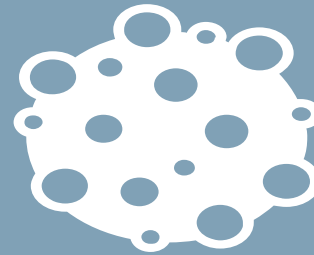




Global Reach



Speed & Delivery



Therapeutic Knowledge



Creative Solutions

A Visual Tool to Aid Traceability

Jesse Pratt
Cleopatra DeLeon

PPD[®]

Outline

+ Introduction/Motivation

Outline

- + Introduction/Motivation
- + Methodology

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 - Design layout
 - Text and positioning data
 - Gather outputs
 - Program the figures
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- + Looking Ahead

Introduction

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- + Important for regulatory reviewers, sponsors, and study team members that interact with the data

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- + Important for regulatory reviewers, sponsors, and study team members that interact with the data
- + Poor traceability can lead to difficulties locating and explaining data anomalies, ultimately compromising quality

Introduction

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- + Two-fold approach
 - Build flow charts to illustrate relationships between data sets and outputs
 - Add hyperlinks using HTML to enhance user interactivity
- + Result shows the descendance of a data set or output easily traced in a comfortable format
- + No specialized software needed, can be built entirely within Base SAS

Methodology

Methodology - Design

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- + Define row and column numbers, ID numbers for each item in the flow chart, show arrows

Methodology – Position and Text Data

+ Create from sketch

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- + Create from sketch
- + Define item ID, row and column numbers, link IDs

Methodology – Gather Outputs

- + Define meaningful folder structure

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- + Define meaningful folder structure

OneDrive > PHUSE2020 > FlowChartDashboard					Search FlowChartDashboard
Name	Status	Date modified	Type		
DataFiles	✓	1/20/2020 5:04 PM	File folder		
HTMLFiles	✓	12/11/2019 10:49 AM	File folder		
SASPrograms	✓	1/20/2020 5:05 PM	File folder		
StaticImages	✓	1/17/2020 12:03 PM	File folder		

Methodology – SAS Program

- + Import positioning data set

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- + Perform calculations for boundary coordinates
- + Use the Graph Template Language (GTL) to output location data for text; rerun iteratively until desired locations obtained
- + Create coordinates for arrows
- + Plot final chart

