Navigate Clinical Study Report Tables and Listings -
The iTable & iListing project

October 2024 / Katja Glaß

Disclaimer

Data presented is

deducted and anonymized

from a real study from 2020

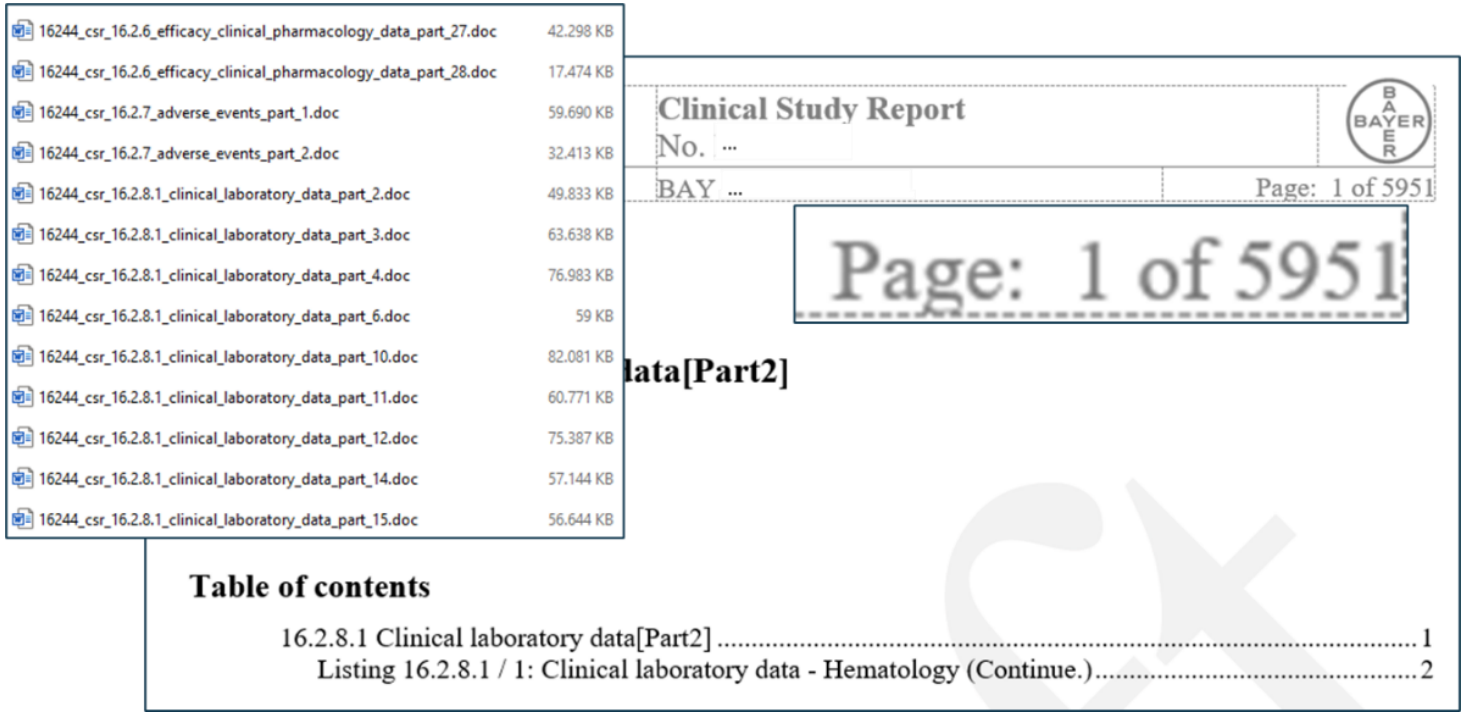
Agenda

- // Introduction
- // Solution
- // Architecture
- // Implementation
- // Use Cases
- // Opportunities
- // Summary

Introduction

iListing & iTable - why?

- “Tables, Figures and Graphs” along with “Appendices” according ICH E3
  - Tables section & listings section
- Listings are a view of clinical database, no summaries
- Numerous huge documents
  - Example phase 3 study,
    84 documents for listings alone,
    each up to 15.000 pages



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16244_csr_16.2.8.1_clinical_laboratory_data_part_11.doc	60.771 KB
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16244_csr_16.2.8.1_clinical_laboratory_data_part_15.doc	56.644 KB

Clinical Study Report
No. ...
BAY ...
Page: 1 of 5951

Page: 1 of 5951

data[Part2]

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Listing 16.2.8.1 / 1: Clinical laboratory data - Hematology (Continue.) 2

Introduction

iListing - why?

- Working with listings?
  - Hardly possible, slow to open / search
  - Tough to find one subject on multiple documents
  - Quality checks are based on listing outputs

- iListing was born
  - Interactive listings
  - Sorting, filtering & more
  - Presented 2021

Introduction

iTable - why?

- Working with tables?
  - Better than listings, less pages, summaries, overviews
  - Still many documents
  - Compare summaries could also be time consuming
  - Linking tables to listings to enable quick insights

- iTable was born
  - Enhance tool
  - Additional features
  - Little effort to create

The Solution

Experimental Version!

iListing / iTable

Enabling quick and easy navigation and filtering for tables and listings - Version from 2024-04-04

Watch demo video

Study Selection

Selection: Example4

○	Study: Voyager PAD (17454)	Pilot study
○	Example for Listings	For all with SWAN access
○	Example for Tables	For all with SWAN access
○	Example for both	For all with SWAN access
●	Example for Subject Info	For all with SWAN access

