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Aligning Dx and Rx timelines

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In this era of personalized medicine, the development of targeted therapeutics goes hand-in-hand with the development of targeted diagnostics or Companion Diagnostics (CDx). These diagnostics are critical with respect to getting the right drug to the right patient at the right time and are required for regulatory approval of the therapeutic. However, the development paths for diagnostics and therapeutics are separate and unique from analytical studies through to regulatory pathways and aligning their development such that simultaneous regulatory submissions can occur is, at the very least, a challenge. This is especially true since the identification of the biomarker that goes into the development of the diagnostic be it a selection, prediction, efficacy or other clinical application of a biomarker often occurs in phase 2 clinical trials of the drug. Note that the biomarker is not a diagnostic, it is a component of a diagnostic, and there is a defined development path, governed by regulatory requirements, for diagnostics once the biomarker has been identified. It is essential, therefore, that not only biomarker discovery/validation efforts, but also diagnostic development efforts be initiated early in the drug development program, albeit at risk. This presentation will describe the diagnostic development pathway and ways to mitigate risk while achieving synergy in the diagnostic and drug development cycles.

Biography

Daniel J. O'Shannessy received his Ph.D. in Biochemistry from the University of Auckland, New Zealand. He has over 20 years of experience in a combination of scientific, business development and strategic planning roles within the biopharmaceutical industry and specifically diagnostics. In his current position as Director Diagnostics Development at Morphotek, he is responsible for all aspects of Companion Diagnostics (CDx) development from concept through to commercialization. In recent years he has held the positions of Chief Operating Officer, Senior Director of Strategic Planning, Oncology Diagnostics, and Chief Scientific Officer at various diagnostics companies.

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