Methodology - HTML

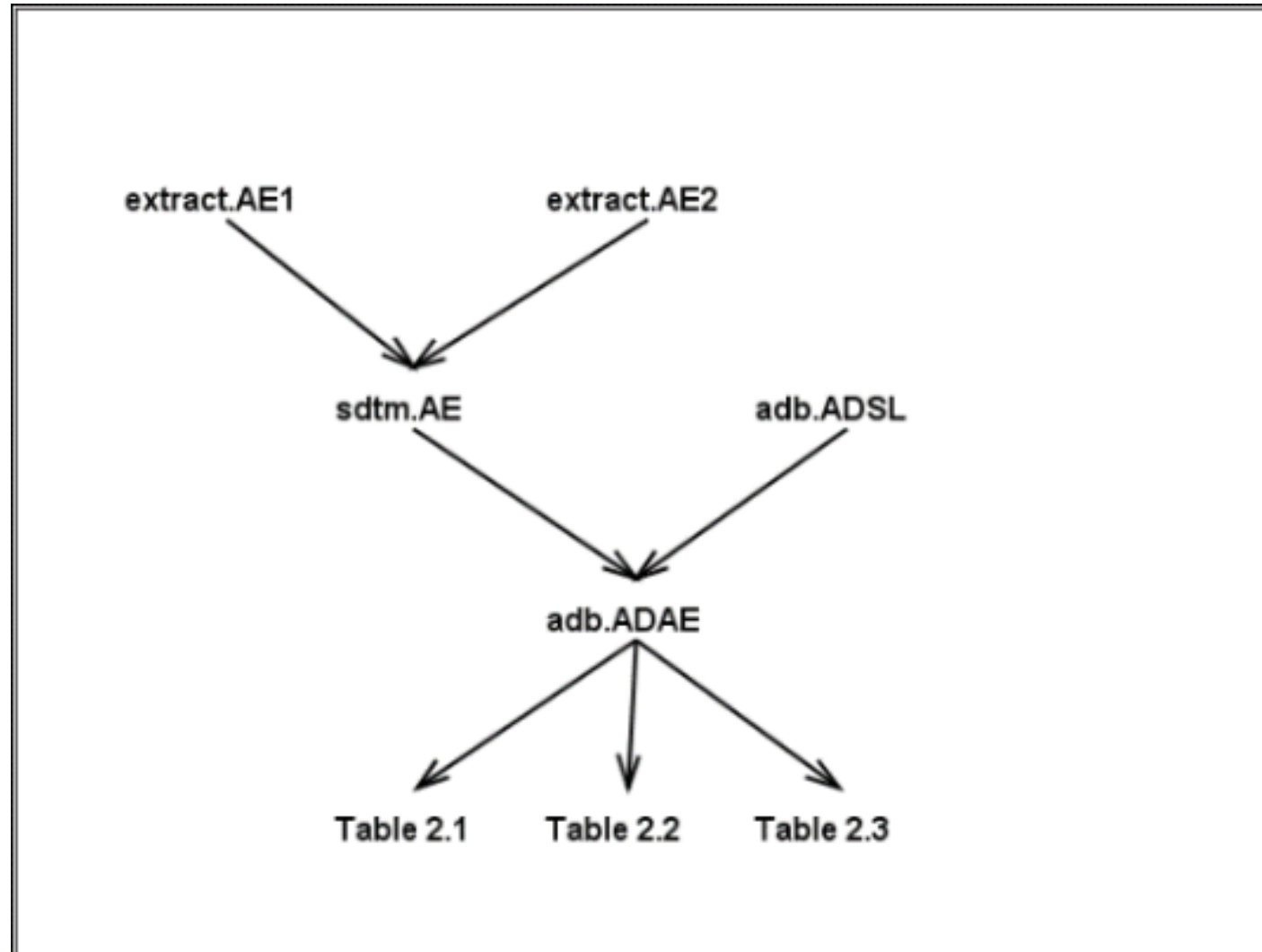
- + Create HTML files out of image files of chart

