



XbiomTM :

Enabling Data Integration for Translational & Precision Medicine

PointCross Life Sciences

Serving the Life Sciences industry since 2009



CORPORATE OFFICE's:
Foster City – California, USA
Silver Spring – Maryland, USA
France – Paris
Bangalore – India

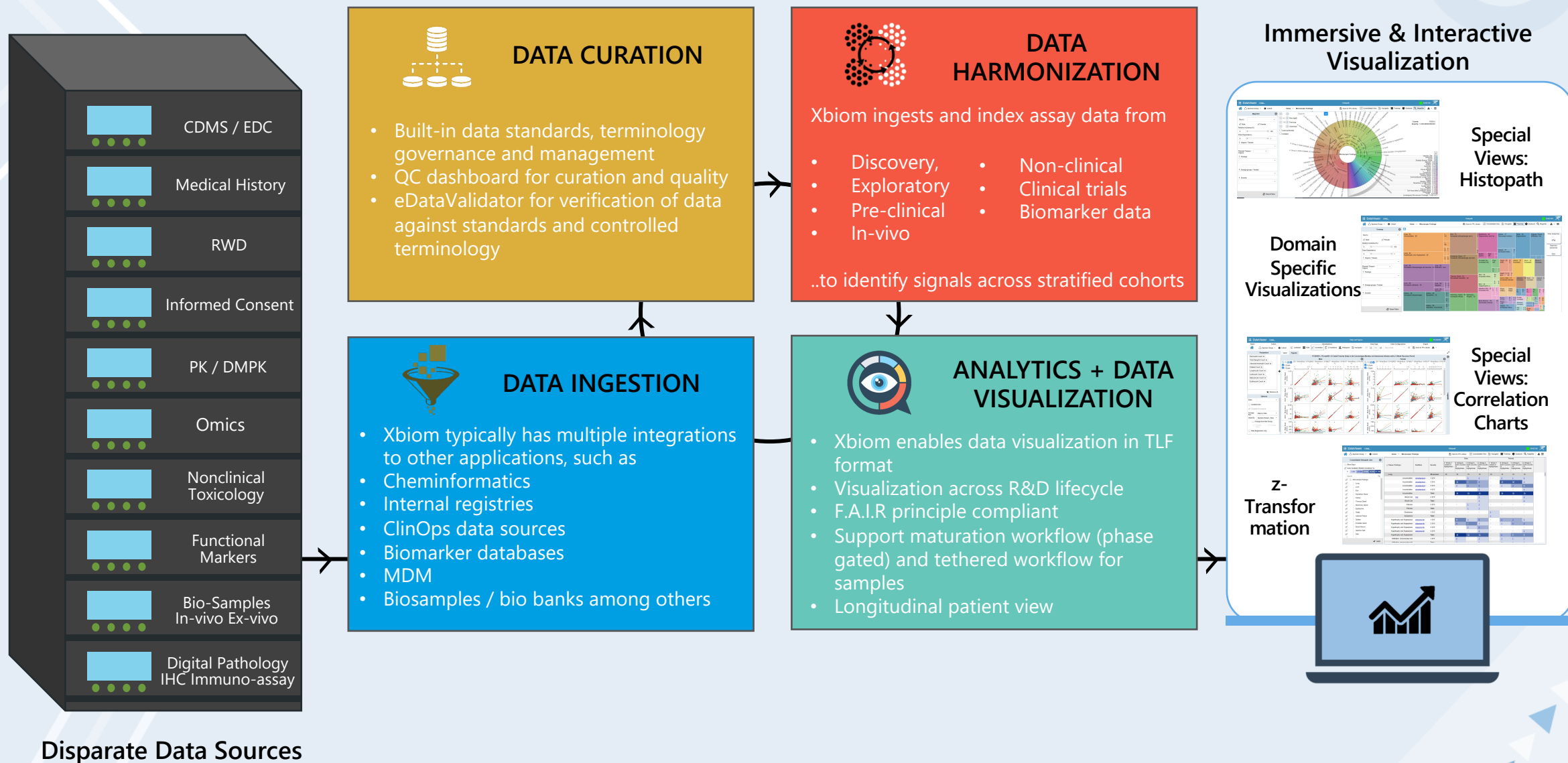
Xbiom is our BioPharma solutions platform for:

- Research insights from nonclinical and clinical studies, assays, biomarkers
- Validated workflows for regulatory nonclinical and clinical submission preparation
- Automated Smart Transformation for data curation from data lakes to target model
- Governance and management of standards, terminology, metadata

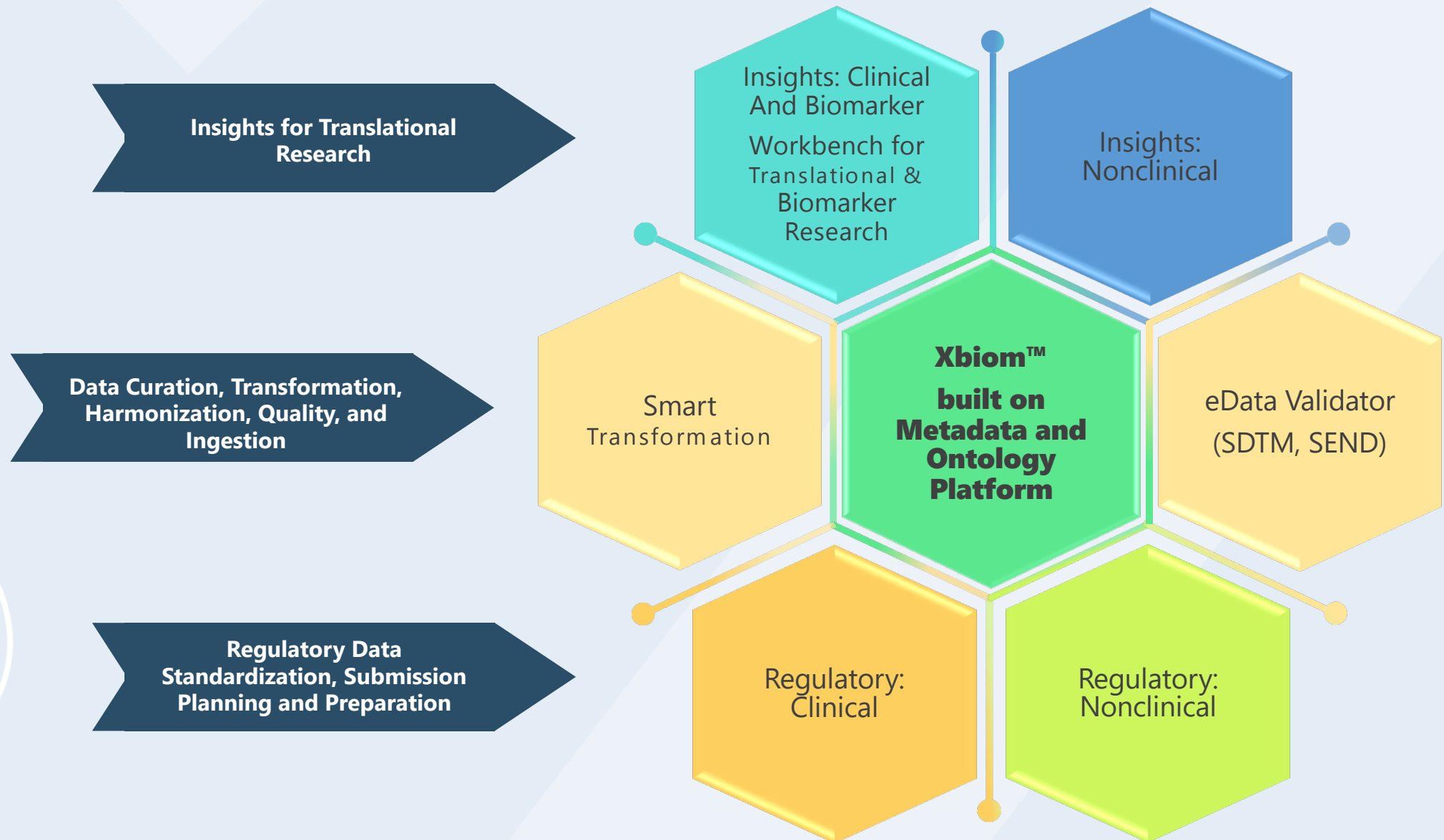


Platinum member of CDISC and contributor to PhUSE

Xbiom: Makes Data Useful



Xbiom™ Suite for Research & Regulatory in Clinical & Nonclinical



What does

Smart Transformation Generate?

Xbiom Smart Transformation provides comprehensive capabilities to ingest source data by mapping and transforming to target models, harmonize terminologies and unit systems, perform data QC and make data available for Search, Aggregation, Analytics and Visualization through Xbiom UDM (integrated data hub with modelled structured data).

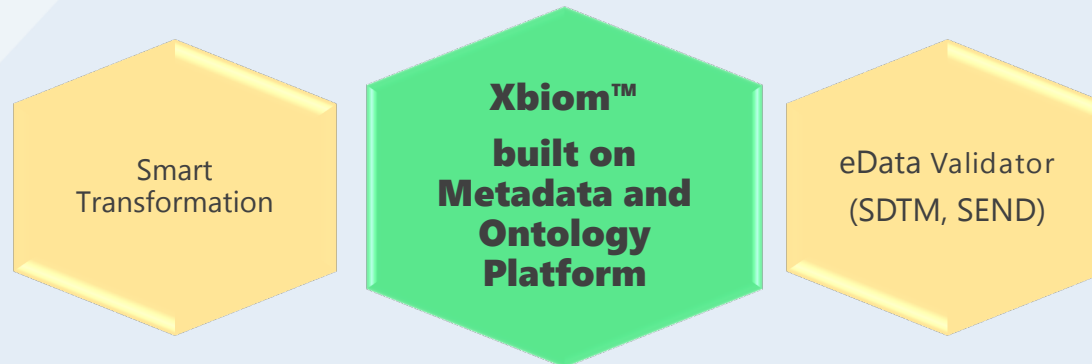
01 Generate a Universal Data Model (UDM) that is flat, simplified, and easily indexed for search; representable as a graphed linked object (RDF, OWL) for use in SPARQL queries, and inference engines

02 Generate a Standard Data Model (SDM) of user's choice for exchange, access by legacy scripted queries (SDTM, ADaM, SEND, Corporate custom standards such as Research Trust DB)

03 Smart Transformation transforms Raw, Fragmented, Non-Standard data to a standard accessible, exploitable form.

04 Regenerate UDM data in Xbiom repository back into any standard SDM – reuse, flexible, repurpose and drive the change in industry

Data Concierge Service: Value for Biotech



The Value from Business Perspective

We are agile – our team includes

- **Bioinformaticians**
- **Molecular Biochemists**
- **Data Scientists**
- **IT Architects and Operations**
- **Physicians**
- **Board Certified Toxicologist**

