An R-Shiny Web Application to Support Early Assessment and Decision Making of Oncology Studies Using Multivariate Tumor Growth Inhibition and Overall Survival Disease Models

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Objectives: To develop a disease modelling and simulation (M&S) R-Shiny application to help assess novel treatments or combinations in comparison to historical control during early oncology clinical development.

Methods: A bi-exponential tumor growth inhibition model [1] was developed using longitudinal tumor size data (sum of longest diameters) from historical trials. Multiple case examples suggest the growth rate (KG) is a good predictor of overall survival (OS) [2]. The impact of covariates (e.g. demographics, prognostic factors, inflammatory markers, etc.) on KG was investigated using PsN and NONMEM. KG estimates as well as baseline covariates were tested in multivariate lognormal models of OS. An interactive application was developed using the RStudio “Shiny” package [3].

Results: An R-Shiny app for the oncology disease M&S platform, including TGI and OS models allows the user to load evolving data (tumor size profiles, KG estimates and patient baseline covariates) from ongoing clinical trial(s) in order to visually assess the effect of the new treatment on KG and OS compared to historical covariate-adjusted control metrics in a timely manner. This application facilitates rapid data visualization and model simulation and also serves as an interactive communication tool for effective team discussion.

Conclusions: Accelerated development of anti-cancer therapies, particularly in combination setting, is often challenging and highly competitive. High quality M&S with rapid turnaround is critical to inform and impact early development decision making (e.g. go-no go, treatment prioritization, etc.).