Methodology - HTML

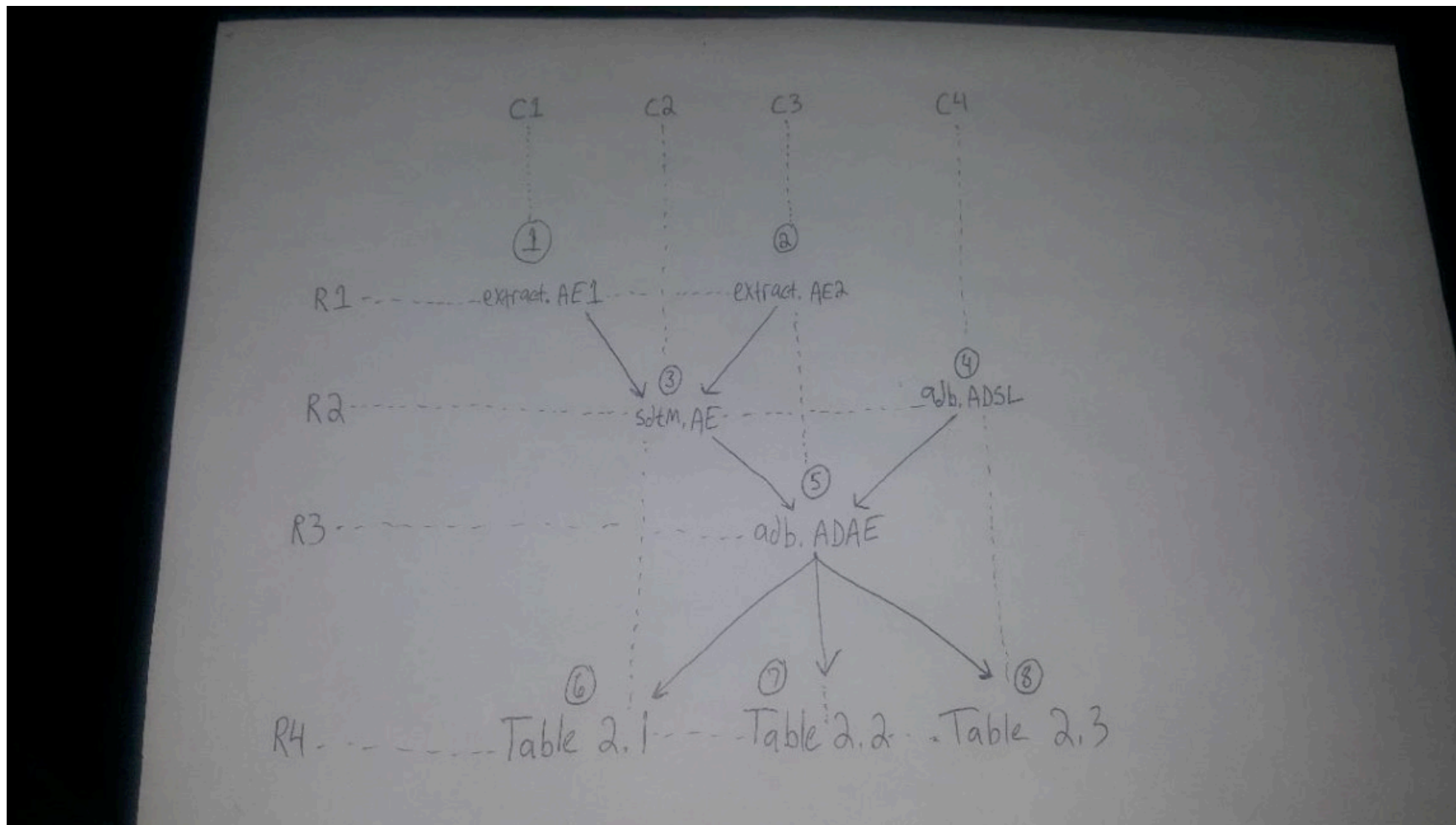
- + Create HTML files out of image files of chart
- + Use HTML code to place links around sections of chart to link to other files (such as outputs, other flow charts, etc.)

Example

Example - ADAE



Example - ADAE



Example - ADAE

	A	B	C	D	E	F
1	BOXID	ROW	COL	ROUGHTTEXT	FROMID	TOID
2	1	1	1	extract.AE1	1	3
3	2	1	3	extract.AE2	2	3
4	3	2	2	sdtm.AE	3	5
5	4	2	4	adb.ADSL	4	5
6	5	3	3	adb.ADAE	5	6
7	6	4	2	Table 2.1	5	7
8	7	4	3	Table 2.2	5	8
9	8	4	4	Table 2.3		

Example - ADAE

BOXID	ROW	COL	ROUGHTTEXT	FROMID	TOID	roughx	roughy
1	1	1	extract.AE1	1	3	20	20
2	1	3	extract.AE2	2	3	60	20
3	2	2	sdtm.AE	3	5	40	40
4	2	4	adb.ADSL	4	5	80	40
5	3	3	adb.ADAE	5	6	60	60
6	4	2	Table 2.1	5	7	40	80
7	4	3	Table 2.2	5	8	60	80
8	4	4	Table 2.3	.	.	80	80