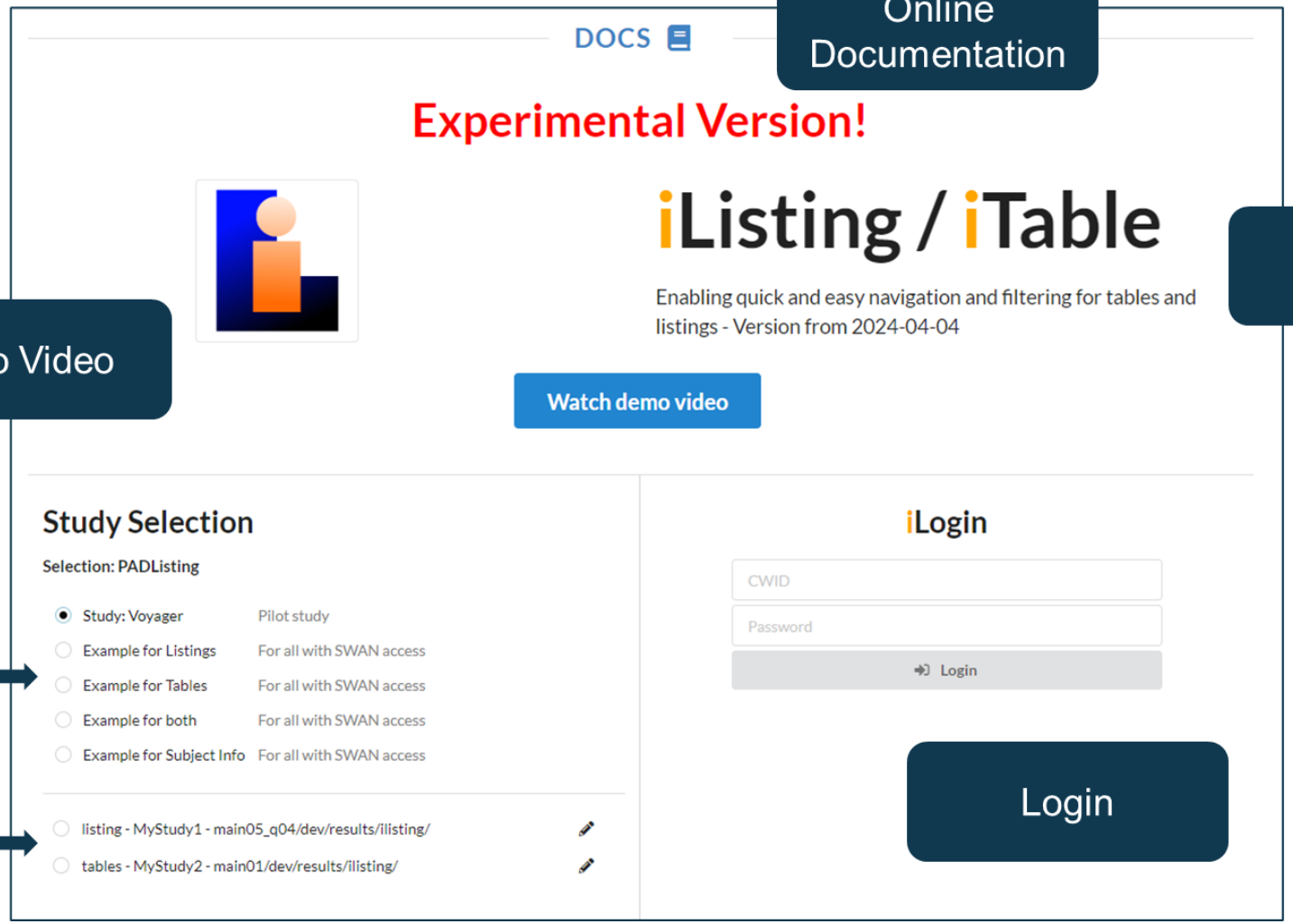
iLogin

sgqyq

••••••••••••

Login

The Solution



Online Documentation

Version

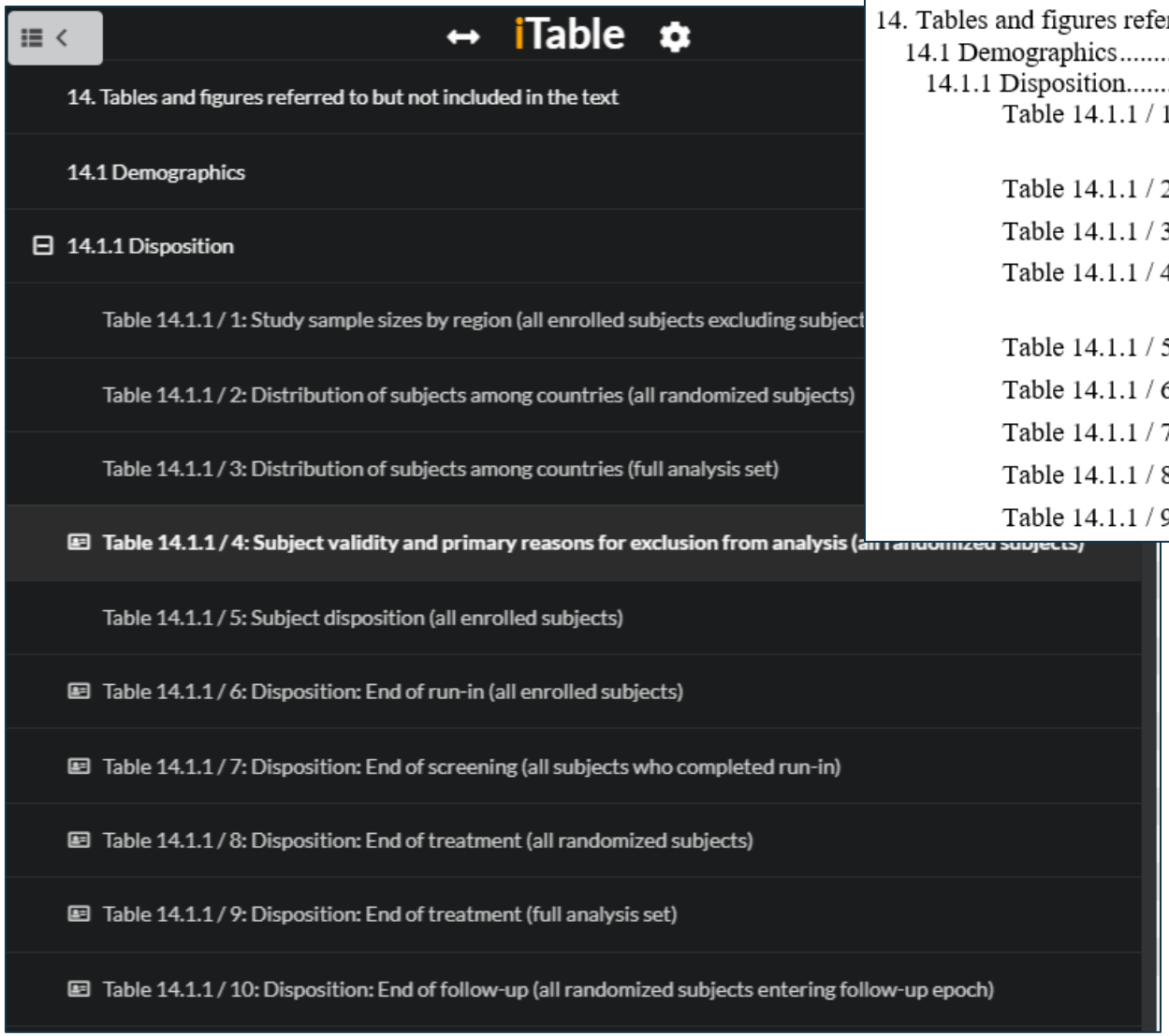
Demo Video

