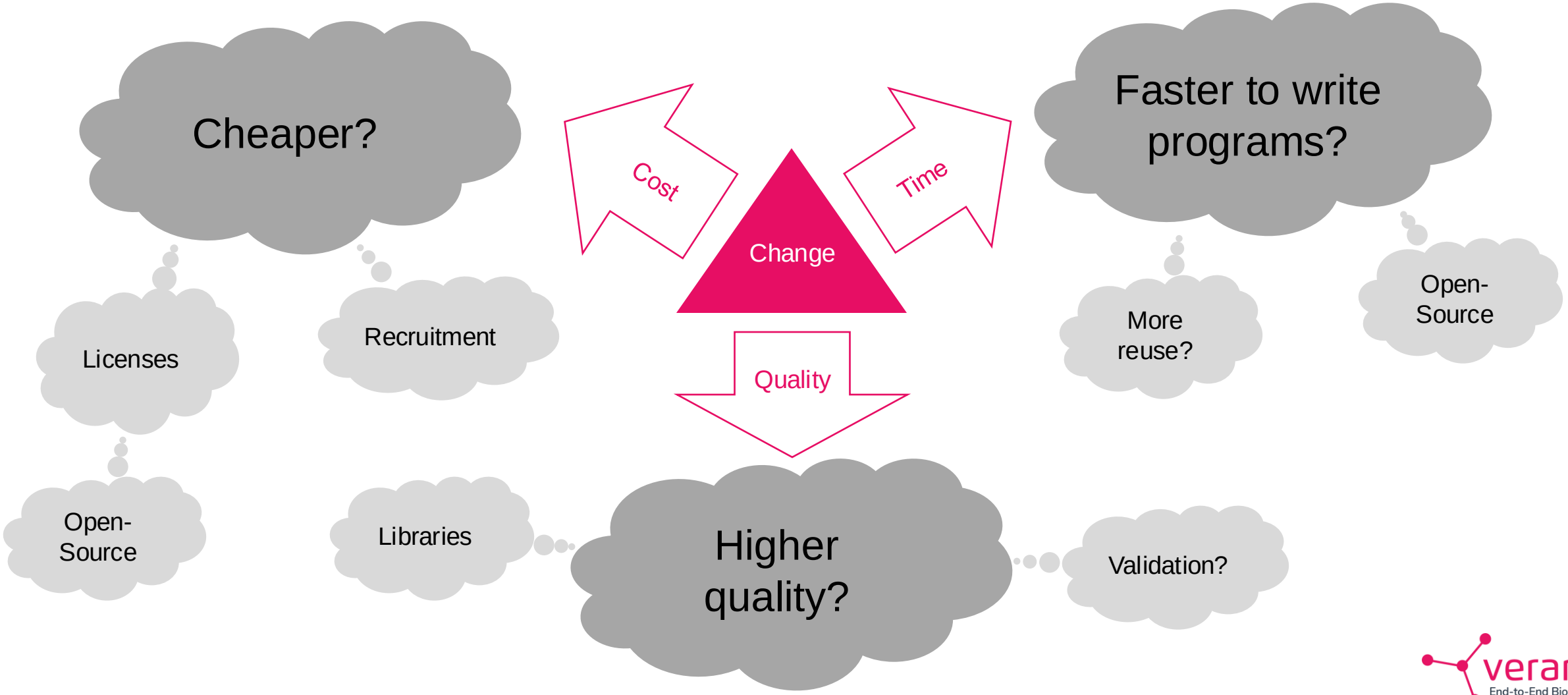
phuse·share
connect·share·advance

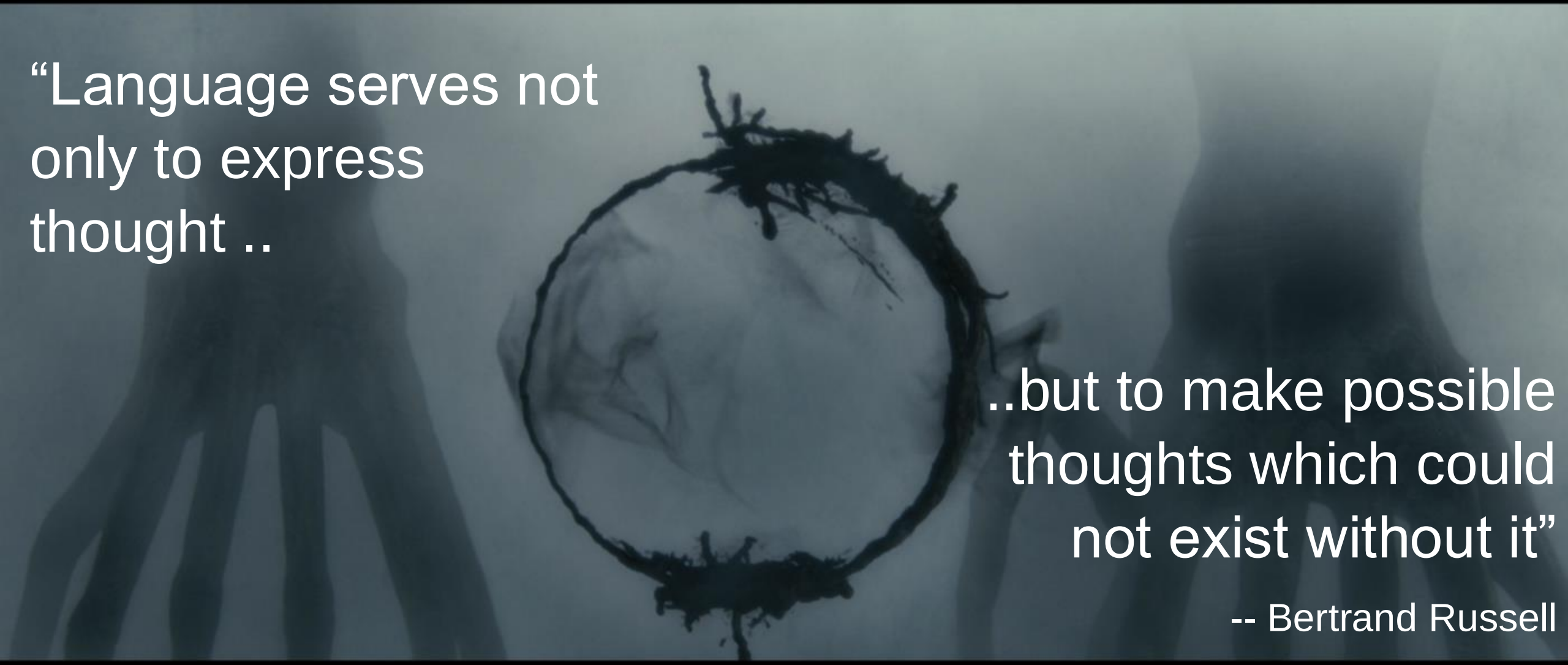
Single Day Event

Planning on R? Risk, Resources and Realism

Stuart Malcolm,
Head of Standards, Efficiency and Automation
Veramed

We've been using SAS forever. Why Change?

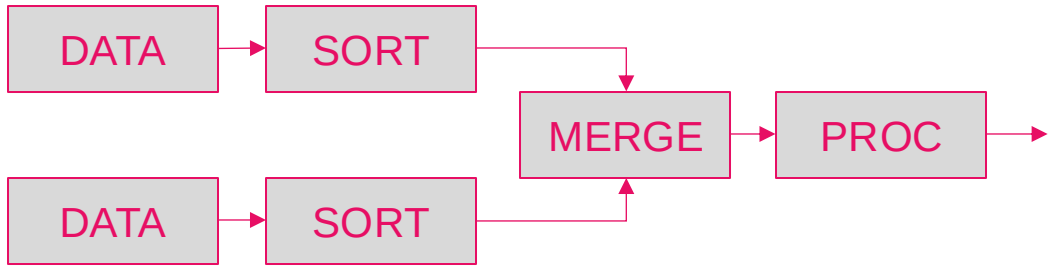



“Language serves not only to express thought ..
..but to make possible thoughts which could not exist without it”
-- Bertrand Russell

