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Making TLF Validation and Other Automation Tools Available to Programmers

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Helping people live better lives

Introduction

Follow up on presentation last year

- Idea: Validating End-Of-Text packages using open source
 - EOT packages – core delivery for statistical programmers
 - Proof-of-concept of validation, but no system
- Now we have the system



Introduction

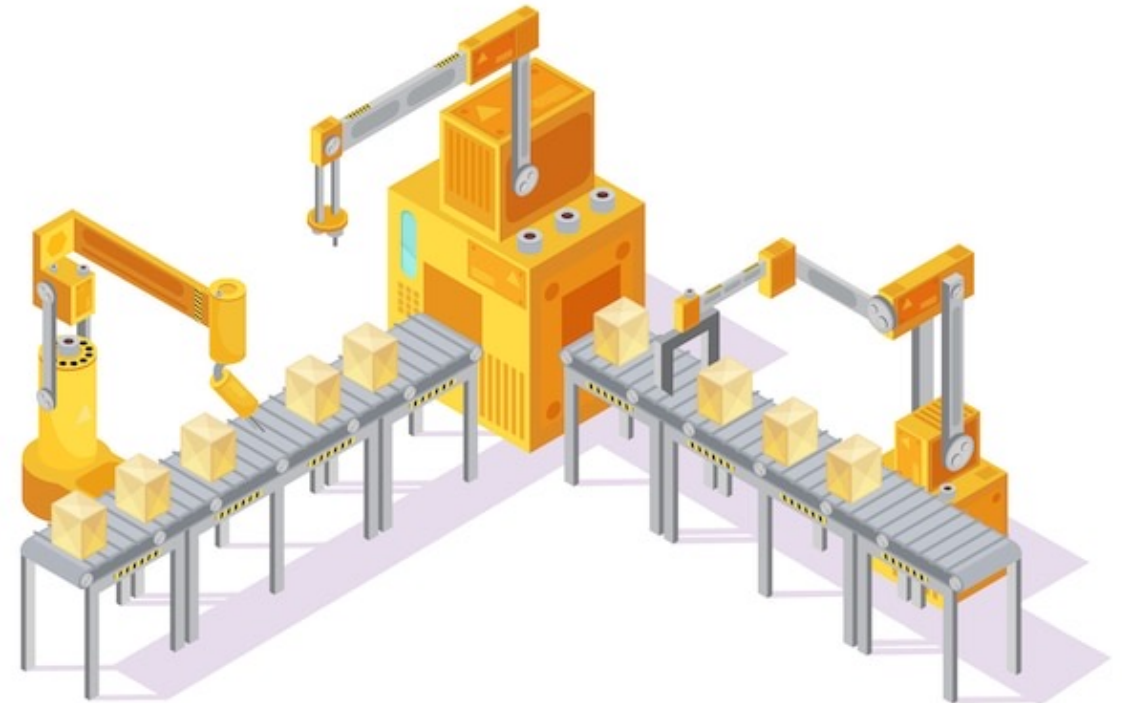
What is the problem?

- The EOT packages are one of the core trial deliveries for statistical programmers
 - Presented in tables, listings, and figures
 - Large Word documents, 1000+ pages
- Data is continuously updated
 - Validation necessary to secure correct and consistent information
 - Manual and time-consuming process with many stakeholders

Automation

What can we improve?

- Manual review
 - Improve consistency and quality
 - Use less time
- MS Word compare
 - Improve scaling
- Requirements
 - Pinpoint changes from version to version
 - Overview of changes



Automation

Why stop here?

- Can we automate more than EOT validation?
- Potential for more applications
- Make it easier to implement the next idea

→ General utility service

- Economics of scale for future development
- Scope: Ad hoc tasks



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Biometrics Utility Service Terminal

The service enables the developer to build smaller containerized applications to process these tasks in their favorite language (R, Python, or any other), and make them readily available to their colleagues, without them being required to have any knowledge of the inner workings or language of the application.

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Login

Biometrics Utility Service Terminal

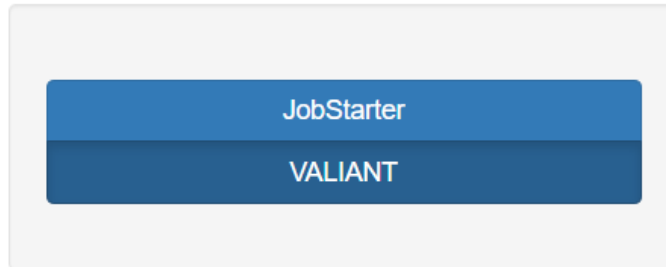
Login with your LSAF credentials

Username

Password

Login

Biometrics Utility Service Terminal



VALIANT

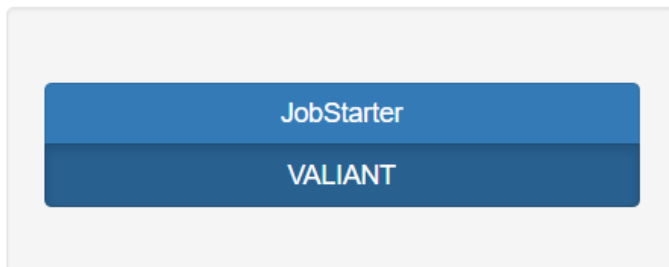
Validation of Analysis Tables - a tool to compare and validate summary tables and/or listings