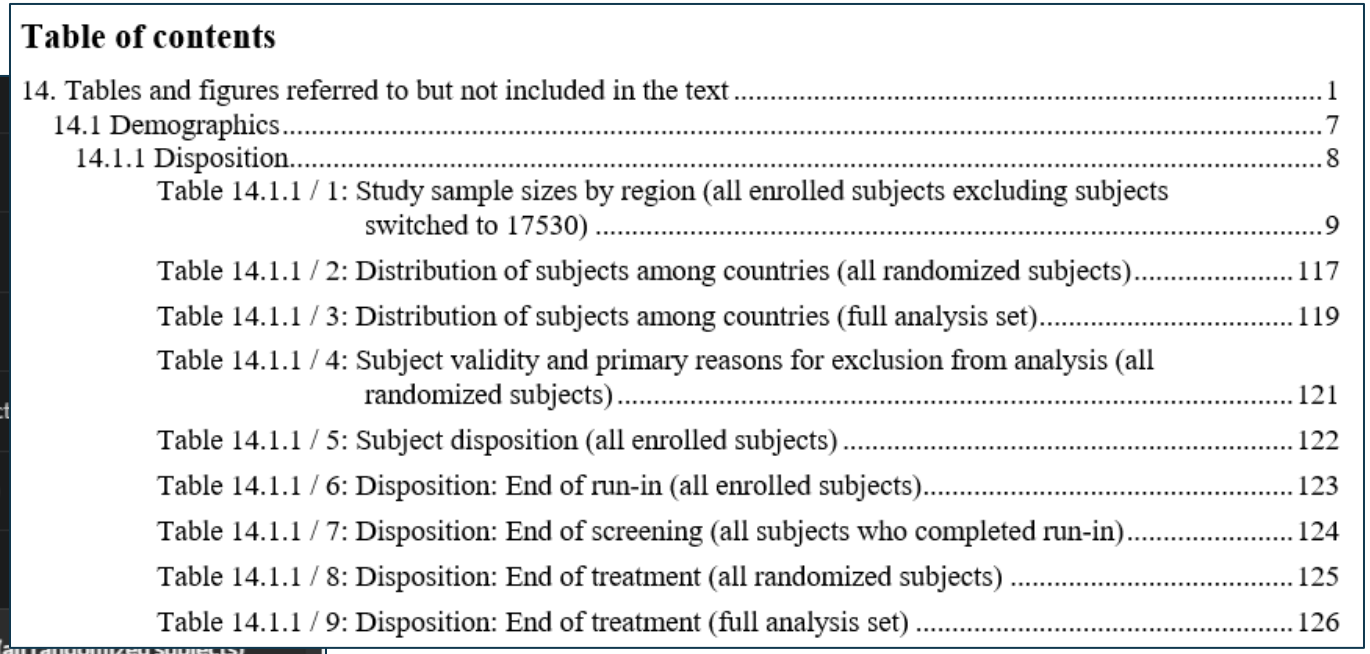
Example Studies

Personal Studies

Login

The Solution





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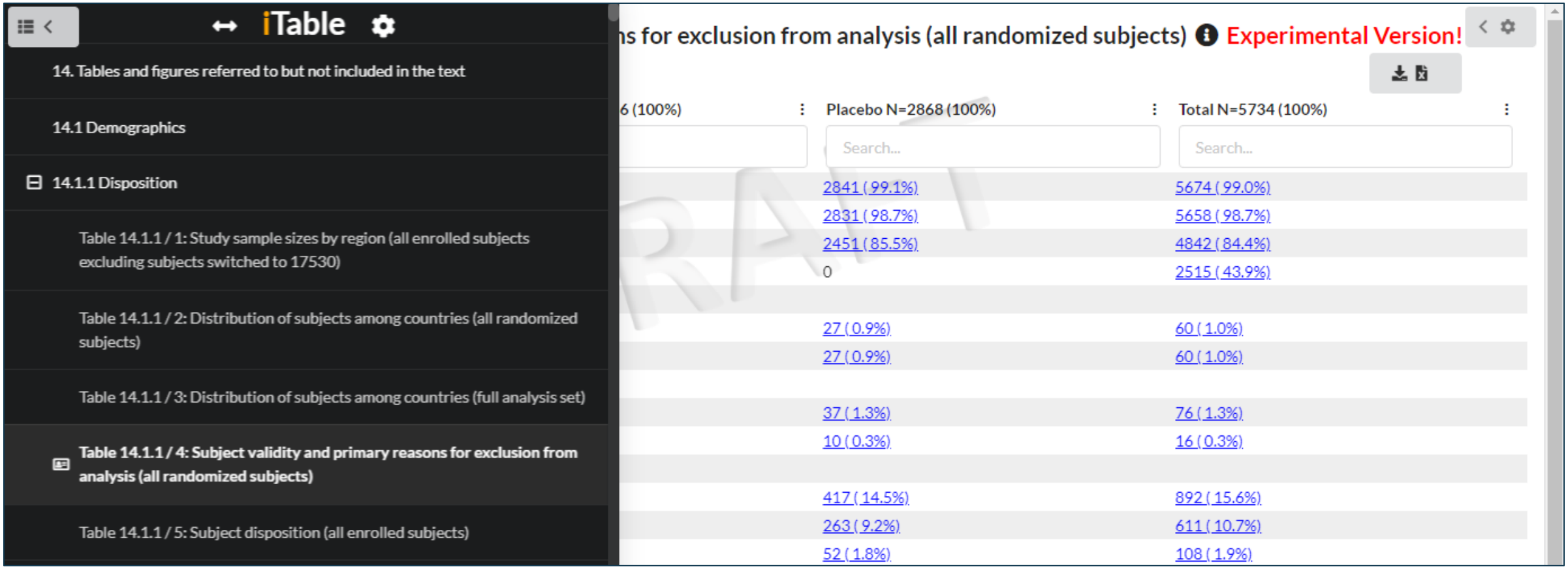
The Solution



