



Connect your Clinical Data & Metadata

CDISC GUF – Sep 2017 - Brussels

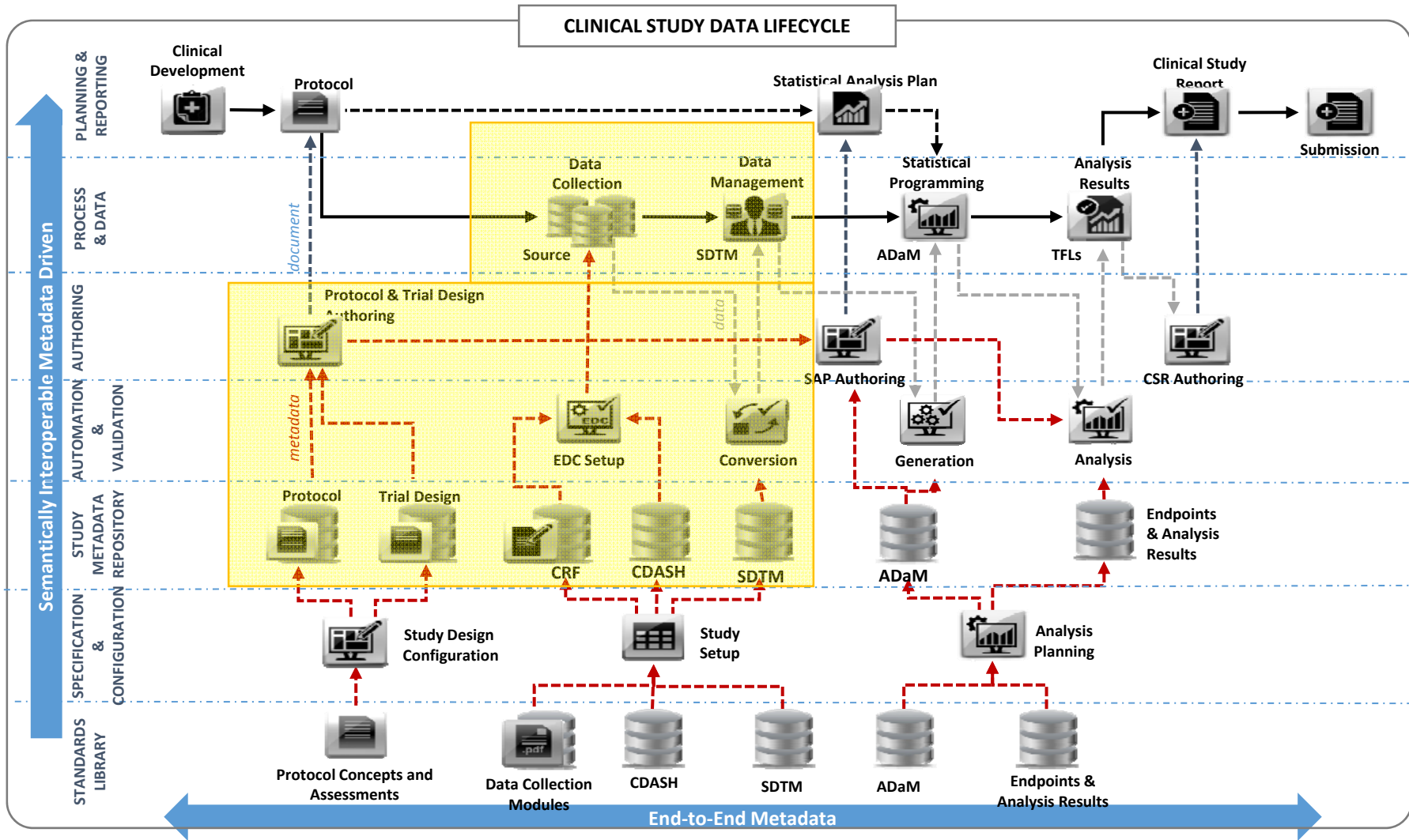
1 Clinical Study Data Lifecycle

2 From **study-level metadata** to raw **subject-level data**

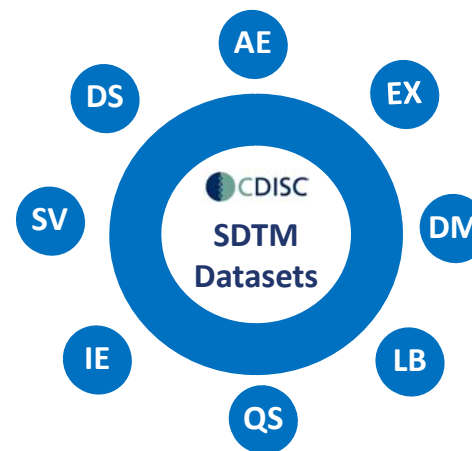
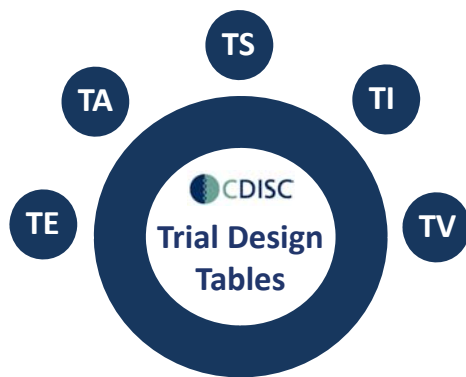
3 In practice