We are not an IT software and services company

The Value from Science Perspective

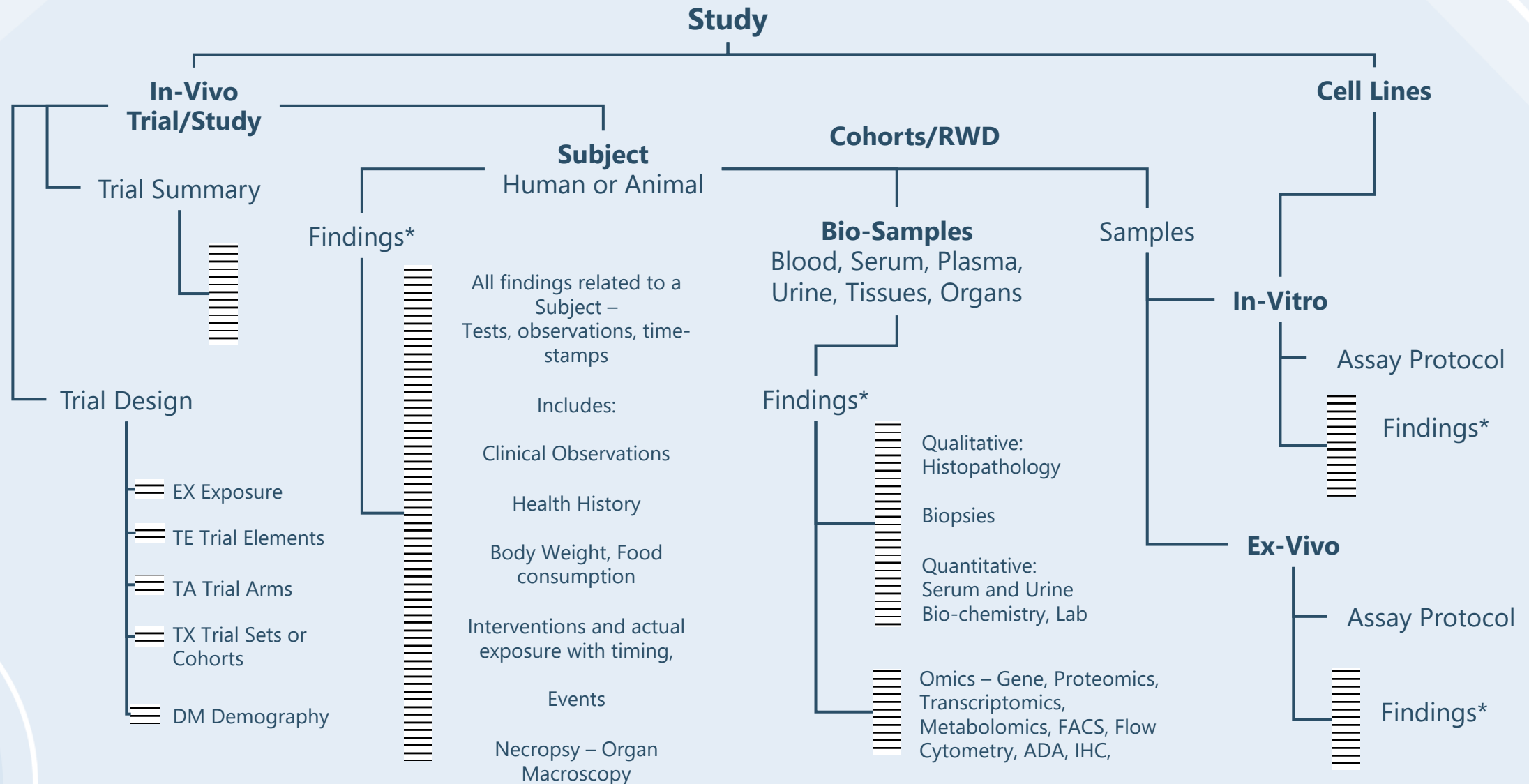
- **Integrate source data from CROs + labs**
 - **Standardize and harmonize source data into analysis-ready data**
 - **Search + select stratified cohorts**
 - **Identify data gaps and sample availability for assays**
- **Augments Biotech's data science to Translational teams**

Normalized Omics data types in Xbiom Ontology

OMICS	Measurement	Measurement Types	Assays, Technologies, Methods	Data Vendors	Reference Dictionaries	Current Biomarker Counts
Genomics	Genetic Variation	Short Variant	DNA Targeted Sequencing, Digital PCR	Foundation Medicines; Sysmex Inostics; Applied Biosystems	NCBI Gene Info, COSMIC	59,670**
		Copy Number Alteration				
		Rearrangements				
Transcriptomics	Sequencing	Targeted RNA Sequencing	Targeted RNA Sequencing	Illumina	NCBI Gene Info	59,670**
	Expression	Gene Expression; Targeted mRNA expression	Microarray, Nanostring	AltheaDx; NanoString Technologies	NCBI Gene Info	
		miRNA expression	qRT-PCR	Covance	miRBase	2,656 (miRNA)
		*Targeted mRNA detection	In situ Hybridization			
Proteomics	Expression	Expression of Proteins	Immunohistochemistry	Mosaic Laboratories	UniProt (SwissProt)	563,972
	Concentration	Concentration of Proteins	Immunoassay, ELISA, Multiplex Assay	Myriad RBM		
	Immune cells Population	*Cell Sorting (Cluster of Differentiation) Cell surface proteins	Flow cytometry			
Metabolomics	Concentration	Concentration of Metabolites	Liquid Chromatography-Mass Spectrometry	BIOCRATES Life Sciences AG	Human Metabolome Database (HMDB)	114,260 (Metabolites)

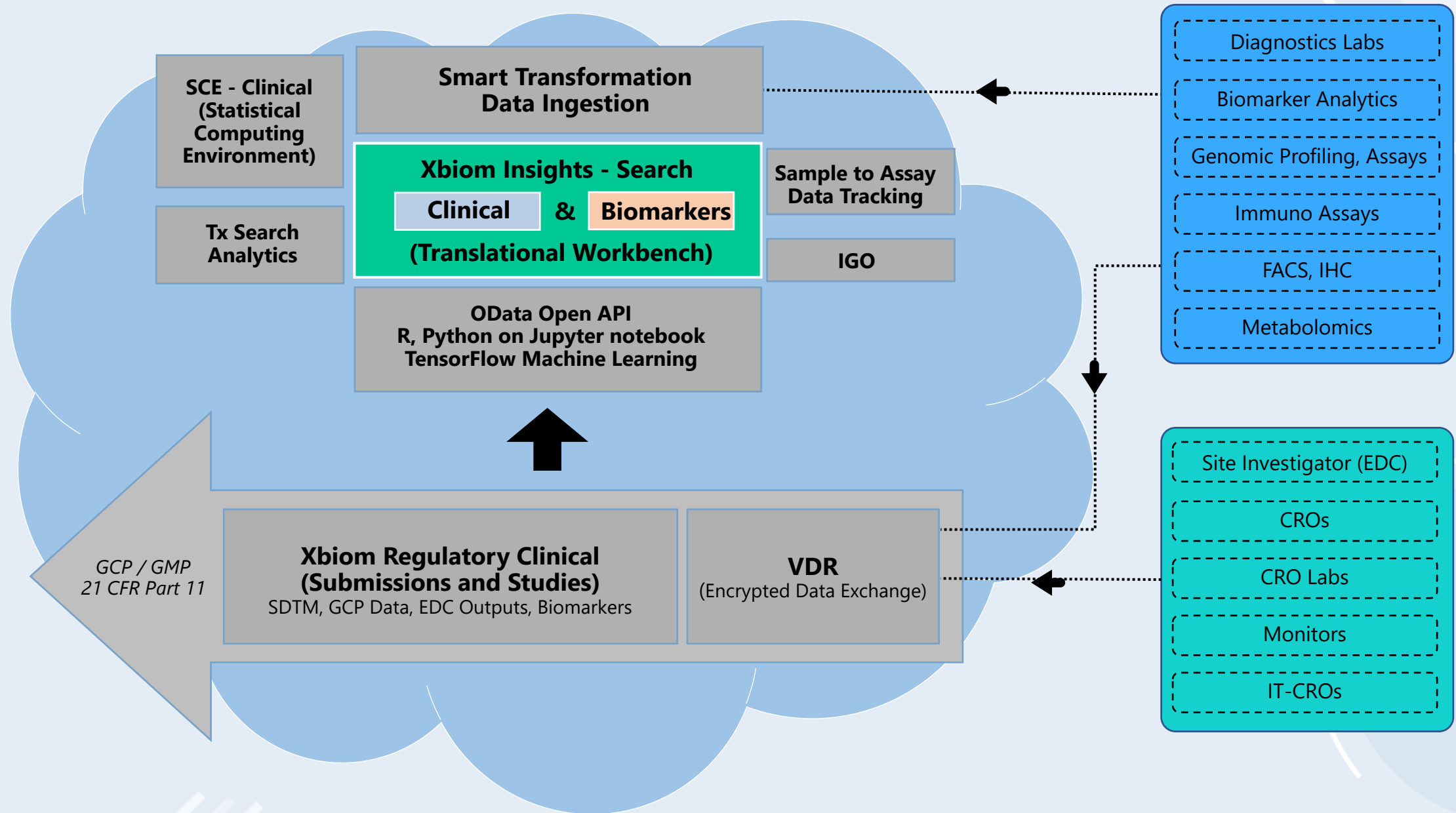
Supports up to date Ontology services from industry standard databases for normalization of Omics data enabling cross study analysis.

UDM – Universal Data Model for Disparate Data



* Findings are held in a common storage model with Observation/Testname, date-Time stamp, Units and other attributes

Xbiom™ Configuration for Clinical and Translational Biomarker Research





Xbiom

Xbiom™ makes data useful

Live Demo

www.pointcrosslifesciences.com

Webinar on Xbiom™

Enabling Data Integration for Translational & Precision Medicine

Sample formats for Immunoassay data received from Vendors

STUDYID	SUBJIDN	SPID	TPT	TESTCD	ORRES	ORRESU	LLOQ	STAT	REASND	D	M	Y	
PC123		1001S01	C1D1	IL_6		6.6 pg/mL		1.1			23	4	2019
PC123		1001S01	C1D1	VEGF_A		68 pg/mL		1.1			23	4	2019
PC123		1001S01	C1D1	VEGF_C		1432 pg/mL		1.1			23	4	2019
PC123		1001S01	C1D1	VEGF_D	BLQ	pg/mL		1.1			23	4	2019

Study	Order	TestProfile	SampleName	Species	SampleType	Anticoagulant	Analyte	Units	LDD	LLOQ	LowRange	HighRange	Result	Comment
PC001	P002	MAP	PC123, Screen	Human	Plasma	EDTA	6Ckine	pg/mL		3.6	11	357	1330	410
PC001	P002	MAP	PC123, Screen	Human	Plasma	EDTA	Adiponectin	ug/mL	0.02	0.13	1.8	15	3.8	

Sample	Assay	Well	Spot	Dilution	Concentration	Sign al	Mean	Calc. Concentrati on	Calc. Conc. CV	Calc. Conc. Mean	SampleID	SUBJID	Compound Name	X250	X5	Sample type
PC001	IL-6	A03	7.00	1.00		659. 00	598.00	0.00	52.38	0.00	Biposysamp1	PC001-121	Vehicle			Biopsy
PC001	GM-CSF	A04	7.00	1.00		536. 00	598.00	0.00	52.38	0.00	Biposysamp2	PC001-121	Vehicle			Biopsy

