**Title: It’s time to integrate the R into PhaRma. How you can help !**

**Lyn Taylor (PAREXEL, on behalf of the R Validation Hub, PSI AIMS SIG and CAMIS)**

The adoption of using R in pharma, comes with many challenges. Key considerations ranging from infrastructure, validation, qualification and testing, reliability and reproducibility, re-training of the workforce and changing long established working practices, need to be addressed. This can seem daunting and lead to companies preferring to stay with the status quo. However, companies embracing the change, are finding key benefits in the functionality of R, and in the engaged wider R community. This is resulting in time saving methods and more efficient statistical reporting of clinical trials. It’s clear that the benefits of R, far outweighs the effort to change in the longer term.

This talk will showcase the wide range of community led and R consortium working groups, aiming to address these challenges, making the transition to R easier, and reducing the duplication of effort across companies. Following an introduction to the current project landscape, the talk will focus on the work of the R Validation Hub and CAMIS project.

The R Validation Hub began as a spin off from PSI AIMS SIG, but is now a leading cross-industry initiative. The hub is a collaboration to support the adoption of R within a biopharmaceutical regulatory setting. A key milestone in 2020 was publication of a white paper exploring a risk-based approach for assessing R package accuracy within a validated infrastructure and this guidance was supported by release of free to use tools: ‘riskmetric’ package and accompanying R Shiny app. More recent work is the sharing of company adoption of R within the GxP framework and ongoing workstreams exploring the testing of packages and possibility for a Pharma package repository.

The talk will conclude with demonstration of the CAMIS repository. Statisticians and programmers working in multiple software systems (e.g. SAS, R, Python), will have found differences in analysis results that warrant further exploration and justification. Whilst some industries, may accept results not being the same, as long as they are “close”, the more highly regulated pharmaceutical industry, generally looks for identical results, or full justification of any differences observed. This can be very challenging and highly time consuming, particularly when accompanying documentation doesn’t fully explain the approach used by the software. Comparing analysis method implementations in software (CAMIS) will shortly release a white paper describing best practices, and invites contribution for the wider community to contribute to an open source github repository to store known differences between the implementation of statistical methods in software.

**Biosketch**

Lyn Taylor has worked in medical research for over 20 years, starting out as a placement student at SmithKline Beecham in the pre-clinical statistics group, before moving into the world of Contract Research Organizations.  Lyn obtained her Ph.D. in Statistical Modelling of Markers of Severity in Rheumatoid Arthritis and continues to have a key interest in autoimmune diseases as well as a broad range of other therapeutic areas. After 11 years at PAREXEL, Lyn gained experience at PRA Health Sciences and PHASTAR, before moving back to PAREXEL in 2022 as an Associate Director, Biostatistics. Lyn was chair of the PSI AIMS SIG for 7 years, and sits on the executive committee of the R Validation Hub.  Lyn vice-chaired the development and approval of a Medical Statistics MSc apprenticeship scheme in England in 2021. In 2022, Lyn became the lead of CAMIS [Comparing Analysis Method Implementations in Software]. Utilizing community contributions into an open source github repository, the CAMIS project aims to document the differences in the methodology used by SAS and R, in order to aid concurrent use of SAS and open source languages in medical research.