2026 Korea CDISC Day

29 October 2026 · Seoul, Korea

From Standard Clinical Data to Actionable Safety Review

Noriki Naruse, Sr. Account Sales, Revvity Japan Co., Ltd.

Daisuke Sakai, Sr. Field Application Scientist, Revvity Japan Co., Ltd.

Euiyeon Cho, Sales, P&D Solution Inc.

29 October 2026

Agenda

1. Japan Clinical Data Visualization Consortium (CDAvC)
2. JASPUG – PhUSE Safety Review templates
3. JMP vs Spotfire
4. Demo by Daisuke Sakai
5. P&D Solution Inc.

Speakers



Noriki Naruse

Sr.Account Sales

Revvity Japan Co.,Ltd.



Daisuke Sakai

Sr. Filed Application Scientist

Revvity Japan Co.,Ltd.



Euiyeon Cho

Sales

P&D Solution inc.

Japan Clinical Data Visualization Consortium (CDAvC)

User Group



Name：**Japan Clinical Data Visualization Consortium (CDAvC)**

Web Site：https://www.eps.co.jp/ja/support/cdavc/

Mailing List ：prj-cdavc-staff@eps.co.jp

Executive board member （Oct 2026）

Chairman ：	Takashi Moriya（Edwards Lifesciences Japan LLC）
Vice chairman：	Tomoko Fujiwara（A2 Healthcare Corporation）
Vice chairman：	Masayuki Kobayashi (Shionogi & Co., Ltd.)
Executive ：	Toru Fudatsuji（Kissei Pharmaceutical Co., Ltd.), Yukinobu Nagumo(Nobelpharma Co., Ltd.), Hiroaki Tanaka（A2 Healthcare Corporation）
Organizer：	EPS Corporation / Revvity Japan Co.,Ltd.

Member Company **39 Companies**（Oct 2026）

Asahi Kasei Therapeutics Corporation, EA Pharma Co., Ltd., EPS Corporation, A2 Healthcare Corporation, Eisai Co., Ltd., Otsuka Pharmaceutical Factory, Inc., Mediscience Plannning Inc., Shionogi & Co., Ltd., CMIC Co.,Ltd., Senju Pharmaceutical Co.,Ltd., Takeda Pharmaceutical Company Limited, Tanabe Pharma Corporation, Daiichi Sankyo Company Limited, Sumitomo Pharma Co.,Ltd., Nippon Shinyaku Co., Ltd., Mochida Pharmaceutical Co., Ltd., Janssen Pharmaceutical K.K.

Other 11 companies

Japan Clinical Data Visualization Consortium



Japan Clinical Data Visualization Consortium



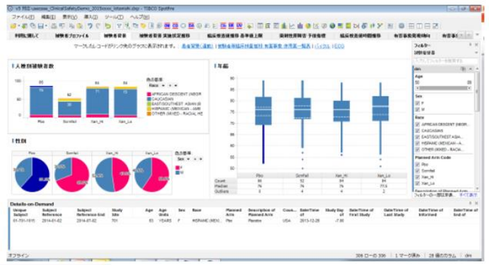
member ：
Composed of one representative from each pharmaceutical company.

Secretariat ：

EPS

revvity signals

Pooling the know-how and Ideas of each company



First Installment

Clinical Safety Review

(SDTM IG 3.2 Compatible)

Development, dissemination, and maintenance of standard templates
Proposal and dissemination of visualization methods
Exchange of views with regulatory authorities

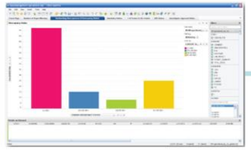
Part 2
Risk Based Monitoring
&
Signal Detection



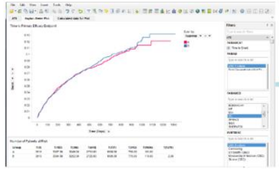
Risk Based Monitoring



Pharmacovigilance



Trial Operations



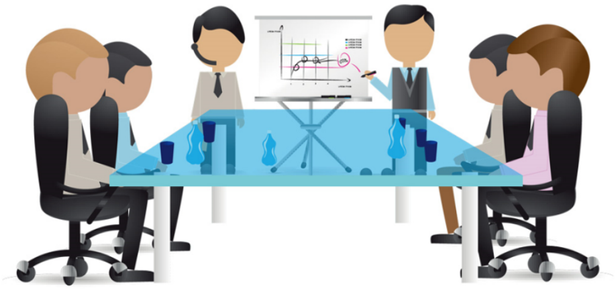
Clinical Effectiveness Visualization (Therapeutic Area)

CDAVC

Purpose of the Activity



As a group formed by volunteers from organizations involved in areas such as the clinical development, safety assessment, and post-marketing surveillance of pharmaceuticals, we aim to enhance the utility of data through clinical data visualization using Spotfire. By facilitating the exchange of ideas and conducting training sessions, we contribute to improving the performance of the organizations to which our members belong.





Standardization of data review （Safety Review）





Regulatory authorities

Common data format
＝**CDISC**

What is the common view?
⇒ Promote the template .
⇒⇒ Advance the standardization of safety reviews.

Common data format
＋ **Common perspective**

Application / Inquiry

Common data format
＋ **Common perspective**

Application / Inquiry

Alliance



Pharmaceutical company A



Pharmaceutical company B

CDAVC

Safety Review : How Standard Templates Work



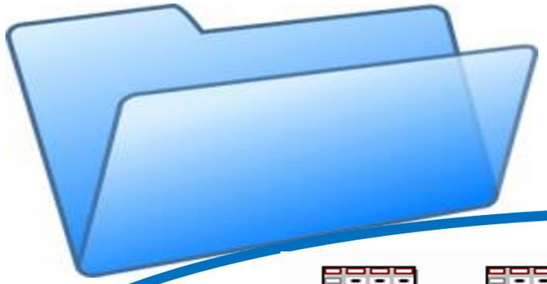
Standard template file



Actions from the reviewer's perspective



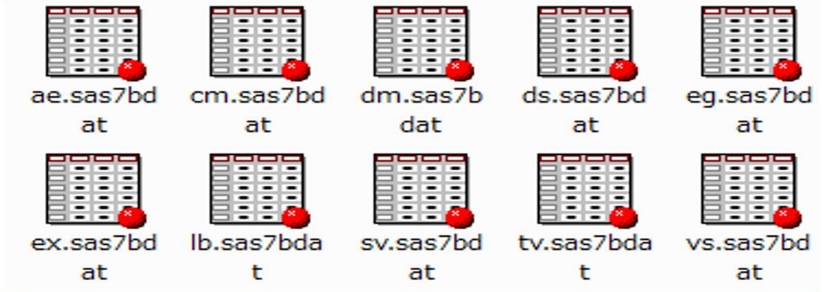
File placement
： Place in the same folder as SDTM(.sas7bdat)



Data Provision Request

Provision and execution of analysis macros

open



Data Provision (Automatic Loading)



PC with Spotfire installed (Reviewer)

CDISC SDTM IG :3.2 Compatible

CDAVC

CDAvC Safety Review Template DXP



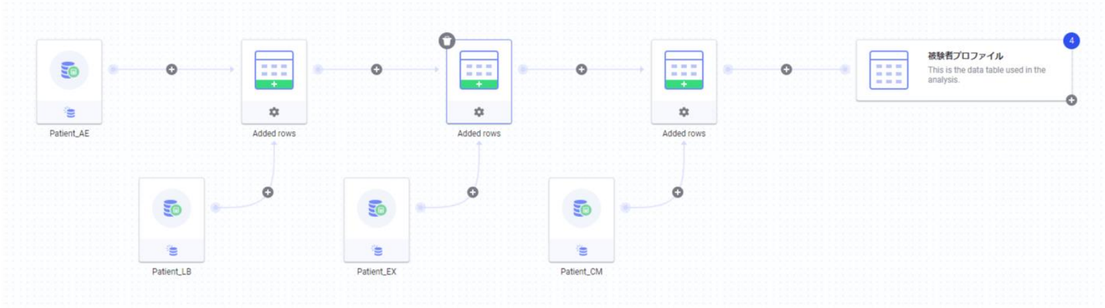
- ae.sas7bdat
- cm.sas7bdat
- dm.sas7bdat
- ds.sas7bdat
- eg.sas7bdat
- ex.sas7bdat
- lb.sas7bdat
- sv.sas7bdat
- tv.sas7bdat
- vs.sas7bdat
- CDAvCSafetyReviewTemplate_Link.dxp

open

- lab limits
- Patient_AE
- Patient_LB
- Patient_EX
- Patient_CM
- 被験者プロファイル
- Lab pivoted
- Lab pivoted (2)

New data created when opening

Data wrangling



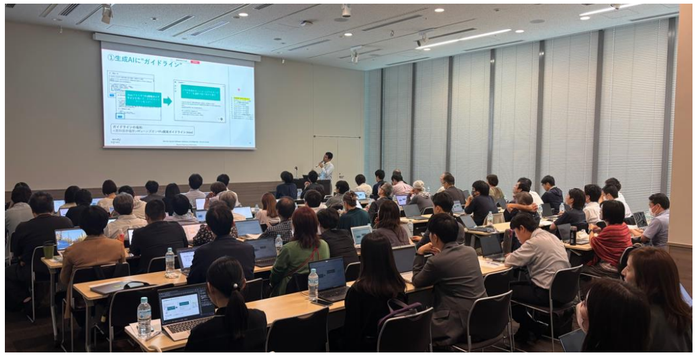
Reuseable by study

JASPUG – PhUSE Safety Review templates

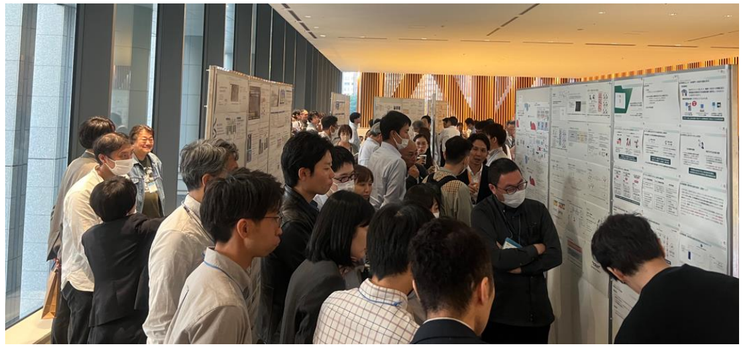
JASPUG
Japan Spotfire Users Group

User driven Japanese Spotfire user community sharing usage idea among user lasting 21 years