4 Key Takeaways

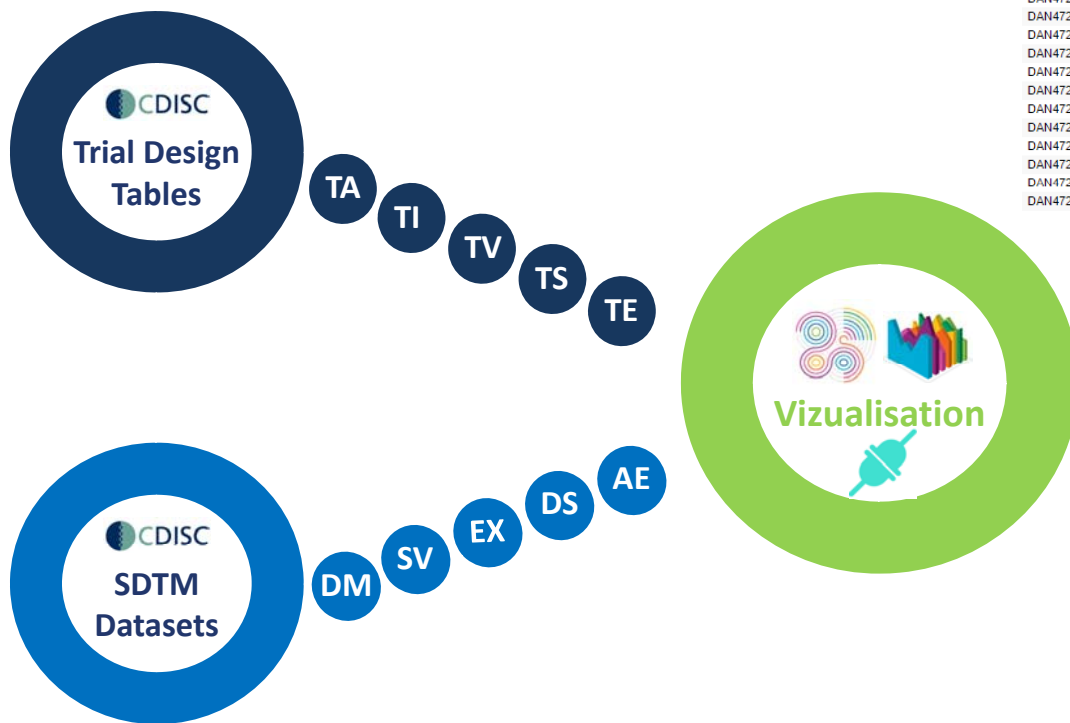




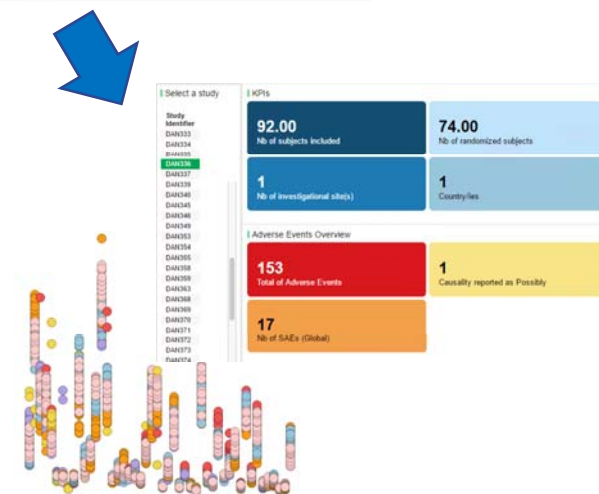
Trial Design Tables & Regular Datasets



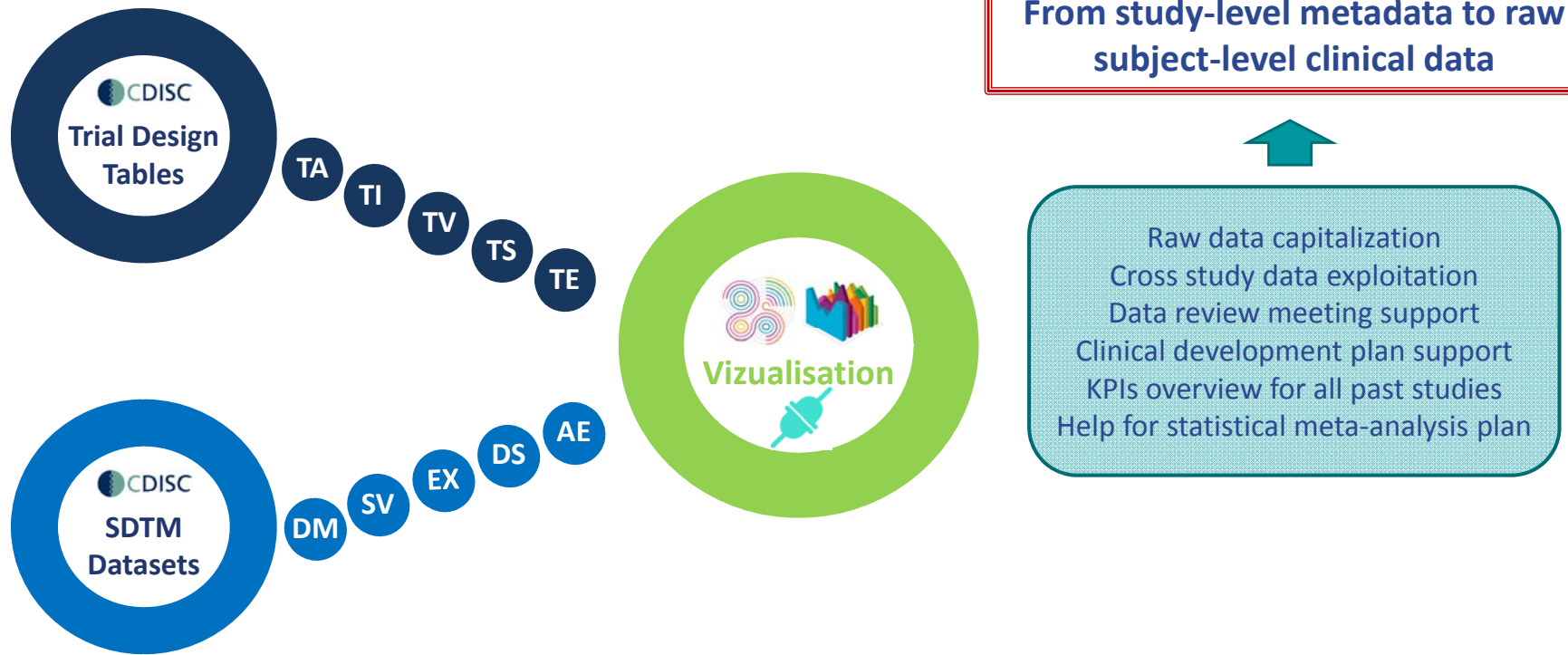
Bringing your SDTM data alive



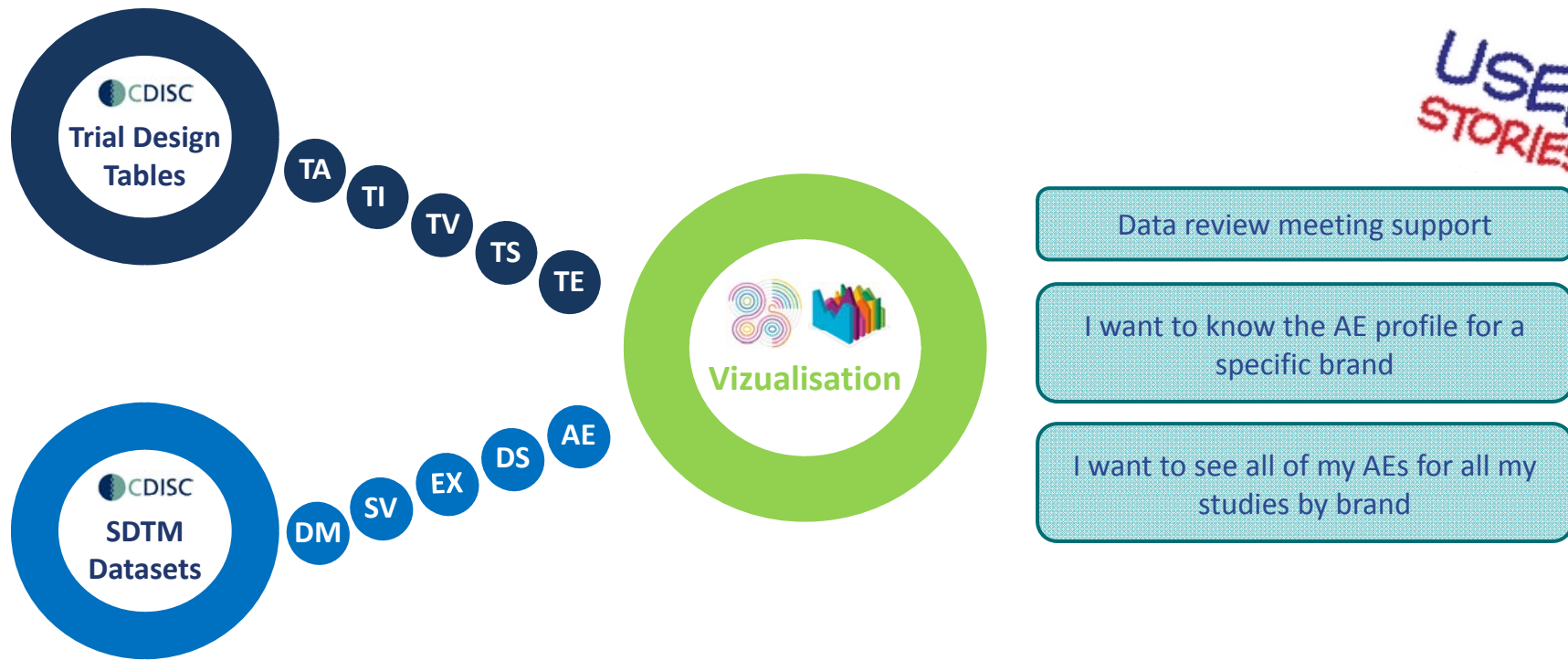
Study Identifier	Domain Abbr...	Category for ...	Result or Find..	Original Units
DAN472	LB	BIOCHEMISTRY	288	umol/L
DAN472	LB	BIOCHEMISTRY	16.81	ng/mL
DAN472	LB	BIOCHEMISTRY	272	umol/L
DAN472	LB	BIOCHEMISTRY	19.15	ng/mL
DAN472	LB	BIOCHEMISTRY	270	umol/L
DAN472	LB	BIOCHEMISTRY	18.23	ng/mL
DAN472	LB	BIOCHEMISTRY	266	umol/L
DAN472	LB	BIOCHEMISTRY	16.87	ng/mL
DAN472	LB	BIOCHEMISTRY	271	umol/L
DAN472	LB	BIOCHEMISTRY	17.14	ng/mL
DAN472	LB	BIOCHEMISTRY	275	umol/L
DAN472	LB	BIOCHEMISTRY	18.71	ng/mL
DAN472	LB	BIOCHEMISTRY	279	umol/L