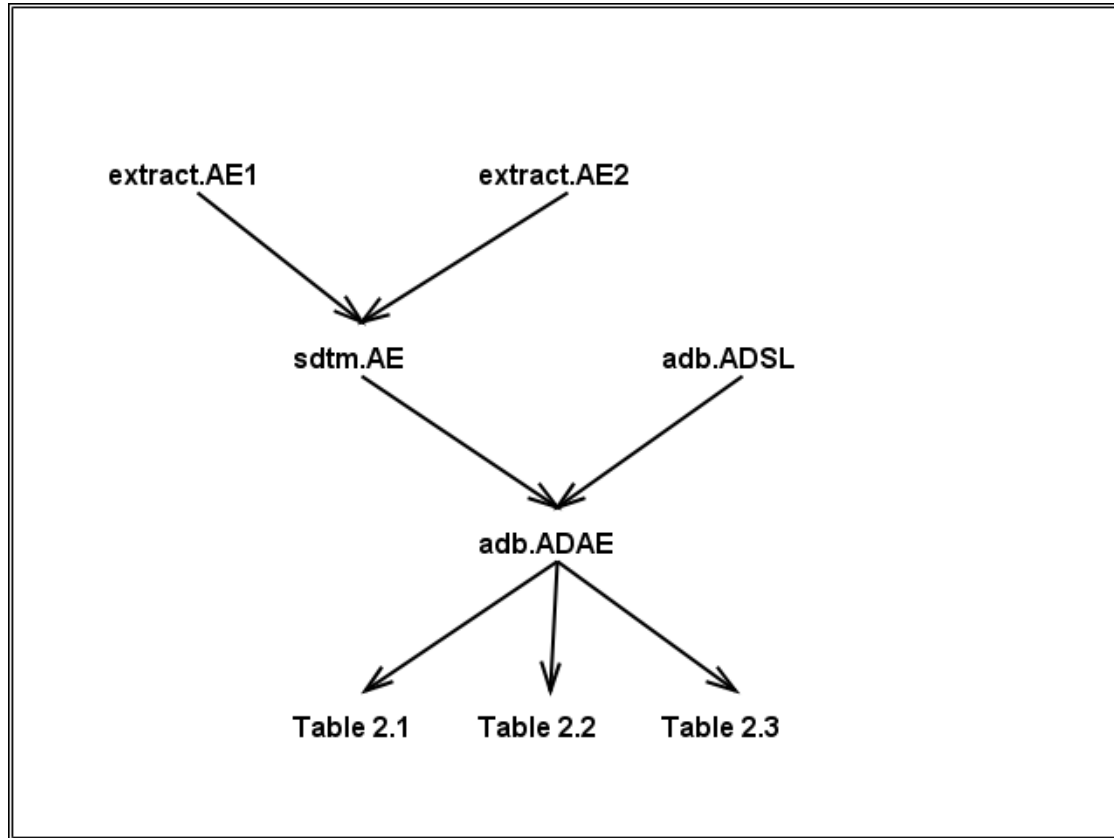
Example - ADAE

BOXID	ROW	COL	ROUGHTTEXT	FROMID	TOID	roughx	roughy	dummyx	dummyy
1	1	1	extract.AE1	1	3	20	20	.	.
2	1	3	extract.AE2	2	3	60	20	.	.
3	2	2	sdtm.AE	3	5	40	40	.	.
4	2	4	adb.ADSL	4	5	80	40	.	.
5	3	3	adb.ADAE	5	6	60	60	.	.
6	4	2	Table 2.1	5	7	40	80	.	.
7	4	3	Table 2.2	5	8	60	80	.	.
8	4	4	Table 2.3	.	.	80	80	.	.
.	.	.	.	.	.	.	.	0	0
.	.	.	.	.	.	.	.	100	100

