



## *Paradigm Shift:*

Novel Methods and Tools to  
Navigate the Evolving Life  
Sciences Landscape



### **PHUSE CANADA SDE**

Ankur Verma, Matthew Kumar

June 8, 2023



**RESTRICTED**



# Agenda

## // Introduction

## // Methods

- // Machine Learning
- // Explainable AI
- // Advanced Methods

## // Tools

- // Insight Generation
- // Process Automation

## // Forward Looking



# *Methods*

**Learn From Data, Explain &  
Generate**



# Machine Learning Methods

Learning From Data or Experience

- // Machine learning can be thought of as “learning from data”. Discover rules & extract information directly from the data and these rules can then be applied to more data
- // Identify relevant and complex signals that are not easily identifiable with classical approaches
- // Methods that work well in a high dimensional feature space.
- // Machine learning algorithms find natural patterns in data that generate insight and help you make better decisions and predictions
- // Helps in detecting interactions and their impact on the target event.
- // Supervised learning & Unsupervised Learning

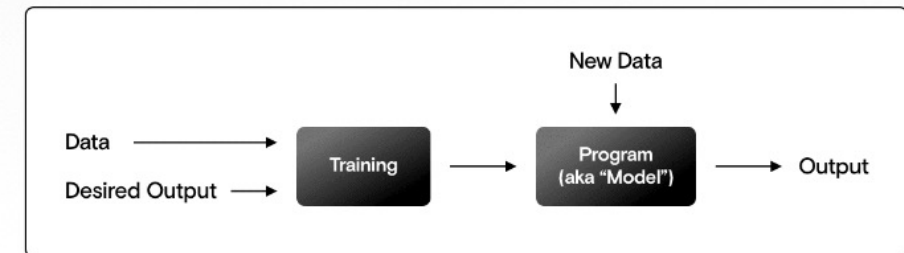
## Traditional Programming

Developers write rules (program) that produce an output.



## Machine Learning

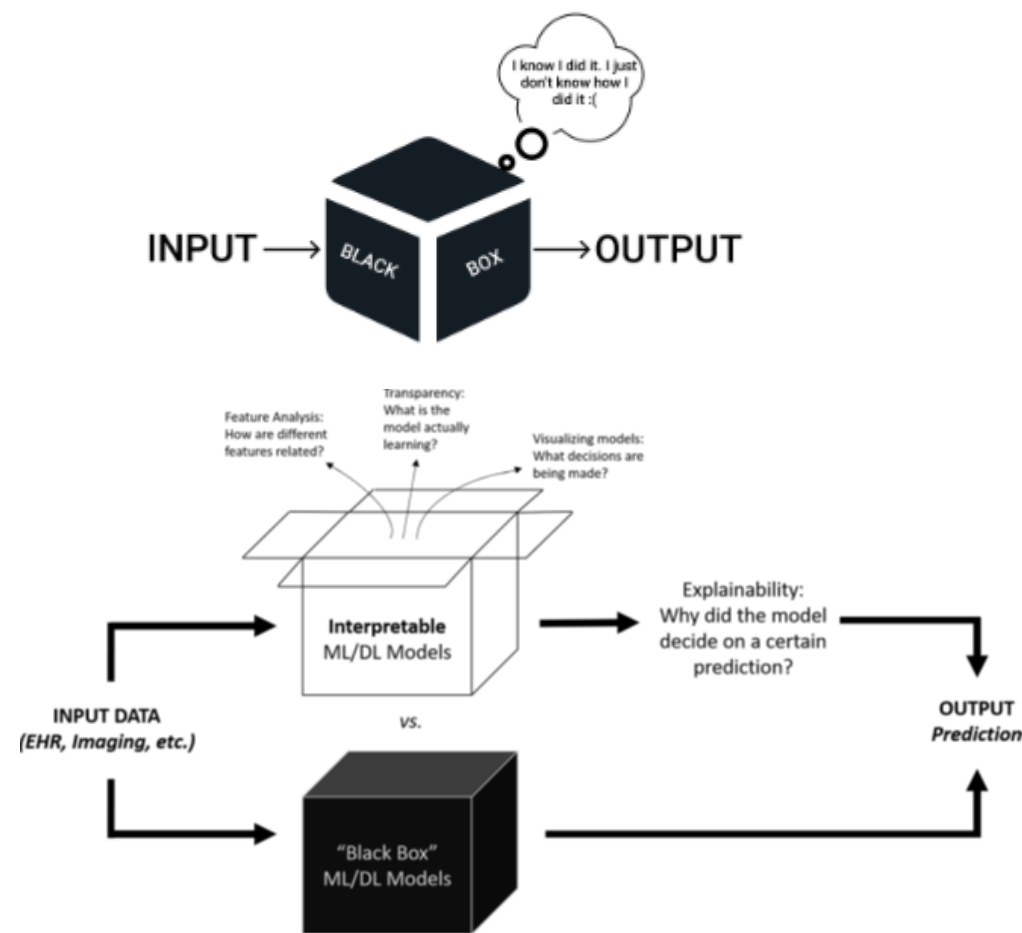
Developers write a training algorithm, that finds rules, which produce the desired output.



# Methods – Explainable AI

*In the field of pharma and health care, it is not enough to get the prediction (the what). The model must also explain how it came to the prediction (the why)*

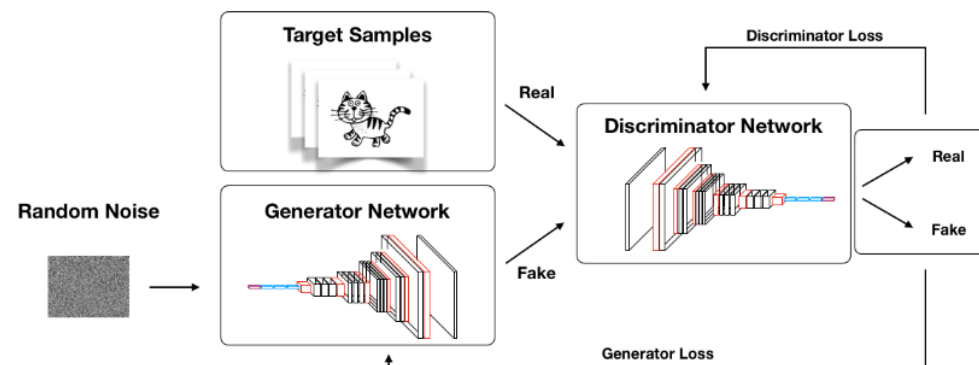
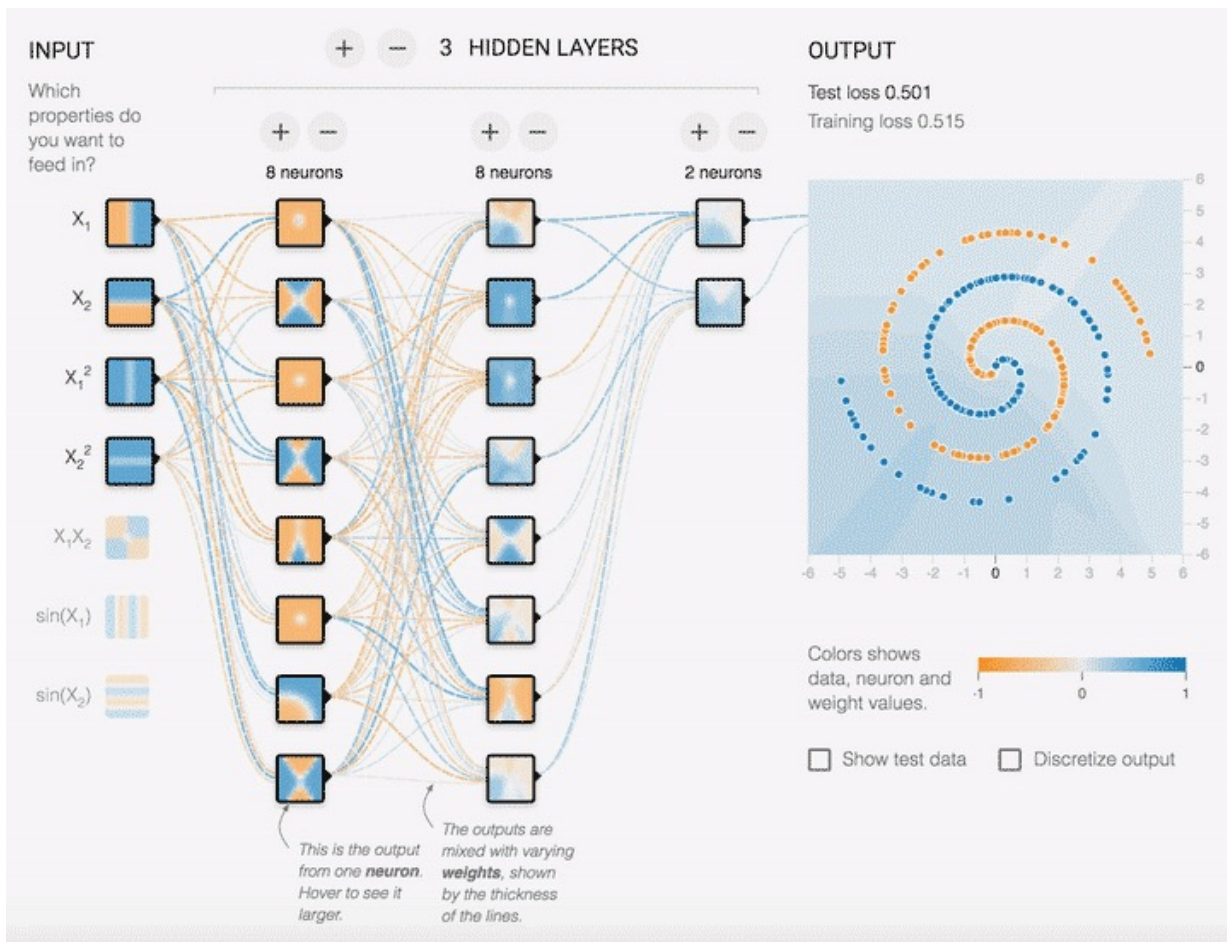
- // Complex learning methods or algorithms which are hard to understand or explain.
- // How can these algorithms be made transparent to anyone?
- // **Global Interpretation** : Which features are important and their impact on the model outcome or target. How the average prediction changes with respect to change in feature values ?
- // **Localized Interpretation** : Instance-level exploration methods that help to understand how does a model yield a prediction for a particular single observation (or a patient in this case). What if scenarios.