Study-level to subject level



In practice...

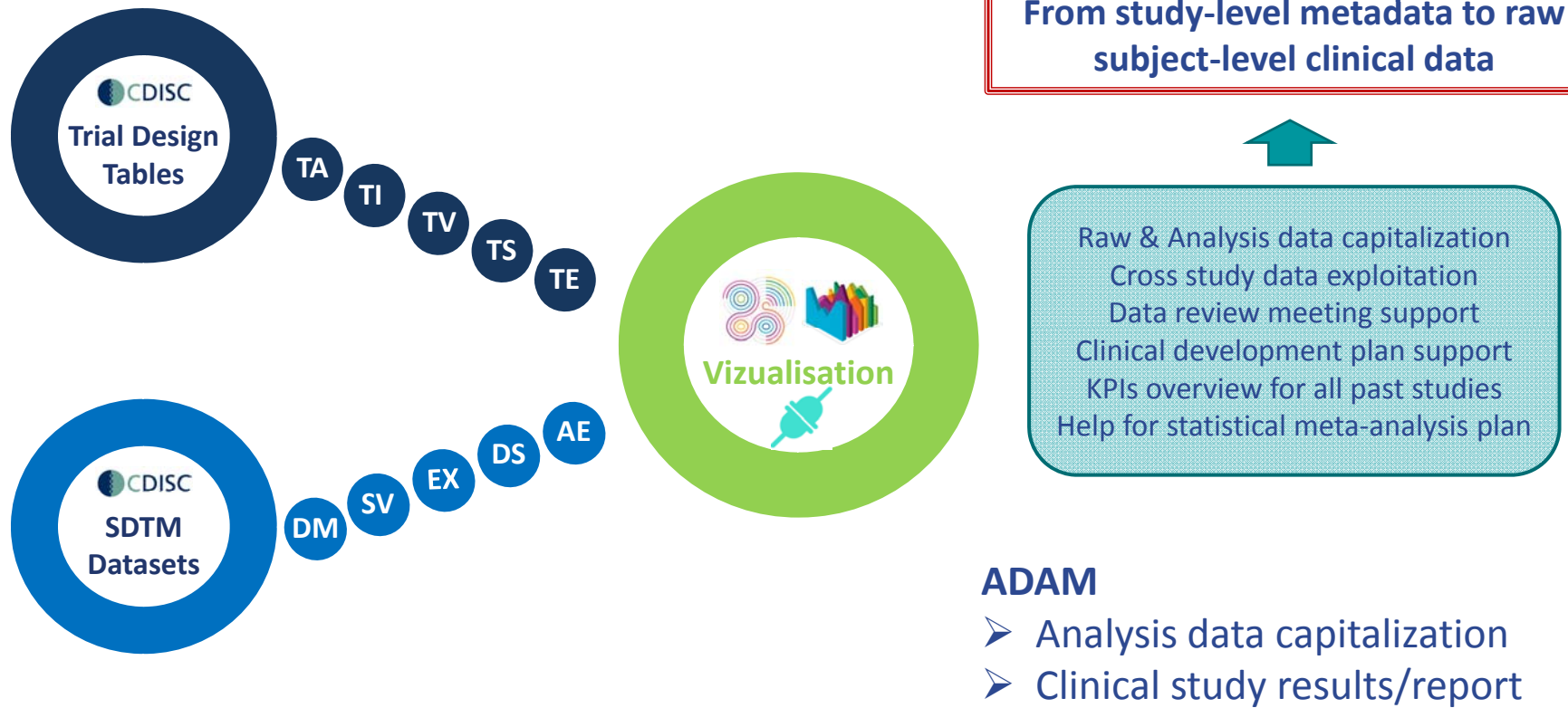


App Demo



DISCLAIMER Data have been created for the demo purpose

Next steps



Key Takeaways

- **Standardized, Integrated Data are useful**
- **Understandable overview of data for the clinical study teams**
- **Quickly consumable metrics for operations & leadership**
- **Stat Team can consider specific cases in SAP redaction or derived data specs**
- **Validates business value of standards governance**