The Solution

Listing 10.2.4 / 5: Demographics Experimental Version! (1)

row	Unique Subject Identifier	Treatment Group	Birth Date	Age/Sex/Race	Ethnicity
Sea...	Search...	Search...	YYYY-MM-DD	Search...	Search...
970	16480	BAY 94-8862	1964------	54/M/A	NOT HISPA

Listing 10.2.7 / 1: Adverse events Experimental Version! (3)

row	Treatment ...	Unique ...	Preferr...	Start Prior ...	Serious	Reasons	Start Date ...	Start Time ...	End Date
Sea...		Search...	Search...				YYYY-I		YYYY-I
3640	BAY 94-8862	016480/54/M...	Chronic obstr...	NO	YES	Requires or Pr...	2014-05-28		2014-06-1
3641	BAY 94-8862	016480/54/M...	Hypertension/...		NO	NO	2014-05-28		2014-05-2
3642	BAY 94-8862	016480/54/M...	Chronic obstr...	NO	YES	Results in Death	2014-08-13		2014-08-1

Listing 10.2.8.1 / 1: Clinical laboratory data - Hematology Experimental Version! (24)

row	Treatment Group	Unique Subject Ide...	Visit	Specimen Collectio...	Laboratory Test	Specim
Sear...	Search...	Search...	Search...	Search...	Search...	Sear
41737	BAY 94-8862	016480/54/M/A	Run In	19MAR2014/08:50	Hematocrit (%) in Blood - ...	NORMA
41738	BAY 94-8862	016480/54/M/A	Run In	19MAR2014/08:50	Hemoglobin (g/dL) in Blood	NORMA
41739	BAY 94-8862	016480/54/M/A	Run In	19MAR2014/08:50	Erythrocytes (T/L) in Blood	NORMA
41740	BAY 94-8862	016480/54/M/A	Run In	19MAR2014/08:50	Ery. Mean Corpuscular Vo...	NORMA

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The Solution

Table 14.3.1 / 2: Overall summary of number of subjects with adverse events (safety analysis set)

Experimental Version! (18)

row		BAY 94-8862 N=2827 (100%)	Placebo N=2831 (100%)
15	Any study drug-related SAE	54 (1.9%)	40 (1.4%)
16	Any SAE related to procedures required by ...	4 (0.1%)	6 (0.2%)
17	Any SAE leading to discontinuation of study...	83 (2.9%)	90 (3.2%)
18	AE with outcome death	89 (3.1%)	105 (3.7%)

Listing 10.2.7 / 1: Adverse events

Experimental Version! (6)

r	T..	Unique Su...	Preferred Term / Reported Term				S..	S..	E..	E..		A..	S..		A..	O..	O..	C..
6...	BA...	031133/63/F/M	Anaemia/Anaemia	N	NO	NO	20...		----...		409/		SE...	NO...	DO...		NO...	YES
6...	BA...	031133/63/F/M	Erysipelas/Erysipelas	N	YES	Re...	20...		20...		41...	23	SE...	NO...	NO...		FA...	YES
7...	BA...	033836/65/F/B	Acute kidney injury/Acute kidney inju...		YES	Re...	20...		20...		36...	5	SE...	NO...	NO...		RE...	YES
7...	BA...	035749/70/M/A	Lung neoplasm malignant/Lung neopl...		NO	NO	20...		20...		11...	45	SE...	NO...	DO...		RE...	NO
7...	BA...	035749/70/M/A	Lung neoplasm malignant/Lung neopl...		YES	Re...	20...		20...		11...	8	SE...	NO...	DO...		RE...	NO
7...	BA...	035749/70/M/A	Nephrolithiasis/Nephrolithiasis		YES	Re...	20...		20...		11...	3	SE...	NO...	DR...		RE...	NO

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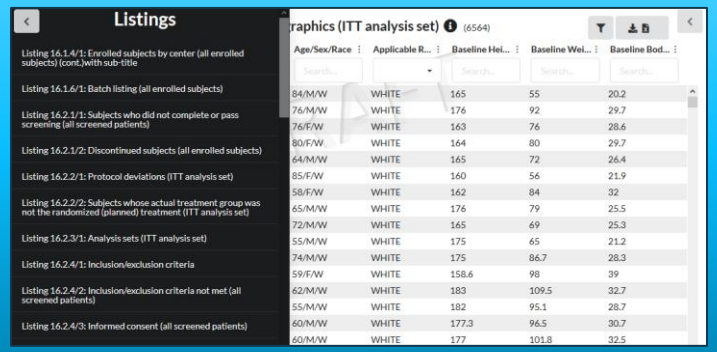
The Architecture

The Architecture

Frontend

- React Web Application
- Backend files
- Access via API (security)