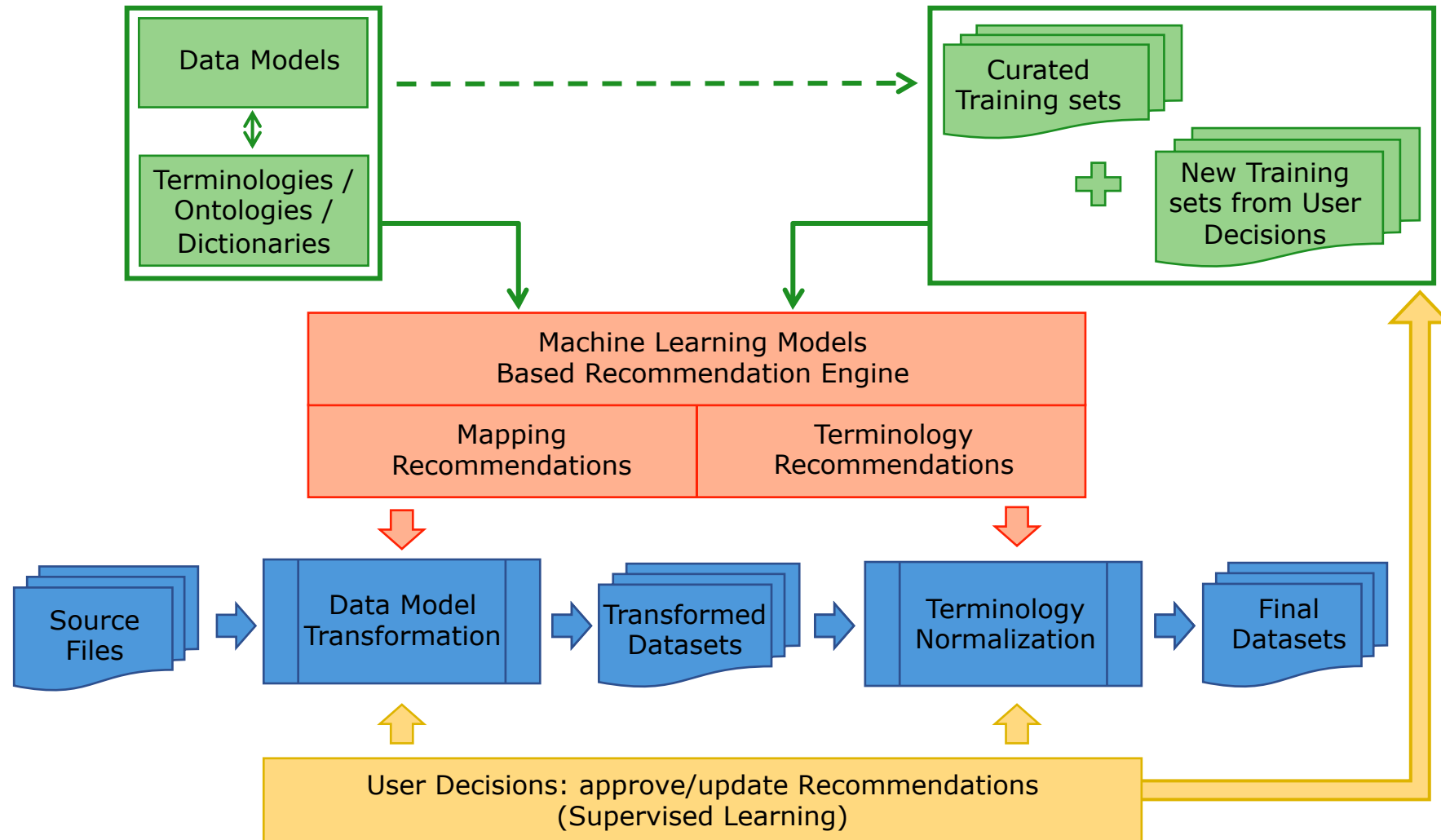
Unique Subject Identifier	Lab Test or Examination Name	Category for Lab Test	Result or Findings as Collected	Unit of the Original Result	Specimen Condition	Method of Test or Examination
PC11801	IL-6	WB		0.6 pg/mL		Human whole Blood Assay
PC11801	IL-8	WB		282.8 pg/mL		Human whole Blood Assay

Analytes							Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)	Interleukin-2 (IL-2)
Units							pg/mL	pg/mL
LDD							15	82
LLOQ							29	162
Low Range								
High Range							ND	ND
<u>Samples</u>	SiteID	SubjectID	SampleID	Visit Type	Date of Collection	Time of Collection		
PC001S78763284	A001	PC123	54323456	C1D1	09/17/2020		43	356

Machine
Readable
Columnar
Format

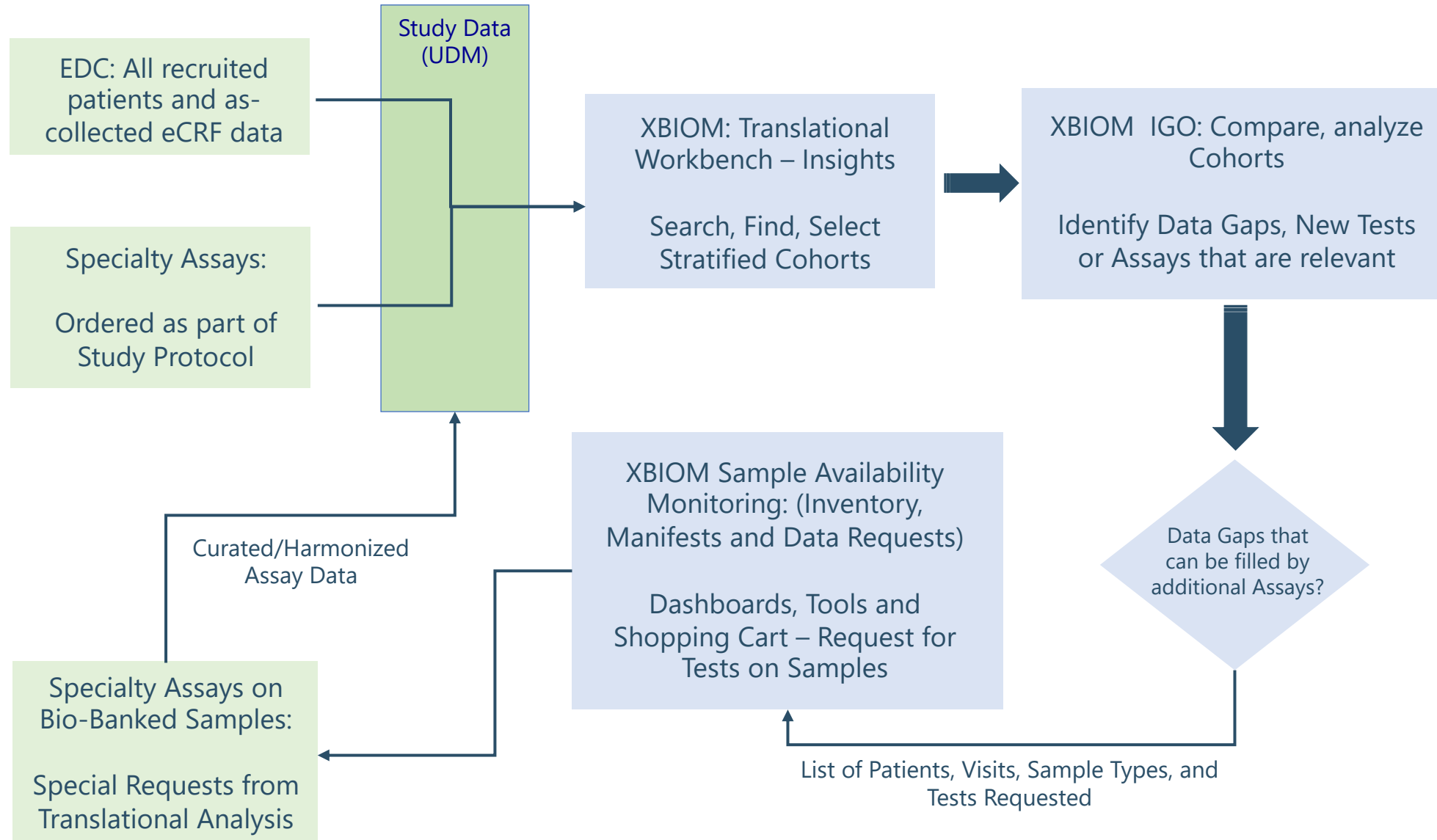
Human
Readable
Pivoted
Format

Data Transformation and Enrichment



Workflow of Data Transformation

Assay data for translational research



Batch Status : Completed

Import Batch Details

Delete

Initiate Process

Export Batch Details

Batch Details

Auto Generate

Dataset Transformations

Metadata Mappings

Terminology Normalization

Controlled Terminology

MedDRA

NCBI Gene Info

UniProt

mirBase

HMDB

Additional Transformations

Derivations

Data Updates

Output

Batch Details



Auto Generate



Dataset Transformations



Metadata Mappings



Controlled Terminology



Additional Transformations



Derivations



Data Updates



Output



Controlled Terminology

» Global

» CDISC

» Model CT

» Local

» External Dictionaries

System Codelist

Standard Units

Unit Conversion Factors

Global GLOBAL SDTM Terminologies

Deploy Terminology Audit Trail Report Business Base : PointCross Xbiom Clinical Insights

Codelist Code

Search... Switch to CDISC CT View

Code	Codelist Name	Codelist Extensible	CDISC Submission Code	CDISC Synonym(s)	CDISC Definition
C141656	10-Meter Walk/Run Functio...	NO	TENMW1TN	Ten Meter Walk/Run Functi...	10-Meter Walk/Run test name.
C141662	4-Stair Ascend Functional T...	NO	A4STR1TN	4 Stair Ascend Functional ...	4-Stair Ascend test name.
C141660	4-Stair Descend Functional ...	NO	D4STR1TN	4-Stair Descend Functional...	4-Stair Descend test name.
C115387	6 Minute Walk Functional T...	NO	SIXMW1TN	SIXMW1TN SIX MINUTE ...	6 Minute Walk Test test name.
C101808	ADNI Auditory Verbal Learni...	NO	AVL01TN	AVL01TN ADNI Auditory ...	ADNI AVLt test name.
C141654	AJCC TNM Staging System...	NO	AJCC1TN	AJCC TNM Staging System...	AJCC TNM Staging System 7th Edition test name.
C135012	AJCC Tumor Grade Respon...	NO	AJCCGRD	AJCC Tumor Grade Respo...	Terminology relevant to the American Joint Committee
C124667	ASSIGN Cardiovascular Dis...	YES	ASSG01TN	ASSG01TN ASSIGN Card...	ASSIGN Cardiovascular Disease 10-Year Risk Score t
C147537	ATLAS Clinical Classificatio...	NO	ATLAS1TN	ATLAS Clinical Classificati...	ATLAS test name.
C101806	Abnormal Involuntary Move...	NO	AIMS01TN	AIMS01TN Abnormal Inv...	Abnormal Involuntary Movement Scale test name.
C66767	Action Taken with Study Tre...	NO	ACN	ACN Action Taken with S...	Terminology specifying changes to the study treatment
C101865	Acute Coronary Syndrome ...	NO	ACSPCAT	ACSPCAT Acute Corona...	A classification of the presentation of acute coronary s
C120984	Acute Physiology and Chro...	NO	APCH1TN	APCH1TN Acute Physiol...	Acute Physiology and Chronic Health Evaluation II tes
C132311	Administration Technique R...	YES	ADTNQRS	Administration Technique ...	Terminology relevant to the product administration tech
C66780	Age Span	YES	AGESPAN	AGESPAN Age Span	Subgroups of populations based on age. (NCI)
C66781	Age Unit	NO	AGEU	AGEU Age Unit	Those units of time that are routinely used to express t
C112434	Airway Questionnaire 20 Qu...	NO	AQ01TN	AQ01TN Airway Questio...	Airway Questionnaire 20 test name.
C119061	Alcohol Use Disorder Identifi...	NO	ADTC01TN	ADTC01TN Alcohol Use ...	Alcohol Use Disorder Identification Test-Consumption
C119059	Alcohol Use Disorder Identifi...	NO	ADT01TN	ADT01TN Alcohol Use Di...	Alcohol Use Disorder Identification Test: Self-Report V
C161622	Alert Verbal Painful Unresp...	NO	AVPU01TN	Alert Verbal Painful Unresp...	Alert Verbal Painful Unresponsive Scale test name.
C100131	Alzheimer's Disease Assess...	NO	ADCTN	ADCTN Alzheimer's Dise...	ADAS-Cog CDISC Version test name.
C106650	Alzheimer's Disease Coope...	NO	ADL03TN	ADL03TN Alzheimer's Di...	Alzheimer's Disease Cooperative Study-Activities of D
C105139	Alzheimer's Disease Coope...	NO	ADL01TN	ADL01TN Alzheimer's Di...	Alzheimer's Disease Cooperative Study-Activities of D

- Controlled Terminology ▾
- » Global

» CDISC

» Model CT

» Local
- » External Dictionaries
- System Codelist

Standard Units

Unit Conversion Factors

External Dictionaries

Deploy Terminology

Audit Trail Report ▾

Business Base : PointCross Xbiom Clinical Insights

Type ▾	Version ▾	URL ▾	Active ▾	Index Status ▾	Reference URL ▾	Short Form ▾	Created On
LOINC		+					
Med-RT		+					
MedDRA		+					
DATABASE	20.1		Yes	Completed		MedDRA	06-NOV-2019 15:02:42
NCBI Gene Info		+					
DATABASE	OCT2019		Yes	Completed	https://www.ncbi.nlm.nih.gov...	NCBIGene	29-NOV-2019 16:10:42
DATABASE	1		No	Completed	https://www.ncbi.nlm.nih.gov...	NCBIGene	04-FEB-2019 15:45:25
Null Flavor		+					
SNOMED		+					
Sponsor Ontology		+					
UNII		+					
UniProt		+					
DATABASE	OCT2019		No	Completed	https://www.uniprot.org/unipr...	UniProt	29-NOV-2019 16:14:11
DATABASE	2019		Yes	Completed	https://www.uniprot.org/unipr...	UniProt	05-FEB-2019 18:51:27
WHODD		+					
mirBase		+					

Total Count : 26

- Controlled Terminology ▾
- Global

CDISC

Model CT

Local
- » External Dictionaries
- System Codelist
- Standard Units
- Unit Conversion Factors**

Unit Conversion Factors

Search...