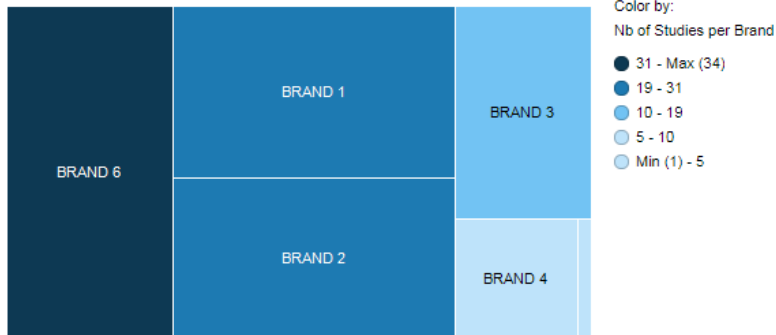
Backup slides



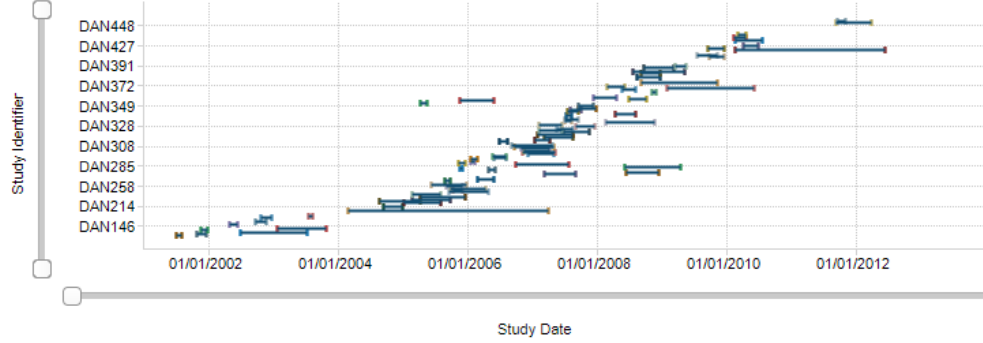
GLOBAL OVERVIEW

CREATED DATA
FOR DEMO PURPOSE

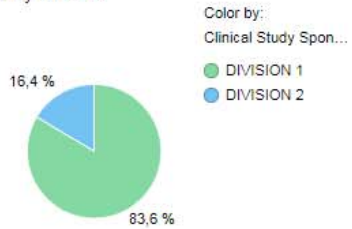
Brand



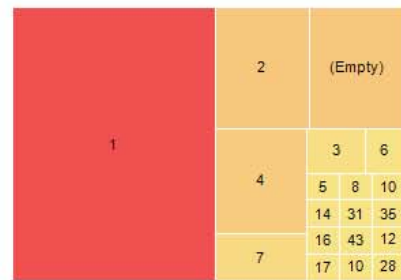
Chronology



By Division



Number of Sites



Involved Countries



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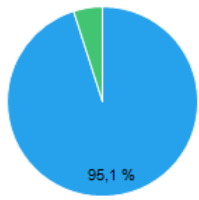
METADATA EXPLORATION

CREATED DATA
FOR DEMO PURPOSE

Study Type

Color by:
Healthy Subject

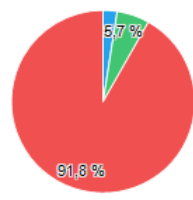
- INTERVENTIONAL
- OBSERVATIONAL



Randomization

Color by:
Healthy Subject

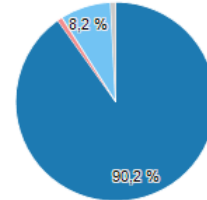
- N
- NA
- Y



Population Status

Color by:
Pediatric Status

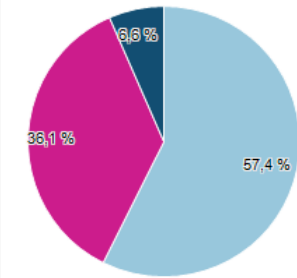
- ADULT
- BOTH
- CHILD
- (Empty)



Gender

Color by:
Sex

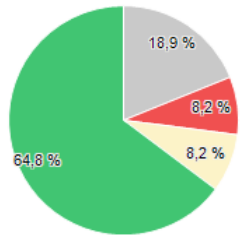
- BOTH
- F
- M



Healthy Subjects Indicator

Color by:
Healthy Subject

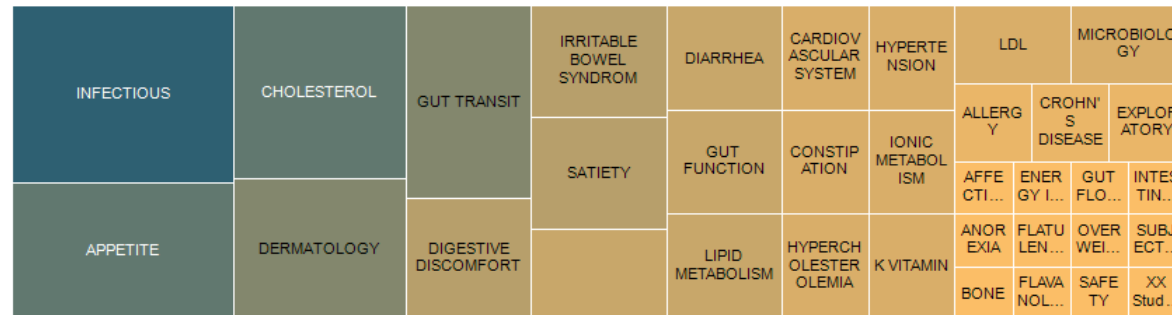
- N
- NA
- Y



Study Indication

Color by:
Nb of Studies

- Max (13)
- Min (1)



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STUDIES SELECTION

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Select the Brand(s):

Type to search in list

(All) 7 values

- BRAND 1
- BRAND 2
- BRAND 3
- BRAND 4
- BRAND 6

Reset filters

Select the search end point(s):

- By category:

- Adverse Event
- Demographics
- Laboratory Test
- Questionnaire
- Substance Use
- Vital Signs Test

- By name:

Type to search in list

(All) 136 values

- 25-Hydroxyvitamin D / Inactive ...
- 3,4-methylenedioxymethamph...
- Age
- Alanine Aminotransferase / SGPT
- Albumin / Microalbumin

Select the test product compound(s):

- By category:

- COMPOSITION
- PROCESS

- By subcategory:

Type to search in list

(All) 11 values

- By name:

Type to search in list

(All) 121 values

Select a study

Study Identifier

DAN146
DAN149
DAN150
DAN151
DAN156
DAN157
DAN187
DAN191
DAN198
DAN229
DAN251
DAN288
DAN301
DAN305
DAN306
DAN307
DAN308
DAN345
DAN378
DAN411
DAN421
DAN427
DAN443
DAN446
DAN456
DAN472

KPIs

6926

Nb of subjects included

5833

Nb of randomized subjects

26

Nb of investigational site(s)

12

Country/ies

Adverse Events Overview

190

Total of Adverse Events

1

Causality reported as Possibly

5

Nb of SAEs (Global)



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ID CARD

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Protocol description

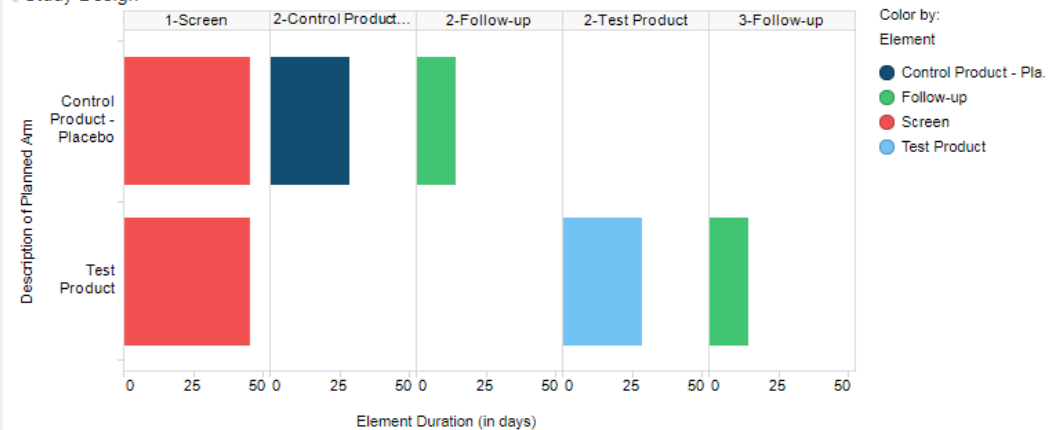
Brand	BRAND 2
Study name	XX Study Name XX
Study Code	DAN472
Study title	Effect xxx on yyy
Clinical Study Sponsor	DANONE RESEARCH
Study Type	INTERVENTIONAL
1 planned Country(ies) of Investigational Sites	GERMANY
Study Indication	XX Study Indication XX

Study Objectives

Trial Summary

Parameter	Parameter Value (full)
Study Secondary Objective	XX Study Secondary Objectives XX
Study Secondary Objective	XX Study Secondary Objectives XX
Study Secondary Objective	XX Study Secondary Objectives XX