# Methods – Deep Learning

## Generative Modelling





# Insight Generation & Process Automation

*Tools*



# Interactive TLFs

## Insight Generation

- // **Intent:** A tool that enables exploration of sub-groups on-the-fly through linked, interactive TLFs
- // **Data:** Ingests ADAM/SDTM data
- // **Audience:** Statisticians, Stat Analysts, Medical Writers, Curious People
  - // Investigation and identification of patient clusters, use in review or verification/validation
  - // Can reduce unnecessary and laborious TLF production
  - // Insights (i.e. subject lists or full asset code) can be exported and reproduced
- // **Tech:** R, Quarto, Shiny, Posit Connect

The screenshot shows a web application titled "DYNAMIC, INTERACTIVE TABLES, LISTINGS AND FIGURES". On the left, there is a sidebar with controls: "Choose variables for the anchor table then click Make Table", a "Group Variable" dropdown set to "TRT01A", "Frequency Variables" with a button for "SEX ETHNIC", and "Numeric Variables" with a button for "BMIBL AGE". A "MAKE TABLE" button is at the bottom of the sidebar. Below the sidebar, a note says: "Next, click any result cell of the anchor table to view associated tables, listings and figures for that subset associated on the right." The main area displays a table with the following data:

|        |                        | var1_Placebo   | var1_Xanomeline High Dose | var1_Xanomeline Low Dose | var1_Total     |
|--------|------------------------|----------------|---------------------------|--------------------------|----------------|
| SEX    | F                      | 53 ( 61.6%)    | 40 ( 47.8%)               | 50 ( 59.5%)              | 143 ( 56.3%)   |
|        | M                      | 33 ( 38.4%)    | 44 ( 52.4%)               | 34 ( 40.5%)              | 111 ( 43.7%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| ETHNIC | HISPANIC OR LATINO     | 3 ( 3.5%)      | 3 ( 3.6%)                 | 6 ( 7.1%)                | 12 ( 4.7%)     |
|        | NOT HISPANIC OR LATINO | 83 ( 96.5%)    | 81 ( 96.4%)               | 78 ( 92.9%)              | 242 ( 95.3%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| BMIBL  | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 23.64 ( 3.672) | 25.35 ( 4.158)            | 25.06 ( 4.271)           | 24.67 ( 4.092) |
|        | Median                 | 23.40          | 24.80                     | 24.30                    | 24.20          |
|        | Q1, Q3                 | 21.20, 25.60   | 22.70, 27.85              | 22.15, 27.80             | 21.90, 27.30   |
|        | Min, Max               | 15.1, 33.3     | 13.7, 34.5                | 17.7, 40.1               | 13.7, 40.1     |
|        | Missing                | 0              | 0                         | 1                        | 1              |
| AGE    | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 75.2 ( 8.59)   | 74.4 ( 7.89)              | 75.7 ( 8.29)             | 75.1 ( 8.25)   |
|        | Median                 | 76.0           | 76.0                      | 77.5                     | 77.0           |
|        | Q1, Q3                 | 69.2, 81.8     | 70.8, 80.0                | 71.0, 82.0               | 70.0, 81.0     |
|        | Min, Max               | 52.89          | 56.88                     | 51.88                    | 51.89          |
|        | Missing                | 0              | 0                         | 0                        | 0              |





# Interactive TLFs

## Starting Screen

Dynamic, Interactive Tables, Listings

DYNAMIC, INTERACTIVE TABLES, LISTINGS AND FIGURES

Choose variables for the anchor table then click Make Table

Group Variable

TRT01A

Frequency Variables

SEX ETHNIC

Numeric Variables

BMIBL AGE

MAKE TABLE

Next, click any result cell of the anchor table to view associated tables, listings and figures for that subset associated on the right.

Anchor Table

|        |                        | var1_Placebo   | var1_Xanomeline High Dose | var1_Xanomeline Low Dose | var1_Total     |
|--------|------------------------|----------------|---------------------------|--------------------------|----------------|
| SEX    | F                      | 53 ( 61.6%)    | 40 ( 47.6%)               | 50 ( 59.5%)              | 143 ( 56.3%)   |
|        | M                      | 33 ( 38.4%)    | 44 ( 52.4%)               | 34 ( 40.5%)              | 111 ( 43.7%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| ETHNIC | HISPANIC OR LATINO     | 3 ( 3.5%)      | 3 ( 3.6%)                 | 6 ( 7.1%)                | 12 ( 4.7%)     |
|        | NOT HISPANIC OR LATINO | 83 ( 96.5%)    | 81 ( 96.4%)               | 78 ( 92.9%)              | 242 ( 95.3%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| BMIBL  | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 23.64 ( 3.672) | 25.35 ( 4.158)            | 25.06 ( 4.271)           | 24.67 ( 4.092) |
|        | Median                 | 23.40          | 24.80                     | 24.30                    | 24.20          |
|        | Q1, Q3                 | 21.20, 25.60   | 22.70, 27.85              | 22.15, 27.80             | 21.90, 27.30   |
|        | Min, Max               | 15.1, 33.3     | 13.7, 34.5                | 17.7, 40.1               | 13.7, 40.1     |
|        | Missing                | 0              | 0                         | 1                        | 1              |
| AGE    | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 75.2 ( 8.59)   | 74.4 ( 7.89)              | 75.7 ( 8.29)             | 75.1 ( 8.25)   |
|        | Median                 | 76.0           | 76.0                      | 77.5                     | 77.0           |
|        | Q1, Q3                 | 69.2, 81.8     | 70.8, 80.0                | 71.0, 82.0               | 70.0, 81.0     |
|        | Min, Max               | 52, 89         | 56, 88                    | 51, 88                   | 51, 89         |
|        | Missing                | 0              | 0                         | 0                        | 0              |

Table

Figure

Listing 1

Listing 2

9

/// Bayer 16:9 Template /// September 2018

RESTRICTED



# Interactive TLFs

## Subgroup Selection

Dynamic, Interactive Tables, Listings and Figures

Choose variables for the anchor table then click Make Table

Group Variable  
TRT01A

Frequency Variables  
SEX ETHNIC

Numeric Variables  
BMIBL AGE

MAKE TABLE

Next, click any result cell of the anchor table to view associated tables, listings and figures for that subset associated on the right.