Web Application



API

Metadata & data

<listing metadata>

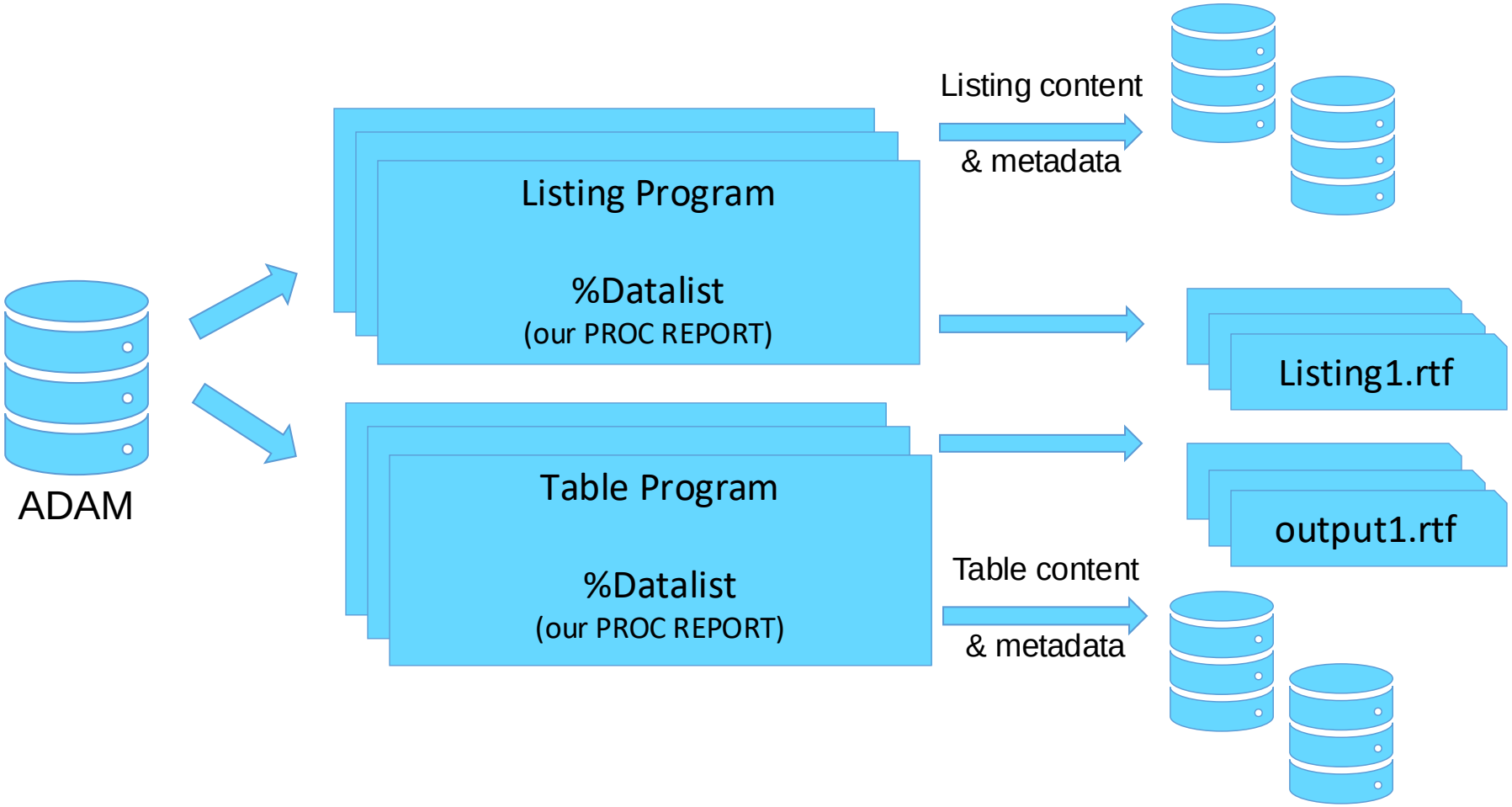
dataX.csv

<table metadata>

dataX.csv

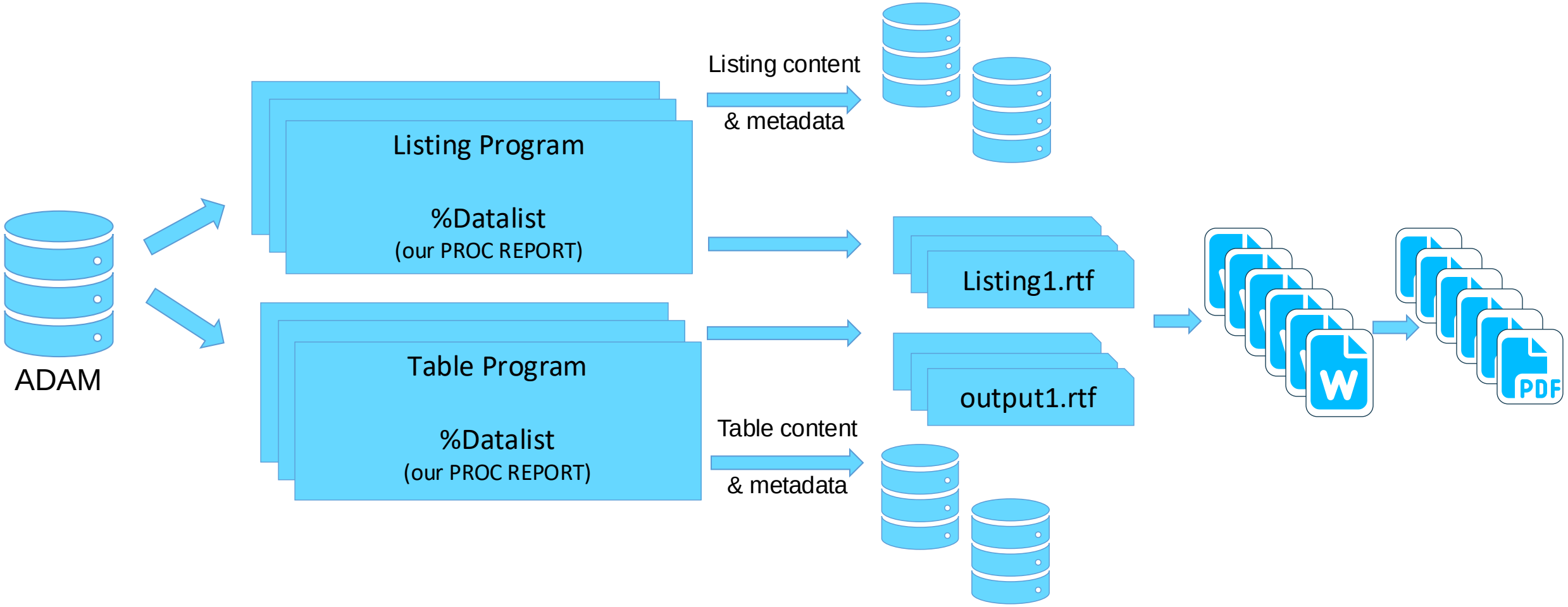
The Architecture

Metadata & Content data generation



The Architecture

Metadata & Content data generation



The Architecture

Backend / Data Generation

CSR Tables

Table Content & Metadata

SAS Program

%iListing4Tab(...)