Computational Science Working Groups

Spotfire Safety Review Templates in PhUSE Code Repository

Japan Spotfire User Group Meeting
Rebeka Revis
Eli Lilly & Company

phuse.eu/cs-working-groups.aspx

Examples where Spotfire Can be Useful

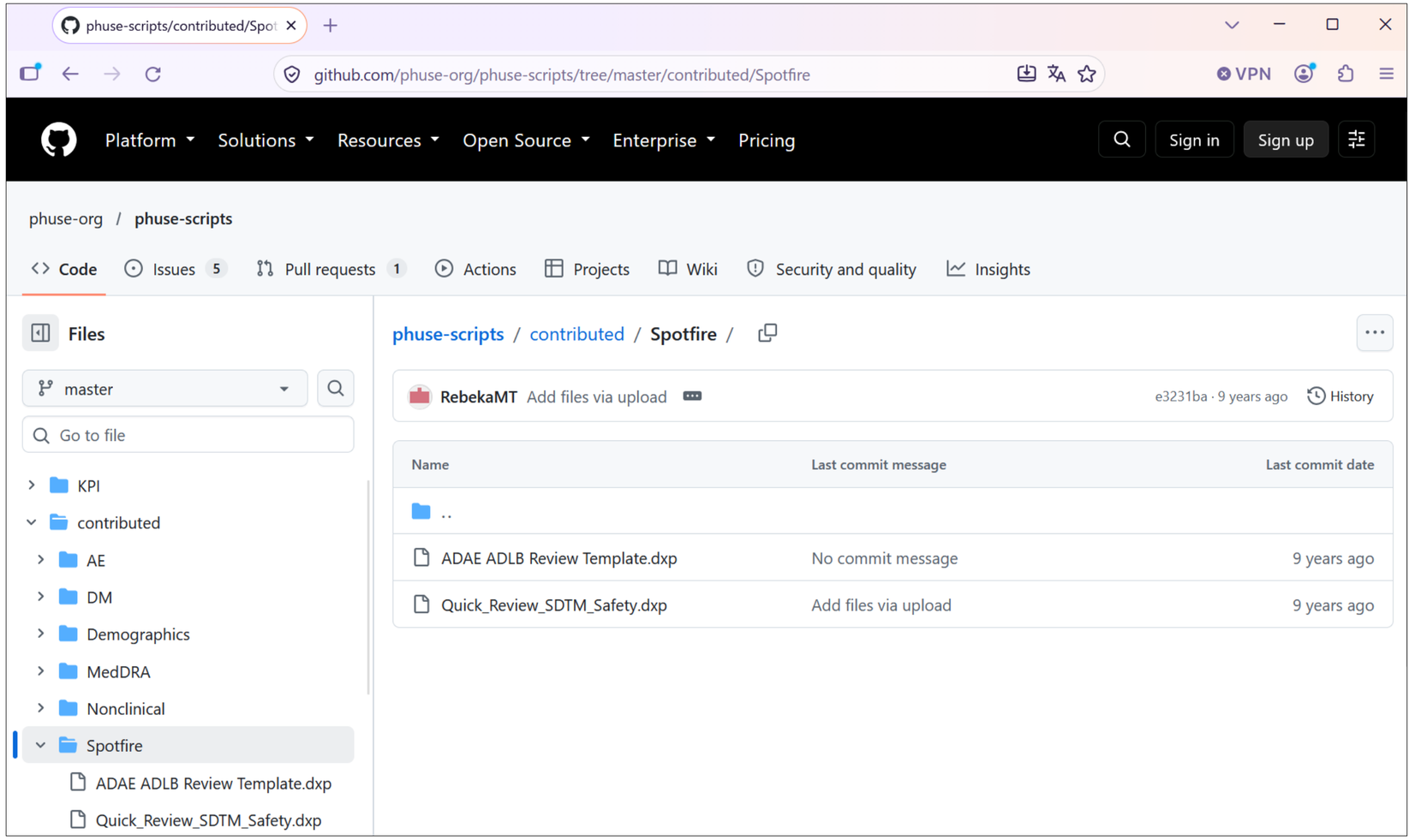
- Data Review and Exploration
- Generating Static Reports included for study reports, submission documents, regulatory response documents.
- Advisory board meeting
- Data mining and publication efforts
- Other



Where to find the Spotfire files?

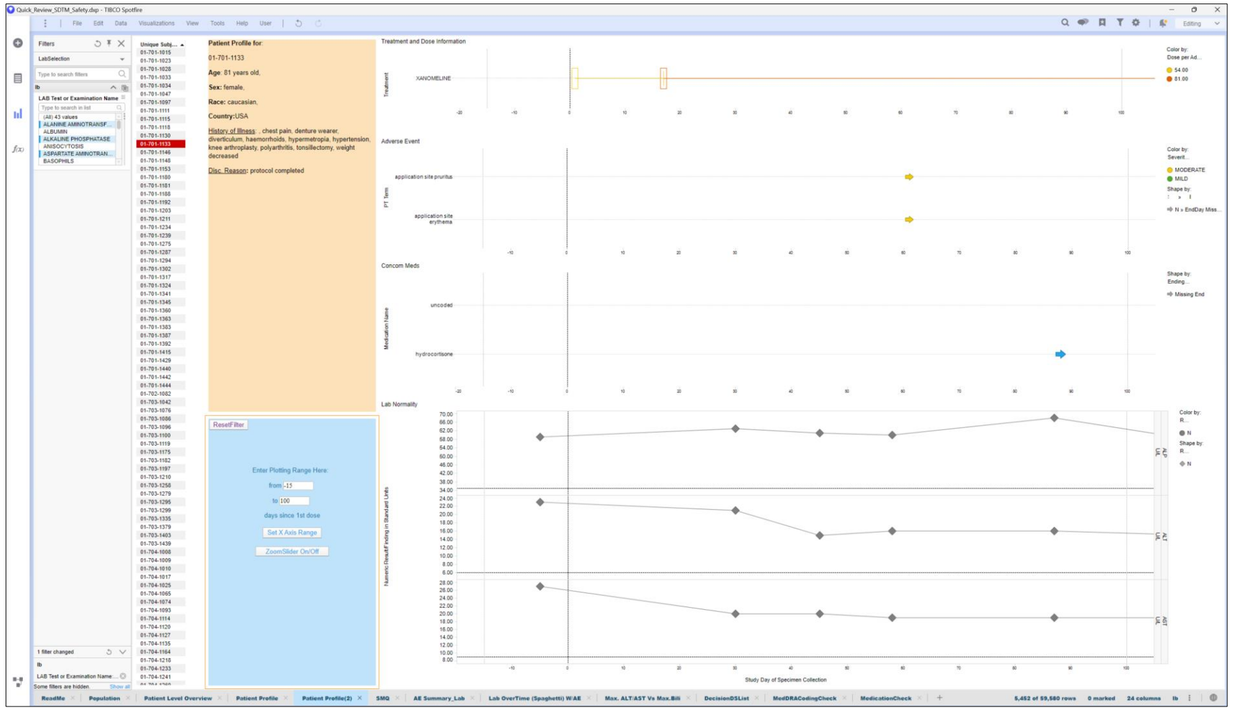
- Uploaded to GitHub as DXP files
  - https://github.com/phuse-org/phuse-scripts/tree/master/contributed/Spotfire
  - DXP files contain:
    - ✓Embedded de-identified ADaM or SDTM data (depending on the package)
      - Original data files: https://github.com/phuse-org/phuse-scripts/tree/master/data
    - ✓Multiple pages with interactive visualizations for safety analyses