Input

Base file (full path in LSAF)

File for comparison (full path in LSAF)

Biometrics Utility Service Terminal



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Validation of Analysis Tables - a tool to compare and validate summary tables and/or listings

Input

Base file (full path in LSAF)

File for comparison (full path in LSAF)

Start service

Result

Job status: **completed**

Summary:

- original_line_nr: 28
- compare_line_nr: 28
- changes: 6
- additions: 1
- removals: 1

Full report in LSAF: [Link](#)

f	1	Body measurements by age stratum and visit - FAS					f	1	Body measurements by age stratum and visit - Full Analysis Set				
n	2						n	2					
	3							3					
n	4	Age stratum: All					n	4	Age stratum: Both				
	5							5					
	6							6					
	7	Placebo	Trt 1	Trt 2	Trt 3	Total		7	Placebo	Trt 1	Trt 2	Trt 3	Total
	8	(N=107)	(N=111)	(N=103)	(N=97)	(N=418)		8	(N=107)	(N=111)	(N=103)	(N=97)	(N=418)
	9							9					
n	11	Screening					n	11	Screening visit				
	12							12					
	13	Height (m)						13	Height (m)				
n	14	n	108	111	103	97	n	14	n	107	111	103	97
	15	Mean (SD)	1.65 (0.07)	1.65 (0.07)	1.66 (0.07)	1.67 (0.07)		15	Mean (SD)	1.65 (0.07)	1.65 (0.07)	1.66 (0.07)	1.67 (0.07)
n	16	Median	1.65	1.65	1.66	1.67	n	16	Min; max	1.5; 1.9	1.5; 1.8	1.5; 1.8	1.5; 1.9
	17							17					
	18	Weight (kg)						18	Weight (kg)				
	19	n	107	111	103	97		19	n	107	111	103	97
	20	Mean (SD)	63.7 (8.9)	65.7 (10.4)	64.3 (9.6)	65.8 (12.0)		20	Mean (SD)	63.7 (8.9)	65.7 (10.4)	64.3 (9.6)	65.8 (12.0)
t	21	Median	62.6	63.8	63.0	62.6	t	21	Min; max	44; 90	47; 93	46; 99	43; 100
	22							22					
	23							23					
	24	N = Number of subjects						24	N = Number of subjects				
	25	n = Number of subjects with observation						25	n = Number of subjects with observation				
	26							26					
	27	FEXXXXXX/YYYYYY/Report/DDMONYYYY-INIT/T_ADBL.sas						27	FEXXXXXX/YYYYYY/Report/DDMONYYYY-INIT/T_ADBL.sas				
	28							28					

Legends

Colors	Links
Added	(f)first change
Changed	(n)ext change
Deleted	(t)op

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Architecture - Components

Data repository:

- SAS® Life Science Analytics Framework (LSAF)
→ Access content using REST API

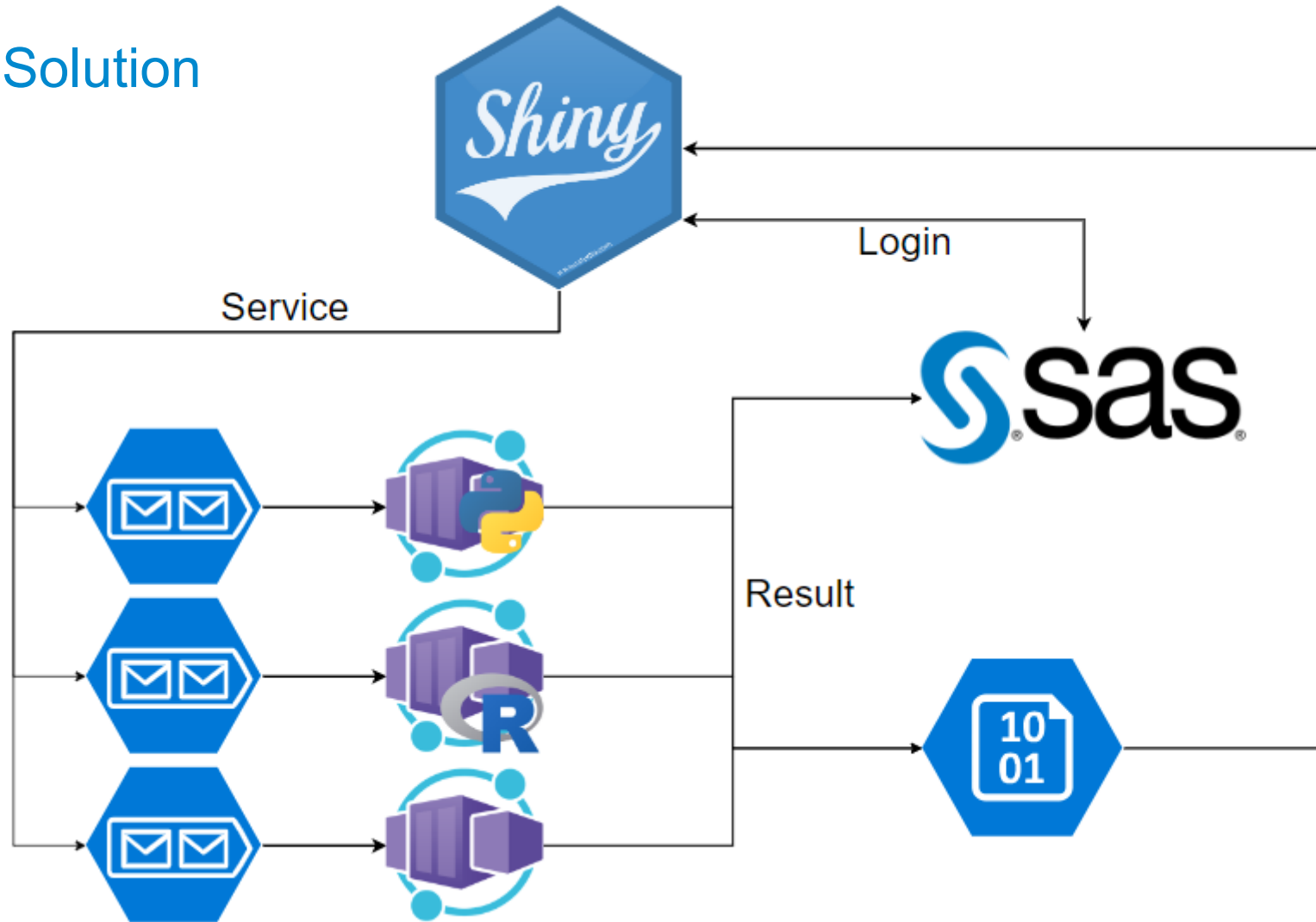
Cloud computing:

- MS Azure
- Storage account
 - Containers for semi-persistent storage
 - Queues for job information
- Container apps
 - Host Docker applications
 - Scaling with demand



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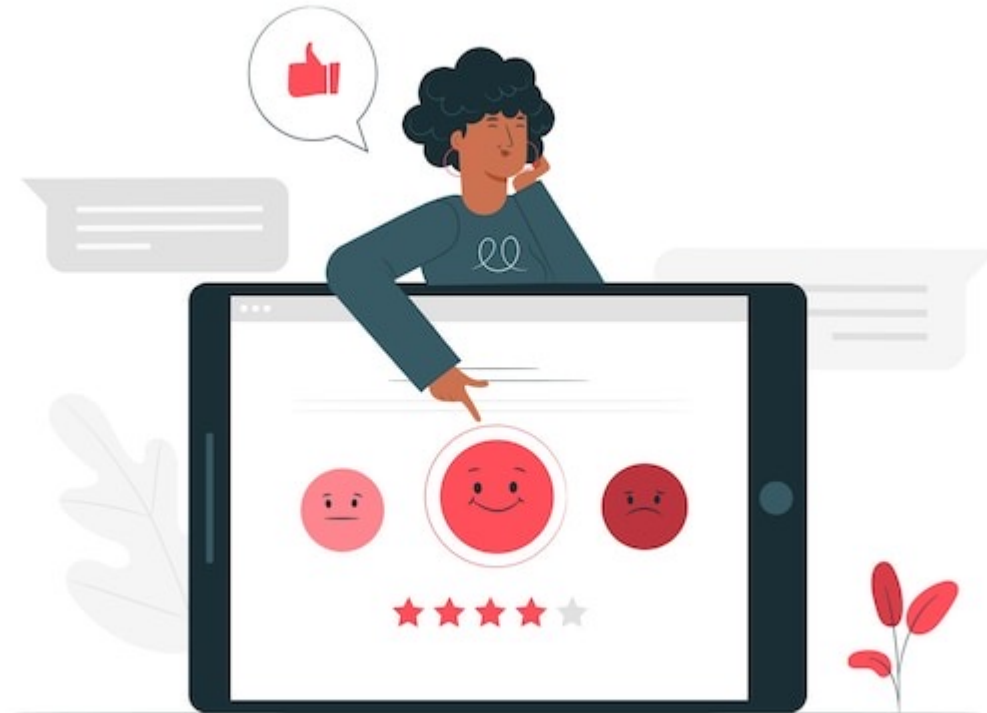
Architecture - Solution



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Next steps

- Broad user testing ongoing
- Improve EOT validation output
- Add new services
 - Administrative/ setup jobs
 - Creation of the EOT package



Reflections

- Azure has a steep learning curve
 - First mover in new GXP environment
 - New for both us and IT!
 - Large IT overhead in initial development
- Coding the first app is quick
- Secure infrastructure takes time
- Container apps are brilliant!

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