Parameter	Source Unit	Destination Unit	Conversion Factor	Parameter PCID	Source Unit PCID	Destination Unit PCID
Glutamate Dehydrogen...	IU/L	ukat/L	0.01667	10001602	10000806	10010784
Glutamate Dehydrogen...	IU/L	U/L	1	10001602	10000806	10010750
Glutathione	mg/dL	mmol/L	0.0325	10001670	10010581	10000790
Gold	mg/L	umol/L	5.077	10001451	10000724	10025415
Growth Hormone Inhibi...	ng/L	pmol/L	0.611	10001779	10000749	10000744
Haptoglobin	mg/L	mmol/L	0.00001	10002444	10000724	10000790
Haptoglobin	mmol/L	g/L	0.01	10002444	10000790	10000825
Haptoglobin	mmol/L	mg/dL	0.1	10002444	10000790	10010581
Haptoglobin	mg/dL	mmol/L	10	10002444	10010581	10000790
HDL Cholesterol	mg/dL	mmol/L	0.0259	10002300	10010581	10000790
HDL Cholesterol	g/L	mmol/L	2.59	10002300	10000825	10000790
HDL Cholesterol	mmol/L	mg/dL	38.61	10002300	10000790	10010581
HDL-Cholesterol Subcl...	mg/dL	mmol/L	0.0259	10001450	10010581	10000790
HDL-Cholesterol Subcl...	mg/dL	mmol/L	0.0259	10001449	10010581	10000790
Height	in	m	0.0254	10001270	10001249	10010556
Hematocrit	mL/dL	%	1	10002226	10010609	10000711
Hematocrit	v/v	%	100	10002226	10025005	10000711
Hemoglobin	g/dL	mmol/L	0.155	10002627	10010476	10000790
Hemoglobin	g/L	mmol/L	0.0155	10002627	10000825	10000790
Hemoglobin	mmol/L	g/L	64.52	10002627	10000790	10000825
Hemoglobin	mmol/L	g/dL	6.45	10002627	10000790	10010476
Hexokinase	U/10^12 Erc	ukat/10^12 Erc	0.0167	10001882	10025865	10025866
Histamine	ug/L	nmol/L	8.997	10001448	10000774	10000761
Homocysteine	mg/L	umol/L	7.397	10002443	10000724	10025415

New Arrival92

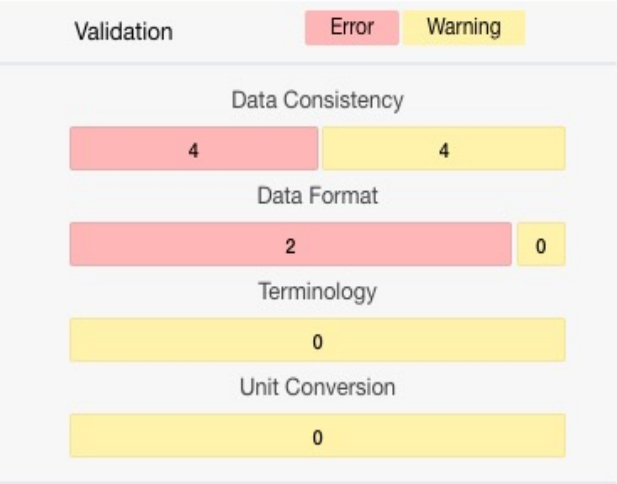
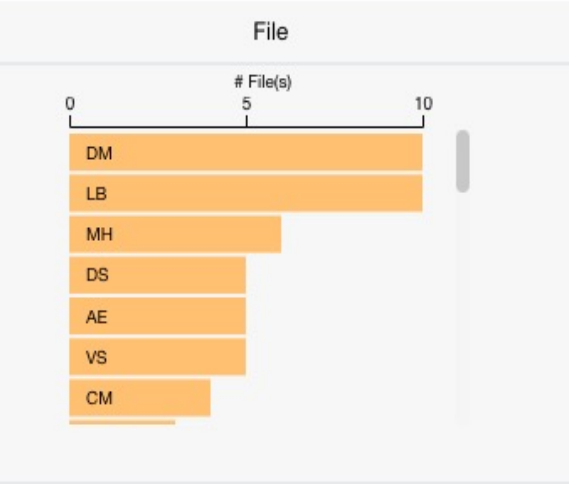
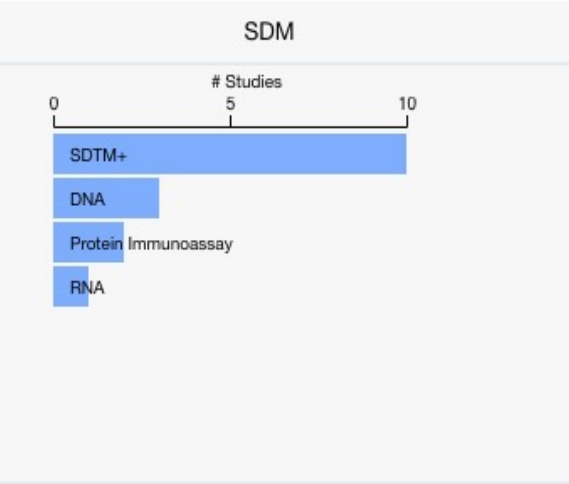
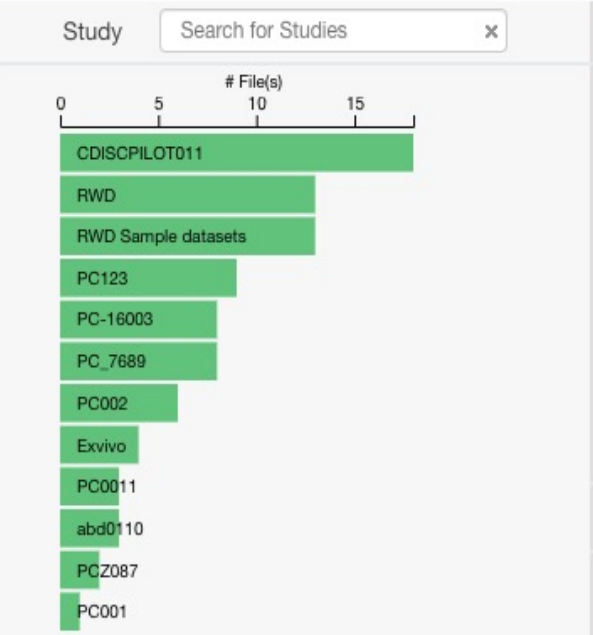
✓ Approved10

✗ Rejected0



New Arrival

Crawl



Summary

Compare Files

Compare Repository

Showing: 92 records

✓ Approve

✗ Reject

	Study ID	SDM	File Na...	Model ...	# Columns	# Rows	Rules Failed	Errors	Warnings	Termin...	Status	No
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<input type="checkbox"/>	RWD S...	SDTM+	MH	71	13	53793	0	0	0	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	LB	87	22	166983	1	0	50000	91	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	PR	72	16	41223	0	0	0	6	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	CM	72	12	44443	0	0	0	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	PE	82	20	9576	1	0	9576	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	SDTM+	0	22	182	1	1	0	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	CV	0	22	199	1	1	0	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	HQ	55	12	57406	0	0	0	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	MI	74	22	164	1	0	328	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	QS	69	19	16	3	1	34	0	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	DM	47	18	1173	1	1	0	1	New Arrival	
<input type="checkbox"/>	RWD S...	SDTM+	VS	81	22	65368	2	0	27959	4	New Arrival	
<input type="checkbox"/>	PC001	DNA	DNA	88	12	645	2	1290	0	0	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	SC	66	17	8211	2	0	8213	7	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	MH	71	13	53793	0	0	0	0	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	LB	87		166983	1	0	50000	91	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	PR	72	16	41223	0	0	0	6	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	CM	72	12	44443	0	0	0	0	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	PE	82	20	9576	1	0	9576	1	New Arrival	
<input type="checkbox"/>	RWD	SDTM+	CV	0	22	182	1	1	0	0	New Arrival	

- Controlled Terminology
- Global
- Standard - CDISC
- Model CT
- Local
- System Codelist
- Metadata Definition
- Standard Units
- Unit Conversion Factors

Codelist Custom Attribute : 0.00001

Dataset LevelVariable LevelValue Level Metadata

+ AddEditDeleteRefreshSaveUndo

<input type="checkbox"/>		Order Number	Domain*	Section	Variable Name*	Variable Label*	Data Type	Select Types
<input type="checkbox"/>		1	Program	General	studyNumber	Study	Text	Multi
<input type="checkbox"/>		1	Study List	General	TestArticle	Test Article	Text	Single
<input type="checkbox"/>		2	Study List	General	DrugType	Drug Type	Text	Single
<input type="checkbox"/>		3	Study List	General	Antibody	Antibody	Text	Single
<input type="checkbox"/>		4	Study List	General	StudyList_DrugLinker	Drug Linker	Text	Single
<input type="checkbox"/>		5	Study List	General	ReleasedDrug	Released Drug	Text	Single
<input type="checkbox"/>		6	Study List	General	StudyType	Study Type	Text	Single
<input type="checkbox"/>		7	Study List	General	StudyCategory	Study Category	Text	Single
<input type="checkbox"/>		8	Study List	General	Species	Species	Text	Single
<input type="checkbox"/>		9	Study List	General	GLPvsnonGLP	QA Type	Text	Single
<input type="checkbox"/>		1	Target	General	targetOnBoneMrrwProgram	Target on BoneMarrow	Text	Single
<input type="checkbox"/>		2	Target	General	General_Other	Other	Text	
<input type="checkbox"/>		1	Test Article	ADC	mAbBackbone	Antibody	Text	Multi
<input type="checkbox"/>		2	Test Article	ADC	DAR	DAR	Integer	
<input type="checkbox"/>		3	Test Article	ADC	ADC_drugLinker	Drug Linker	Text	Multi
<input type="checkbox"/>		4	Test Article	ADC	PayloadReleasedDrug	Released Drug	Text	Multi
<input type="checkbox"/>		1	Test Article	Drug Linker	ADCstability	ADC stability	Text	Single
<input type="checkbox"/>		2	Test Article	Drug Linker	reactivehandle	Reactive handle	Text	
<input type="checkbox"/>		3	Test Article	Drug Linker	CleavageSite	Cleavage Site	Text	Single
<input type="checkbox"/>		4	Test Article	Drug Linker	DrugLinker_Other	Other	Text	
<input type="checkbox"/>		1	Test Article	General	Testarticletype	Drug Type	Text	Single
<input type="checkbox"/>		2	Test Article	General	Program	Program	Text	
<input type="checkbox"/>		3	Test Article	General	CASNUMBER	CAS NUMBER	Text	
<input type="checkbox"/>		4	Test Article	General	drugClass	Compound Class	Text	Single

Saved Search CriteriaSearch CriteriaShow Search Results

Enter Search Criteria

Molecular Biomarkers

Molecular Biomarkers

B1 AND C1 AND C2 AND C3 OR C4 AND D1 AND D2

Search

Clear

Refresh

No. of Results: Studies-0; Subjects-0

Study SummarySubject History-BaselineClinical ParametersMolecular BiomarkersBiosamplesSDTM Variables

Molecular Biomarkers

Matched Studies-3; Subjects-447

D1

Macromolecule type

DNA

Biomarkers

KRAS

Method

FMI

Vendor

Measurement type

Copy Number Al...

