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Why Accurate Time to response prediction matters?

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Experienced Biostatistics Lead with extensive background in oncology drug development across various phases.
Demonstrated expertise in leading statistical team, managing comprehensive data analyses, and interfacing with regulatory authorities, with proficient in using innovative statistical techniques to enhance drugs development.

Sarah-Laure Rincourt
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Biostatistician with 5+ years in life sciences. Passionate about uncovering insights from population health data (genomic, clinical, epidemiological, etc.) through innovative analysis.

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Clement holds a master's degree in statistics with a specialization in biostatistics from Paris Cité university in France. Prior to joining Servier, he successfully completed a 6-month internship at Servier, focusing on tipping point analysis in clinical trials. He's now a statistics project lead working on submission dossier for oncology clinical trials in the Servier Global Biometrics team.

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The entire process of clinical trials, from study design to regulatory submission, requires precise planning for strategic milestones to effectively manage logistic challenges, better allocate resources, and anticipate activities that enable the timely delivery of effective drugs to patients.

While researchers have focused on time-to-event-based endpoints, to predict when the target number of events, accounting for the censor, will be reached in oncology clinical trials, less attention has been given to single arm trials based on response-based endpoints, such as Objective Response Rate, which are commonly used in oncology early phase assessments or bridging studies for registrational trials. In both scenarios, accurate time to response predictions could optimise the entire process of drug development, making timely Go/NGo decision and facilitate proactive communication with health authorities.

Motivated by a case study from an oncology bridging trial, we proposed two approaches for time-to- response prediction. The first approach assumes consistency between historical data from the global study and the bridging study, while the second approach considers a random response process over a maximum follow up. Both methods allow for predicting, with varying confidence levels ranging from as low as 25% to over 90%, the probability of reaching the target by a specific month and year at the latest.

To Optimise communication with study stakeholder regarding the predictions and their impact on the timelines and key milestones, a user-friendly shinyapp was developed. This app allows to vary the scenarios and generate report.

Keywords: Response-based endpoints, historical data, consistency, time-to-target-response- prediction, study milestones.