Metadata & data

<table metadata>

dataX.csv

CSR Listings

Listing Content & Metadata

SAS Program

%iListing (...)

Metadata & data

<listing metadata>

dataX.csv

The Implementation

The Implementation

The Metadata

Generic information

- Study / pool number
- Metadata version
- Type (tables or listings)
- Location of metadata files
- Is special subject-linkage available
- Does subject filters apply (these should only apply for listings)

The Implementation

The Metadata

Order of tables or listings with section hierarchy if applicable

Per table / listing

- Identifier of the content dataset
- Title (including number)
- Footnotes
- Related origin program name
- Related final document name
- Display variables
- Split variables (in case column shrink/enlarge should be available)
- Subject variables (for subject filters)
- Number of observations (for completeness checks)
- Variables

The Implementation

The Metadata

Per table / listing

- Variables
  - Id
  - Label
  - Is it a date variable?
  - Is it a dropdown variable?
  - Does this belong to a “split-group” to enlarge/shrink content

The Implementation

The „split“ feature

Table 14.1.3 / 1: Demographics by Region (full analysis set) Experimental Version!

row	Pooled region	+	BAY 94-8862	Placebo	Total
1	Europe	Race			
2	Europe	WHITE	1158 (98.0%)	1141 (97.0%)	2299 (97.5%)
3	Europe	BLACK OR AFRICAN A...	10 (0.8%)	10 (0.9%)	20 (0.8%)
4	Europe	ASIAN	11 (0.9%)	20 (1.7%)	31 (1.3%)
5	Europe	AMERICAN INDIAN O...	0	0	0
6	Europe	NATIVE HAWAIIAN O...	0	0	0
7	Europe	NOT REPORTED	2 (0.2%)	5 (0.4%)	7 (0.3%)
8	Europe	MULTIPLE	1 (<0.1%)	0	1 (<0.1%)
9	Europe	Sex			
10	Europe	Male	818 (69.2%)	859 (73.0%)	1677 (71.1%)
11	Europe	Female	364 (30.8%)	317 (27.0%)	681 (28.9%)
12	Europe	Age (YEARS)			

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The Implementation

The „split“ feature

- Consider performance first
- What to implement in backend / file generation
- What to implement in frontend / display

NAME	_NAME_ILI1	_NAME_ILI2	_NAME_ILI3	_NAME_ILI4
Number (%) of subjects with pre-randomi	Number (%) of subje			
Any AE	Number (%) of subje	Any AE		
Maximum intensity for any AE	Number (%) of subje	Any AE	Maximum intensity for any AE	
MILD	Number (%) of subje	Any AE	Maximum intensity for any AE	MILD
MODERATE	Number (%) of subje	Any AE	Maximum intensity for any AE	MODERATE
Any study drug-related AE	Number (%) of subje	Any AE	Any study drug-related AE	
Any AE related to procedures require	Number (%) of subje	Any AE	Any AE related to procedures requ	
Any AE leading to discontinuation o	Number (%) of subje	Any AE	Any AE leading to discontinuatior	
Any SAE	Number (%) of subje	Any SAE		
Any study drug-related SAE	Number (%) of subje	Any SAE	Any study drug-related SAE	
Any SAE related to procedures requi	Number (%) of subje	Any SAE	Any SAE related to procedures rec	
Any SAE leading to discontinuation	Number (%) of subje	Any SAE	Any SAE leading to discontinuatic	
AE with outcome death	Number (%) of subje	AE with outcome		

NAME

is split up into

_NAME_ILI1
_NAME_ILI2
_NAME_ILI3
_NAME_ILI4

The Implementation

The „split“ feature

```
"tf_adae_1" : {
        "id" : "tf_adae_1",
        "titles" : ["Table 14.3.1 / 1: Overall summary of number of subjects …"],
        ...,
        "columnGroupBase" :
             [{ "_NAME_" :
                 [ "_NAME__ILI1" , "_NAME__ILI2" , "_NAME__ILI3" , "_NAME__ILI4" ]
             }],
        "vars" : {
            "_name_" : {
                "id" : "_name_",
                "isDate" : false,
                "isDropdown" : true,
                "columnGroupBase" : "_NAME__ILI1 _NAME__ILI2 _NAME__ILI3 _NAME__ILI4",
                "label" : " "
            },
            "_name__ili1" : {
                "id" : "_name__ili1",
                "isDate" : false,
                "isDropdown" : true,
                "columnGroupParent" : "_NAME_",
                "label" : " "
            },
            ...
        }
```

The Implementation

Virtualization over Pagination

Pagination:

- Divides content into discrete pages, requiring users to navigate between them.
- Drawbacks:
  - Load Times
  - User Frustration
  - Limited Visibility

Show 10 entries Search:

	table_name	libname	dataset
1	eu_ema_shortages	eu_ema	shortages
2	us_clinical_trials_brief_summaries	us_clinical_trials_brief	summaries
3	us_fda_drugs_products	us_fda_drugs	products
4	us_clinical_trials_designs	us_clinical_trials	designs
5	us_clinical_trials_links	us_clinical_trials	links
6	us_fda_drugs_aplication_docs	us_fda_drugs_aplication	docs
7	us_fda_ndc_product	us_fda_ndc	product
8	us_clinical_trials_result_groups	us_clinical_trials_result	groups
9	us_fda_ndc_excluded_packages	us_fda_ndc_excluded	packages
10	us_clinical_trials_provider_documents	us_clinical_trials_provider	documents

Showing 1 to 10 of 111 entries Previous 1 2 3 4 5 … 12 Next

Screenshot from https://phuse-org.shinyapps.io/01_podr/

The Implementation

Virtualization over Pagination

Virtualization:

- Loads only the visible items in a list or grid, dynamically rendering as the user scrolls.
- Benefits
  - Performance
  - User Experience
  - Scalability