Short Variant

Molecular Biomarkers

Matched Studies-1; Subjects-85

D2

Macromolecule type

Cells

Biomarkers

Method

Vendor

Measurement type

Additional Biomarker Criteria

Flow Cytometry-Cell Sorting

Cell Type (Cytotoxic T cells) with Protein Biomarker (CD3+;CD16+;CD56+) with Unit (%) with Test Detail (CD3+;CD16+;CD56+) with Method (flow cytometry assay) has value between 11.2 14.9

Molecular Biomarkers

Flow Cytometry-Cell Sort...

Flow Cytometry-Cell Sorting

Cell Type ↑	Protein Biomarker	Value
<input type="checkbox"/> Cytotoxic T cells	CD3+;CD4-;CD8+	Min: 50.8Max: 60.3
<input type="checkbox"/> Cytotoxic T cells	CD3+;CD4-;CD8+	Min: 50.8Max: 60.3
<input checked="" type="checkbox"/> Cytotoxic T cells	CD3+;CD16+;CD56+	Min: 11.2Max: 14.9
<input type="checkbox"/> Cytotoxic T cells	CD3+;CD16+;CD56+	Min: 11.2Max: 14.9
<input type="checkbox"/> Cytotoxic T cells	CD3+;CD4+;CD8-	Min: 34.8Max: 46.9

Page 1 of 1

Displaying 1 - 518 of 518

Apply

Close

Home

Cohort

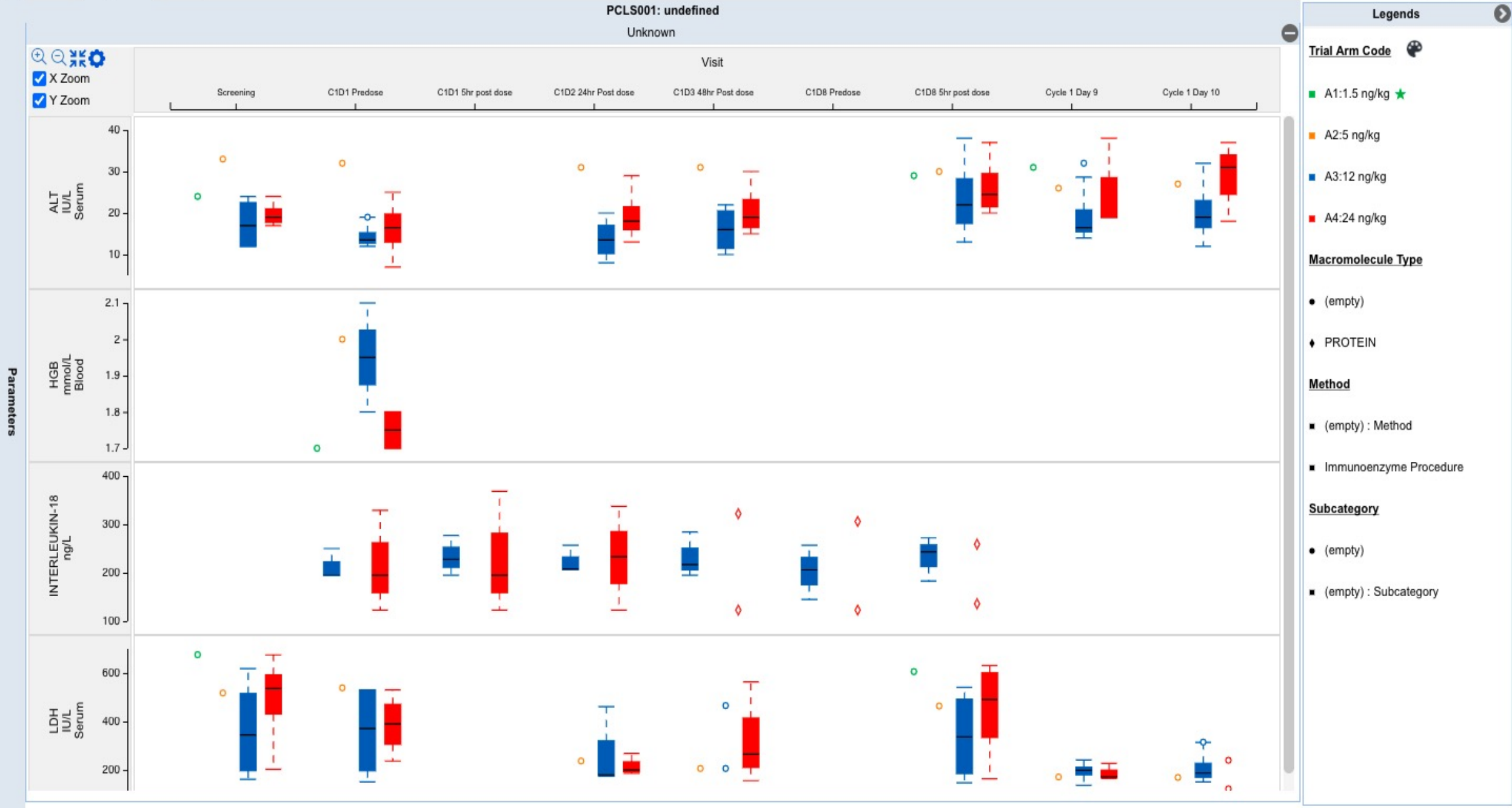
Visualizations

Chart Type

Chart Configurations

Export

TableFiguresR Templates



Home

Cohort

Visualizations

Chart Type

Chart Configurations

Export

Home

TrialArms

Cohort

Add Study

Cartesian

Tiles

Correlation

Z-Transform

Histogram

Navigator

Whisker

Scatter

Line

Bar

Visit Scale

Save to TFL Library

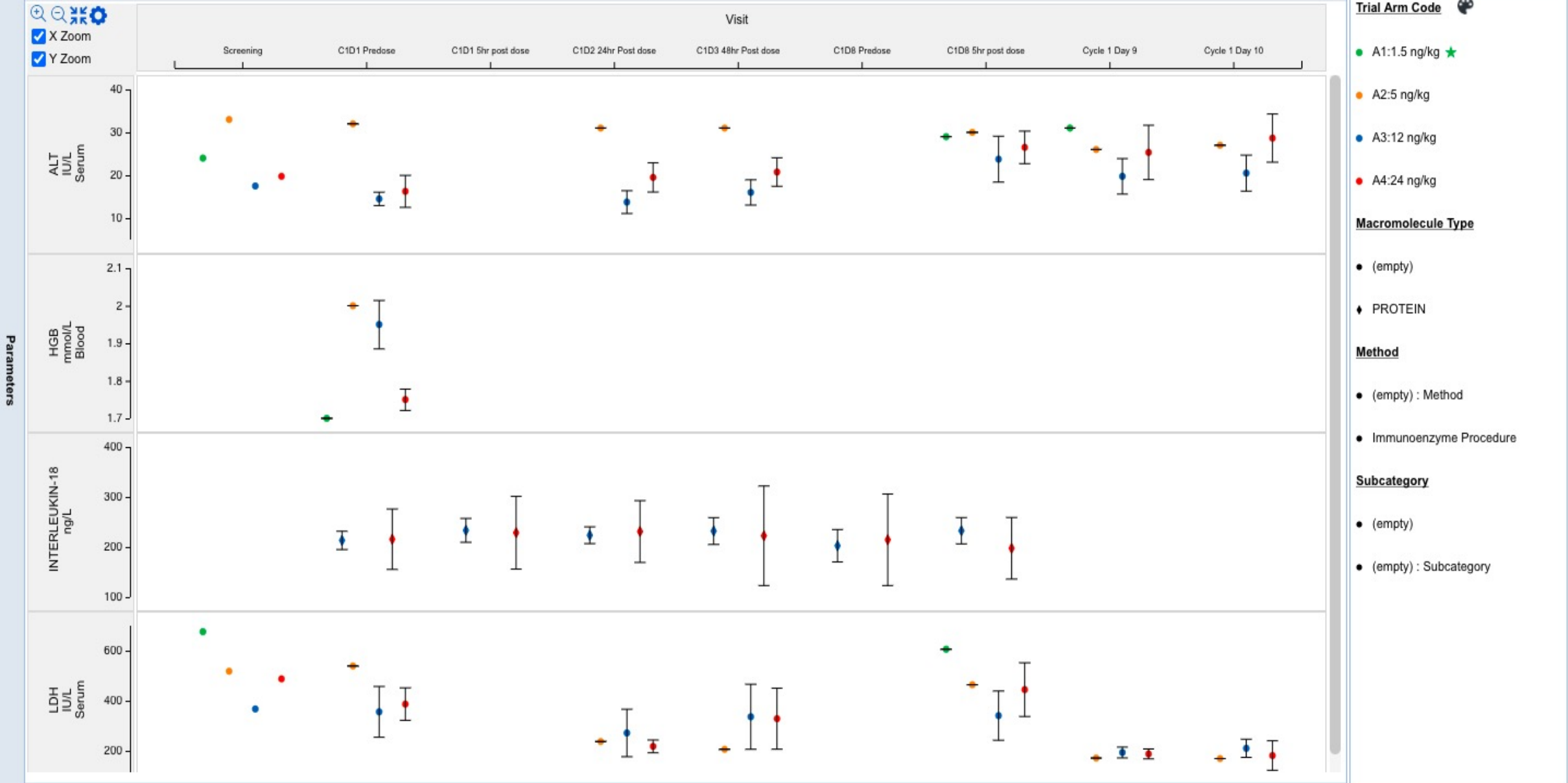
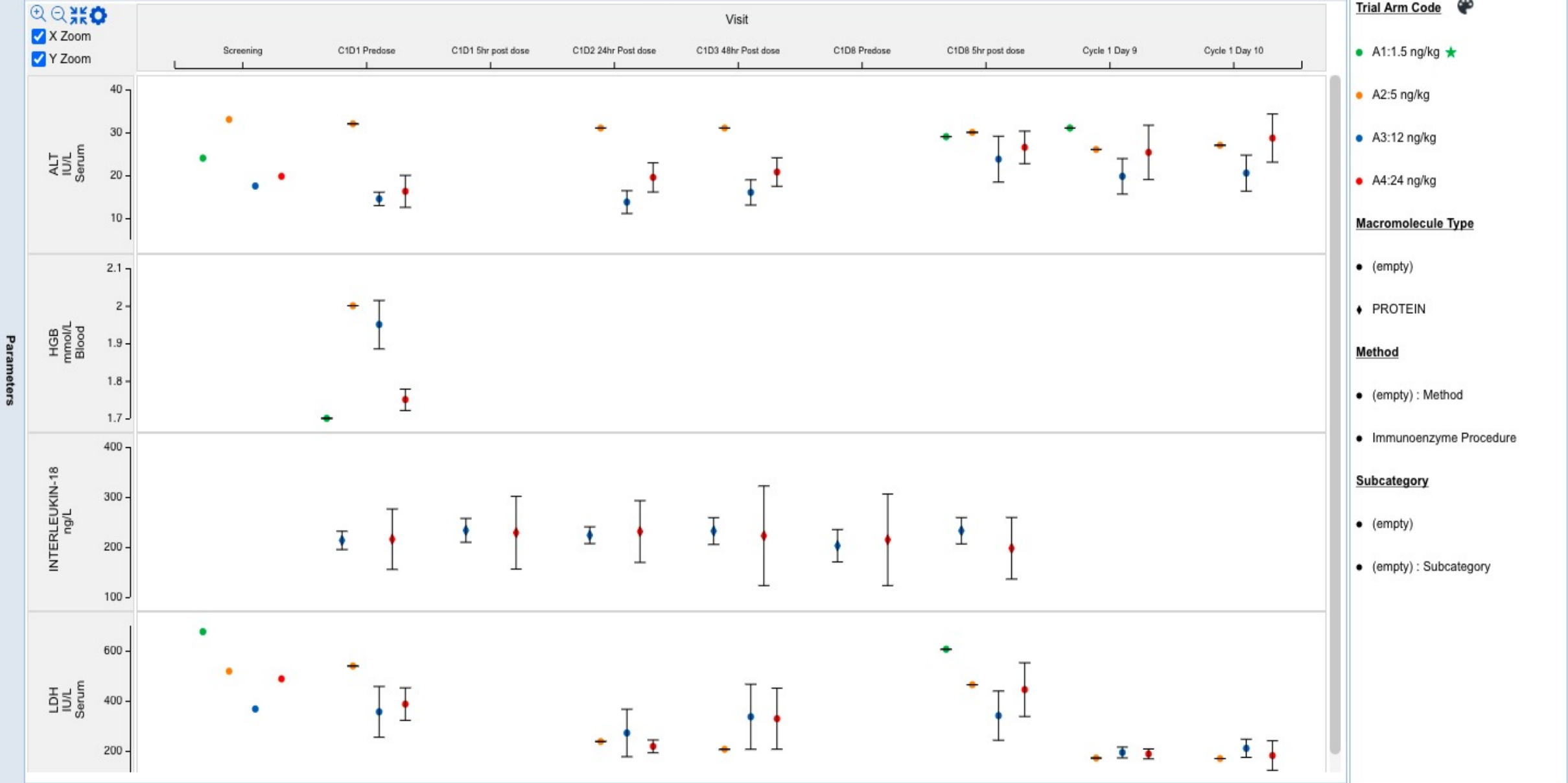
Table