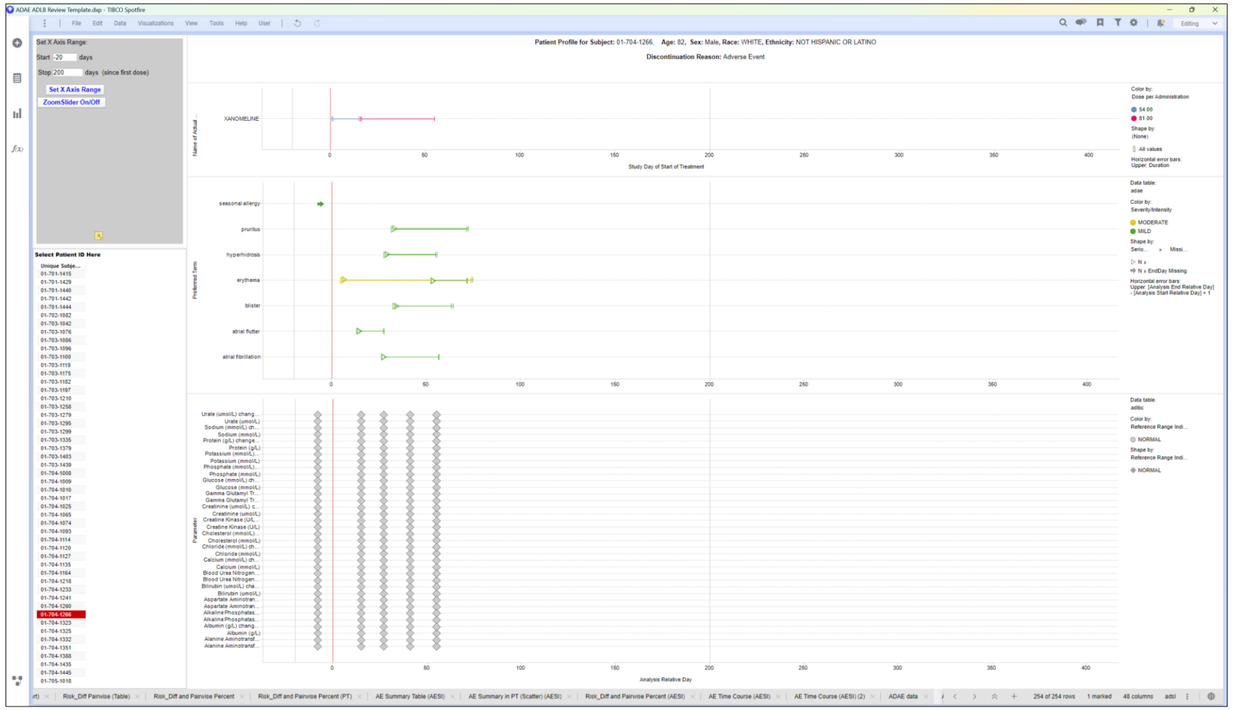


ADAE ADLB Review Template.dxp

Quick_Review_SDTM_Safety.dxp



Quick_Review_SDTM_Safety.dxp



ADAE ADLB Review Template.dxp

JMP vs Spotfire

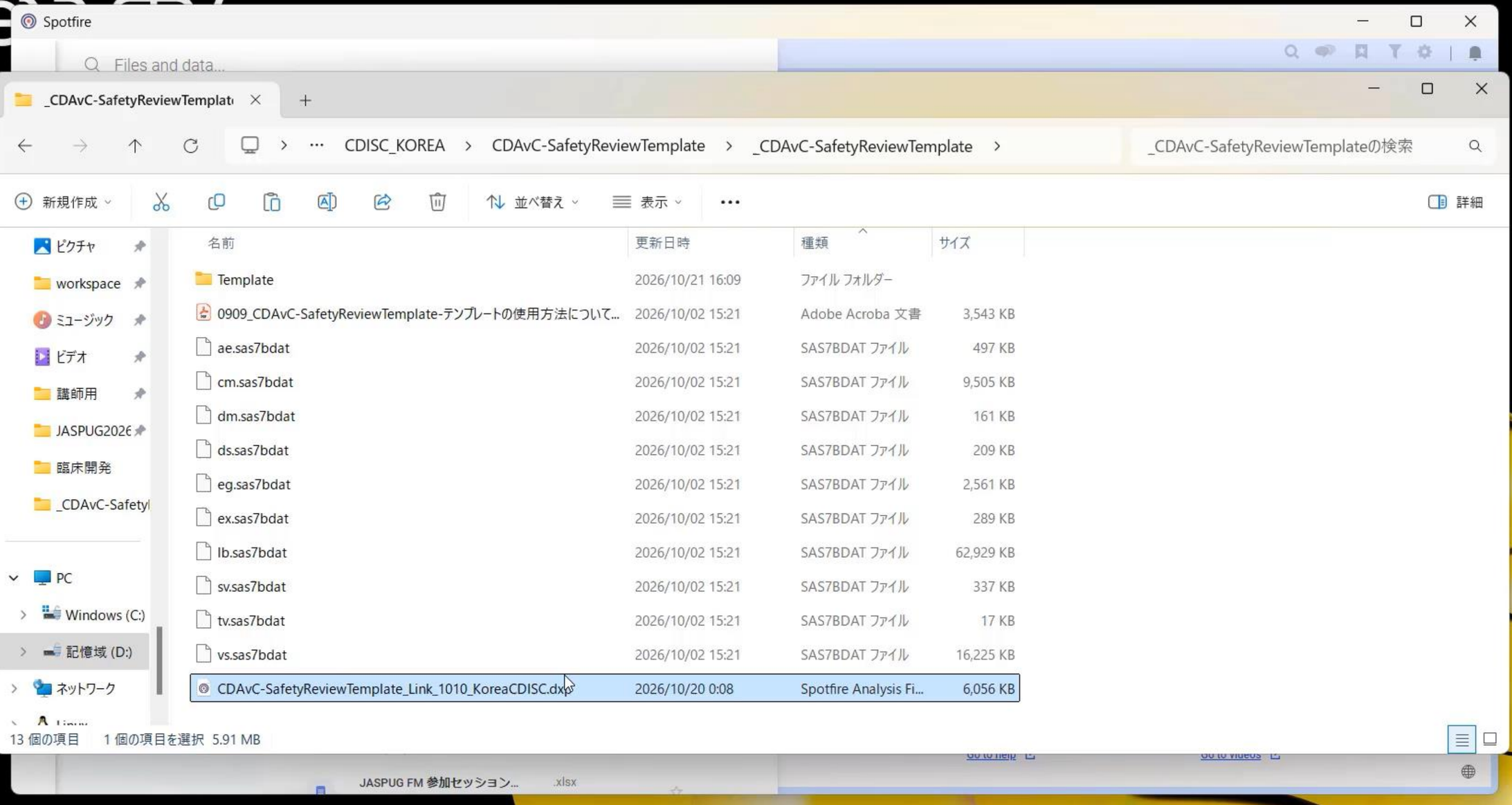
JMP

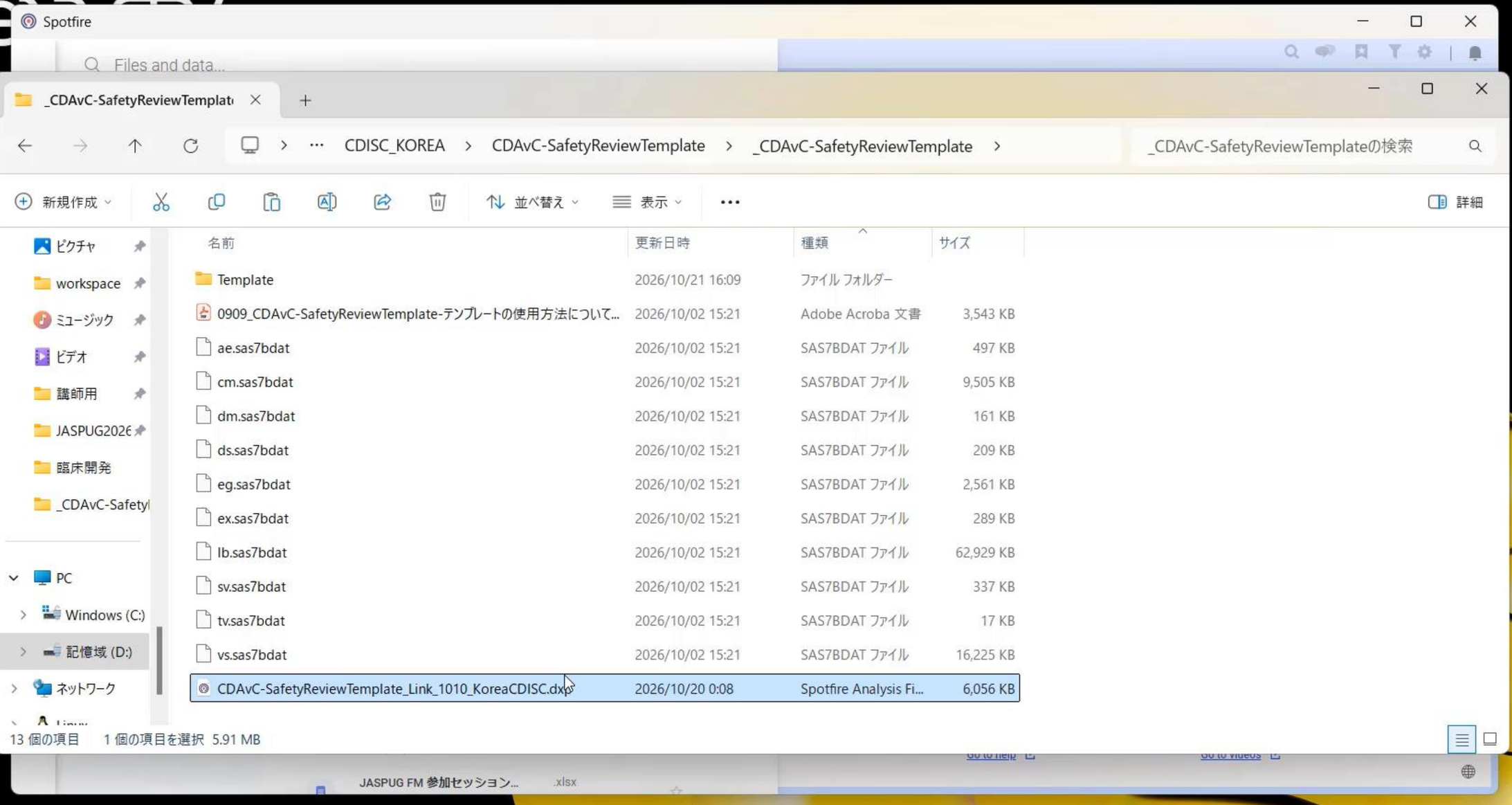
- Macintosh look
- Great tool for individual statistics
- Especially Between-group comparison generating p-value in Clinical
- Graph Builder technology is very close to Spotfire

Spotfire

- Windows look
- Exploratory Data Analysis + template
- Many user use in the meeting to gain insights on the fly
- Enterprise use

Demo by Daisuke Sakai


Spotfire
Files and data...
_CDAvC-SafetyReviewTemplat
CDISC_KOREA
CDAvC-SafetyReviewTemplate
_CDAvC-SafetyReviewTemplate
_CDAvC-SafetyReviewTemplateの検索
新規作成
並べ替え
表示
詳細
ピクチャ
workspace
ミュージック
ビデオ
講師用
JASPUG2026
臨床開発
_CDAvC-Safety
PC
Windows (C:)
記憶域 (D:)
ネットワーク
名前
更新日時
種類
サイズ
Template 2026/10/21 16:09 ファイル フォルダー
0909_CDAvC-SafetyReviewTemplate-テンプレートの使用方法について... 2026/10/02 15:21 Adobe Acroba 文書 3,543 KB
ae.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 497 KB
cm.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 9,505 KB
dm.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 161 KB
ds.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 209 KB
eg.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 2,561 KB
ex.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 289 KB
lb.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 62,929 KB
sv.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 337 KB
tv.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 17 KB
vs.sas7bdat 2026/10/02 15:21 SAS7BDAT ファイル 16,225 KB
CDAvC-SafetyReviewTemplate_Link_1010_KoreaCDISC.dxp 2026/10/20 0:08 Spotfire Analysis Fi... 6,056 KB
13 個の項目 1 個の項目を選択 5.91 MB
JASPUG FM 参加セッション... .xlsx


Spotfire
Files and data...
_CDAvC-SafetyReviewTemplat
CDISC_KOREA
CDAvC-SafetyReviewTemplate
_CDAvC-SafetyReviewTemplate
_CDAvC-SafetyReviewTemplateの検索
新規作成
並べ替え
表示
詳細
ピクチャ
workspace
ミュージック
ビデオ
講師用
JASPUG2026
臨床開発
_CDAvC-Safety
PC
Windows (C:)
記憶域 (D:)
ネットワーク
名前
更新日時
種類
サイズ
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CDAvC-SafetyReviewTemplate_Link_1010_KoreaCDISC.dxp 2026/10/20 0:08 Spotfire Analysis Fi... 6,056 KB
13 個の項目 1 個の項目を選択 5.91 MB
JASPUG FM 参加セッション... .xlsx

CDAvC-SafetyReviewTemplate_Link_1010_KoreaCDISC.dxp - Spotfire

File Edit Data Visualizations View Tools Help User

Editing

本templateにて利用できるデータセットの形式

・SDTMIG v3.2に準拠

【制約事項】

・テンプレート利用規約に同意いただけた場合、【同意】ボタンを押下してご利用ください。

同意

利用に関して | 被験者プロファイル | 被験者背景 | 被験者背景 実施状況推移 | 薬剤性肝障害 | 薬剤性肝障害 予後指標 | 臨床検査値時間推移 | バイタル | 有害事象発現傾向 | 有害事象一覧表 | QTc推移

No active visualization

CDAvC-SafetyReviewTemplate_Link_1010_KoreaCDISC.dxp - Spotfire

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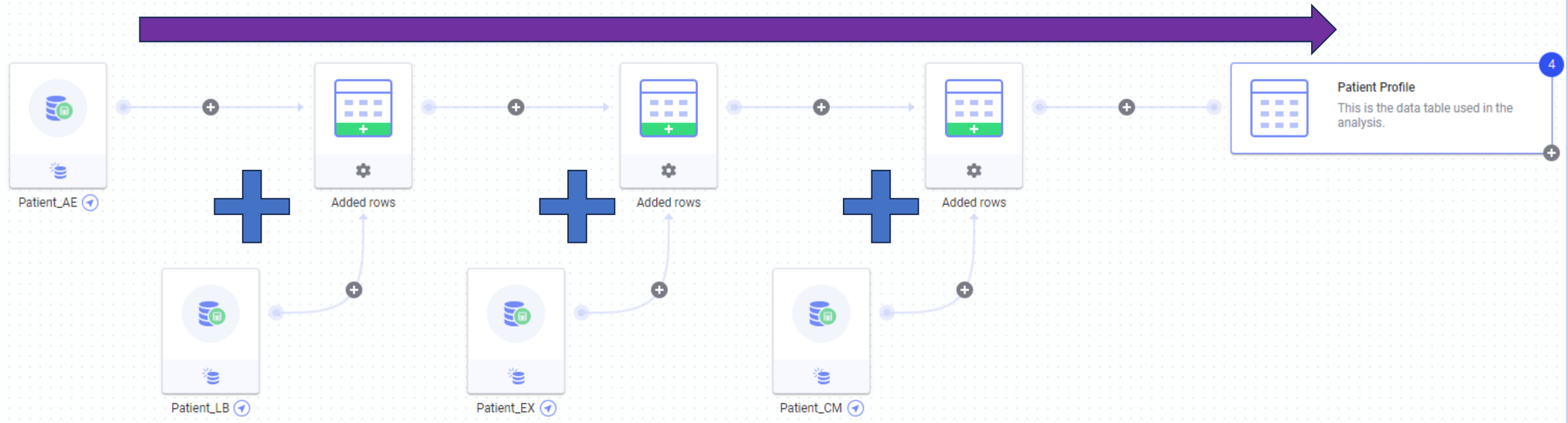
Editing