Study Design



Study documentation

Document Name	Hyperlink
Final Protocol	Click here to access
Final Study Global Planning	Click here to access
Final CRF	Click here to access
Final CSR Other Vol.	Click here to access
Database storage	Click here to access

Data Content

Category	Parameter Name
Adverse Event	
Demographics	Age
Demographics	Date/Time of Birth
Demographics	Race
Demographics	Sex
Laboratory Test	Alanine Aminotransferase / SGPT
Laboratory Test	Apolipoprotein A1
Laboratory Test	Apolipoprotein B



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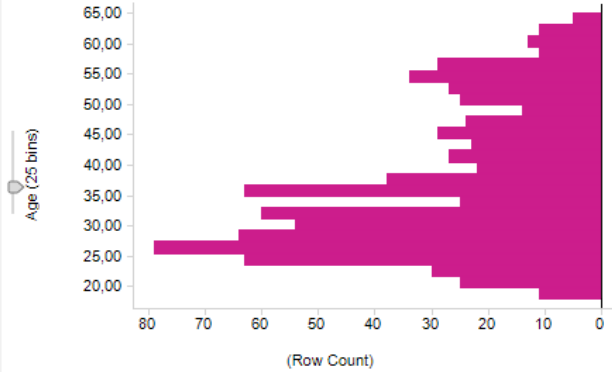