Where | Query Builder | Tasks | Share

	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	VISITNUM	VISIT	VISITDY	EXSTDTC	EXENDTC	EXSTDY	EXENDY
1	CDISCPILOT01	EX	01-701-1015	1	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2014-01-02	2014-01-16	1	15
2	CDISCPILOT01	EX	01-701-1015	2	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	4	WEEK 2	14	2014-01-17	2014-06-18	16	168
3	CDISCPILOT01	EX	01-701-1015	3	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	12	WEEK 24	168	2014-06-19	2014-07-02	169	182
4	CDISCPILOT01	EX	01-701-1023	1	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2012-08-05	2012-08-27	1	23
5	CDISCPILOT01	EX	01-701-1023	2	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	4	WEEK 2	14	2012-08-28	2012-09-01	24	28
6	CDISCPILOT01	EX	01-701-1028	1	XANOMELINE	54	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2013-07-19	2013-08-01	1	14
7	CDISCPILOT01	EX	01-701-1028	2	XANOMELINE	81	mg	PATCH	QD	TRANSDERMAL	4	WEEK 2	14	2013-08-02	2014-01-06	15	172
8	CDISCPILOT01	EX	01-701-1028	3	XANOMELINE	54	mg	PATCH	QD	TRANSDERMAL	12	WEEK 24	168	2014-01-07	2014-01-14	173	180
9	CDISCPILOT01	EX	01-701-1033	1	XANOMELINE	54	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2014-03-18	2014-03-31	1	14
10	CDISCPILOT01	EX	01-701-1034	1	XANOMELINE	54	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2014-07-01	2014-07-15	1	15
11	CDISCPILOT01	EX	01-701-1034	2	XANOMELINE	81	mg	PATCH	QD	TRANSDERMAL	4	WEEK 2	14	2014-07-16	2014-12-17	16	170
12	CDISCPILOT01	EX	01-701-1034	3	XANOMELINE	54	mg	PATCH	QD	TRANSDERMAL	12	WEEK 24	168	2014-12-18	2014-12-30	171	183
13	CDISCPILOT01	EX	01-701-1047	1	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	3	BASELINE	1	2013-02-12	2013-02-25	1	14
14	CDISCPILOT01	EX	01-701-1047	2	PLACEBO	0	mg	PATCH	QD	TRANSDERMAL	4	WEEK 2	14	2013-02-26	2013-03-09	15	26

Not everything is a table!



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Picking the right tool for the job

Use-case	SAS	R	Python
Data Processing (Tabular)		Medium	Medium
Statistics			Medium
Graphics	Low		Medium
Interactive Applications	Low		
Metadata Processing (Non-Tabular)	Low	Medium	
API and Automation	Low	Medium	
Third-party Libraries			