Listing 10.2.3.1 / 1: Clinical laboratory data - General chemistry Experimental Version! (1618040)

row	Treatme...	Unique S...	Visit	Specime...	Laborato...	Specime...	Value	Flag	Normal R...	Normal R...	Standard...
1		006340/63/...	Run In	06DEC2013...	Hemoglobin ...	NORMAL	10.9	HIGH		6.5	%
2		006340/63/...	Run In	06DEC2013...	Urate (mg/d...	NORMAL	8.3	NORMAL	2.5	8.3	mg/dL
3		006340/63/...	Run In	06DEC2013...	Magnesium (...	INSUFFICIE...					
4		006340/63/...	Run In	06DEC2013...	Sodium (mm...	NORMAL	141	NORMAL	135	145	mmol/L
5		006340/63/...	Run In	06DEC2013...	Potassium (...	NORMAL	4.3	NORMAL	3.4	5.4	mmol/L
6		006340/63/...	Run In	06DEC2013...	Creatinine (...	NORMAL	1.55	HIGH	0.45	1.35	mg/dL
7		006340/63/...	Run In	06DEC2013...	Glomerular ...	NORMAL	46.9				mL/min/1.7...
8		006340/63/...	Run In	06DEC2013...	Blood Urea ...	NORMAL	24	NORMAL	4	24	mg/dL
9		006340/63/...	Run In	06DEC2013...	Protein (g/d...	NORMAL	6.4	NORMAL	6	8	g/dL
10		006340/63/...	Run In	06DEC2013...	Albumin (g/d...	NORMAL	4.2	NORMAL	3.3	4.9	g/dL
11		006340/63/...	Run In	06DEC2013...	C Reactive P...	NORMAL	7.27	HIGH		2.87	mg/L
12		006340/63/...	Run In	06DEC2013...	Aspartate A...	NORMAL	30	NORMAL	11	36	U/L
13		006340/63/...	Run In	06DEC2013...	Alanine Ami...	NORMAL	29	NORMAL	6	43	U/L

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The Implementation

Sort & Filter

Performance:

- How to sort / filter / store status
- Index list as display list
  - [1, 2, 3, 4]
  - Reverse sorting -> [4, 3, 2, 1]
  - Filtering -> [1, 2, 4]

Listing 10.2.3.1 / 1: Clinical laboratory data - General chemistry Experimental Version! (1618040)

r..	Treatm...	Unique ...	Visit	Specim...	Laborat...	Specim...	Value	Flag	Normal ...	Normal ...	Standar...
1		006340/6...	Run In	06DEC201...	Hemoglobi...	NORMAL	10.9	HIGH		6.5	%
2		006340/6...	Run In	06DEC201...	Urate (mg/...	NORMAL	8.3	NORMAL	2.5	8.3	mg/dL
3		006340/6...	Run In	06DEC201...	Magnesiu...	INSUFFICI...					
4		006340/6...	Run In	06DEC201...	Sodium (m...	NORMAL	141	NORMAL	135	145	mmol/L
5		006340/6...	Run In	06DEC201...	Potassium ...	NORMAL	4.3	NORMAL	3.4	5.4	mmol/L
6		006340/6...	Run In	06DEC201...	Creatinine ...	NORMAL	1.55	HIGH	0.45	1.35	mg/dL
7		006340/6...	Run In	06DEC201...	Glomerula...	NORMAL	46.9				mL/min/1....
8		006340/6...	Run In	06DEC201...	Blood Urea...	NORMAL	24	NORMAL	4	24	mg/dL
9		006340/6...	Run In	06DEC201...	Protein (g/...	NORMAL	6.4	NORMAL	6	8	g/dL
10		006340/6...	Run In	06DEC201...	Albumin (g...	NORMAL	4.2	NORMAL	3.3	4.9	g/dL
11		006340/6...	Run In	06DEC201...	C Reactive ...	NORMAL	7.27	HIGH		2.87	mg/L
12		006340/6...	Run In	06DEC201...	Aspartate ...	NORMAL	30	NORMAL	11	36	U/L
13		006340/6...	Run In	06DEC201...	Alanine A...	NORMAL	29	NORMAL	6	43	U/L

DRAFT

The Implementation

Sort & Filter

Listing 10.2.3.1 / 1: Clinical laboratory data - General chemistry Experimental Version! (1618040)

row	Treatm...	Unique ...	Visit	Spe...	Laborat...	Specim...	Value	Flag	Normal...	Normal...	Standa...
Se...		Sear...		Sear...			Sear...		Sear...	Sear...	
1		006340/6...	Run In	06DEC20...	Hemoglobi...	NORMAL	10.9	HIGH		6.5	%
2		006340/6...	Run In	06DEC20...	Urate (mg/...	NORMAL	8.3	NORMAL	2.5	8.3	mg/dL
3		006340/6...	Run In	06DEC20...	Magnesiu...	INSUFFICI...					
4		006340/6...	Run In	06DEC20...	Sodium (m...	NORMAL	141	NORMAL	135	145	mmol/L
5		006340/6...	Run In	06DEC20...	Potassium ...	NORMAL	4.3	NORMAL	3.4	5.4	mmol/L
6		006340/6...	Run In	06DEC20...	Creatinine...	NORMAL	1.55	HIGH	0.45	1.35	mg/dL
7		006340/6...	Run In	06DEC20...	Glomerula...	NORMAL	46.9				mL/min/1....
8		006340/6...	Run In	06DEC20...	Blood Ure...	NORMAL	24	NORMAL	4	24	mg/dL
9		006340/6...	Run In	06DEC20...	Protein (g/...	NORMAL	6.4	NORMAL	6	8	g/dL
10		006340/6...	Run In	06DEC20...	Albumin (g...	NORMAL	4.2	NORMAL	3.3	4.9	g/dL
11		006340/6...	Run In	06DEC20...	C Reactive...	NORMAL	7.27	HIGH		2.87	mg/L
12		006340/6...	Run In	06DEC20...	Aspartate ...	NORMAL	30	NORMAL	11	36	U/L
13		006340/6...	Run In	06DEC20...	Alanine A...	NORMAL	29	NORMAL	6	43	U/L

DRAFT

The Implementation

Linking tables to listings

Metadata:

"subjectmetadataset" : "s_t_adds_4",

"subject" : "SUBJIDN",

"list_id" : "l_16_2_4_5_demo_1",

Table Dataset

NAME	_COL1_	_COL2_	_COL3_	_RO
Subjects valid for full analysis	2833 (98.8%)	2841 (99.1%)	5674 (99.0%)	1
Subjects valid for safety analysis	2827 (98.6%)	2831 (98.7%)	5658 (98.7%)	2
Subjects valid for per protocol ar	2391 (83.4%)	2451 (85.5%)	4842 (84.4%)	3
Subjects valid for pharmacokine	2515 (87.8%)	0	2515 (43.9%)	4
				5
Excluded from full analysis	33 (1.2%)	27 (0.9%)	60 (1.0%)	6
PROCEDURE DEVIATIONS	33 (1.2%)	27 (0.9%)	60 (1.0%)	7

Subject-Table Dataset

_ROW	SUBJIDN	METADAT	COLUMN
1	86	t_adds_4	_COL1_
1	99	t_adds_4	_COL1_
1	148	t_adds_4	_COL1_
1	171	t_adds_4	_COL1_
1	173	t_adds_4	_COL1_
1	204	t_adds_4	_COL1_
1	282	t_adds_4	_COL1_
1	323	t_adds_4	_COL1_

Filter

The Implementation

Linking tables to listings

Table 14.1.2 / 1: Demographics (full analysis set) Experimental Version!

row		BAY 94-8862 N=2833 (10...	Placebo N=2841 (100%)	Total N=5674 (100%)
1	Race			
2	WHITE	1777 (62.7%)	1815 (63.9%)	3592 (63.3%)
3	BLACK OR AFRICAN AME...	140 (4.9%)	124 (4.4%)	264 (4.7%)
4	ASIAN	717 (25.3%)	723 (25.4%)	1440 (25.4%)
5	AMERICAN INDIAN OR A...	78 (2.8%)	76 (2.7%)	154 (2.7%)
6	NATIVE HAWAIIAN OR O...	11 (0.4%)	7 (0.2%)	18 (0.3%)
7	NOT REPORTED	9 (0.3%)	10 (0.4%)	19 (0.3%)
8	MULTIPLE	101 (3.6%)	86 (3.0%)	187 (3.3%)
9	Sex			
10	Male	1953 (68.9%)	2030 (71.5%)	3983 (70.2%)
11	Female	880 (31.1%)	811 (28.5%)	1691 (29.8%)
12	Age (YEARS)			
13	n	2833	2841	5674
14	Mean (SD)	65.44 (8.94)	65.67 (9.15)	65.56 (9.05)
15	Median	66	66	66
16	Q1, Q3	60.00, 72.00	60.00, 72.00	60.00, 72.00
17	Min, Max	32.0, 89.0	28.0, 89.0	28.0, 89.0
18	Age group (years) category			
19	18 - 44 years	49 (1.7%)	65 (2.3%)	114 (2.0%)
20	45 - 64 years	1156 (40.8%)	1109 (39.0%)	2265 (39.9%)
21	65 - 74 years	1197 (42.3%)	1203 (42.3%)	2400 (42.3%)
22	>= 75 years	431 (15.2%)	464 (16.3%)	895 (15.8%)

DRAFT

Use Cases

Use Cases

Utilizing iListing & iTables

- Medical Writer,
  - Write CSR, narratives, …
- Reviewer
  - Deep dive into data
- Quality Checks
  - Cross checks of values

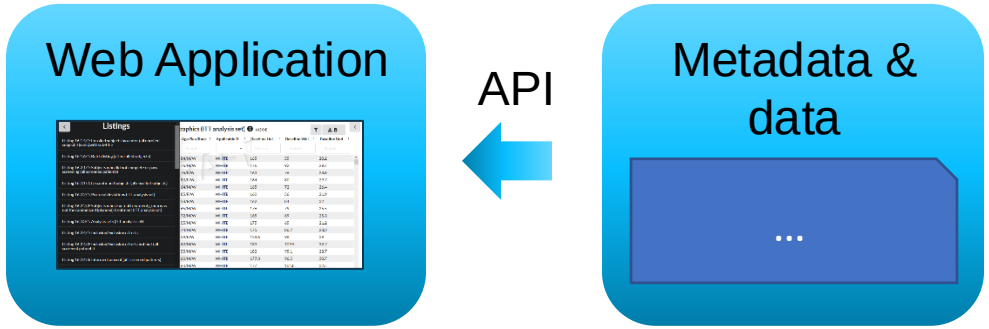
- Browse deliverables
- Smooth and quick navigation
- Access data at the fingertips

Use Cases

Utilizing iListing & iTables

- Potential for others
  - Statisticians, Statistical Analysis (if no better tool is available)
  - External Medical Writing
  - Authorities

- Enable security
- Package



Opportunities

Opportunities

Options forward

- Additional enhancements
- Utilization in open space
- Concept is tool agnostic
  - RShiny
  - Vue
  - …

- Utilizing the Analysis Result Standards
  - Developing ARS+, ARD+

Opportunities

Options forward

- Analysis Result Standards utilization
  - Checkout solution {cards} / {cardx}

```
df_continuous_ard <-
  ard_continuous(
    ADSL,
    by = ARM,
    variables = AGE,
    statistic = ~ continuous_summary_fns(c("median", "p25", "p75", "mean", "sd", "min",
  )
df_continuous_ard |> head(5)
#> {cards} data frame: 5 x 10
#>   group1 group1_level variable stat_name stat_label   stat
#> 1    ARM      Placebo      AGE    median     Median     76
#> 2    ARM      Placebo      AGE       p25         Q1     69
#> 3    ARM      Placebo      AGE       p75         Q3     82
#> 4    ARM      Placebo      AGE      mean       Mean 75.209
#> 5    ARM      Placebo      AGE        sd         SD   8.59
#> ℹ 4 more variables: context, fmt_fn, warning, error
```

Summary

Summary

- iListing & iTable very successful @Bayer
- Medical Writing enabled fluent access to data
- Quality function works much smarter
- Effort for programming minimal (~30’ updating & running macros)

- Most important
  - Performance
  - User feedback

Summary

- Potential
  - Enlarge scope
  - Enable authorities
  - Utilize / enhance new standards (ARS)

Thank you!

//////////

Bye-Bye