CREATED DATA FOR DEMO PURPOSE

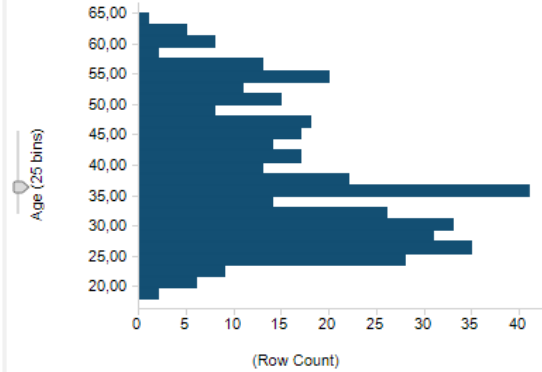
Age per Sex



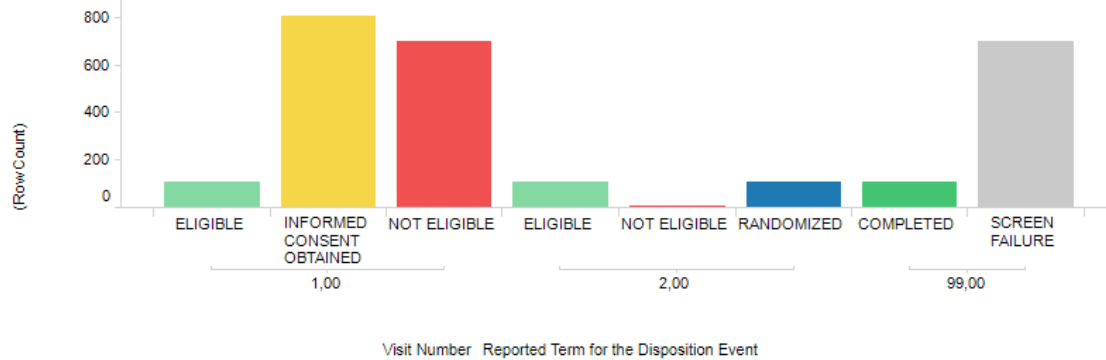
Histogram – Age



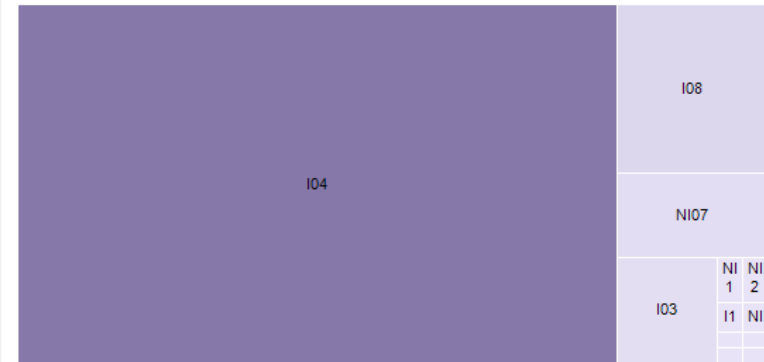
Histogram – Age



Subject's Disposition



Inclusion/Exclusion Criteria

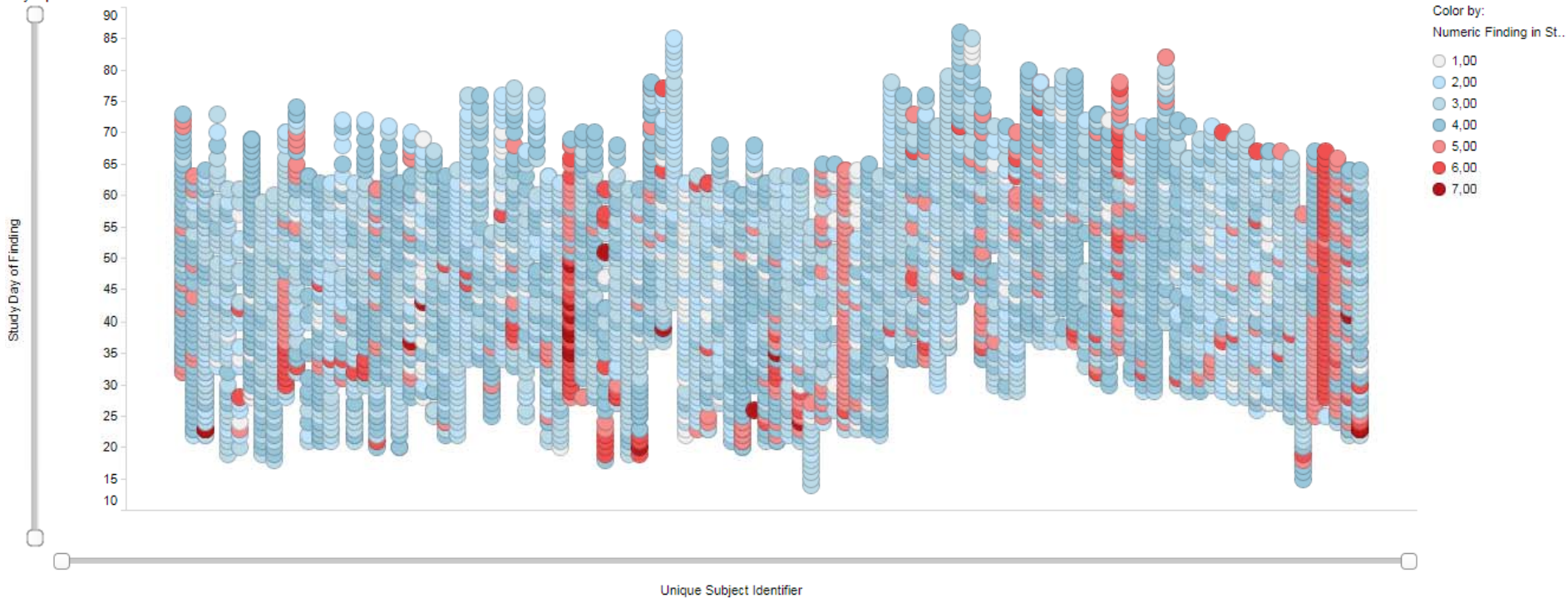


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Symptoms Assessment

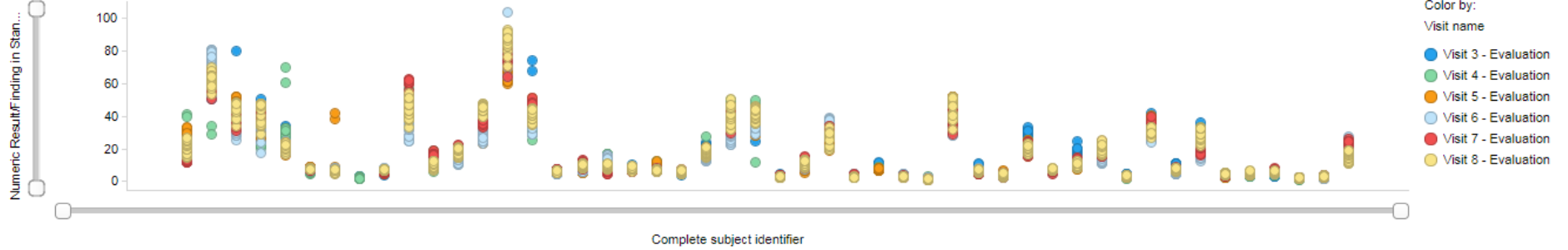


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LAB Review Parameter A



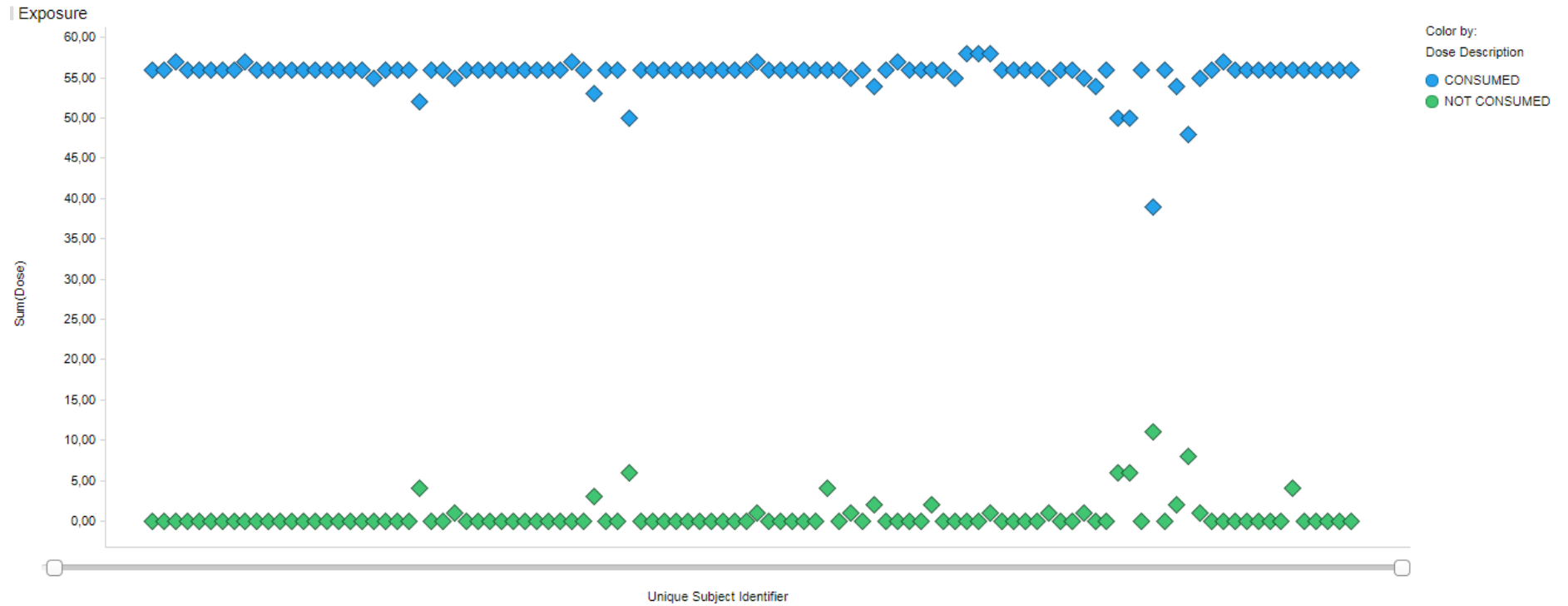
LAB Review Parameter B



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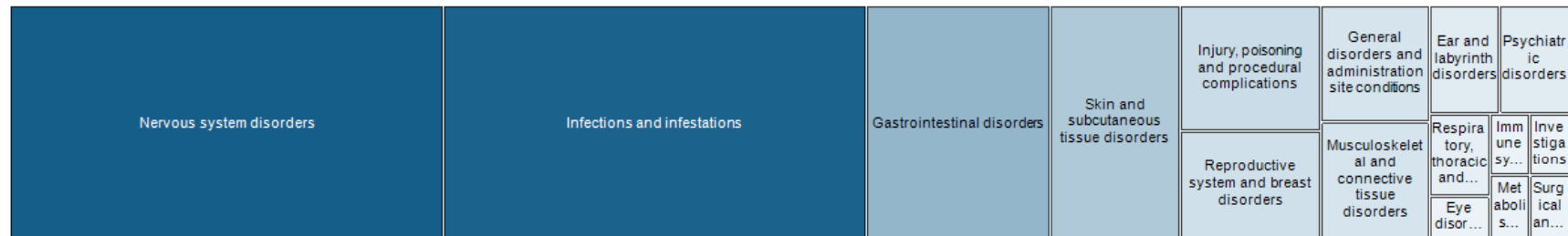


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Row Count per AESOC

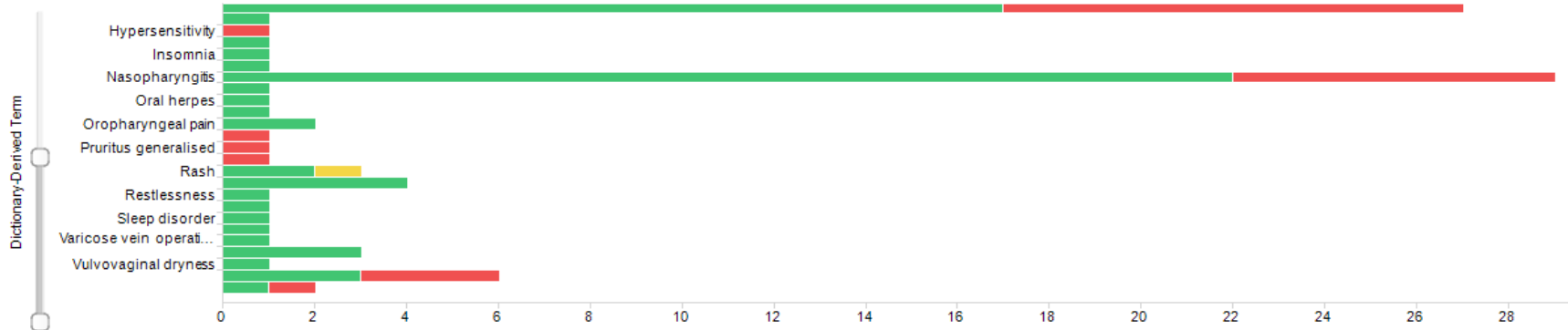


Color by:
(Row Count)

- Max (40)
- Min (1)

Hierarchy:
AESOC

Distribution – Dictionary-Derived Term



Color by:
Severity/Intensity

- MILD
- MODERATE
- SEVERE



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Reset filters

Number of selected subjects: 4

Adverse Events - per Coded Term

Nasopharyngitis	Dysgeusia	Fatigue	Gastroesophageal reflux di...	Rash	Vertigo			
			Drug erupt...	Dysme nomh...	Oropharyng...	Wound		
	Dyspepsia	Rash maculopapular	Abdo o...	Col d...	Geni tal...	Glos sitis	Glos so...	Hae m...
			Arth ra...	Cyst itis	Her p...	M...	Or...	Or...
Headache	Vulvovaginal mycotic infection	Ankle fracture	Asp ar...	Dizz in...	Hyp er...	Oral prur	Pr...	Re...
		Back pain	Ble p...	Eryt h...	Incr e...	Pai n in	Si...	Sl...