Type to search

Data tables

- ae
- lb
- dm
- cm
- tv
- sv
- ex
- vs
- eg
- ds
- lab limits
- Patient_AE
- Patient_LB
- Patient_EX
- Patient_CM
- Patient Profile
- Lab pivoted
- Lab pivoted (2)

Patient Profile | Rename | Reload | Key columns (0) | Replace | Delete | Settings



Patient Profile

- Added calculated column: Lab Test
- Added calculated column: Color Flag
- Added calculated column: Marker Size
- Added calculated column: Shape Flag

INFORMATION | DATA | COLUMN PROPERTIES | DATA TABLE PROPERTIES

Unique Su...	Join ID	Event Type	Event Detail	Event	Start/End	Day In Study	Baseline R...	x ULN	Lab Test	Color Flag	Ma
String	Integer	String	String	String	String	Real	Real	Real	String	String	
SAMPLE01...	100001	AE	MILD - PR...	Sample_PT...	Study Day ...	2.00			*Non-lab E...	AE MI	
SAMPLE01...	100002	AE	MILD - RE...	Sample_PT...	Study Day ...	8.00			*Non-lab E...	AE MI	
SAMPLE01...	100002	AE	MILD - RE...	Sample_PT...	Study Day ...	10.00			*Non-lab E...	AE MI	
SAMPLE01...	100003	AE	MILD - PR...	Sample_PT...	Study Day ...	2.00			*Non-lab E...	AE MI	
SAMPLE01...	100004	AE	MILD - PO...	Sample_PT...	Study Day ...	3.00			*Non-lab E...	AE MI	
SAMPLE01...	100004	AE	MILD - PO...	Sample_PT...	Study Day ...	26.00			*Non-lab E...	AE MI	
SAMPLE01...	100005	AE	MODERAT...	Sample_PT...	Study Day ...	3.00			*Non-lab E...	AE MO	
SAMPLE01...	100006	AE	MILD - PO...	Sample_PT...	Study Day ...	22.00			*Non-lab E...	AE MI	
SAMPLE01...	100007	AE	MILD - PR...	Sample_PT...	Study Day ...	21.00			*Non-lab E...	AE MI	
SAMPLE01...	100008	AE	MILD - PO...	Sample_PT...	Study Day ...	3.00			*Non-lab E...	AE MI	

23457 rows 13 columns

ADAE ADLB Review Template_1010_KoreaCDISC.dxp - Spotfire

File Edit Data Visualizations View Tools Help User

Editing

Over View of Visuals

----------All AEs----------

Reset All Filters

Adverse Event Summary - Includes a few figures and tables for the summary of adverse events at different MedDRA Hierarchy.

For subset summary use the filter panel.

Risk Difference for Adverse Events - Includes table and figures for the summary of risk difference for adverse events at different MedDRA Hierarchy.

For subset summary use the filter panel.

Patient Level Display - Includes patient profile for adverse event data for individual patients and for the analyses population.

----------AESIs----------

Adverse Event Summary - AESI - Includes table and figure for the summary of adverse events analyses explore by various SMQs

Risk Difference for Adverse Events - AESI -Risk difference at PT level for selected SMQs

Adverse Event Over Time -Plot of adverse event over time for all the patients with specific PTs (for selected PT or SMQs).

----------AE Lab Profile----------

Patient Profile - Lab&AE

---------- Labs----------

Lab Over Time - Includes heatmaps, boxplot and line chart (mean, median) over time

Lab Meeting Threshold/Shift - Includes visuals for patients meeting certain lab threshold for a selected lab, lab shift from baseline to post baseline

Two Labs Correlatioin -Includes visuals for lab1 vs. Lab2 measures (selected lab pair) with values as original unit, xULN.

Filters

Filtering scheme

Type to search filters

adae

adsl

Planned Treatment for Period 01
- Placebo
- Xanomeline Low Dose
- Xanomeline High Dose

Actual Treatment for Period 01
- Placebo
- Xanomeline High Dose
- Xanomeline Low Dose

Pooled Age Group 1
- <65
- >80
- 65-80

Race
- AMERICAN INDIAN OR ALASKA NATIVE
- BLACK OR AFRICAN AMERICAN
- WHITE

Sex
- F
- M

Ethnicity
- HISPANIC OR LATINO
- NOT HISPANIC OR LATINO

Safety Population Flag
- Y

Completers of Week 8 Population Flag
- N
- Y

Completers of Week 16 Population Flag
- N
- Y

Completers of Week 24 Population Flag
- N
- Y

Pooled Baseline BMI Group 1
- <25
- >=30

Some filters are hidden. Show all

FrontPage | Population | Patient Level Overview | AE Summary (Barchart) w/Lab | AE Summary Table | AE Summary in PT (Scatter) | AE Summary PT Nested in SOC | EventOnSet | EventOnSet (byseverity)

No active visualization

ADAE ADLB Review Template_1010_KoreaCDISC.dxp - Spotfire

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Over View of Visuals

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adae

adsl

Planned Treatment for Period 01
- Placebo
- Xanomeline Low Dose
- Xanomeline High Dose

Actual Treatment for Period 01
- Placebo
- Xanomeline High Dose
- Xanomeline Low Dose

Pooled Age Group 1
- <65
- >80
- 65-80

Race
- AMERICAN INDIAN OR ALASKA NATIVE
- BLACK OR AFRICAN AMERICAN
- WHITE

Sex
- F
- M

Ethnicity
- HISPANIC OR LATINO
- NOT HISPANIC OR LATINO

Safety Population Flag
- Y

Completers of Week 8 Population Flag
- N
- Y

Completers of Week 16 Population Flag
- N
- Y

Completers of Week 24 Population Flag
- N
- Y

Pooled Baseline BMI Group 1
- <25
- >=30

Some filters are hidden. Show all

FrontPage | Population | Patient Level Overview | AE Summary (Barchart) w/Lab | AE Summary Table | AE Summary in PT (Scatter) | AE Summary PT Nested in SOC | EventOnSet | EventOnSet (byseverity)

No active visualization

Thank You.
Next, P&D Solutions Introduction

About P&D Solution

23 yrs

Data analytics specialist

Focused solely on data visualization & analytics since 2003

40+

Projects per year

Across manufacturing, pharma/bio, finance and public sector

4,000+

Trainees per year

Training delivered to ~200 companies, agencies and universities

300+

Clients

Long-term partnerships with industry leaders

Spotfire in Korea: 23 Years as Distributor

Spotfire distributor in Korea since 2003

We brought Spotfire to Korea and have led the Korean market for 23 years

The standard in Korean manufacturing

Trusted by Samsung Electronics · SK hynix, Hyundai Motor and more

Expanding into pharma & bio

Used for R&D and data analysis at Korean pharma companies such as Daewoong and Daewon

Korea’s Spotfire training hub

4,000+ trainees a year · ~200 organizations · university curricula for 10+ years

Spotfire™

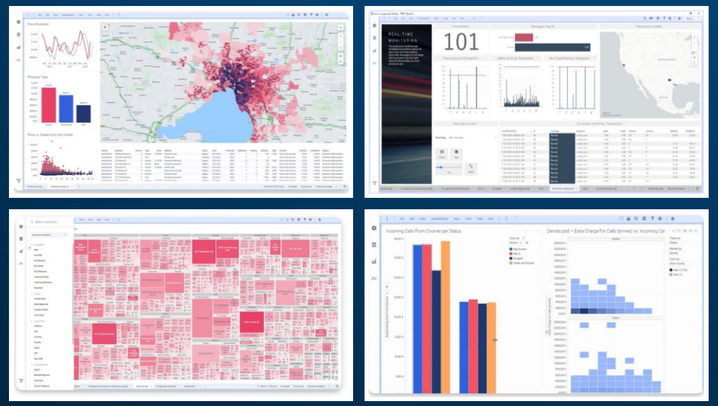
Since 2003

Spotfire Distributor in Korea

Certified Education Partner

TOP Producing VAR Award, AP

2013 · 2014



Leading Korean Companies Trust P&D

300+ companies & institutions

Pharma, Bio & Healthcare

대웅제약 · 유한양행 · HANDOK · 종근당 · LSK Global PS

Manufacturing, Semiconductor & IT

SAMSUNG · SAMSUNG DISPLAY · SAMSUNG ELECTRO-MECHANICS · SAMSUNG SDI · SK hynix · SK siltron · LG전자 · LG디스플레이 · LG화학 · HYUNDAI · SEMES · Amkor Technology · STECO

CORNING · EcoPro · NEXEN TIRE · Qcells · LB Semicon · LS-Nikko 동제련 · LS MnM · LS ITC · NAVIEN · LG CNS · LG U+

Finance, Retail & Services

신한카드 · 우리은행 · 하나은행 · Samsung Card · Hyundai Card · MG새마을금고 · 나이스정보통신 · CJ 제일제당 · CJ CHEILJEDANG · CJ OLIVENETWORKS · SSG.COM · LG생활건강 · AMOREPACIFIC · 신세계 푸드

DAESANG · Samyang Foods · JINAIR · 크린토피아 · KYOBO 교보문고

Public, Research & Education

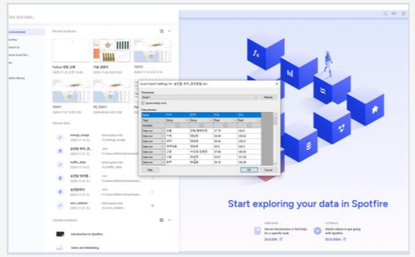
KISTEP · KRISO 선박해양플랜트연구소 · 경찰청 · 서울대학교 · 연세대학교 · 고려대학교 · 서강대학교 · 이화여자대학교 · 중앙대학교 · 부산대학교 · 전남대학교 · 충남대학교 · 충북대학교

영남대학교 · 조선대학교 · 울산대학교 · 서울과학기술대학교 · 가톨릭대학교 · 부경대학교 · 한국해양대학교 · 순천향대학교 · 국립공주대학교 · 국립한밭대학교 · 한국교통대학교 · 선문대학교

Spotfire at a Glance

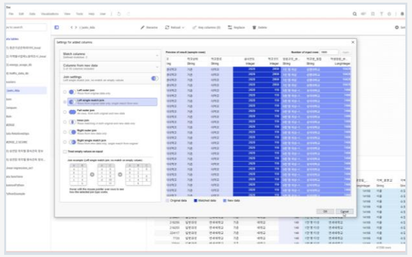
One platform from data to decision

01 Connect



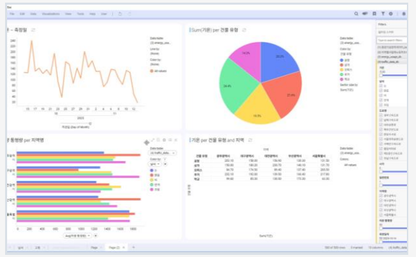
Databases, cloud and local files in one place