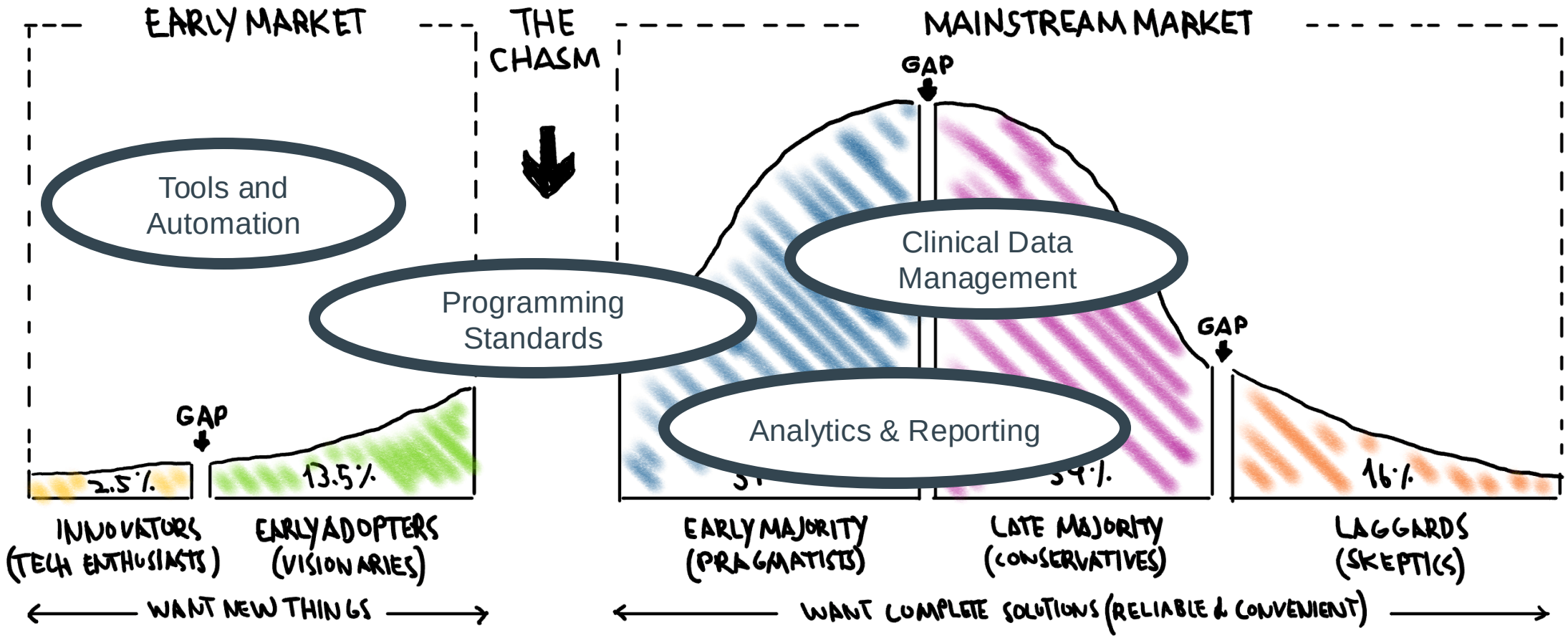
Clinical Data Management

Analytics & Reporting

Tools and Automation

Programming Standards

Crossing the technology adoption chasm



Graphic by Santeri Liukkonen - The Lost Book of Sales (www.lostbookofsales.com)
Original Technology Adoption Lifecycle by Geoffrey Moore