Anchor Table

|        |                        | var1_Placebo   | var1_Xanomeline High Dose | var1_Xanomeline Low Dose | var1_Total     |
|--------|------------------------|----------------|---------------------------|--------------------------|----------------|
| SEX    | F                      | 53 ( 61.6%)    | 40 ( 47.6%)               | 50 ( 59.5%)              | 143 ( 56.3%)   |
|        | M                      | 33 ( 38.4%)    | 44 ( 52.4%)               | 34 ( 40.5%)              | 111 ( 43.7%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| ETHNIC | HISPANIC OR LATINO     | 3 ( 3.5%)      | 3 ( 3.6%)                 | 6 ( 7.1%)                | 12 ( 4.7%)     |
|        | NOT HISPANIC OR LATINO | 83 ( 96.5%)    | 81 ( 96.4%)               | 78 ( 92.9%)              | 242 ( 95.3%)   |
|        | Total                  | 86             | 84                        | 84                       | 254            |
| BMIBL  | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 23.64 ( 3.672) | 25.35 ( 4.158)            | 25.06 ( 4.271)           | 24.67 ( 4.092) |
|        | Median                 | 23.40          | 24.80                     | 24.30                    | 24.20          |
|        | Q1, Q3                 | 21.20, 25.60   | 22.70, 27.85              | 22.15, 27.80             | 21.90, 27.30   |
|        | Min, Max               | 15.1, 33.3     | 13.7, 34.5                | 17.7, 40.1               | 13.7, 40.1     |
|        | Missing                | 0              | 0                         | 1                        | 1              |
| AGE    | n                      | 86             | 84                        | 84                       | 254            |
|        | Mean (SD)              | 75.2 ( 8.59)   | 74.4 ( 7.89)              | 75.7 ( 8.29)             | 75.1 ( 8.25)   |
|        | Median                 | 76.0           | 76.0                      | 77.5                     | 77.0           |
|        | Q1, Q3                 | 69.2, 81.8     | 70.8, 80.0                | 71.0, 82.0               | 70.0, 81.0     |
|        | Min, Max               | 52.89          | 56.88                     | 51.88                    | 51.89          |
|        | Missing                | 0              | 0                         | 0                        | 0              |

Table

EXPAND TERMS

System Organ Class

System Organ Class Preferred Term

var1\_Placebo

▼ Cardiac Disorders (14)

Cardiac Disorders 25 ( 8.6%)

Atrial Fibrillation 1 ( 0.3%)

Atrial Hypertrophy 2 ( 0.7%)

Atrioventricular Block First Degree 1 ( 0.3%)

Atrioventricular Block Second Degree 1 ( 0.3%)

Bradycardia 4 ( 1.4%)

Bundle Branch Block Left 1 ( 0.3%)

Bundle Branch Block Right 2 ( 0.7%)

Cardiac Failure Congestive 1 ( 0.3%)

Myocardial Infarction 4 ( 1.4%)

Sinus Arrhythmia 2 ( 0.7%)

Sinus Bradycardia 2 ( 0.7%)

Supraventricular Extrasystoles 2 ( 0.7%)

Tachycardia 2 ( 0.7%)

▼ Ear And Labyrinth Disorders (2)

Ear And Labyrinth Disorders 2 ( 0.7%)

Ear Pain 2 ( 0.7%)

▼ Eye Disorders (6)

Eye Disorders 8 ( 2.8%)

Conjunctivitis 4 ( 1.4%)

Eye Allergy 1 ( 0.3%)

Eye Pruritus 1 ( 0.3%)

Eye Swelling 1 ( 0.3%)

Glaucoma 1 ( 0.3%)

▼ Gastrointestinal Disorders (11)

Gastrointestinal Disorders 23 ( 7.9%)

Abdominal Pain 1 ( 0.3%)

Constipation 1 ( 0.3%)



# Interactive TLFs

## Safety Table Plus

| Table                    |                                      |              | Figure | Listing 1 | Listing 2 |
|--------------------------|--------------------------------------|--------------|--------|-----------|-----------|
| EXPAND TERMS             |                                      |              | Search |           |           |
| System Organ Class       | System Organ Class Preferred Term    | var1_Placebo |        |           |           |
| ▼ Cardiac Disorders (14) |                                      |              |        |           |           |
|                          | Cardiac Disorders                    | 25 ( 8.6%)   |        |           |           |
|                          | Atrial Fibrillation                  | 1 ( 0.3%)    |        |           |           |
|                          | Atrial Hypertrophy                   | 2 ( 0.7%)    |        |           |           |
|                          | Atrioventricular Block First Degree  | 1 ( 0.3%)    |        |           |           |
|                          | Atrioventricular Block Second Degree | 1 ( 0.3%)    |        |           |           |
|                          | Bradycardia                          | 4 ( 1.4%)    |        |           |           |
|                          | Bundle Branch Block Left             | 1 ( 0.3%)    |        |           |           |
|                          | Bundle Branch Block Right            | 2 ( 0.7%)    |        |           |           |
|                          | Cardiac Failure Congestive           | 1 ( 0.3%)    |        |           |           |
|                          | Myocardial Infarction                | 4 ( 1.4%)    |        |           |           |
|                          | Sinus Arrhythmia                     | 2 ( 0.7%)    |        |           |           |
|                          | Sinus Bradycardia                    | 2 ( 0.7%)    |        |           |           |
|                          | Supraventricular Extrasystoles       | 2 ( 0.7%)    |        |           |           |
|                          | Tachycardia                          | 2 ( 0.7%)    |        |           |           |



Dynamic, Interactive Tables, Listing 1: Atrial Fibrillation (AFib) | MedlinePlus

medlineplus.gov/atrialfibrillation.html

National Library of Medicine

MedlinePlus  
Trusted Health Information for You

Search MedlinePlus GO

About MedlinePlus What's New Site Map Customer Support

Health Topics Drugs & Supplements Genetics Medical Tests Medical Encyclopedia Español

Home → Health Topics → Atrial Fibrillation

### Atrial Fibrillation

Also called: AF, AFib

On this page

- Basics
  - Summary
  - Start Here
  - Diagnosis and Tests
  - Treatments and Therapies
- Learn More
  - Related Issues
  - Specifics
  - Genetics
- See, Play and Learn
  - Videos and Tutorials
- Research
  - Clinical Trials
  - Journal Articles
- Resources
  - Reference Desk
  - Find an Expert
- For You
  - Patient Handouts

**Summary**

An arrhythmia is a problem with the speed or rhythm of the heartbeat. Atrial fibrillation (AF) is the most common type of arrhythmia. The cause is a disorder in the heart's electrical system.

Often, people who have AF may not even feel symptoms. But you may feel :

- Palpitations -- an abnormal rapid heartbeat
- Shortness of breath
- Weakness or difficulty exercising
- Chest pain
- Dizziness or fainting
- Fatigue
- Confusion

AF can lead to an increased risk of stroke. In many patients, it can also cause chest pain, heart attack, or heart failure.

Doctors diagnose AF using family and medical history, a physical exam, and a test called an electrocardiogram (EKG), which looks at the electrical waves your heart makes. Treatments include medicines and procedures to restore normal rhythm.

**MEDICAL ENCYCLOPEDIA**

- Atrial fibrillation - discharge
- Atrial fibrillation or flutter
- Cardiac ablation procedures
- Cardiac event monitors
- Digitalis toxicity
- Heart palpitations
- Heartbeat