02 Prepare



No-code joins, pivots and calculated columns, plus Python / R

03 Visualize



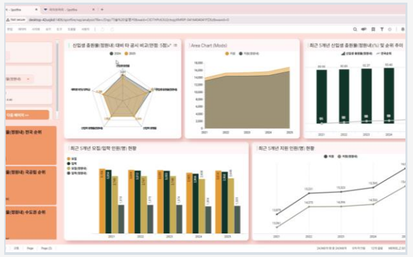
Interactive dashboards with linked marking, filtering and drill-down

04 Analyze



Built-in regression, clustering and forecasting, plus Python / R

05 Share



Publish to Web Player and automate PDF, PPT and Excel reports

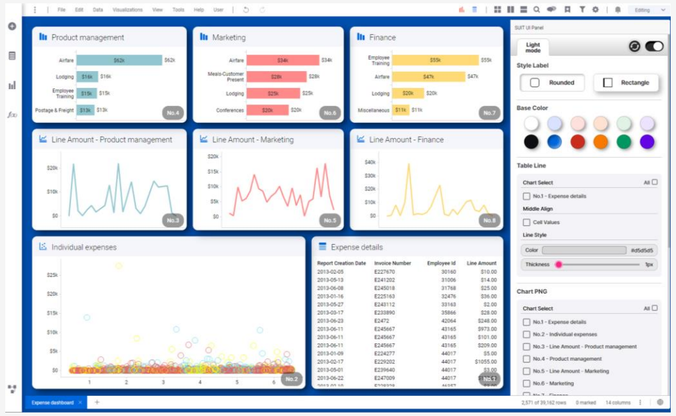
P&D Solution supports every step — in Korean

Korean Training, Services & Support



01 Korean Training

Monthly bootcamps, on-site and online courses · 28-seat classroom · 4,000+ trainees a year



02 Korean Professional Services

Tailored dashboards, data integration and advanced analytics with Python, R and SAS



03 Korean Tech Support

Local engineers supporting you in Korean, plus our own extensions P&D SUIT and P&D PRES

Get Started with Spotfire

01 Spotfire trial & license

The Safety Review templates in today’s demo run on Spotfire. P&D Solution provides trials and licenses in Korea

02 Implementation, training & support in Korean

The Spotfire distributor in Korea supports you from adoption to everyday use

Spotfire trial & license inquiries

P&D Solution
eycho@pndsolution.com
www.pndsolution.com

Thank You

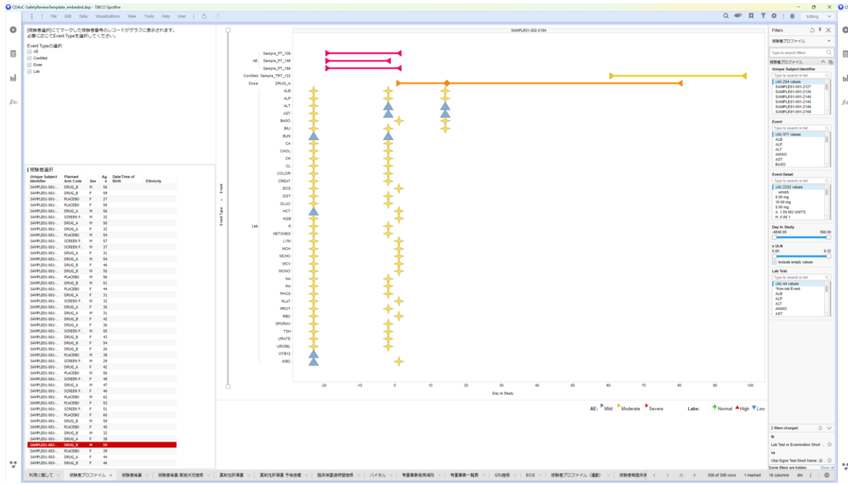
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Daisuke Sakai · Daisuke.Sakai@revvity.com
Euiyeon Cho · eycho@pndsolution.com

