GLOBAL GATORS SYMPOSIUM

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Bio

Pharmacokinetic/pharmacodynamic modeling and simulation (PK/PD-MS) has emerged as pivotal tool in guiding clinical trial design and decision-making across the pharmaceutical R&D value chain. Effective PK/PD-MS hinges on a robust understanding of the translational line of sight (Figure 1), linking target engagement, pathway modulation, and clinical outcomes via established biomarker associations.

However, the increasing trend towards first-in-class assets and genetics-guided target discovery introduces novel challenges, with many drug targets lacking a well-defined translational line of sight. This trend also impairs the effectiveness of streamlining drug development via PK/PD-MS since there is a lack of PD biomarkers essential for constructing predictive PK/PD models.

This presentation explores the imperative for de-novo biomarker discovery to elucidate the translational line of sight for emerging drug targets. Highlighting Novo Nordisk's human-centric approach, leveraging human cell cultures and advanced ex-vivo systems, we delve into our approach for identifying novel PD biomarkers. Rigorous qualification processes ensure the readiness of biomarker candidates for early clinical decision-making, including independent validation and assessment of variability in human cohort data.

Our conclusions underscore the critical role of innovative biomarker discovery in advancing predictive PK/PD modeling, facilitating informed decision-making, and streamlining therapeutic development in an era of increasingly complex drug targets

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Abstract

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