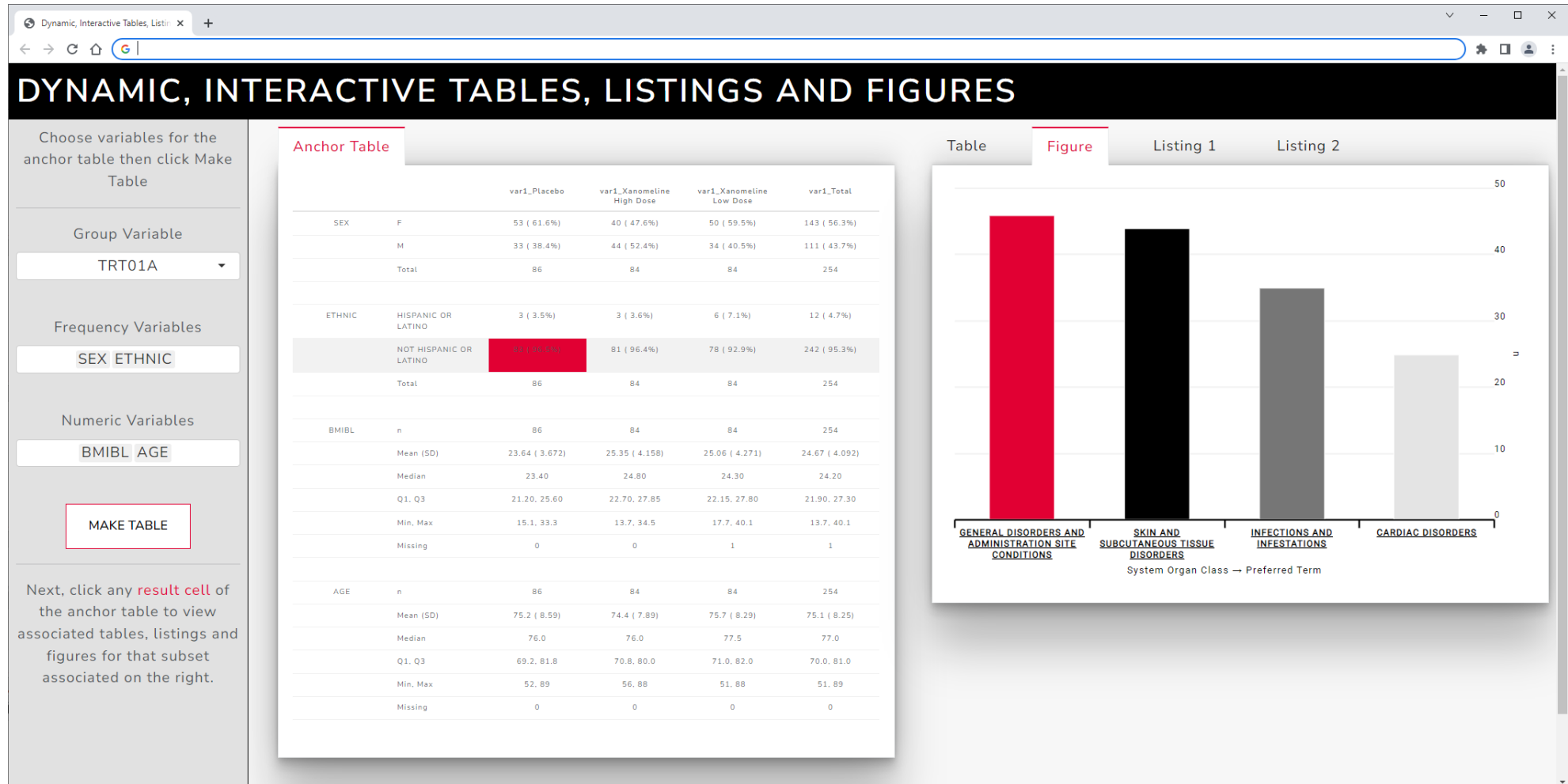
**Related Health Topics**

- Arrhythmia
- Heart Health Tests



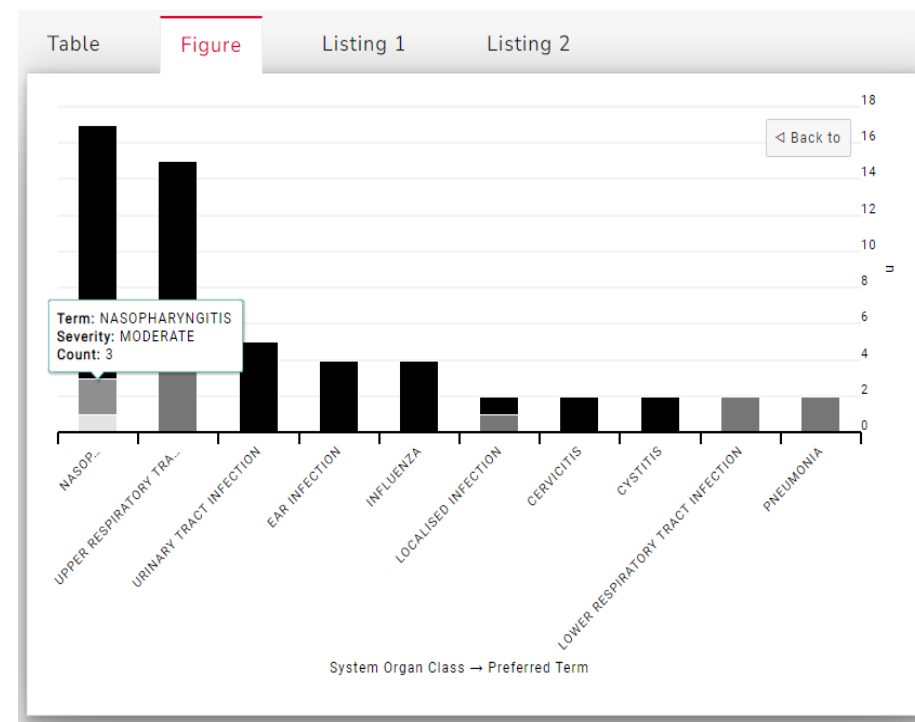
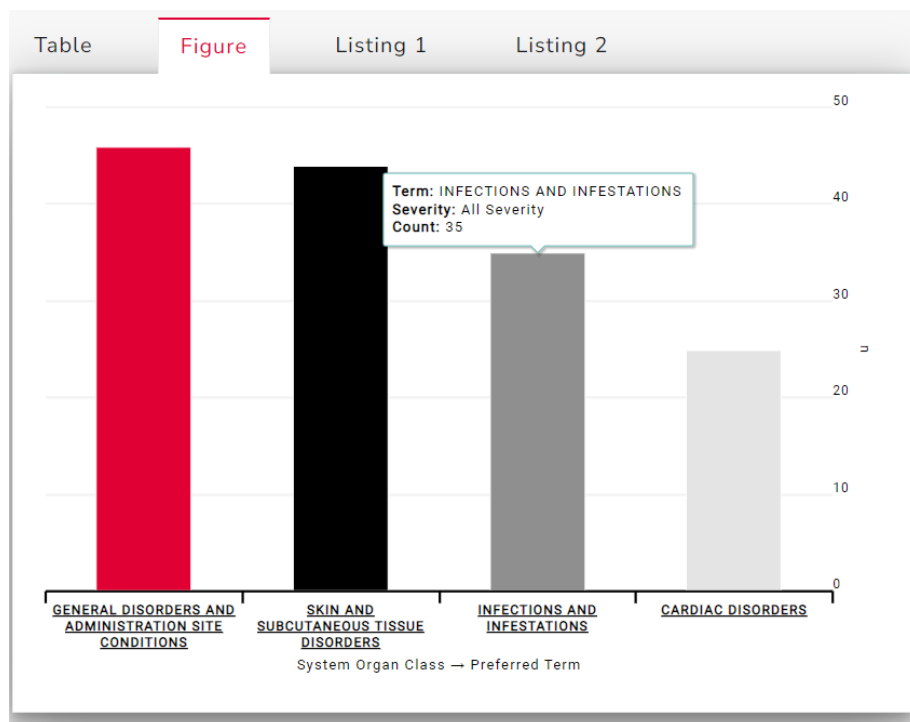
# Interactive TLFs