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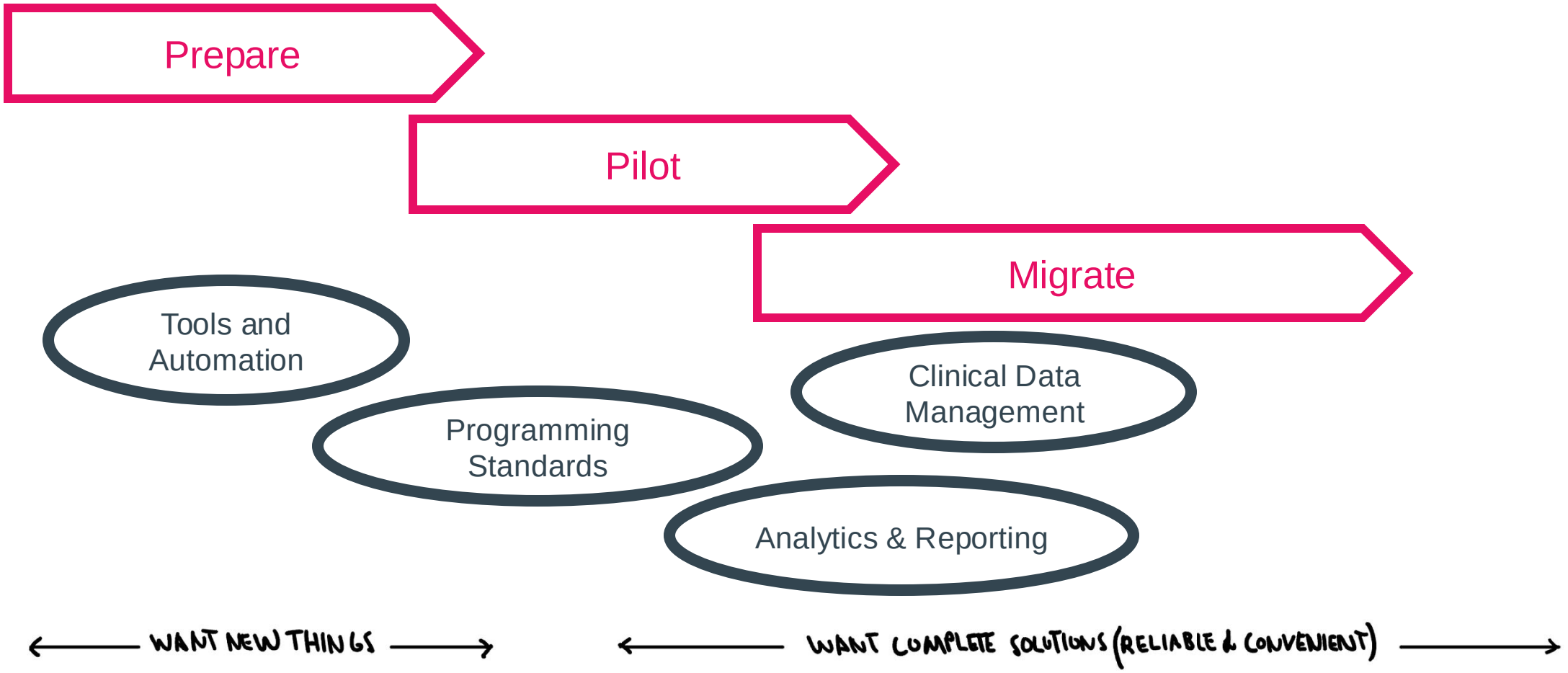
Crossing the technology adoption chasm



Crossing the technology adoption chasm

Prepare → Pilot → Migrate

Technology
- Platform / SCE
- Package management
- Data access

Process
- SOP / WI
- Guidelines
- QC / Validation

People
- Training
- Skills

PoC projects
- Experiments
- Design Uncertainty

Example projects
- Completed studies
- Lessons learned
- Training aids

Pilot projects
- Blended teams
- Phased handover

New studies
- Systemic rollout
- Office hours / support

Legacy results
- Integrated/Pooled
- Meta analyses

Reproducibility
- Archived projects
- Maintenance mode

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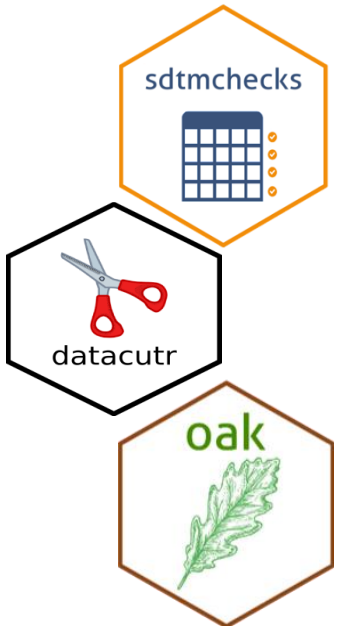
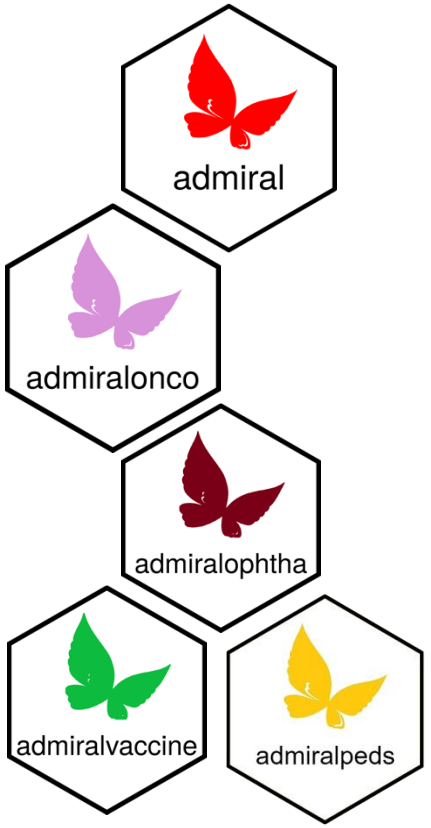
Pharmaverse: End-to-End Clinical Reporting Packages