Subjects

Unique Subject Identif

- DAN472-001-0011
- DAN472-001-0016
- DAN472-001-0026
- DAN472-001-0030
- DAN472-001-0037
- DAN472-001-0038
- DAN472-001-0041
- DAN472-001-0048
- DAN472-001-0049

- DAN472-001-0063
- DAN472-001-0074
- DAN472-001-0077
- DAN472-001-0081

Selected Adverse Events - Details

Unique Subject I...	Reported Ter...	Dictionary-De...	Preferred T...	AESOC	AESOCOD	Severity/
DAN472-001-0063	INTERMITTE...	Headache	10019211	Nervous syste...	10029205	MILD
DAN472-001-0063	COMMON CO...	Nasopharyngitis	10028810	Infections and ...	10021881	MILD
DAN472-001-0074	COMMON CO...	Nasopharyngitis	10028810	Infections and ...	10021881	MILD
DAN472-001-0074	LUMBALGO	Back pain	10003988	Musculoskelet...	10028395	MILD
DAN472-001-0074	EXANTHEMA ...	Rash	10037844	Skin and subc...	10040785	SEVERE
DAN472-001-0077	METALLIC TA...	Dysgeusia	10013911	Nervous syste...	10029205	MILD
DAN472-001-0077	HEADACHE	Headache	10019211	Nervous syste...	10029205	MILD
DAN472-001-0077	FATIGUE	Fatigue	10016256	General disord...	10018065	MILD
DAN472-001-0077	VAGINAL DRY...	Vulvovaginal d...	10047791	Reproductive ...	10038604	MILD
DAN472-001-0077	PAINFUL JOI...	Arthralgia	10003239	Musculoskelet...	10028395	MILD
DAN472-001-0077	VERTIGO INT...	Vertigo	10047340	Ear and labyri...	10013993	MILD
DAN472-001-0081	VAGINAL YEA...	Vulvovaginal ...	10064899	Infections and ...	10021881	MODERA
DAN472-001-0081	COMMON CO...	Nasopharyngitis	10028810	Infections and ...	10021881	MODERA

Concomitant Medications - per Coded Term

IBUPROFEN	PARACETAMOL	CANDESARTAN	DIENOGEST	METAMIZOLE...	A...	CEFU	CEPA	CICLO	DITEM	DO RZ	ER GO	ERIP
		LEVOTHYROIDINE SODI...	DROSPIRENONE	PREDNISONONE	A...	ESTR	FR OV	GA LA	HE RB	HY BRI	HY PE	IBERO
	ENOXAPARIN...	RIZATRIPNAN B...	ETORICOXIB	AL...	EU	IBU PR	LISIN...	MA G...	MA G...	ME D...	ME R...	
	BENZOCAIN	TRAMADOL HY...	CERTOSTAT	A...	FE	IPR AT	ME TA	NA R...	NA SIC	NIT R...	NIT R...	
ETHINYLESTRADIOL	LEVONORGESTREL	MEDICETYL PYRI...	XYLOMETAZO...	BI...	FE	KA RR	MIN MIS	NU ER	PR VA	SI...	S...	
				C...	FO	KLI PR	NA PR	OM EP	RIV AR	VI TA	X AL	ZI NC

Selected Concomitant Medications - Detail

Unique Subject I...	Reported Name of D...	Standardized Medic...	Medication Cl...	Medicati...	Subcategory ...
DAN472-001-0063	YAZ 1/2 (ETHINYLES...	ETHINYLESTRADIOL	ESTROGENS	L02AA	Prescription
DAN472-001-0063	YAZ 2/2(DROSPIRE...	DROSPIRENONE	PROGESTOG...	G03AC	Prescription
DAN472-001-0063	CICLOPOLI(CICLOPI...	CICLOPIROX	OTHER ANTI...	D01AE	Prescription
DAN472-001-0077	VALETTE	CERTOSTAT	PROGESTOG...	G03AA	Prescription
DAN472-001-0081	ETHINYL ESTRADIO...	ETHINYLESTRADIOL	ESTROGENS	L02AA	Prescription
DAN472-001-0081	LEVONORGESTREL...	LEVONORGESTREL	PROGESTOG...	G03AC	Prescription
DAN472-001-0081	CLOTRIMAZOL	CLOTRIMAZOLE	ANTIINFECTI...	A01AB	Self-medication
DAN472-001-0081	PARACETAMOL	PARACETAMOL	ANILIDES	N02BE	Self-medication



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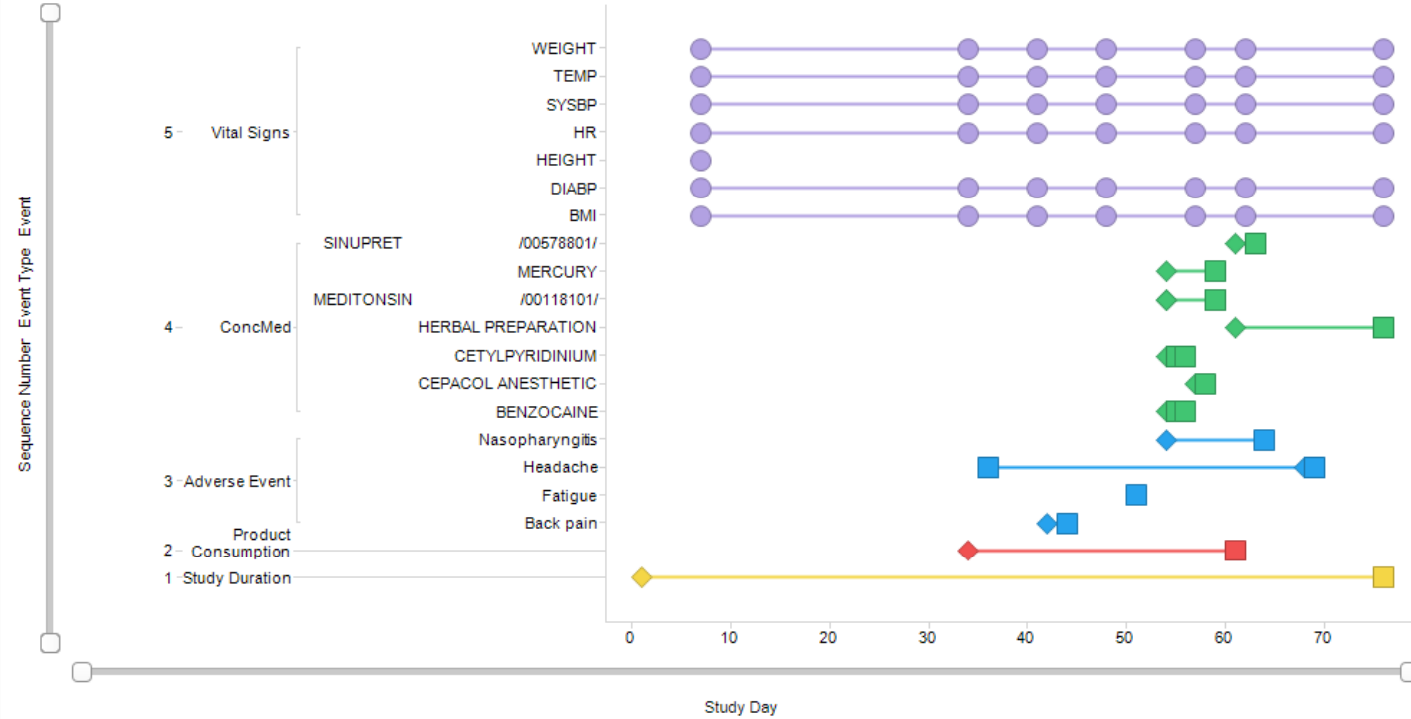
Reset filters