## Figures – Top AEs by MEDDRA SOC Term



# Interactive TLFs

Figures – Drill down to MEDDRA PT Term







# Interactive TLFs

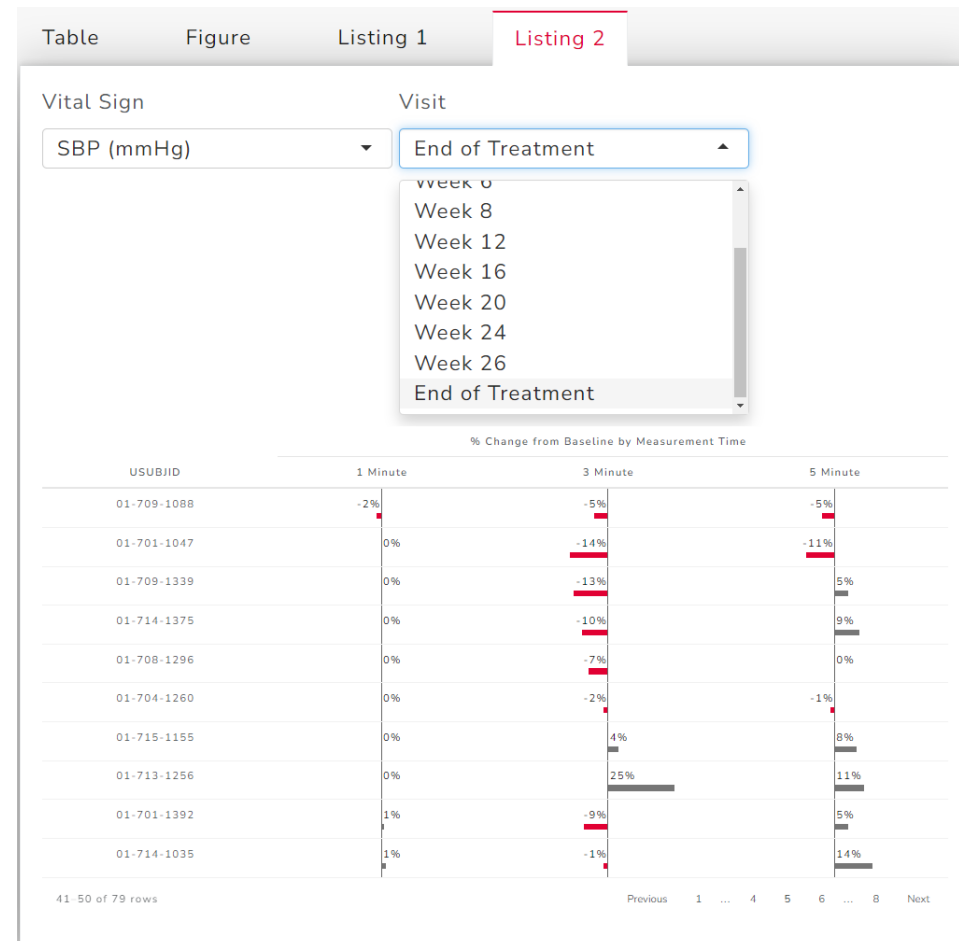
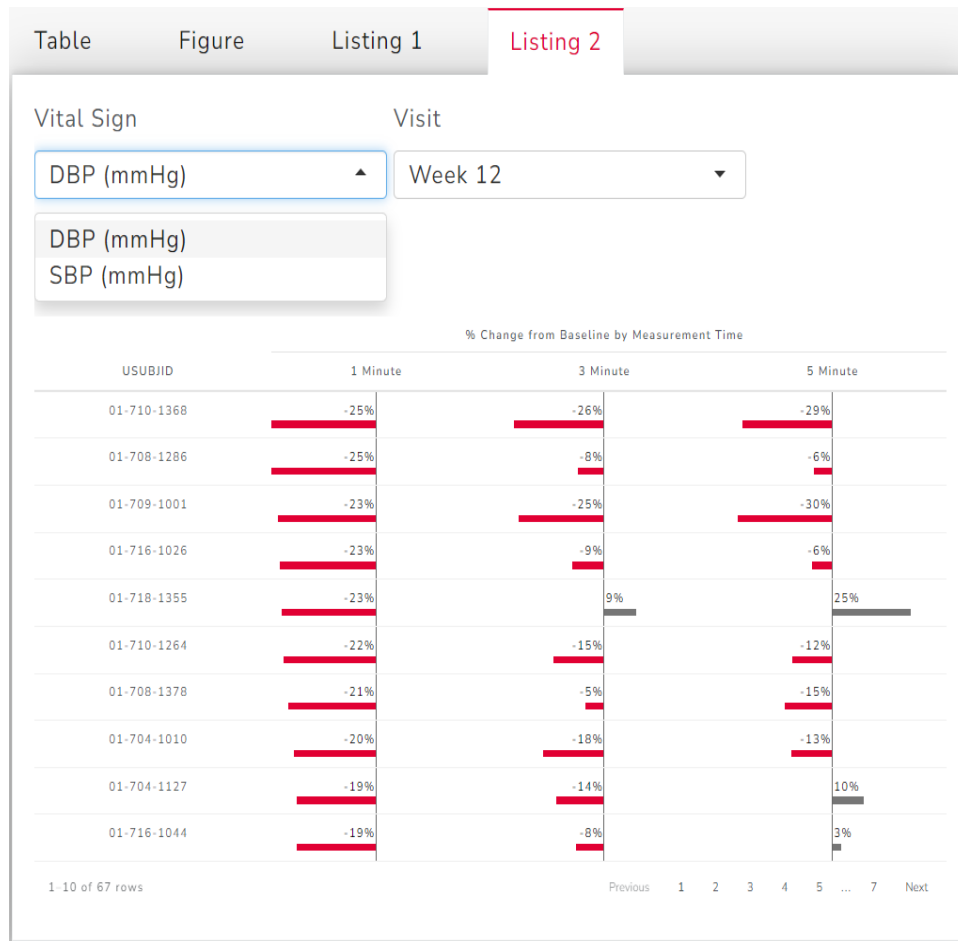
## Listings 1 – Searchable and Quick Export

| Table      Figure      Listing 1      Listing 2 |         |                            |          |          |
|-------------------------------------------------|---------|----------------------------|----------|----------|
| EXPORT CSV                                      |         |                            |          |          |
| Search                                          |         |                            |          |          |
| USUBJID                                         | ARM     | Study Completion Milestone |          |          |
|                                                 |         | 8 Weeks                    | 16 Weeks | 24 Weeks |
|                                                 |         |                            |          | No       |
| 01-701-1047                                     | Placebo | ✗ No                       | ✗ No     | ✗ No     |
| 01-701-1387                                     | Placebo | ✗ No                       | ✗ No     | ✗ No     |
| 01-703-1096                                     | Placebo | ✗ No                       | ✗ No     | ✗ No     |
| 01-703-1175                                     | Placebo | ✗ No                       | ✗ No     | ✗ No     |
| 01-704-1010                                     | Placebo | ✓ Yes                      | ✓ Yes    | ✗ No     |
| 01-704-1233                                     | Placebo | ✓ Yes                      | ✓ Yes    | ✗ No     |
| 01-704-1260                                     | Placebo | ✓ Yes                      | ✗ No     | ✗ No     |
| 01-704-1435                                     | Placebo | ✓ Yes                      | ✗ No     | ✗ No     |
| 01-705-1018                                     | Placebo | ✗ No                       | ✗ No     | ✗ No     |
| 01-705-1059                                     | Placebo | ✓ Yes                      | ✓ Yes    | ✗ No     |
| 1–10 of 25 rows                                 |         |                            |          |          |
| Previous    1    2    3    Next                 |         |                            |          |          |



# Interactive TLFs

## Listings 2 – Interactive and Visual





# Auto-Narratives

## Process Automation

- // **Intent:** A data driven reporting engine that automates the production of patient narratives
- // **Data:** Configurable for ADAM data
- // **Audience:** Stat Analysts, Medical Writers
  - // Generates patient narratives, but also a generic reporting engine
  - // Uses document templates and custom business logic
  - // Single or batch report processing, results provided as a ZIP archive
  - // Flexible document outputs:
    - // Static: Docx, PDF
    - // Interactive: HTML
- // **Tech:** R, Rmarkdown, Shiny, Posit Connect

The screenshot displays the 'Patient Narratives' web application. On the left, a panel titled 'Select the patients you wish to generate a report for. You can generate reports for all patients using the checkbox below.' shows a table with a 'Select All' checkbox and a list of patient IDs under the 'USUBJID' column. The IDs are: 01-715-1405, 01-701-1440, 01-708-1286, 01-710-1358, 01-704-1017, 01-710-1021, 01-709-1088, 01-713-1448, 01-701-1181, and 01-705-1031. Below the table, there are radio buttons for 'Docx', 'PDF', and 'HTML' (selected), and a 'Download' button.

On the right, a 'Preview' section shows a rendered document titled 'Patient Profile Narratives'. The document includes an 'Overview' section with patient details: Subject: 01-705-1303, Age: 72, Sex: M, Race: WHITE, Site Name: 705. It also lists 'Investigations Drug(s) Administered: Xanomeline High Dose' and 'Disposition: Adverse Event'. An 'Exposure' section notes the first and last recorded dates of treatment. An 'Adverse Events' section includes a table summarizing events.

| Reported Term | AE Start Date | AE End Date | Severity | Outcome                    |
|---------------|---------------|-------------|----------|----------------------------|
| PRURITUS      | 2014-02-08    | 2014-03-03  | MILD     | NOT RECOVERED/NOT RESOLVED |
| RASH          | 2014-02-08    | 2014-03-03  | MILD     | NOT RECOVERED/NOT RESOLVED |
| PRURITUS      | 2014-02-08    | 2014-03-03  | MILD     | RECOVERED/RESOLVED         |
| RASH          | 2014-02-08    | 2014-03-03  | MODERATE | RECOVERED/RESOLVED         |



# Auto-Narratives

## Process Automation

Patient Narratives

Individual Reports   Compiled Reports

Select the patients you wish to generate a report for. You can generate reports for all patients using the checkbox below.

☒ Select All

| USUBJID     |
|-------------|
| 01-715-1405 |
| 01-701-1440 |
| 01-708-1286 |
| 01-710-1358 |
| 01-704-1017 |
| 01-710-1021 |
| 01-709-1088 |
| 01-713-1448 |
| 01-701-1181 |
| 01-705-1031 |

Select a format and click the download button below. All reports are compressed into a single zip file.

☒ Docx ☐ PDF ☐ HTML

Download

ADaM data for this demonstration are obtained from the [phuse github repository](#)

[https://matt-kumar.shinyapps.io/narratives/\\_w\\_f2b59422/session/a06f67f4884f5b2005e73c3fc1b3852a/download/gen?w=f2b59422](https://matt-kumar.shinyapps.io/narratives/_w_f2b59422/session/a06f67f4884f5b2005e73c3fc1b3852a/download/gen?w=f2b59422)

### Preview

Below is a preview of what the selected document format looks like when rendered.