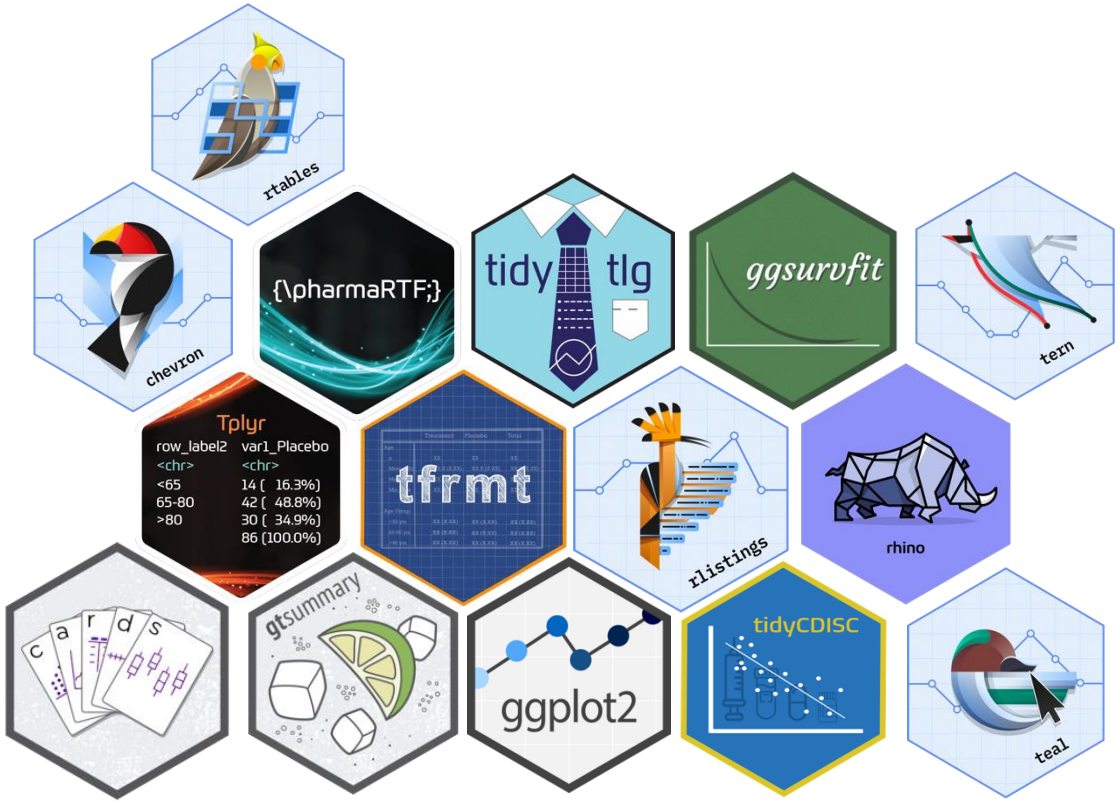
SDTM



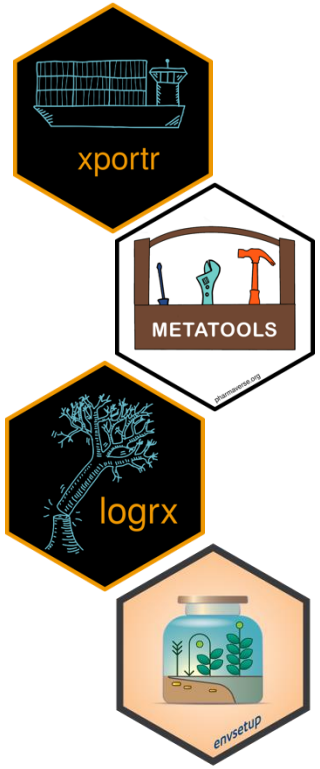
ADaM



TFL



Utility



https://pharmaverse.org/

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Comparing Analysis Method Implementations in Software

CAMIS

cross-industry **PHUSE DVOST Working Group**, run in collaboration with members from PHUSE, PSI, ASA and IASCT.

Repository

The repository below provides examples of statistical methodology in different software and languages, along with a comparison of the results obtained and description of any discrepancies.

Methods		R	SAS	Python	Comparison
Summary Statistics	Rounding	R	SAS	Python	R vs SAS
	Summary statistics	R	SAS	Python	R vs SAS
	Skewness/Kurtosis	R	SAS	Python	R vs SAS
General Linear Models	One Sample t-test	R	SAS	Python	R vs SAS
	Paired t-test	R	SAS	Python	R vs SAS
	Two Sample t-test	R	SAS	Python	R vs SAS
	ANOVA	R	SAS	Python	R vs SAS