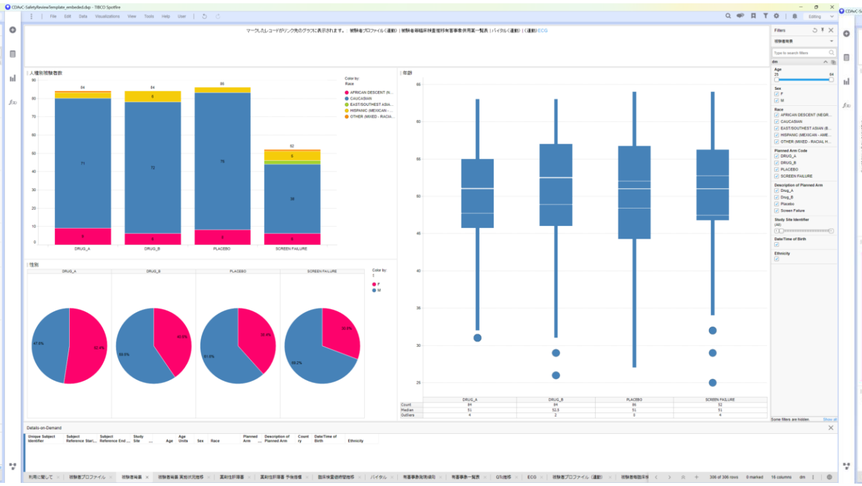
2026 Korea CDISC Day · 29 October 2026

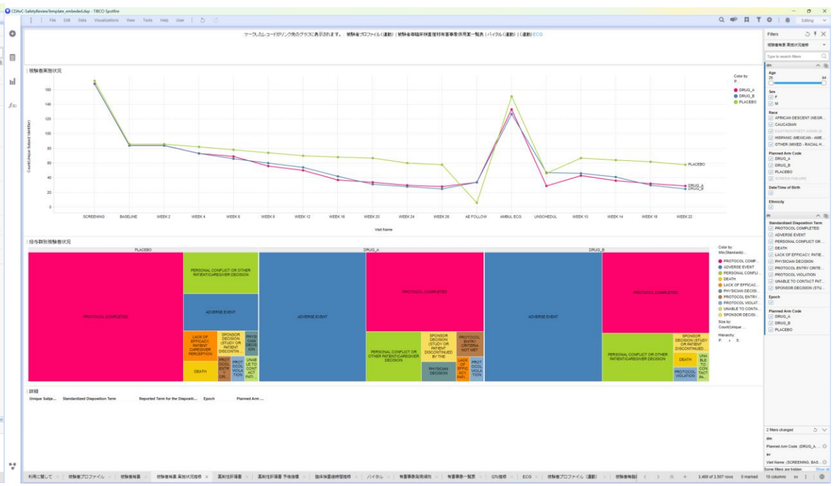


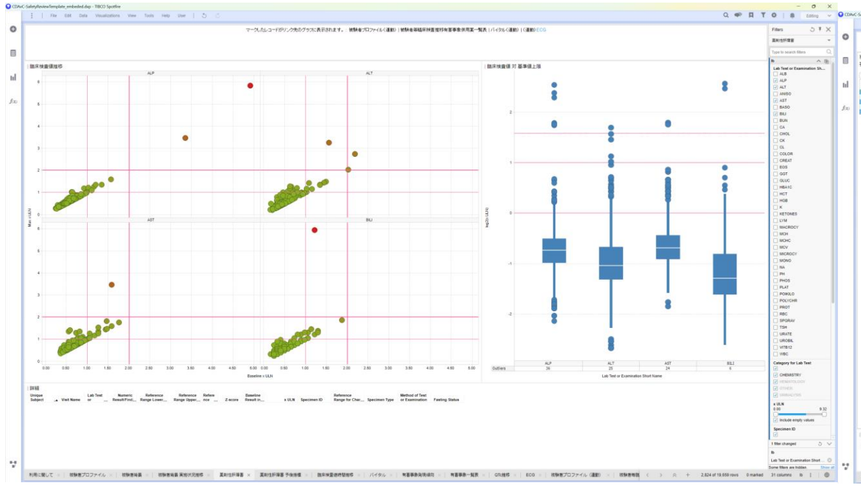
Appendix

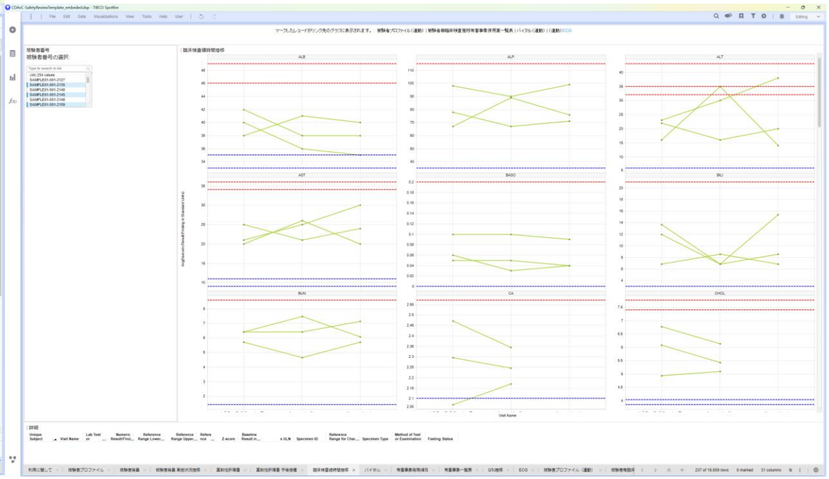
CDAvC Safety Review template sample

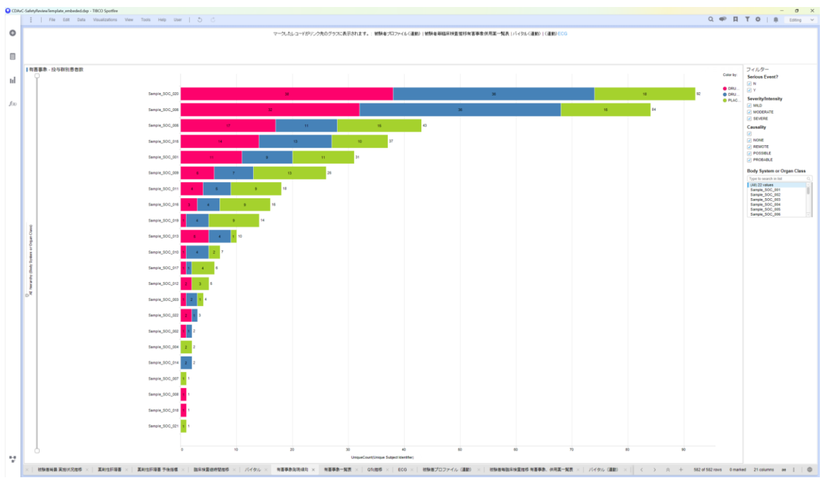




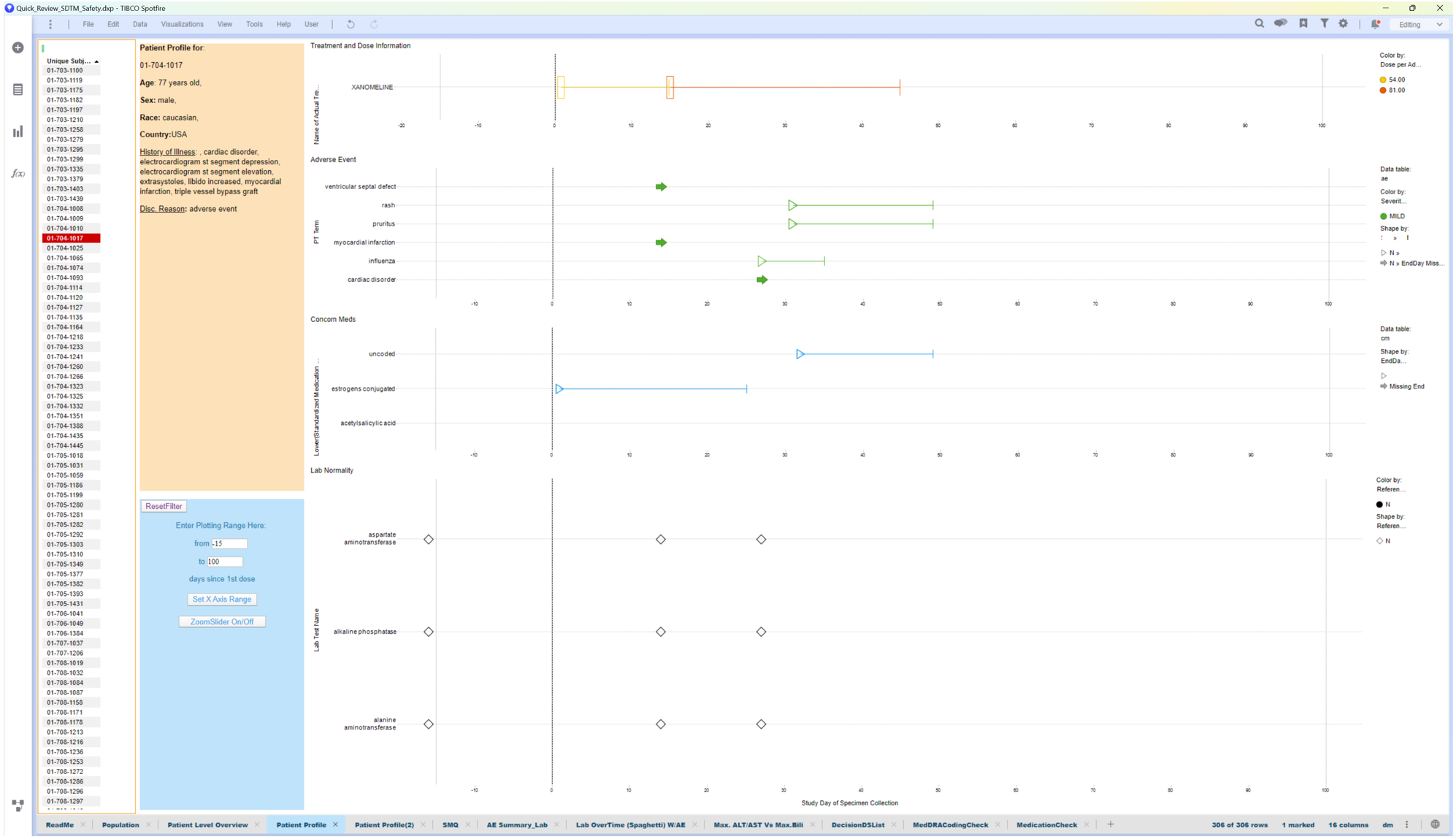




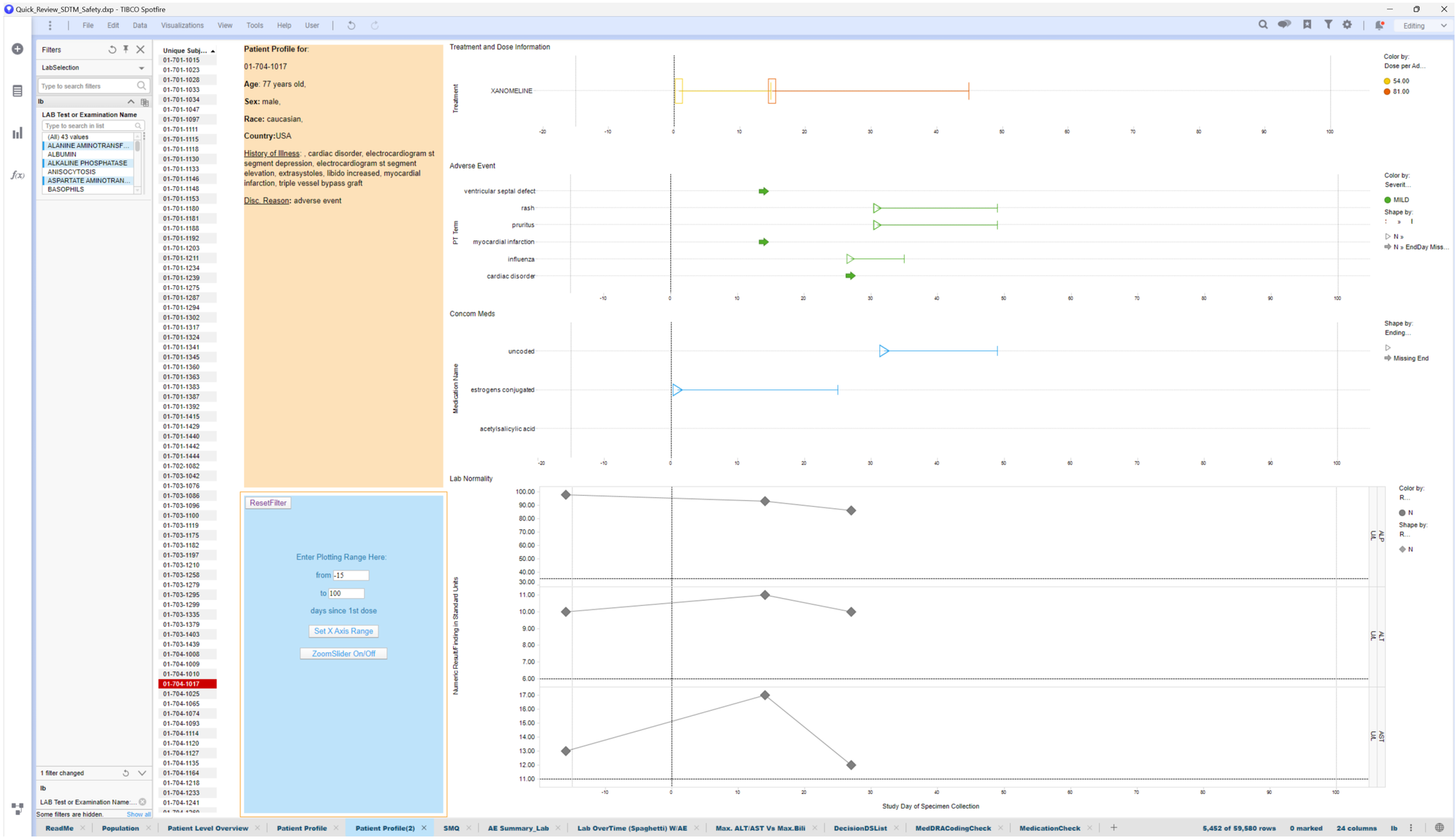




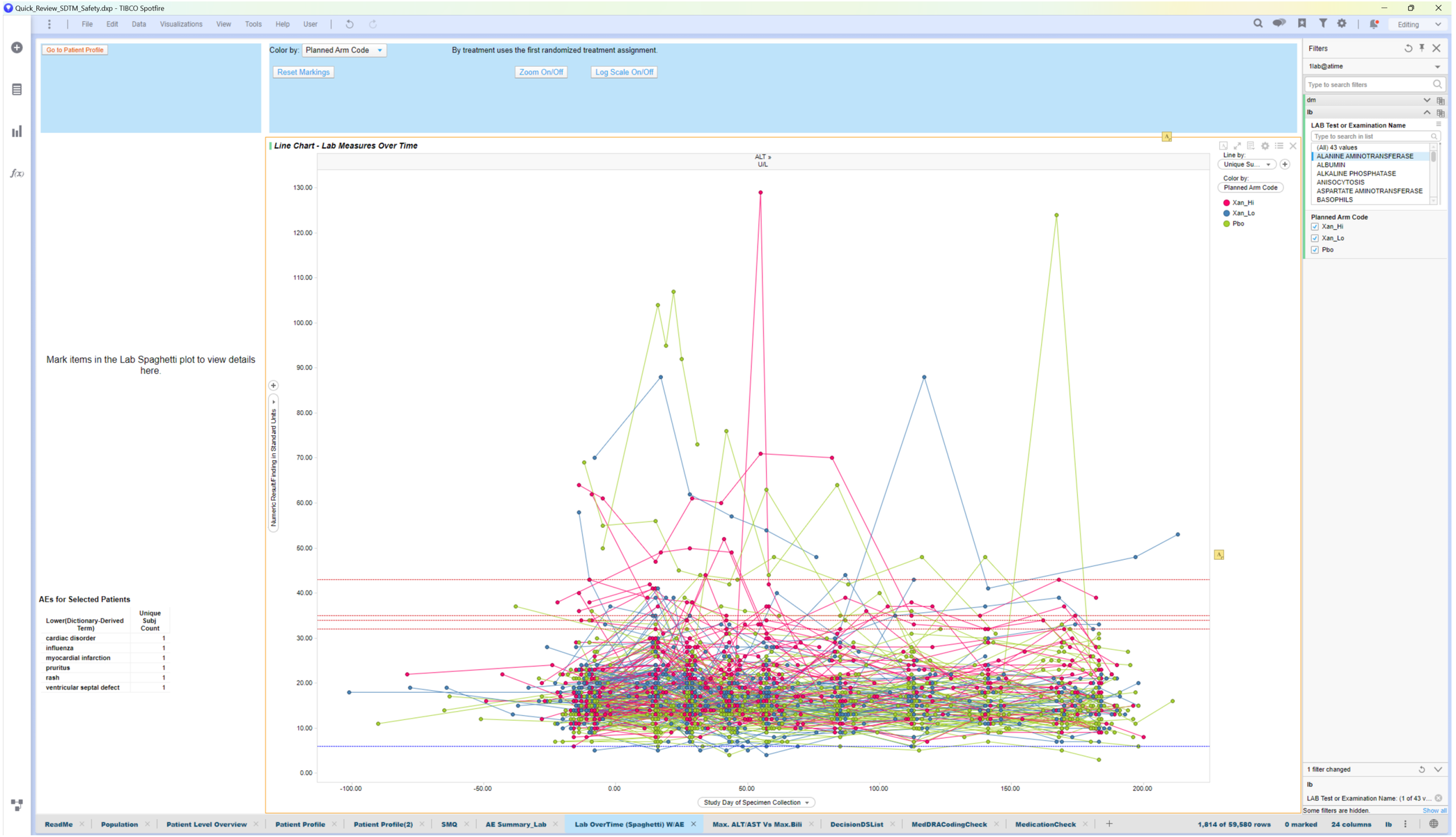