01-705-1303.docx - Read-Only - Compatibility Mode - Saved to this PC

File Home Insert Design Layout References Mailings Review View Classification Help Search Share Comments

Clipboard Font Paragraph Protection Styles Voice

Classification: RESTRICTED NO CLASSIFICATION INTERNAL RESTRICTED SECRET

#### Patient Profile Narratives

##### Overview

**Subject:** 01-705-1303  
**Age:** 72  
**Sex:** M  
**Race:** WHITE  
**Site Name:** 705  
**Investigations Drug(s) Administered:** Xanomeline High Dose  
**Disposition:** Adverse Event

##### Exposure

Subject 01-705-1303's first recorded date of treatment was 2013-12-16. The last recorded date of treatment was 2014-06-02.

##### Adverse Events

The following table summarizes any adverse events experienced by subject 01-705-1303.

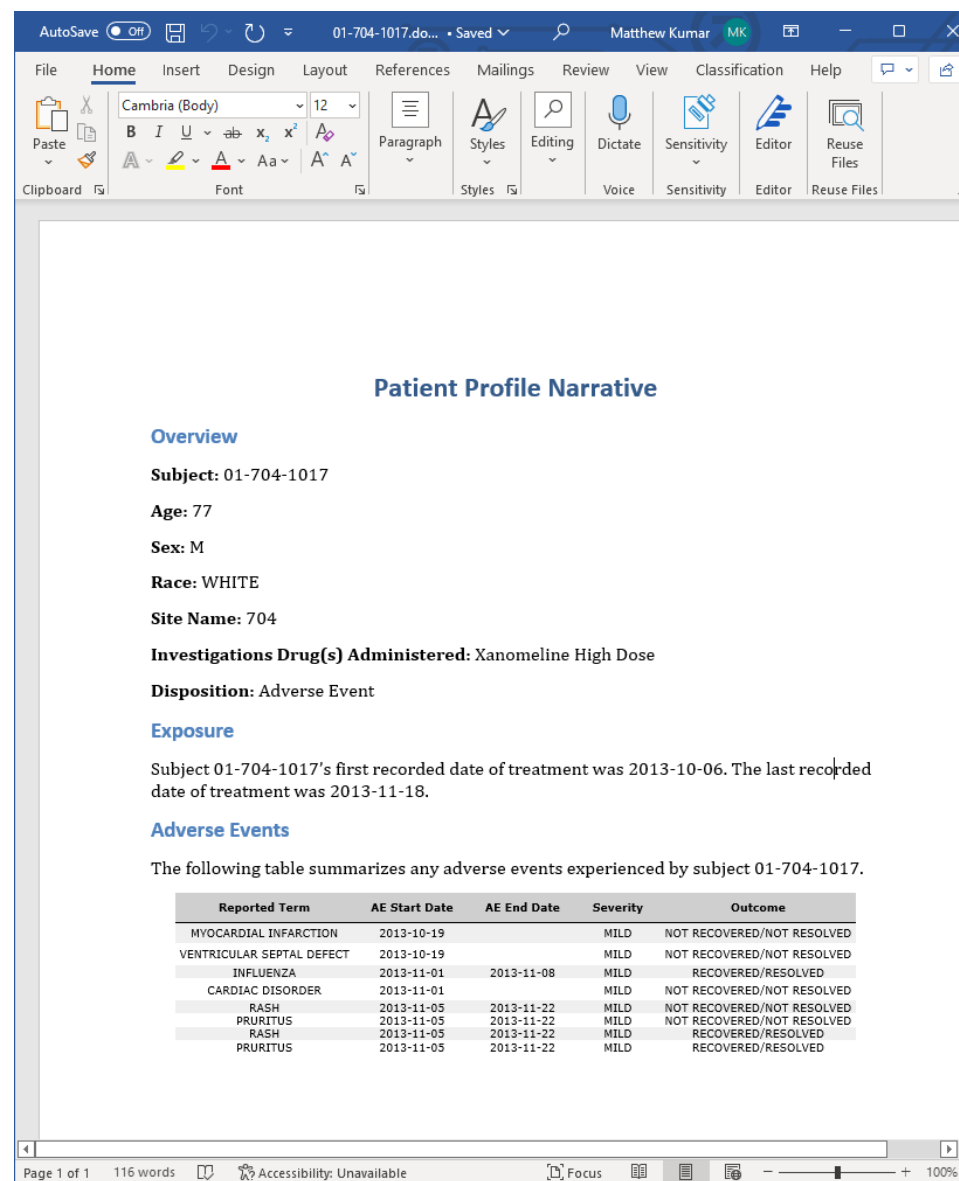
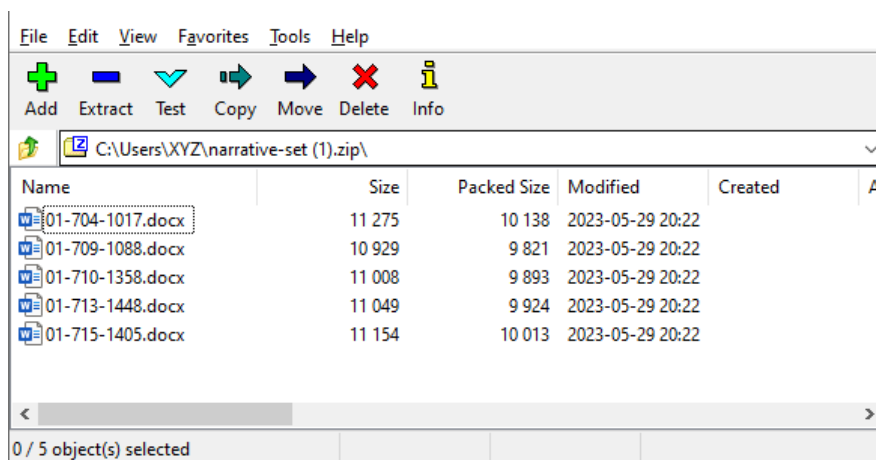
| Reported Term | AE Start Date | AE End Date | Severity | Outcome                    |
|---------------|---------------|-------------|----------|----------------------------|
| PHURITUS      | 2014-02-05    | 2014-03-02  | WILD     | NOT RECOVERED/NOT RESOLVED |
| RASH          | 2014-02-05    | 2014-03-02  | WILD     | NOT RECOVERED/NOT RESOLVED |
| PHURITUS      | 2014-02-05    | 2014-03-02  | WILD     | RECOVERED/RESOLVED         |
| RASH          | 2014-02-05    | 2014-03-02  | MODERATE | RECOVERED/RESOLVED         |

Page 1 of 1 89 words



# Auto-Narratives

Batch Download, Select Patients, Docx





# Auto-Narratives

pdf, compiled

appended\_format.pdf - Adobe Acrobat Reader (32-bit)

File Edit View Sign Window Help

Home Tools 01-704-1017.pdf appended\_format.p...