Number of selected subjects: 1

Subject(s) selection

Unique Subject Identi...
DAN472-001-0063

Patient Profile

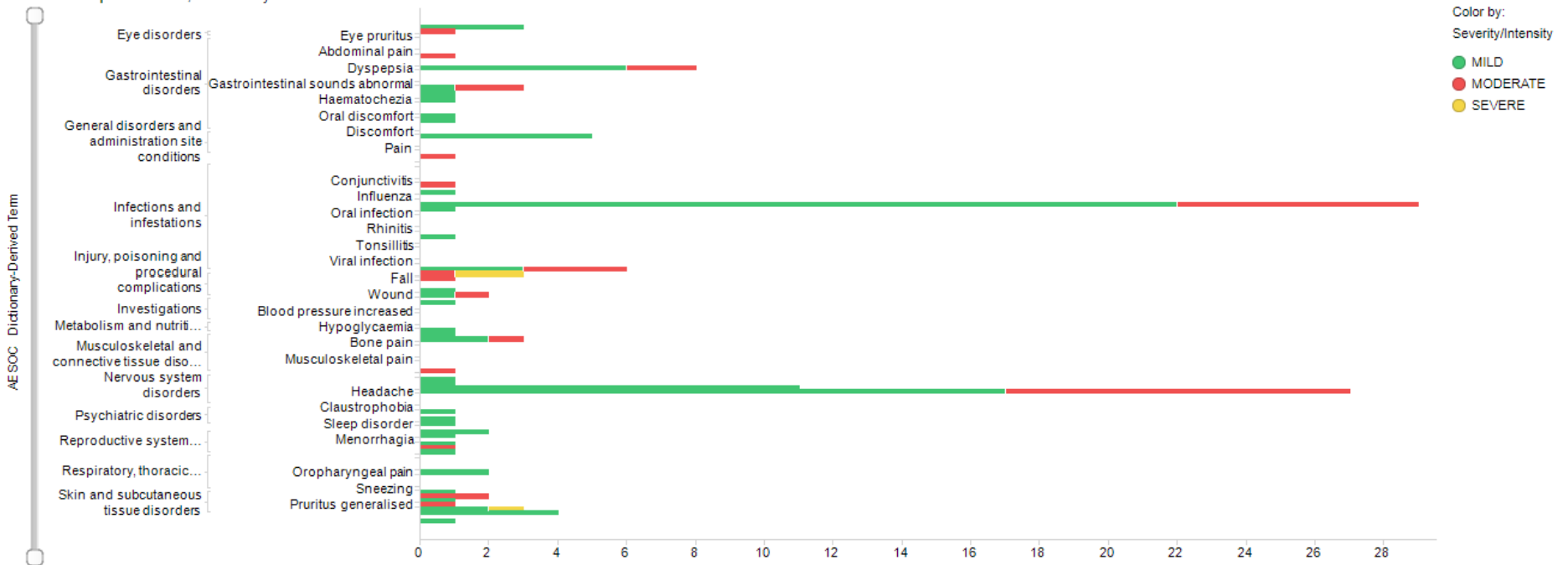


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FOR DEMO PURPOSE

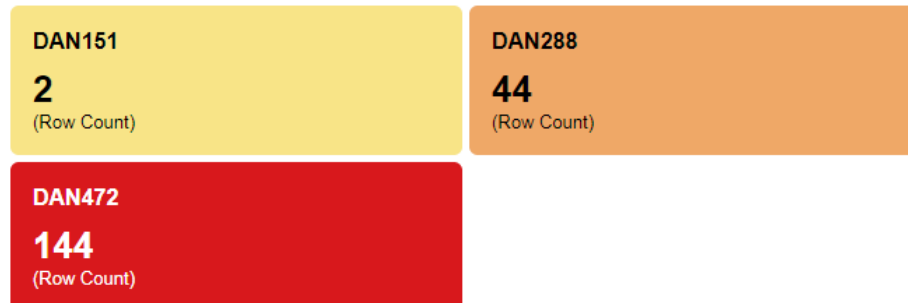
Row Count per AESOC, Dictionary-Derived Term



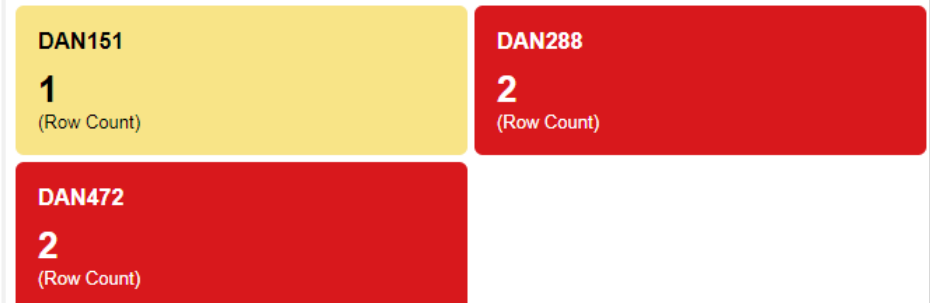


CREATED DATA
FOR DEMO PURPOSE

KPI Chart - Adverse Event



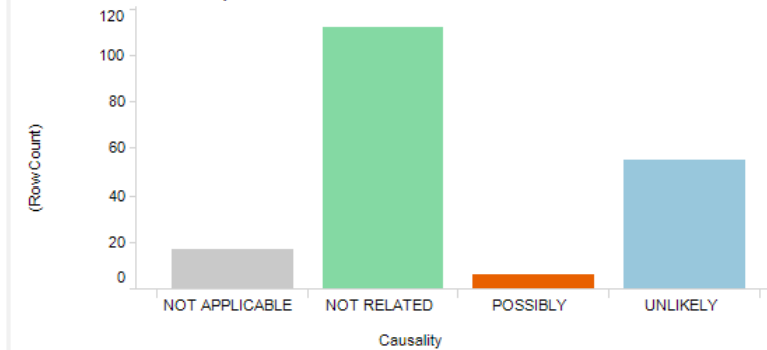
KPI Chart - Serious Adverse Event



Row Count per AESOC



Distribution - Causality





CREATED DATA
FOR DEMO PURPOSE



Adverse Events - SOC



Study & Brand information

Study Identifier	Brand
DAN113	BRAND 6
DAN284	BRAND 6
DAN288	BRAND 2
DAN336	BRAND 3
DAN472	BRAND 2



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