-02-01
Discontinuation date	
Discontinuation reason	
Completion date	2016-02-22

Reproductive Status

Not applicable

Substance use

Substance	Frequency
ALCOHOL	OCCASIONALLY
TOBACCO	DAILY

Cancer History

Location	Start Date	Time since Diagnosis
LUNG AND RESPIRATORY TRACT - ADENOCARCINOMA G3	2015-09-22	132 Days
EXTENT AT STUDY ENTRY	PRIMARY	

Medical History

Medical Condition	Body system or Organ Class	Ongoing at treatment start
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	✓
Coronary artery disease	Cardiac disorders	✓
Duodenitis	Gastrointestinal disorders	✓
Hypertension	Vascular disorders	✓
Myocardial Ischaemia	Cardiac disorders	✓

Subject ID Filter: 125-01

Calendar view for 2016 (January and February)

Exposure: 2016-02-01 to 2016-02-22

Adverse Events encountered:

- ATRIAL FLUTTER
- DIARRHEA
- GGT INCREASED
- HYPOKALAEMIA
- HYPOKALAEMIA
- HYPOKALAEMIA
- HYPONATREMIA
- HYPONATREMIA
- IMPAIRED RENAL FUNCTION
- IMPAIRED RENAL FUNCTION
- LEUCOCYTOPENIA
- NEUTROPENIA
- TACHYCARDIA
- THROMBOCYTOPENIA

Chemotherapy Medication given:

- CISPLATIN
- DOCETAXEL
- FLUOROURACIL

ECG test results

Label view: Short code

ECG Test	Result
EGHRMN	✓
EGHRSI	✓
INIP	✓
PRAG	✓
PRSB	✓
QRSAG	✓
QRSSB	✓
QTAG	✓
OTCBAG	✓

Business & Decision Life Sciences

Search for Subjects: 125-01

Site: 125

Arm: Treatment A

Age: 71

Sex: ♂

Race: WHITE

Current Selection : 125-01

Subject ID Filter: 125-01

Calendar view for 2016 (January and February)

Exposure: 2016-02-01 to 2016-02-22

Adverse Events encountered:

- ATRIAL FLUTTER
- DIARRHEA
- GGT INCREASED
- HYPOKALAEMIA
- HYPOKALAEMIA
- HYPONATREMIA
- HYPONATREMIA
- IMPAIRED RENAL FUNCTION
- IMPAIRED RENAL FUNCTION
- LEUCOCYTOPENIA
- NEUTROPENIA
- TACHYCARDIA
- THROMBOCYTOPENIA

Chemotherapy Medication given:

- CISPLATIN
- DOCETAXEL
- FLUOROURACIL

Color legend for toxicity grade of adverse event (if any occurred):

- #Males: 1 (Blue), 2 (Green), 3 (Yellow), 4 (Orange)

Randomization date: 2016-01-19

Discontinuation date: 2016-02-09

Discontinuation reason: 1 FINGER HYPERPLASIA OF THE LIVER

Completion date: 2016-02-09

Abnormalities in Physical Examination

Abdomen: 1 FINGER HYPERPLASIA OF THE LIVER

Head, Eyes, ...: INCOMPLETE DENTITION, THE RIGHT BE...

Neck: ON THE RIGHT SIDE BEHIND THE ANGUL...

Substance use

ALCOHOL: REGULARLY

TOBACCO: DAILY

Medical History

Pair and Concomitant Medical History

Squamous cell carcinoma of the... Neoplasms benign, malignant and unspecified (incl cysts an...

Extent at Study Entry: PRIMARY

Cancer History

Blood Urea Nitrogen

Calcium

Chloride

Creatine Kinase

Creatinine

Creatinine Clearance

Eosinophils

Eosinophils/Total Cells

Erythrocytes

Musculoskeletal

8 February 2016

Blood Urea Nitrogen (BUN) had a value of 9.5 mmol/L

Normal values ranges between 3.2 mmol/L and 8.2 mmol/L

9.500

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – BENEFITS (III)

- SDTM data available for STAT immediately (or at any moment in time) and for data review meetings (IDMC, DSMB, SRC, etc.)
- Possibility to program external data that are integrated and/or uploaded data in TrialMaster (Questionnaires, IWRS, Lab Ranges, etc.) to be converted into SDTM automatically → part of the vendor issues are solved
- No additional time needed for data conversion for Submission, shorten the time for final analysis

# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – CHALLENGES

Mostly from programming point of view:

- Good knowledge of the system and good programming skills are required



- Very good knowledge of SDTM is required as SDTM template contains issues (missing variables, sorting, etc.). In case SDTM template is to be corrected, it is managed by Anju team via scripts → time consuming

Example: Domain SV is missing EPOCH variable

- Only one Clinical Database Administrator / Programmer can work on the export template module at the time → time consuming



# PROGRAMMING OF SDTM DATA WITHIN EDC SYSTEM – CHALLENGES

- After the study GO LIVE, any update in SDTM domains implies a Mid Study Change which require deployment by Anju team (in UAT and production environments).
- Anju SDTM Module experts are based in US only → time-zone difference to be taken into account when you have a question or issue



Time consuming

# CONCLUSION

- Beneficial and useful solution to help in review / monitoring of your data in real time. It allows to have your data in SDTM at any moment in time during the course of your study.
- It's quite challenging to set-up, so it needs careful consideration before the start of the project:
  - Need careful understanding at the beginning of the project of all analyses to be performed during the course of your study.
  - All planned meetings (e.g. DSMB, SRC, IDMC, etc.) where your SDTM & ADaM outputs are required quickly and within short timelines should be taken into account as well.
- In case only a mid-project/interim analysis & DBL is planned, a standard conversion process outside the EDC system can be sufficient.



THANK YOU FOR YOUR ATTENTION  
**Q&A**