Figures

R Templates

PCLS001: undefined

Unknown



Home

Cohort

Data

Numerical Tables

Export

Home

TrialArms

Cohort

Add Study

Source Data

Add Columns

Cohorts

Visit

Parameters

Time Points

Custom

Save to TFL Library

Excel

Parameters

Table

Figures

R Templates

PCLS001: undefined									
Sex : Unknown					Subcategory :				
Sample Type :					Blood	Serum			
Test Name :					Hemoglobin Measurement	Alanine Aminotransferase Measurement	Lactate Dehydrogenase Measurement	Interleukin-18	
Trial Arm Code	Visit	Macromolecule Type	Method	Standard Units :	mmol/L	IU/L	IU/L	ng/L	
A1:1.5 ng/kg	C1D1 Predose			Mean	1.7				
				SD	0				
				Count	1				
A2:5 ng/kg	C1D1 Predose			Mean	2	32	539		
				SD	0	0	0		
				Count	1	1	1		
A3:12 ng/kg	C1D1 Predose	PROTEIN	Immunoenzyme Procedure	Mean				213.3	
				SD				31.75	
				Count				3	
A3:12 ng/kg	C1D1 Predose			Mean	1.95	14.5	355.7		
				SD	0.129	3.109	202.7		
				Count	4	4	4		
A4:24 ng/kg	C1D1 Predose	PROTEIN	Immunoenzyme Procedure	Mean				215.6	
				SD				104.5	
				Count				3	
A4:24 ng/kg	C1D1 Predose			Mean	1.75	16.25	386.7		
				SD	0.05773	7.455	129.6		
				Count	4	4	4		
A3:12 ng/kg	C1D1 5hr p...	PROTEIN	Immunoenzyme Procedure	Mean				233.3	
				SD				41.25	
				Count				3	
A4:24 ng/kg	C1D1 5hr p...	PROTEIN	Immunoenzyme Procedure	Mean				228.6	
				SD				125.9	
				Count				3	

Options

View Type: ☐ Individual ☒ Summary

Visit:

All

Consider Exclusions : ☐

Combine Sex : ☐

Value By:

Numeric Result - Standard

Show Value in Rows : ☒

Operations:

☒ Mean

☐ Unique Count

☒ SD

☐ Values

☒ Count☐ Unique Values☐ SE☐ Coefficient of Variation☐ Sum☐ Variance☐ Min☐ Change From Ref group☐ Max☐ %Change From Ref group☐ Median☐ Fold Change From Ref group

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Cohort

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R Templates

Configure Chart

Please drag/drop columns from the left side to the appropriate sections to configure the chart.

Fields

Trial Arm Code (string)

StudyID (string)

Domain (string)

Sample Type (string)

Day Range (string)

Visit (string)

Epoch (string)

Time Point (string)

Sex (string)

USUBJID (string)

PoolID (string)

Short Test Name (string)

Test Name (string)

Standardized Result (string)

Numeric Result - Standard Units (decim...)

Standard Units (string)

SI Result (decimal)

SI Result Unit (string)

Category (string)

Severity (string)

ExclusionFL (string)

R

Title Configurator

Sample Type

Common Y-axis for each Row

Column By

Common X-axis for each Column

Y-Axis

Numeric Result - Standard Unit

Chart Type

Whi... Sca... Line Bar

Group By

Trial Arm Code

Macromolecule Type

Method

Subcategory

Grouping Criteria: Mean

X-Axis

Visit

Close

Apply

Legends

Trial Arm Code

A1:1.5 ng/kg

A2:5 ng/kg

A3:12 ng/kg

A4:24 ng/kg

Macromolecule Type

(empty)

PROTEIN

Method

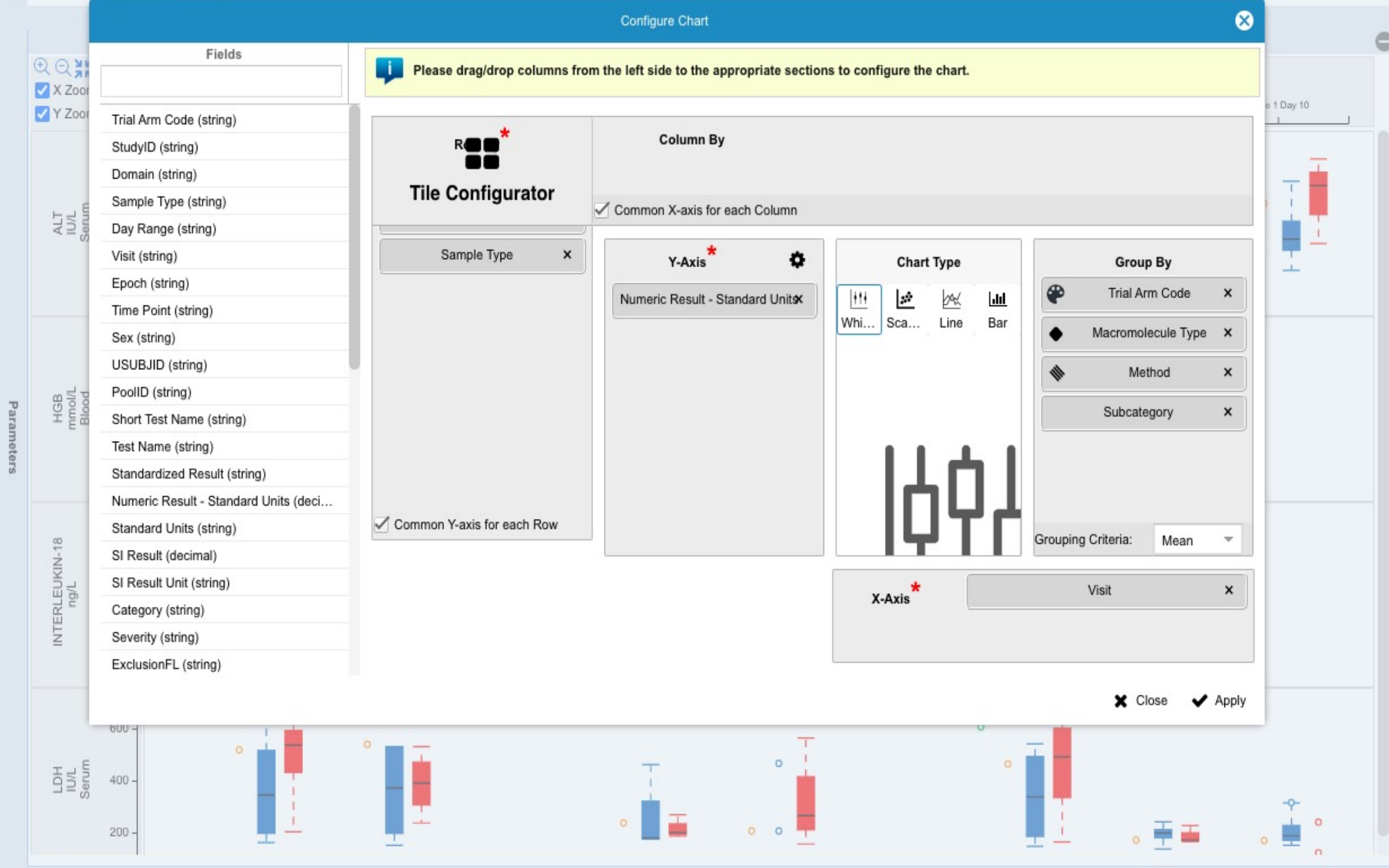
(empty) : Method

Immunoenzyme Procedure

Subcategory

(empty)

