Biomarkers have gained tremendous attention in Oncology pharmaceutical development, as they promise actionable insights for clinicians. The high costs and long duration of clinical development programs, paired with high levels of attrition, require the quantification of the risks when progressing in the different phases of oncology drug development. The role of biomarkers in quantifying these risks may be undervalued.

In this keynote presentation, we will critically assess the translational efforts in utilizing biomarkers in oncology clinical development, and we will provide a comprehensive overview of available statistical techniques to facilitate the translation between preclinical and clinical stages.