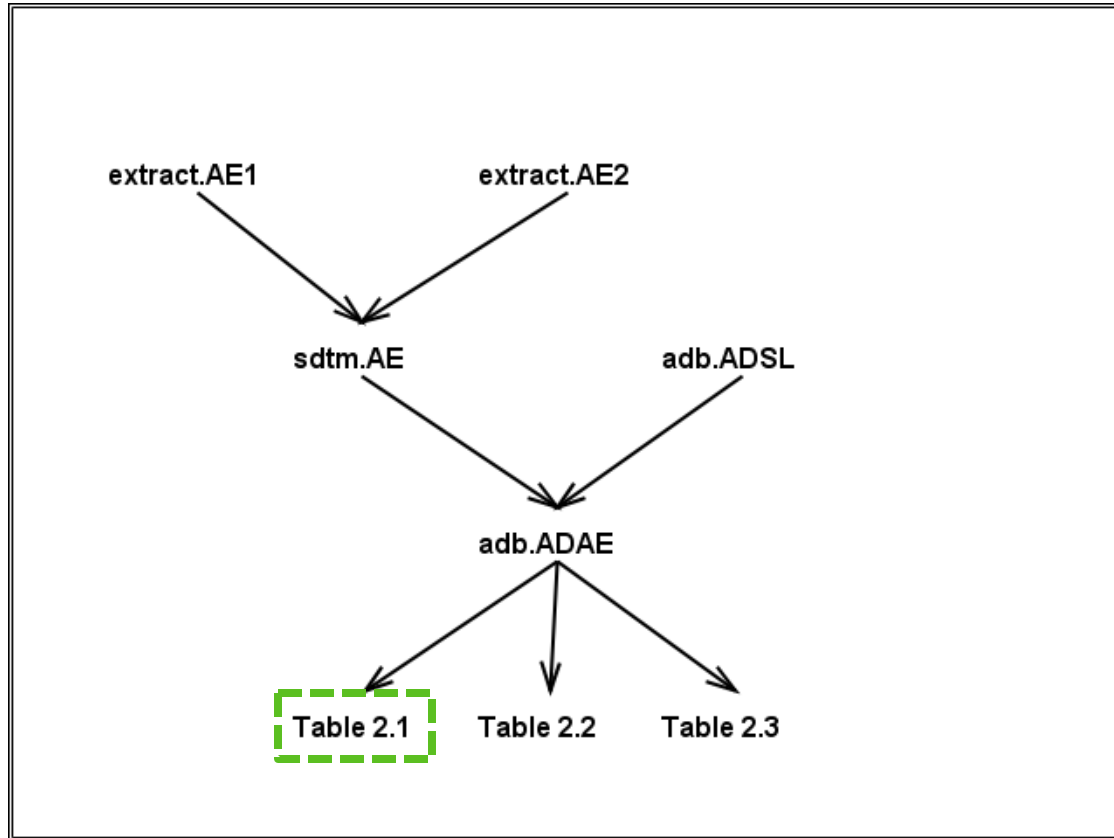
Example - ADAE

roughx	roughy	dummyx	dummyy	DATAWIDTH	DATAHEIGHT	BOTTOMX	BOTTOMY	TOPX	TOPY
.	.	10	0	.	.	.	.	.	.
.	.	130	90	.	.	.	.	.	.
20	20	.	.	17.950338688	5.1125889866	28.975169344	20	28.975169344	14.887411013
60	20	.	.	17.950338688	5.1125889866	68.975169344	20	68.975169344	14.887411013
40	40	.	.	13.603892776	5.1125889866	46.801946388	40	46.801946388	34.887411013
80	40	.	.	16.060579408	5.1125889866	88.030289704	40	88.030289704	34.887411013
60	60	.	.	16.249555192	5.1125889866	68.124777596	60	68.124777596	54.887411013
40	80	.	.	14.359795912	5.1125889866	47.179897956	80	47.179897956	74.887411013
60	80	.	.	14.359795912	5.1125889866	67.179897956	80	67.179897956	74.887411013
80	80	.	.	14.359795912	5.1125889866	87.179897956	80	87.179897956	74.887411013