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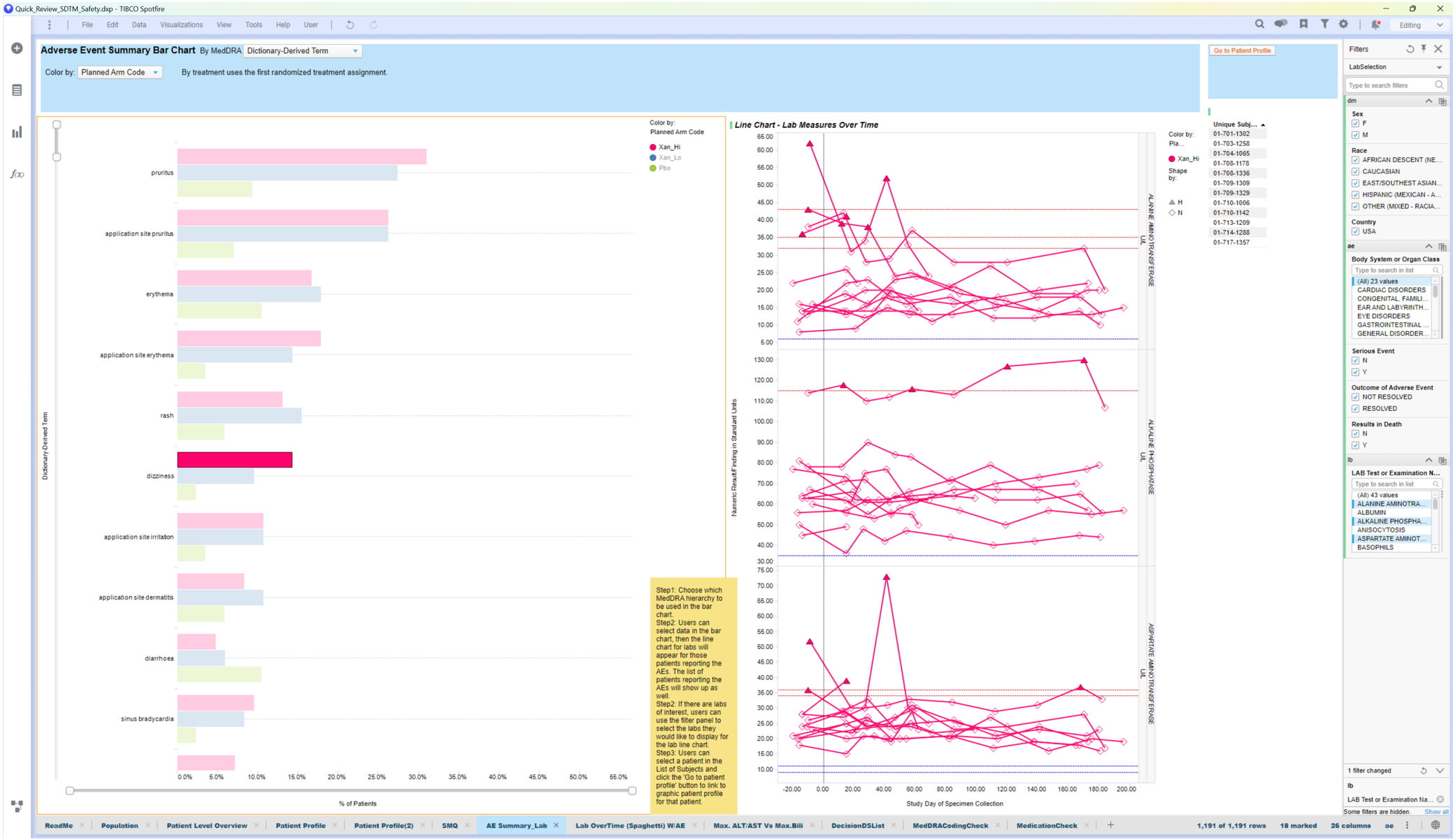
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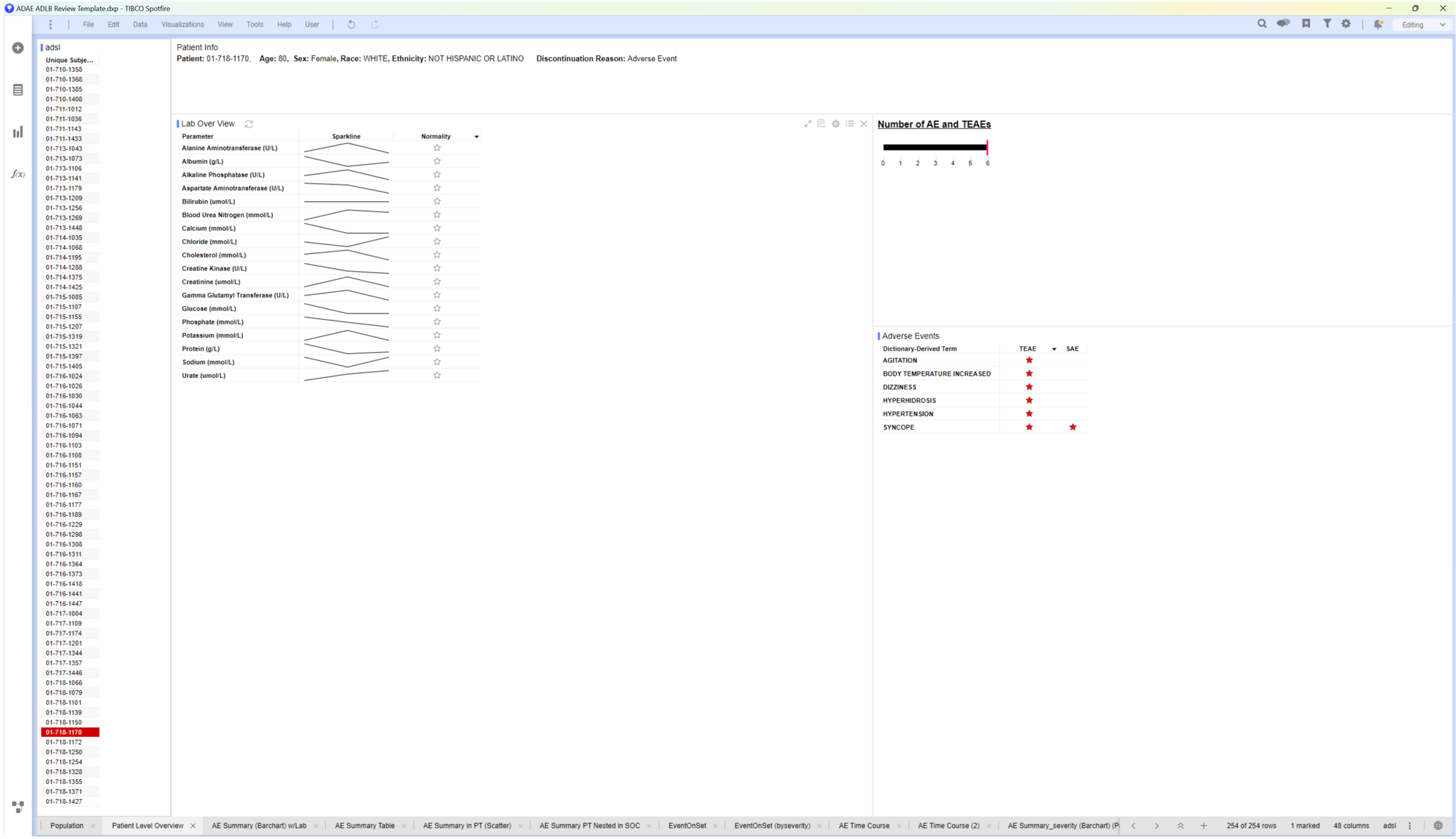
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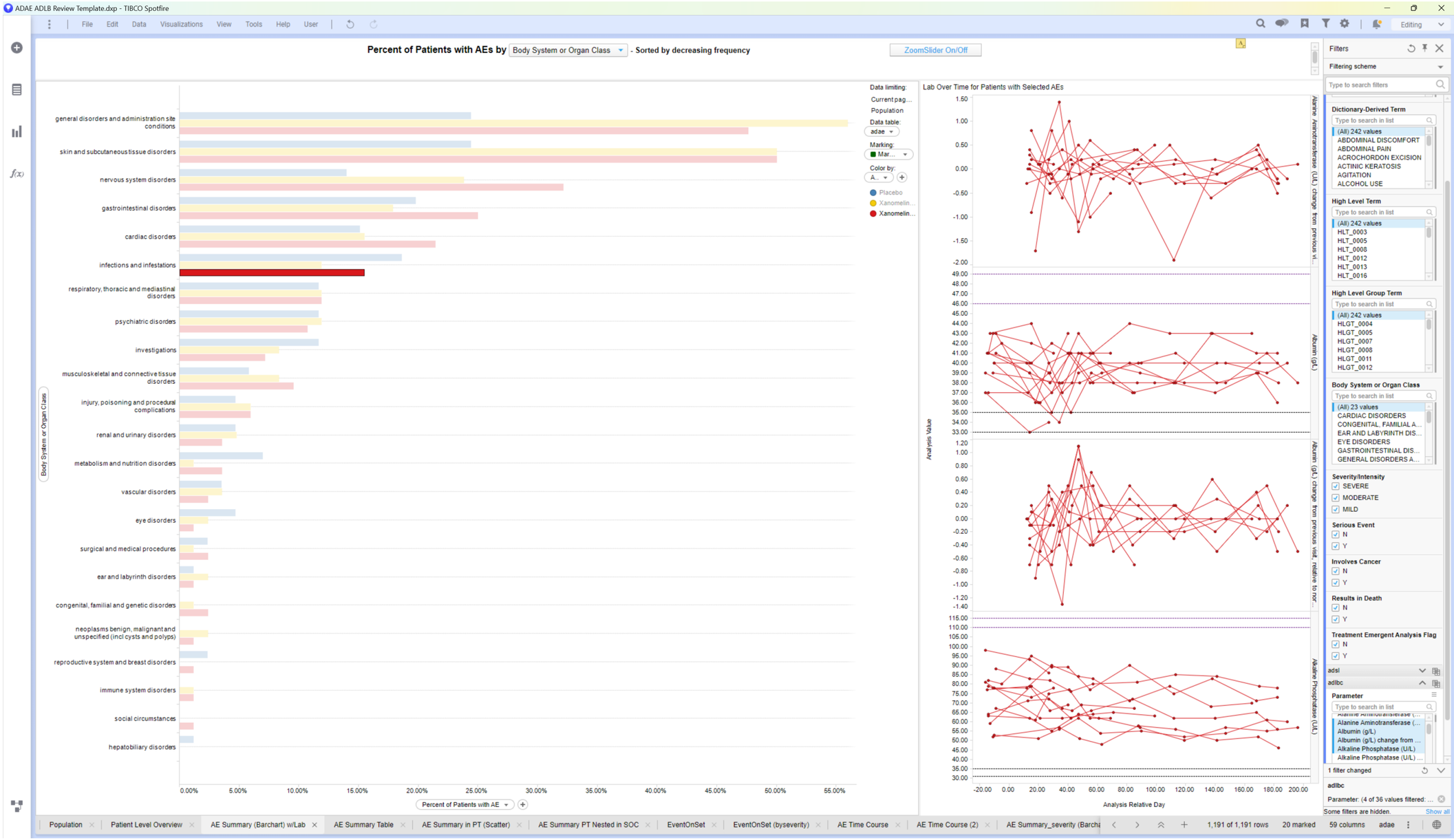
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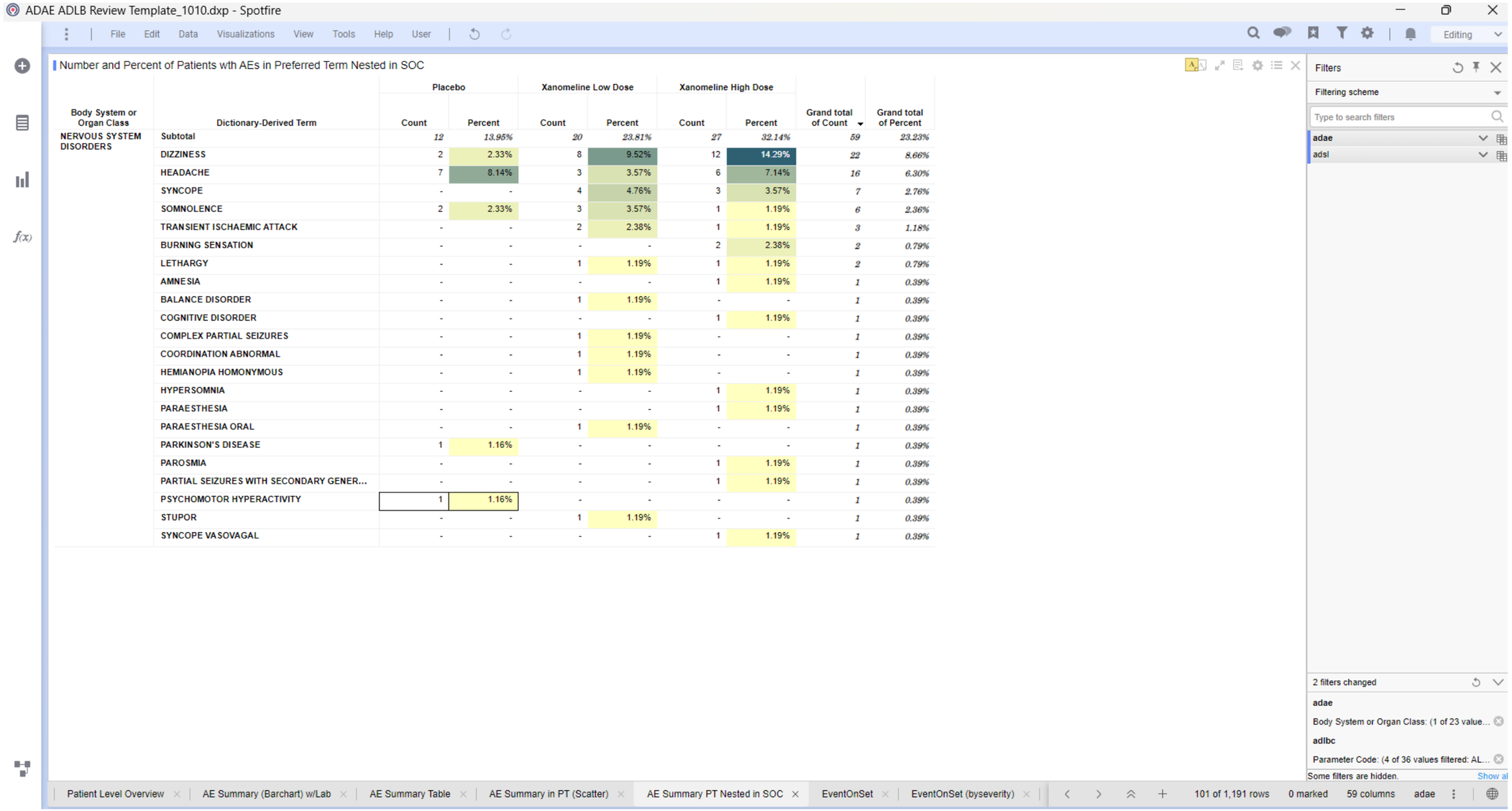
ADAE ADLB Review Template.dxp