	ANCOVA	R	SAS	Python	R vs SAS
	MANOVA	R	SAS	Python	R vs SAS
	Linear Regression	R	SAS	Python	R vs SAS

Why don't I get the exact same result using different implementations of the same statistical method?

Whitepaper

https://psiaims.github.io/CAMIS/

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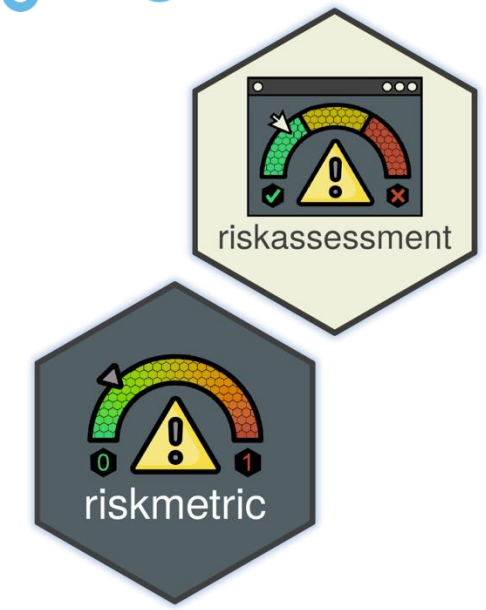
Risk-based approach to package management

formed in 2018 by the PSI AIMS Special Interest Group and is supported by the R Consortium.

Clinical Statistical Reporting in a Multilingual World

R Package Validation Framework



The {riskmetric} package, and
The {riskassessment} app

***Andy Nicholls**, Statistics Director,*
Head of Statistical Data Sciences, GSK
***Paulo R. Bargo**, Director Scientific Computing,*
Statistics & Decision Sciences, Janssen R&D
***John Sims**, Director, Analytical Systems Architect &*
Data Science - Pfizer Vaccine Research