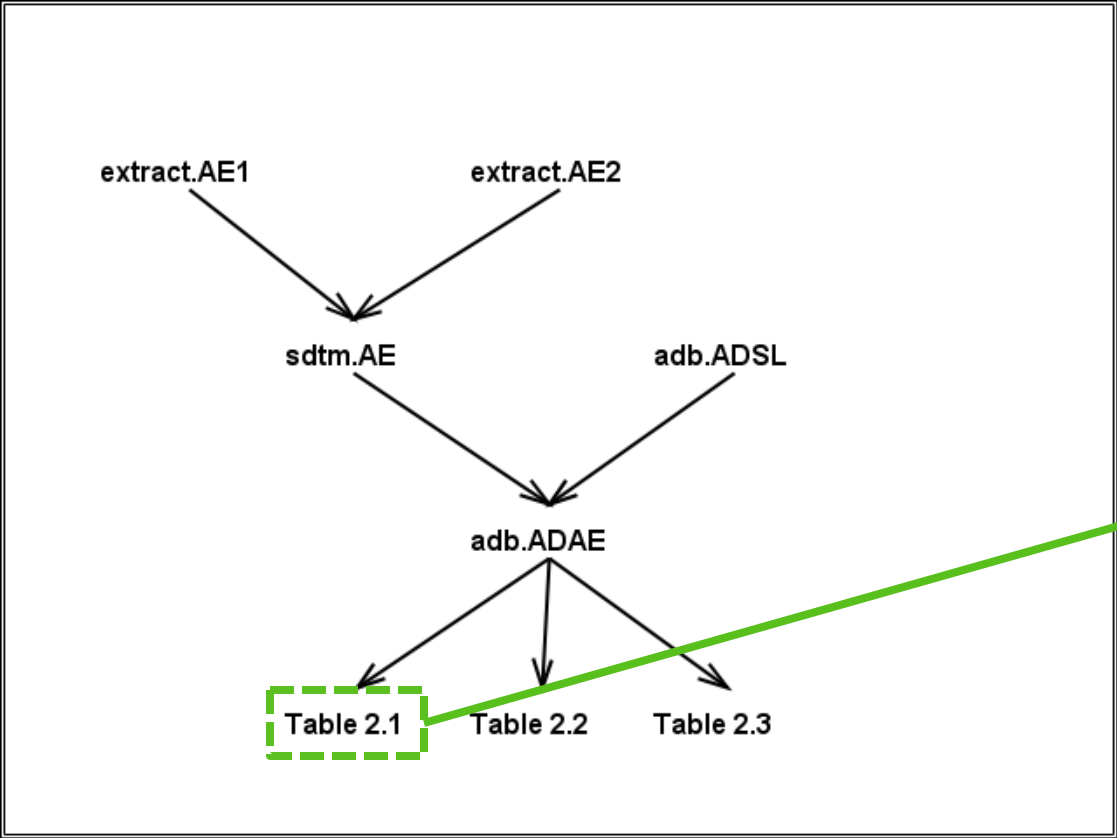
Example - ADAE



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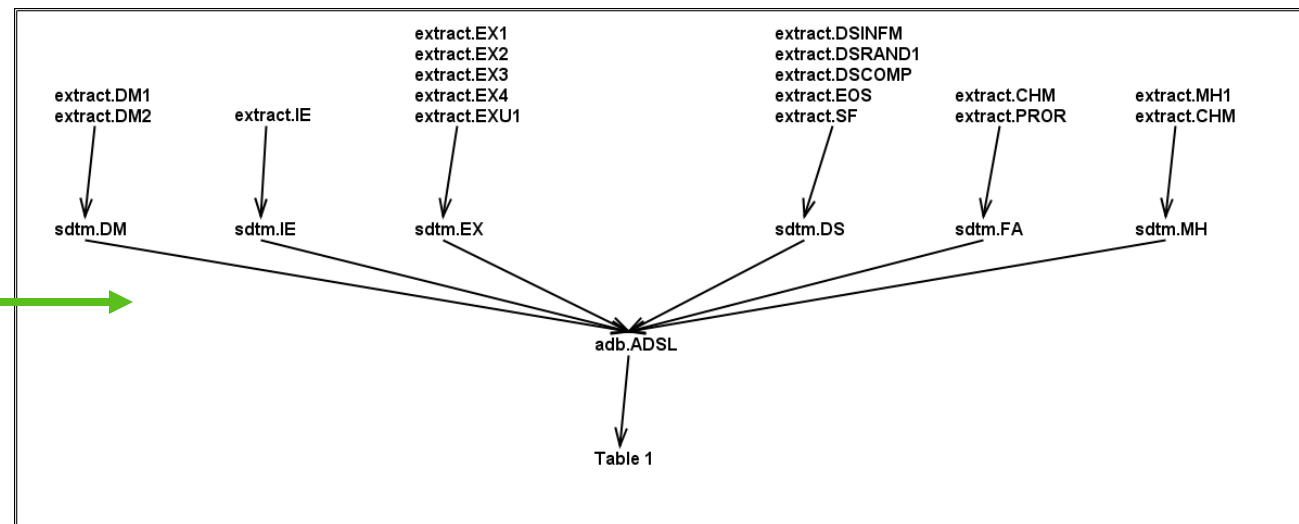
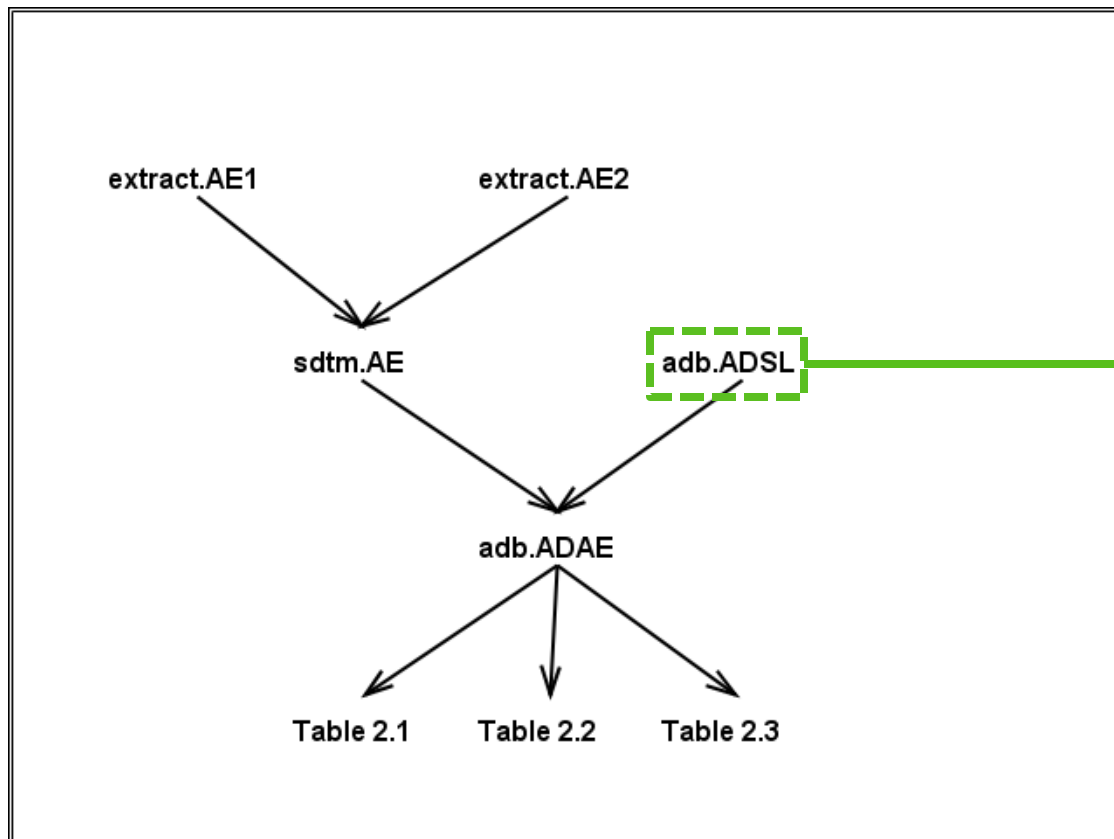


Example - ADAE



Adverse Event	Placebo (n=XXX)	Treatment (n=XXX)
Headache	X	X
Dizziness	X	X
Fatigue	X	X
Upset Stomach	X	X
Fainting	X	X
Nausea	X	X
Total	XX	XX

Example - ADAE



Concluding Thoughts

Opportunities for Enhancement

- + Still a few steps requiring manual development, such as flow chart design

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- + Leverage standardized folder structures and naming conventions for SAS libraries, data sets, and outputs to programmatically identify and collect data sources
- + Automate drawing the flow charts by using generic templates of common data source groupings

References

- + *Applying an Experimental GTL Feature to CONSORT Diagrams*, Shane Rosanbalm, PharmaSUG 2019 DV-021
- + *Murach's HTML, XHTML, and CSS*, Anne Boehm, 2010, Mike Murach & Associates, Inc.

Thank you for your time!

Questions?

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