1 / 12

105%

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

95

96

97

98

99

100

101

102

103

104

105

106

107

108

109

110

111

112

113

114

115

116

117

118

119

120

121

122

123

124

125

126

127

128

129

130

131

132

133

134

135

136

137

138

139

140

141

142

143

144

145

146

147

148

149

150

151

152

153

154

155

156

157

158

159

160

161

162

163

164

165

166

167

168

169

170

171

172

173

174

175

176

177

178

179

180

181

182

183

184

185

186

187

188

189

190

191

192

193

194

195

196

197

198

199

200

201

202

203

204

205

206

207

208

209

210

211

212

213

214

215

216

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243

244

245

246

247

248

249

250

251

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

270

271

272

273

274

275

276

277

278

279

280

281

282

283

284

285

286

287

288

289

290

291

292

293

294

295

296

297

298

299

300

301

302

303

304

305

306

307

308

309

310

311

312

313

314

315

316

317

318

319

320

321

322

323

324

325

326

327

328

329

330

331

332

333

334

335

336

337

338

339

340

341

342

343

344

345

346

347

348

349

350

351

352

353

354

355

356

357

358

359

360

361

362

363

364

365

366

367

368

369

370

371

372

373

374

375

376

377

378

379

380

381

382

383

384

385

386

387

388

389

390

391

392

393

394

395

396

397

398

399

400

401

402

403

404

405

406

407

408

409

410

411

412

413

414

415

416

417

418

419

420

421

422

423

424

425

426

427

428

429

430

431

432

433

434

435

436

437

438

439

440

441

442

443

444

445

446

447

448

449

450

451

452

453

454

455

456

457

458

459

460

461

462

463

464

465

466

467

468

469

470

471

472

473

474

475

476

477

478

479

480

481

482

483

484

485

486

487

488

489

490

491

492

493

494

495

496

497

498

499

500

501

502

503

504

505

506

507

508

509

510

511

512

513

514

515

516

517

518

519

520

521

522

523

524

525

526

527

528

529

530

531

532

533

534

535

536

537

538

539

540

541

542

543

544

545

546

547

548

549

550

551

552

553

554

555

556

557

558

559

560

561

562

563

564

565

566

567

568

569

570

571

572

573

574

575

576

577

578

579

580

581

582

583

584

585

586

587

588

589

590

591

592

593

594

595

596

597

598

599

600

601

602

603

604

605

606

607

608

609

610

611

612

613

614

615

616

617

618

619

620

621

622

623

624

625

626

627

628

629

630

631

632

633

634

635

636

637

638

639

640

641

642

643

644

645

646

647

648

649

650

651

652

653

654

655

656

657

658

659

660

661

662

663

664

665

666

667

668

669

670

671

672

673

674

675

676

677

678

679

680

681

682

683

684

685

686

687

688

689

690

691

692

693

694

695

696

697

698

699

700

701

702

703

704

705

706

707

708

709

710

711

712

713

714

715

716

717

718

719

720

721

722

723

724

725

726

727

728

729

730

731

732

733

734

735

736

737

738

739

740

741

742

743

744

745

746

747

748

749

750

751

752

753

754

755

756

757

758

759

760

761

762

763

764

765

766

767

768

769

770

771

772

773

774

775

776

777

778

779

780

781

782

783

784

785

786

787

788

789

790

791

792

793

794

795

796

797

798

799

800

801

802

803

804

805

806

807

808

809

810

811

812

813

814

815

816

817

818

819

820

821

822

823

824

825

826

827

828

829

830

831

832

833

834

835

836

837

838

839

840

841

842

843

844

845

846

847

848

849

850

851

852

853

854

855

856

857

858

859

860

861

862

863

864

865

866

867

868

869

870

871

872

873

874

875

876

877

878

879

880

881

882

883

884

885

886

887

888

889

890

891

892

893

894

895

896

897

898

899

900

901

902

903

904

905

906

907

908

909

910

911

912

913

914

915

916

917

918

919

920

921

922

923

924

925

926

927

928

929

930

931

932

933

934

935

936

937

938

939

940

941

942

943

944

945

946

947

948

949

950

951

952

953

954

955

956

957

958

959

960

961

962

963

964

965

966

967

968

969

970

971

972

973

974

975

976

977

978

979

980

981

982

983

984

985

986

987

988

989

990

991

992

993

994

995

996

997

998

999

1000

1001

1002

1003

1004

1005

1006

1007

1008

1009

1010

1011

1012

1013

1014

1015

1016

1017

1018

1019

1020

1021

1022

1023

1024

1025

1026

1027

1028

1029

1030

1031

1032

1033

1034

1035

1036

1037

1038

1039

1040

1041

1042

1043

1044

1045

1046

1047

1048

1049

1050

1051

1052

1053

1054

1055

1056

1057

1058

1059

1060

1061

1062

1063

1064

1065

1066

1067

1068

1069

1070

1071

1072

1073

1074

1075

1076

1077

1078

1079

1080

1081

1082

1083

1084

1085

1086

1087

1088

1089

1090

1091

1092

1093

1094

1095

1096

1097

1098

1099

1100

1101

1102

1103

1104

1105

1106

1107

1108

1109

1110

1111

1112

1113

1114

1115

1116

1117

1118

1119

1120

1121

1122

1123

1124

1125

1126

1127

1128

1129

1130

1131

1132

1133

1134

1135

1136

1137

1138

1139

1140

1141

1142

1143

1144

1145

1146

1147

1148

1149

1150

1151

1152

1153

1154

1155

1156

1157

1158

1159

1160

1161

1162

1163

1164

1165

1166

1167

1168

1169

1170

1171

1172

1173

1174

1175

1176

1177

1178

1179

1180

1181

1182

1183

1184

1185

1186

1187

1188

1189

1190

1191

1192

1193

1194

1195

1196

1197

1198

1199

1200

1201

1202

1203

1204

1205

1206

1207

1208

1209

1210

1211

1212

1213

1214

1215

1216

1217

1218

1219

1220

1221

1222

1223

1224

1225

1226

1227

1228

1229

1230

1231

1232

1233

1234

1235

1236

1237

1238

1239

1240

1241

1242

1243

1244

1245

1246

1247

1248

1249

1250

1251

1252

1253

1254

1255

1256

1257

1258

1259

1260

1261

1262

1263

1264

1265

1266

1267

1268

1269

1270

1271

1272

1273

1274

1275

1276

1277

1278

1279

1280

1281

1282

1283

1284

1285

1286

1287

1288

1289

1290

1291

1292

1293

1294

1295

1296

1297

1298

1299

1300

1301

1302

1303

1304

1305

1306

1307

1308

1309

1310

1311

1312

1313

1314

1315

1316

1317

1318

1319

1320

1321

1322

1323

1324

1325

1326

1327

1328

1329

1330

1331

1332

1333

1334

1335

1336

1337

1338

1339

1340

1341

1342

1343

1344

1345

1346

1347

1348

1349

1350

1351

1352

1353

1354

1355

1356

1357

1358

1359

1360

1361

1362

1363

1364

1365

1366

1367

1368

1369

1370

1371

1372

1373

1374

1375

1376

1377

1378

1379

1380

1381

1382

1383

1384

1385

1386

1387

1388

1389

1390

1391

1392

1393

1394

1395

1396

1397

1398

1399

1400

1401

1402

1403

1404

1405

1406

1407

1408

1409

1410

1411

1412

1413

1414

1415

1416

1417

1418

1419

1420

1421

1422

1423

1424

1425

1426

1427

1428

1429

1430

1431

1432

1433

1434

1435

1436

1437

1438

1439

1440

1441

1442

1443

1444

1445

1446

1447

1448

1449

1450

1451

1452

1453

1454

1455

1456

1457

1458

1459

1460

1461

1462

1463

1464

1465

1466

1467

1468

1469

1470

1471

1472

1473

1474

1475

1476

1477

1478

1479

1480

1481

1482

1483



# Auto-Narratives

HTML, interactive dataviz

Patient Profile Narrative

Overview

Subject: 01-701-1192

Age: 80

Sex: F

Race: WHITE

Site Name: 701

Investigations Drug(s) Administered: Xanomeline Low Dose

Disposition: Completed

Exposure

Subject 01-701-1192's first recorded date of treatment was 2012-07-22. The last recorded date of treatment was 2013-

Adverse Events

The following table summarizes any adverse events experienced by subject 01-701-1192.

| Reported Term               | AE Start Date | AE End Date | Severity | Outcome                    |
|-----------------------------|---------------|-------------|----------|----------------------------|
| NASAL MUCOSA BIOPSY         | 2012-08-03    | 2012-08-03  | MILD     | RECOVERED/RESOLVED         |
| SECRETION DISCHARGE         | 2012-08-07    | 2012-09-14  | MILD     | NOT RECOVERED/NOT RESOLVED |
| ERYTHEMA                    | 2012-08-07    | 2012-09-14  | MILD     | NOT RECOVERED/NOT RESOLVED |
| COUGH                       | 2010-06-01    |             | MODERATE | NOT RECOVERED/NOT RESOLVED |
| SECRETION DISCHARGE         | 2012-08-07    | 2012-09-14  | MILD     | RECOVERED/RESOLVED         |
| ERYTHEMA                    | 2012-08-07    | 2012-09-14  | MILD     | RECOVERED/RESOLVED         |
| PNEUMONIA                   | 2012-09-07    | 2012-10-06  | MODERATE | NOT RECOVERED/NOT RESOLVED |
| MUSCULAR WEAKNESS           | 2012-09-07    | 2012-09-30  | MODERATE | NOT RECOVERED/NOT RESOLVED |
| COUGH                       | 2010-06-01    |             | MILD     | NOT RECOVERED/NOT RESOLVED |
| PNEUMONIA                   | 2012-09-07    | 2012-10-06  | MODERATE | RECOVERED/RESOLVED         |
| MUSCULAR WEAKNESS           | 2012-09-07    | 2012-09-30  | MODERATE | RECOVERED/RESOLVED         |
| APPLICATION SITE IRRITATION | 2012-12-05    | 2012-12-16  | MILD     | NOT RECOVERED/NOT RESOLVED |
| APPLICATION SITE ERYTHEMA   | 2012-12-05    |             | MILD     | NOT RECOVERED/NOT RESOLVED |
| APPLICATION SITE PRURITUS   | 2012-12-05    |             | MILD     | NOT RECOVERED/NOT RESOLVED |
| APPLICATION SITE IRRITATION | 2012-12-05    | 2012-12-16  | MILD     | RECOVERED/RESOLVED         |

Age Distribution

Subject 01-701-1192  
Age: 80





# *Forward Looking*

**Method-enabled Tools**



# Forward Looking

## Method-enabled Tools

AI, ML and LLM powered tools in the clinical domains

The screenshot shows a Shiny web application interface. At the top, there's a blue header bar. Below it, a 'User Setup' section contains an 'API Key' input field (masked with dots) and a 'Model' dropdown menu set to 'GPT-4'. Below the 'User Setup' section, there are two columns: 'Question' and 'Response'. The 'Question' column has a 'Prompt' input field with the text 'What's 2 + 2' and a 'Submit' button. The 'Response' column has a 'Response' output field showing '2 + 2 equals 4.' and a 'Clear' button.