https://www.pharmar.org/

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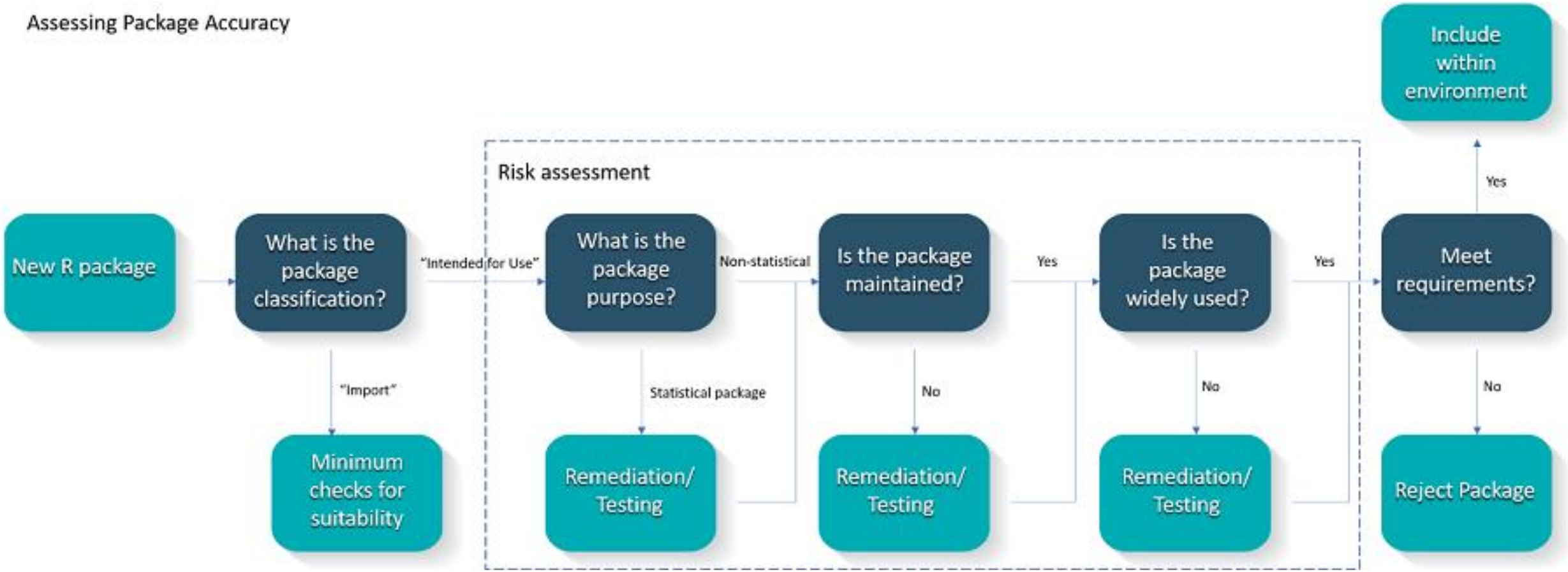
New process: A risk-based approach to R package validation

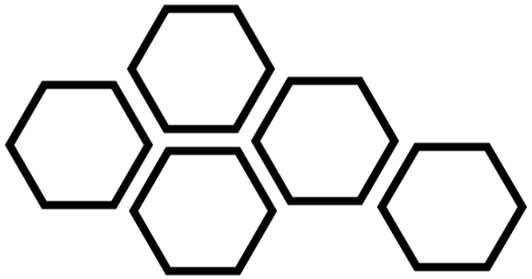


People, training and skills

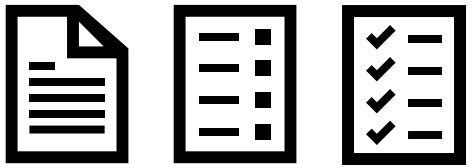
- R training for SAS programmers?
- Clinical Trial training for (new) R programmers?
- What about management team?
- New software development lifecycle skills
  - Package management
  - Risk-based validation
  - Automated testing
  - Open-Source
  - Release management
  - Change management

Languages & Platforms

Approved Packages



Company Packages & Tools



Standards & Processes

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Questions?

Contact

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Thank you

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The Global Healthcare Data Science Community

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