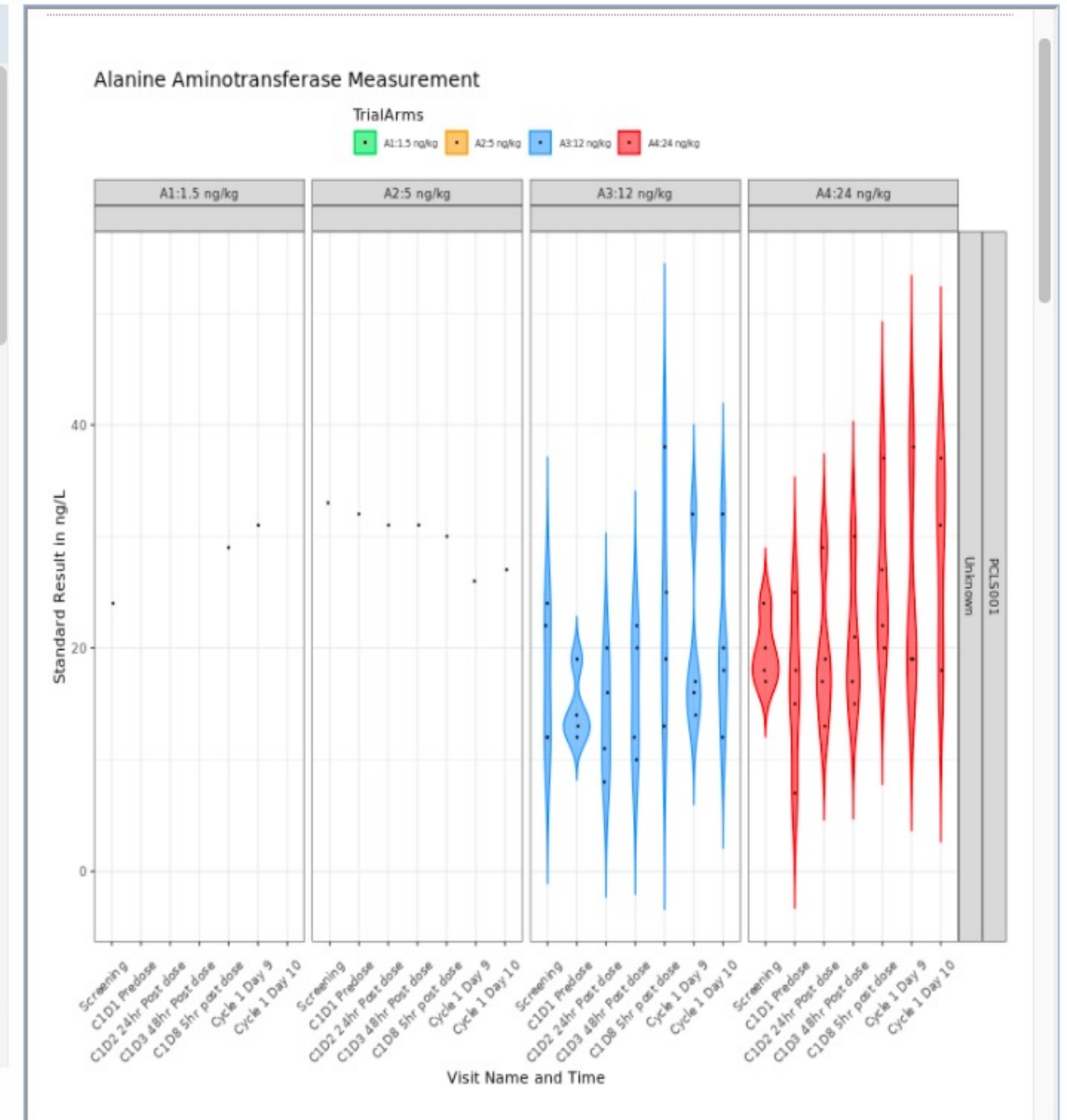
(empty) : Subcategory



Violin Plots

```
1  ```{r setup, include=FALSE}
2  knitr::opts_chunk$set(echo = FALSE)
3  ```
4  ```{r, warning=FALSE, include=FALSE}
5  require(dplyr)
6  library(tidyverse)
7  ```
8  ```{r IGOData, warning=TRUE}
9  ## Don't change the below lines of code.
10 IGOJson <- RJSONIO::fromJSON('<<IGOData>>'); configKeys <- c(<<Key>>); confi
11 IGOConfig <- setNames(as.list(configValues), configKeys); # str(IGOConfig)
12 col<-c(unique(names(unlist(IGOJson))))
13 for (i in 1:length(IGOJson)){ IGOJson[[i]][c(col[(col %in% names(IGOJson[[i]
14 df <- data.frame(do.call('rbind', IGOJson), stringsAsFactors = FALSE) ); df <
15 df <- df %>% mutate_all(type.convert) %>% mutate_if(is.factor, as.character)
16
17 #colnames(df)<- c(strsplit(IGOConfig$sudmColumnsLabels, "\\|")[[1]]) ## Chan
18 #str(df)
19 ```
20
21 ```{r include=FALSE}
22 library(ggplot2)
23 library(gridExtra)
24 ```
25 ---
26 `r IGOConfig$title`
27
28 ---
29
30 ```{r , axis parameters and annotations ,echo=FALSE}
```

Parameters



ALT IU/L Serum

HGB mmol/L Blood

INTERLEUKIN-18 ng/L

LDH IU/L Serum

Study Drug

Treatment Name

Dose Form

Route of Administration

Fasting Status

Events

Clinical Events

Adverse Events

Deaths

Findings About Interventions/Events

Findings About

Test Findings

Laboratory Test Results

ECG Test Results

Immunogenicity Specimen Assessments

Morphology

Physical Examination

Reproductive System Findings

Vital Signs

Name of Procedure

Clinical Endpoints (ADS)

Questionnaires

Interventions

Concomitant Medications

Substance Use

Add Study

Search Criteria

Show Search Results

Enter Search Criteria

B1 OR C1 AND C2 AND C3

Search

Clear

Refresh

No. of Results: Studies-1; Subjects-11

Study Summary

Subject History-Baseline

Clinical Parameters

Molecular Biomarkers

Biosamples

SDTM Variables

Clinical Events

Matched Studies-1; Subjects-36

Type of Event

Edema

Severity

C1

Include Baseline Data

Clinical Endpoints (ADS)

Matched Studies-2; Subjects-1833

Parameter

Progression-free Survival (Da...

Range in DAYS

Min: >= 1

Max: <= 1219

C2

Adverse Events

Matched Studies-2; Subjects-5

Adverse Events

*Immune system disorders

Severity/Intensity

Confirmed DLT

C3

Include Baseline Data

+ Add Study

+ New Instance

X Close

Add Study

Search Criteria

[Show Search Results](#)No. of Results: *Studies-13; Subjects-8279*

Open Documents ▼

[Show All Studies](#)

Type to filter the studies

<input type="checkbox"/>		Study ID	Project ID	Study Title	Study Drug	Disease	Subjects Matched	Subjects with Biological Samples Available	Subjects with Biomarker Data Available	Searched Parameter
<input type="checkbox"/>		PCLS001			PC compound	UNKNOWN	10 of 10	0 of 10	10 of 10	0
<input type="checkbox"/>		Preclinical					12 of 12	0 of 12	12 of 12	0
<input type="checkbox"/>		Exvivo					22 of 22	0 of 22	15 of 22	0
<input checked="" type="checkbox"/>		PC001		Saftey and Efficac...	PC Compound	Metastatic colorect...	243 of 243	0 of 243	0 of 243	0
<input type="checkbox"/>		PCZ087					205 of 205	0 of 205	88 of 205	0
<input type="checkbox"/>		PC_16003					0 of 0	0 of 0	0 of 0	0
<input type="checkbox"/>		COVID-19					1254 of 1254	0 of 1254	0 of 1254	0
<input type="checkbox"/>		NIDA-CTN-0001		BUPRENORPHIN...	BUPRENORPHIN...	OPIATE DEPEND...	138 of 138	0 of 138	0 of 138	0
<input type="checkbox"/>		PCTEST1					3807 of 3807	0 of 3807	250 of 3807	0
<input type="checkbox"/>		SpeciesTest					1225 of 1225	0 of 1225	682 of 1225	0
<input type="checkbox"/>		SSP-001	IMP001	SAMPLE STUDY ...	TEST PRODUCT ...		0 of 0	0 of 0	0 of 0	0
<input checked="" type="checkbox"/>		PCTEST2	PointCross	Safety and Efficac...	PC Compound	Metastatic colorect...	1225 of 1225	99 of 1225	890 of 1225	0
<input type="checkbox"/>		SAMP001	PointCross	Saftey and Efficac...	PC Compound	Metastatic colorect...	138 of 138	0 of 138	100 of 138	0

Total Count : 13 Selected Record(s) : 2

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Cartesian

Tiles

Correlation

Z-Transform

Histogram

Navigator

Whisker

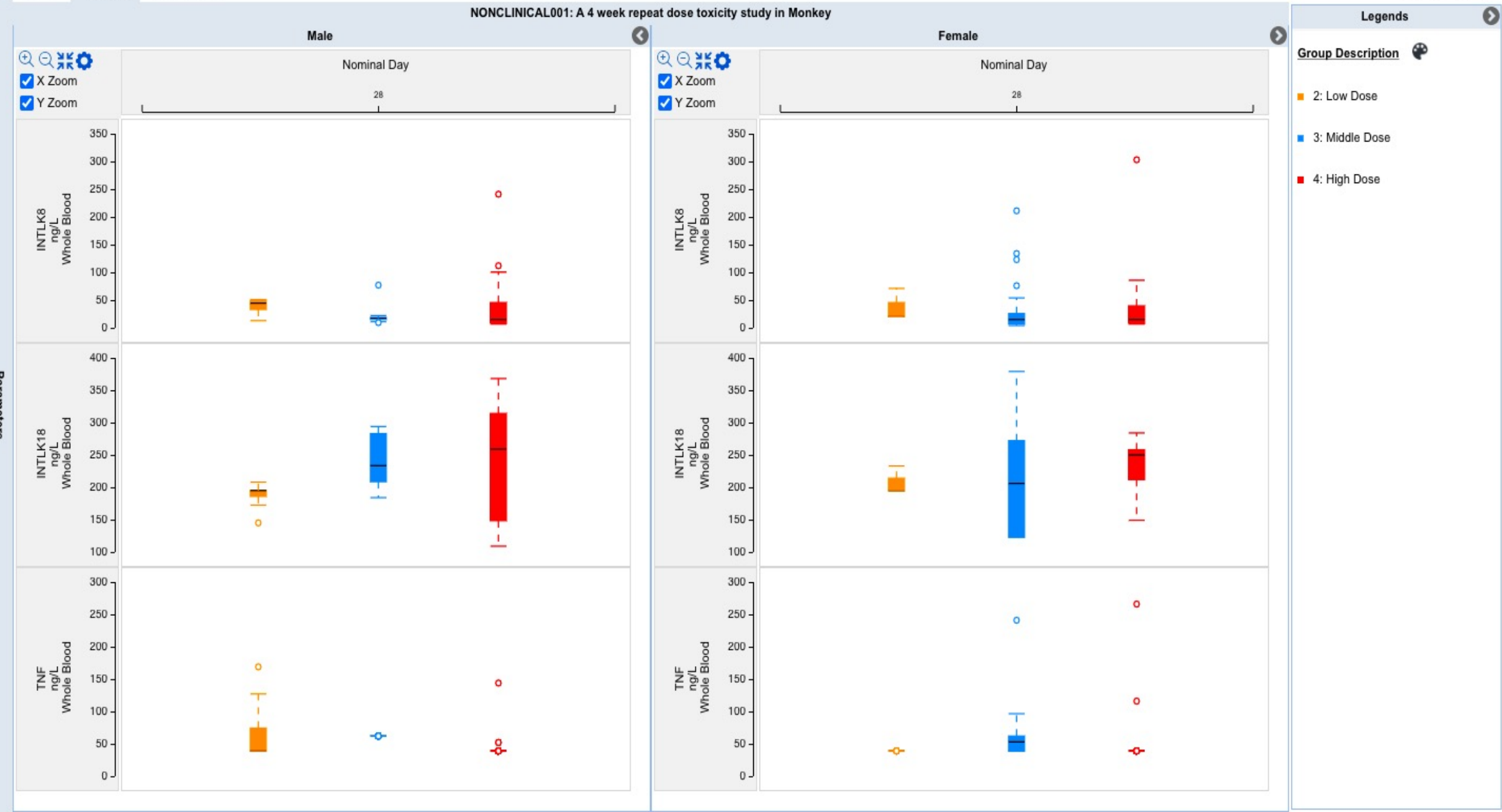
Scatter

Line

Bar

Days Scale

Save to TFL Library



Parameters

Select Parameter

Search

Study Design

Study Summary

Subject History

Demographics

Clinical Parameters

Adverse Events

Clinical Endpoints (ADS)

Best Response

Overall Survival (Days)

Progression-free Survival (Days)

Laboratory Test Results

Blood

Clinical Events

Molecular Biomarkers

Molecular Biomarkers

Cells

flow cytometry assay

DNA

FMI

Copy Number Alteration

Short Variant

RNA

Nanostring

Targeted mRNA expres...