The screenshot shows a Shiny web application interface. At the top, there's a blue header bar. Below it, a 'User Setup' section contains an 'API Key' input field (masked with dots) and a 'Model' dropdown menu set to 'GPT-4'. Below the 'User Setup' section, there's a 'Prompt Setup' section with a 'Check for Differences' button. Below the 'Prompt Setup' section, there are two tables: 'Original Table' and 'New Table'. Both tables show the same data, but the 'New Table' has some cells highlighted in yellow.

| Characteristic | Diet         | Exercise     | P        |
|----------------|--------------|--------------|----------|
| Overall N      | 73 (100%)    | 71 (100%)    |          |
| Age (Years)    |              |              | 0.9676*  |
| N              | 73           | 71           |          |
| Mean (SD)      | 41.4 (13.57) | 41.8 (14.11) |          |
| Median         | 41           | 43           |          |
| Range          | 18.0, 65.0   | 18.0, 65.0   |          |
| Sex, n (%)     |              |              | 0.2653** |
| Female         | 40 (54.8%)   | 32 (45.1%)   |          |
| Male           | 33 (45.2%)   | 39 (54.9%)   |          |

| Characteristic | Diet         | Exercise     | P        |
|----------------|--------------|--------------|----------|
| Overall N      | 11 (33%)     | 71 (100%)    |          |
| Age (Years)    |              |              | 0.9676*  |
| N              | 73           | 71           |          |
| Mean (SD)      | 41.4 (13.57) | 41.8 (14.11) |          |
| Median         | 41           | 11           |          |
| Range          | 18.0, 65.0   | 18.0, 65.0   |          |
| Sex, n (%)     |              |              | 0.2653** |
| Female         | 40 (54.8%)   | 32 (99%)     |          |
| Male           | 33 (45.2%)   | 39 (54.9%)   |          |



# Forward Looking

## Method-enabled Tools

I will paste you a SAS program. I want you to tell me all the variables derived in this program. If you can, also tell me how they are derived.

Please paste the SAS program, and I will analyze it for you.

AI-generated content may be incorrect

```
%let path1=/folders/myfolders/test1;
%let path2=/folders/myfolders/test2;

%include "&path2/setup.sas";

**** CREATE EMPTY ADEF DATASET CALLED EMPTY_ADEF;
%let metadatafile=&path1/adam_metadata.xlsx;
%include "&path1/make_empty_dataset.sas";
%make_empty_dataset(metadatafile=&metadatafile,dataset=ADEF)

** calculate changes from baseline for all post-baseline visits;
%include "&path2/cfb.sas";
%cfb(indata=sdtm.xp, outdata=adef, dayvar=xpdy, avalvar=xpstresn);

proc sort
data = adam.adsl
(keep = usubjid siteid country age agegr1 agegr1n sex race randdt trt01p trt01pn ittf1)
out = adsl;
by usubjid;

%include "&path2/dtc2dt.sas";
data adef;
merge adef (in = inadef) adsl (in = inadsl);
by usubjid ;
```

### Chat session

Clear chat View code Show raw JSON

In the provided SAS program, the following variables are derived:

1. `usubjid`: It is not derived, but it is used as a merging key for the `adef` and `adsl` datasets.
2. `trtp`: Derived from the `trt01p` variable by renaming it.
3. `trtpn`: Derived from the `trt01pn` variable by renaming it.
4. `param`: Derived from the `xptest` variable by renaming it.
5. `paramcd`: Derived from the `xptestcd` variable by renaming it.
6. `avisit`: Derived from the `visit` variable by renaming it.
7. `aval`: Derived from the `xporres` variable by renaming it.
8. `avisitn`: Derived by converting `visitnum` to a formatted number using the `input()` and `put()` functions.
9. `crit1`: A constant string variable with the value "Pain improvement from baseline of at least 2 points".
10. `RESPFL`: Derived from the `chg` variable by checking if the change is between .z and -2 (inclusive). If yes, it is assigned 'Y', otherwise 'N'.
11. `crit1f1`: Derived from the `RESPFL` variable. If `RESPFL` is 'Y', then it is assigned 'Y', otherwise 'N'.

Additionally, the `cfb` macro is called to calculate the changes from baseline for all post-baseline visits. This macro takes the input dataset `sdtm.xp`, output dataset `adef`, day variable `xpdy`, and aval variable `xpstresn`. The macro is included from the file "&path2/cfb.sas".

AI-generated content may be incorrect

In this SAS program, what are the datasets that are created

In the provided SAS program, the following datasets are created:

1. `EMPTY_ADEF`: This empty dataset is created by calling the `%make_empty_dataset()` macro with `metadatafile` and `dataset=ADEF` as parameters. The macro is included from the file "&path1/make\_empty\_dataset.sas".
2. `adef`: This dataset is created through a series of data steps and merges, including the call to the `%cfb()` macro. It starts with the output from the `%cfb()` macro and undergoes several transformations before being combined with the `adsl` dataset.
3. `adsl`: This dataset is created by sorting the `adam.adsl` dataset and keeping only specific variables. It is then used to merge with the `adef` dataset.
4. `adam.adef`: This dataset is created by sorting the `adef` dataset according to the sort order specified in the metadata file. The sorting process is performed using the `%make_sort_order()` macro, which is included from the file "&path1/make\_sort\_order.sas".

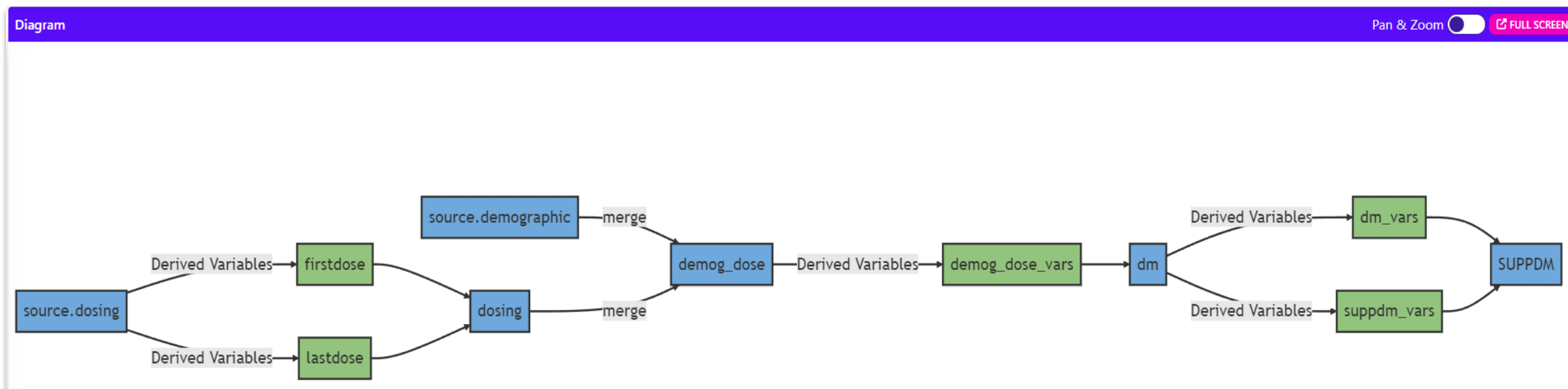
These are the datasets created directly in the provided SAS program. Note that the input datasets `sdtm.xp` and `adam.adsl` are used, but they are not created within this program.

AI-generated content may be incorrect



# Forward Looking

## Method-enabled Tools





*Thank you!*

**Q & A**



# Contact

// **Ankur Verma** ([Ankur.Verma@Bayer.com](mailto:Ankur.Verma@Bayer.com))

// **Matthew Kumar** ([Matthew.Kumar@Bayer.com](mailto:Matthew.Kumar@Bayer.com))