ADAE ADLB Review Template.dxp

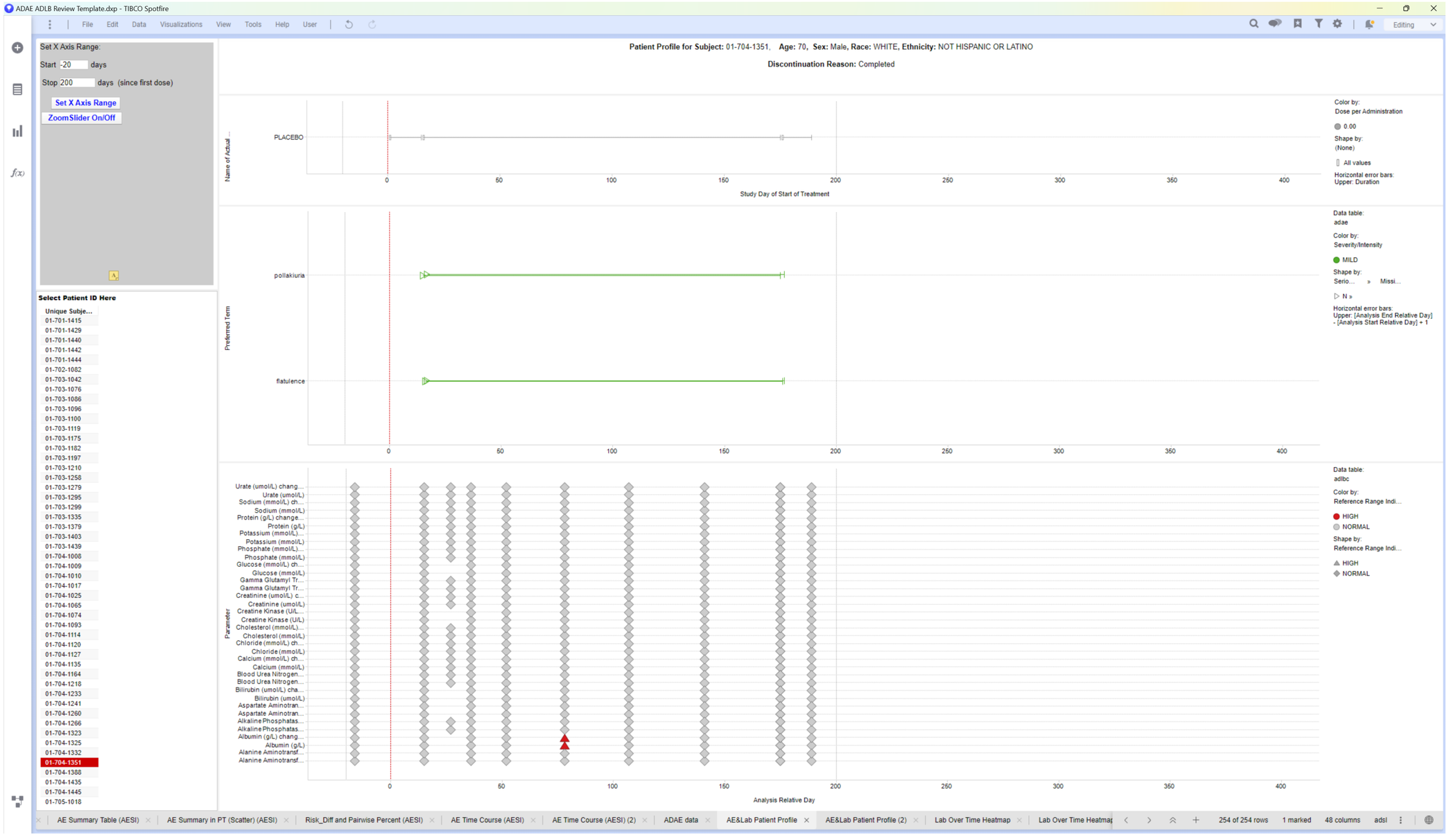


ADAE ADLB Review Template.dxp



Body System or Organ Class	Dictionary-Derived Term	Placebo		Xanomeline Low Dose		Xanomeline High Dose		Grand total of Count	Grand total of Percent
		Count	Percent	Count	Percent	Count	Percent		
NERVOUS SYSTEM DISORDERS	*Subtotal*	*12*	*13.95%*	*20*	*23.81%*	*27*	*32.14%*	*59*	*23.23%*
	DIZZINESS	2	2.33%	8	9.52%	12	14.29%	*22*	*8.66%*
	HEADACHE	7	8.14%	3	3.57%	6	7.14%	*16*	*6.30%*
	SYNCOPE	-	-	4	4.76%	3	3.57%	*7*	*2.76%*
	SOMNOLENCE	2	2.33%	3	3.57%	1	1.19%	*6*	*2.36%*
	TRANSIENT ISCHAEMIC ATTACK	-	-	2	2.38%	1	1.19%	*3*	*1.18%*
	BURNING SENSATION	-	-	-	-	2	2.38%	*2*	*0.79%*
	LETHARGY	-	-	1	1.19%	1	1.19%	*2*	*0.79%*
	AMNESIA	-	-	-	-	1	1.19%	*1*	*0.39%*
	BALANCE DISORDER	-	-	1	1.19%	-	-	*1*	*0.39%*
	COGNITIVE DISORDER	-	-	-	-	1	1.19%	*1*	*0.39%*
	COMPLEX PARTIAL SEIZURES	-	-	1	1.19%	-	-	*1*	*0.39%*
	COORDINATION ABNORMAL	-	-	1	1.19%	-	-	*1*	*0.39%*
	HEMIANOPIA HOMONYMOUS	-	-	1	1.19%	-	-	*1*	*0.39%*
	HYPERSOMNIA	-	-	-	-	1	1.19%	*1*	*0.39%*
	PARAESTHESIA	-	-	-	-	1	1.19%	*1*	*0.39%*
	PARAESTHESIA ORAL	-	-	1	1.19%	-	-	*1*	*0.39%*
	PARKINSON'S DISEASE	1	1.16%	-	-	-	-	*1*	*0.39%*
	PAROSMIA	-	-	-	-	1	1.19%	*1*	*0.39%*
	PARTIAL SEIZURES WITH SECONDARY GENER...	-	-	-	-	1	1.19%	*1*	*0.39%*
	PSYCHOMOTOR HYPERACTIVITY	1	1.16%	-	-	-	-	*1*	*0.39%*
	STUPOR	-	-	1	1.19%	-	-	*1*	*0.39%*
	SYNCOPE VASOVAGAL	-	-	-	-	1	1.19%	*1*	*0.39%*

ADAE ADLB Review Template.dxp



ADAE ADLB Review Template.dxp