In Situ Hybridization

KRAS

PROTEIN

Biosample

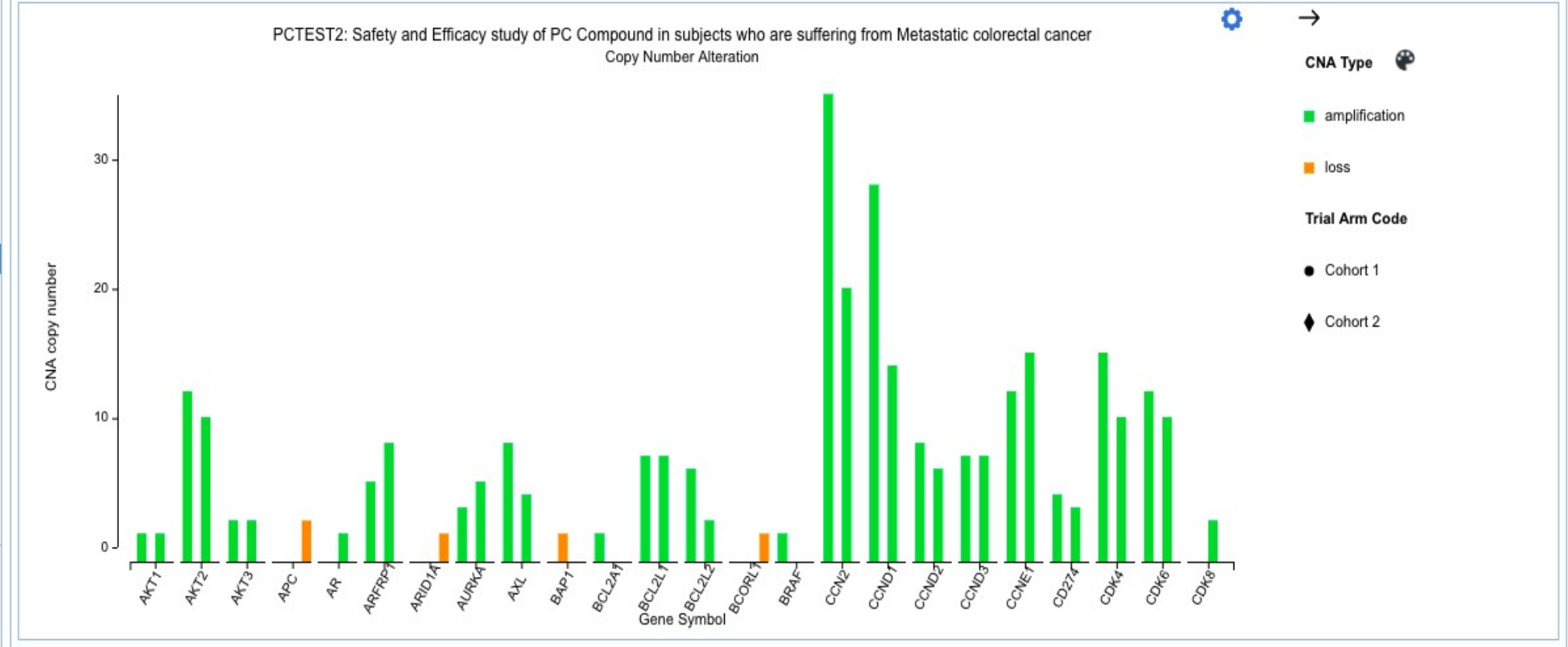
Biosample Availability

DemographicsIn Situ HybridizationCopy Number Alteration

Trial Arm Code	StudyID	USUBJID	Species	Sex	Method	Macromolecule Type	Gene Symbol	Gene ID	CNA copy number	CNA t
Cohort 2	PCTEST2	PCTEST2 SUBJ01220d51ba35tri	Human	Male	FMI	DNA	CCNE1	898	8	exons 10
Cohort 2	PCTEST2	PCTEST2 SUBJ01773e19af3dtri	Human	Male	FMI	DNA	CDK4	1019	16	exons 7
Cohort 2	PCTEST2	PCTEST2 SUBJ022600aa8d69tri	Human	Male	FMI	DNA	ARFRP1	10139	8	exons 6
Cohort 2	PCTEST2	PCTEST2 SUBJ022600aa8d69tri	Human	Male	FMI	DNA	AURKA	6790	8	exons 8
Cohort 2	PCTEST2	PCTEST2 SUBJ022600aa8d69tri	Human	Male	FMI	DNA	BCL2L1	598	8	exons 4
Cohort 2	PCTEST2	PCTEST2 SUBJ053c95d20167tri	Human	Male	FMI	DNA	BCORL1	63035	0	exons 4
Cohort 1	PCTEST2	PCTEST2 SUBJ059cccdf26f8tri	Human	Male	FMI	DNA	CCN2	1490	10	exons 5
Cohort 1	PCTEST2	PCTEST2 SUBJ059cccdf26f8tri	Human	Male	FMI	DNA	CCND1	595	10	exons 5
Cohort 2	PCTEST2	PCTEST2 SUBJ0662cebd93b9tri	Human	Male	FMI	DNA	CCND3	896	6	exons 5
Cohort 1	PCTEST2	PCTEST2 SUBJ0813112361c0tri	Human	Male	FMI	DNA	CDK4	1019	16	exons 7
Cohort 1	PCTEST2	PCTEST2 SUBJ098e011cb730tri	Human	Male	FMI	DNA	BRAF	673	8	exons 18
Cohort 1	PCTEST2	PCTEST2 SUBJ0af70038319btri	Human	Male	FMI	DNA	CDK6	1021	15	exons 7
Cohort 2	PCTEST2	PCTEST2 SUBJ0b20618aafc6tri	Human	Male	FMI	DNA	CCNE1	898	6	exons 10

Total Rows: 1897Filtered Rows: 299

Save to TFL Library



6 HOURS POST



Notes

Status: Draft

Title: Correlation graph



PCLS001 ;

Unknown

ALB - Serum (g/dL)

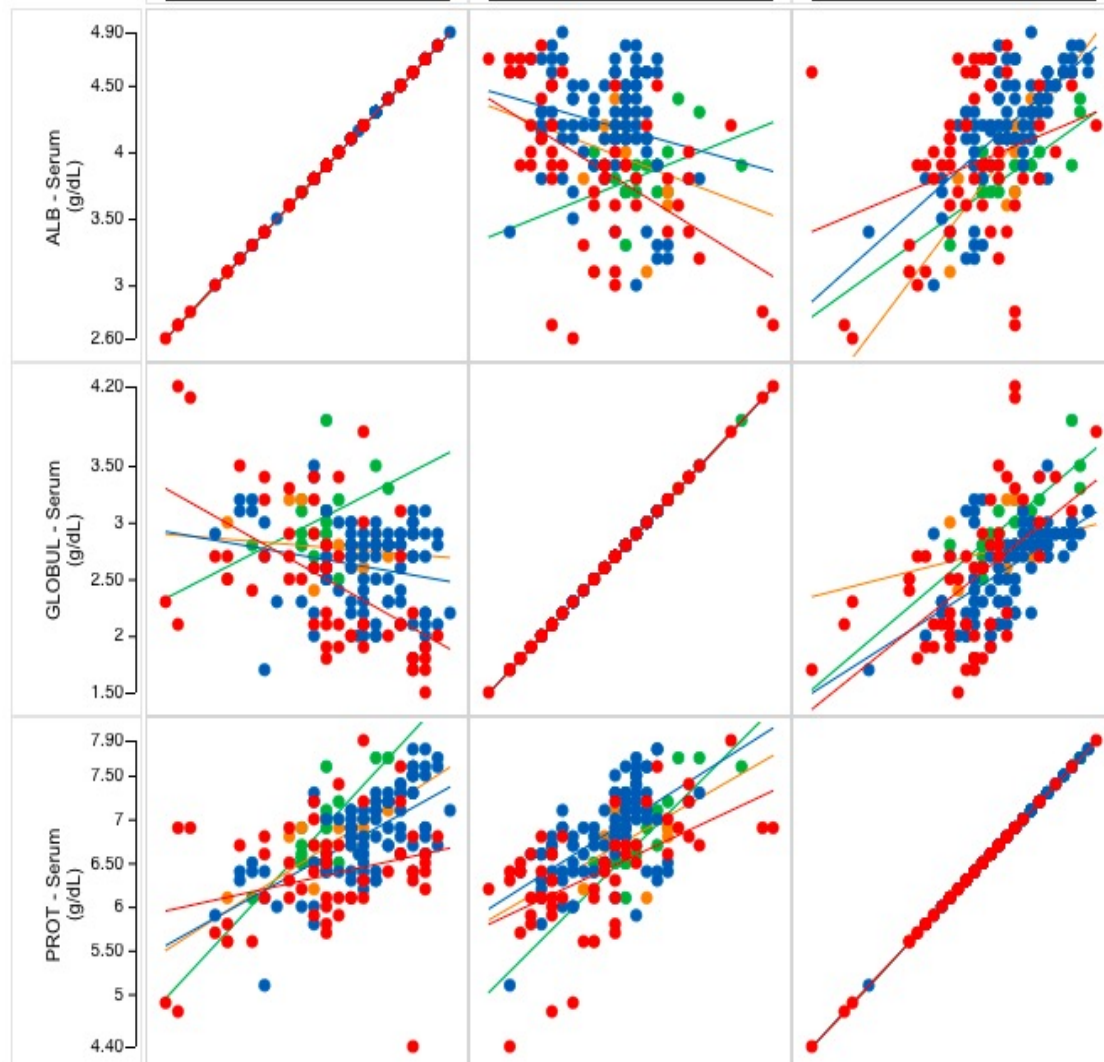
GLOBUL - Serum (g/dL)

PROT - Serum (g/dL)

2.6 2.8 3 3.2 3.4 3.6 3.8 4 4.2 4.4 4.6 4.8

1.5 2 2.5 3 3.5 4

4.5 5 5.5 6 6.5 7 7.5



Trial Arm Code

- A1: 1.5 ng/kg
- A2: 5 ng/kg
- A3: 12 ng/kg
- A4: 24 ng/kg

Discussion Board

Add a comment



, rajalaxmi

a few seconds ago

Albumin and Globulin correlation turns from positive to negative with an increase in dosage.

Reply



, rajalaxmi

a few seconds ago

And both have a positive correlation with Total Protein

Reply

Saved Search Criteria

Search Criteria

Show Search Results

Show all

Personal

Published

History

WorkSpaces

Page 1 of 1

Enter Search Criteria

Displaying 1 - 6 of 6

Details	Date
<u>PC202002,PC201909-2021-04-15T08:56:27.735Z</u> P, Karuna	23-APR-2021 17:51:38 (UTC +05:30)
<u>Test</u> Kumar, Praveen	23-APR-2021 16:34:22 (UTC +05:30)
<u>Analysis Workspace</u> P, Karuna	16-APR-2021 19:00:23 (UTC +05:30)
<u>PC202002,PC201909-2021-04-15T09:27:53.638Z</u> , lakshmi	15-APR-2021 15:17:15 (UTC +05:30)
<u>PC202002,PC201909-2021-04-15T09:21:54.051Z</u> , lakshmi	15-APR-2021 14:55:50 (UTC +05:30)
<u>PC9571S,PC201909-2021-04-14T11:31:15.036Z</u> P, Karuna	15-APR-2021 14:55:16 (UTC +05:30)

Share X Delete Open in IGO

PC202002,PC201909-2021-04-15T08:56:27.735Z 23-APR-2021 17:51:38 (UTC +05:30)
by P, Karuna

TFLs (4)

Cohorts (0)

Criteria	Description
A1	STUDYID eq 'PC202002'
A2	STUDYID eq 'PC201909'

PCLS001: undefined

30 of 4889 Record(s)

Total Subject(s)	10
Reported Subject(s)	10
A3:12 Ng/kg	4
Cytokines	4
Interleukin-8	4

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