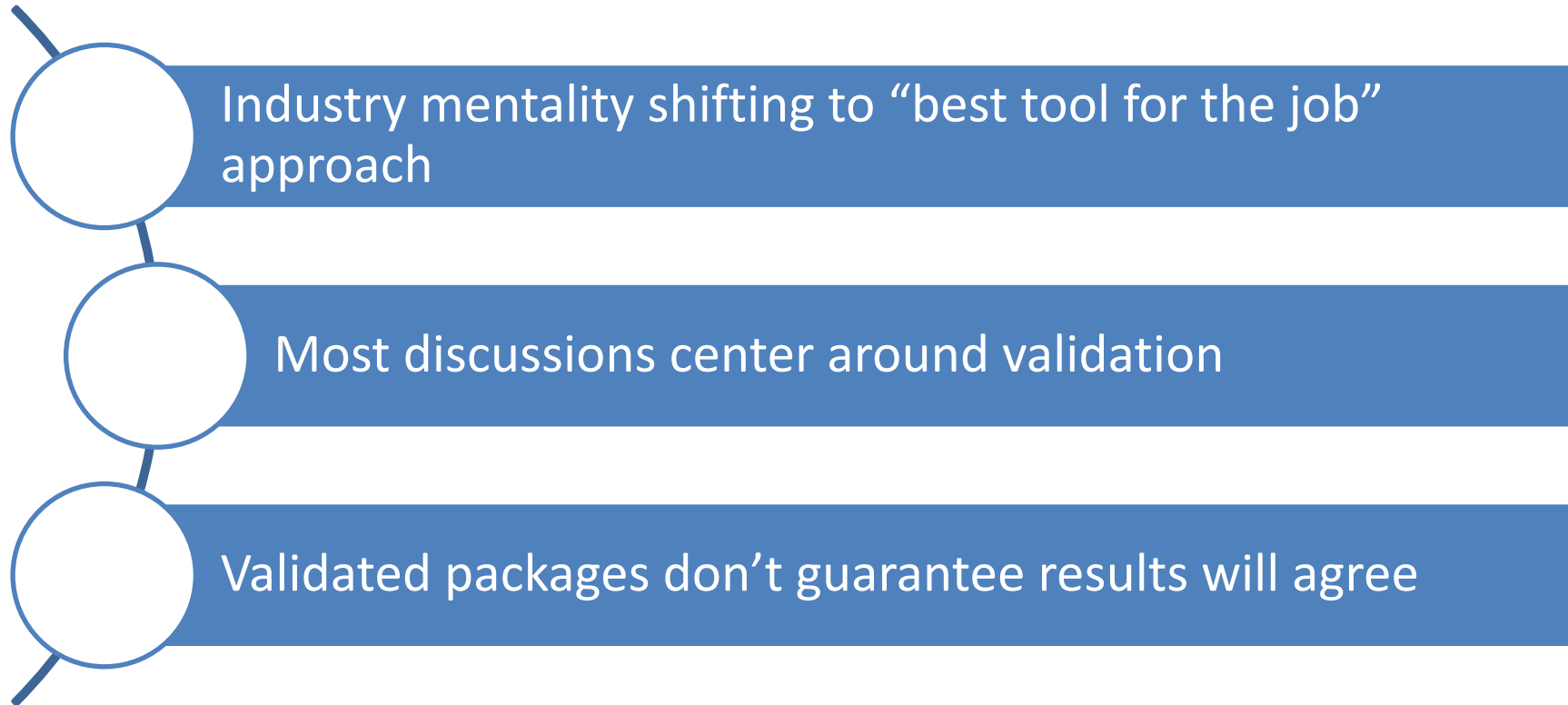


Clinical Statistical Reporting in a Multilingual World

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Project Overview



Why?

	R results			SAS results	
	AFB=No	AFB=Yes		AFB=No	AFB=Yes
Event - n	168	47		168	47
Censored - n	254	31		254	31
Time to event (years)					
25th percentile (95% CI)	0.94 (0.55, 1.47)	0.26 (0.05, 1.11)		0.94 (0.51, 1.45)	0.26 (0.05, 0.90)
Median (95% CI)	5.91 (4.32, NE)	2.37 (1.27, 4.24)		5.91 (4.31, 6.46)	2.37 (1.15, 3.77)
75th percentile (95% CI)	6.44 (6.44, NE)	6.43 (4.24, NE)		6.44 (6.44, 6.46)	6.43 (4.24, 6.43)
Min, Max	(0.0, 6.5)	(0.0, 6.4)		(0.0, 6.5)	(0.0, 6.4)
Landmark estimates					
1-year event-free rate (95% CI)	0.739 (0.699, 0.782)	0.641 (0.543, 0.757)		0.739 (0.695, 0.779)	0.641 (0.524, 0.736)
3-year event-free rate (95% CI)	0.642 (0.595, 0.691)	0.455 (0.351, 0.589)		0.642 (0.591, 0.687)	0.455 (0.335, 0.567)
5-year event-free rate (95% CI)	0.530 (0.472, 0.595)	0.315 (0.211, 0.470)		0.530 (0.467, 0.589)	0.315 (0.195, 0.442)
p-value		0.0010			0.0010
Hazard ratio (95% CI)		0.583 (0.421, 0.806)			0.584 (0.422, 0.808)

Project Goals

Document and build a repository of common analyses

- Outline differences in implementation
- Document differences in capabilities and known discrepancies

Establish a general framework for approaching new analyses

- Recommend approach for investigation
- Establish a framework for effectively communicating findings or potential issue areas



Project Team

Atorus

Janssen

Bayer

Lilly

Chrestos

Merck

Experis

Novartis

FDA

R Consortium

Frontage Labs

Yale

GSK

Roche



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**Working
Groups**



Current Status

White paper sub-team has commenced

- Paused, but restarting momentum after US Connect

POC investigation of 4 common analyses

- Linear models
- CMH
- Mixed Models
- Survival Analysis

Public GitHub repository and Bookdown site for project content here:

- <https://github.com/phuse-org/CSRMLW>
- https://phuse-org.github.io/CSRMLW_bookdown/



Types of Questions

How is rounding of numbers handled in SAS® vs R?

Generic Scenario



5's round up using **round()**

rounde() function available to round 5's to even



round() uses IEC 60559 standard followed to round 5's to even

Simple functions available to round 5's up

Types of Questions

Is the "row means differ" alternate hypothesis available in R?

Examples from CSRMLW Use Case CMH



Standard output from **PROC FREQ** with cmh requested



Standard CMH available in base R, but no match for this alternate hypothesis

Available in **vcdExtra** package, but required updates to package code for use with sparse data

Types of Questions

How are ties handled by default?

Examples from CSRMLW Use Case **Survival Analysis**



Breslow method default, Efron available



Efron method default, Breslow available

When the project ends

The repository lives on with public contributions

- Expand deeper into existing use cases
- Expand current classes of models to other languages
- Expand to new classes of models



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