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Companion diagnostics: Technical, regulatory and reimbursement challenges for the 21st Century

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Abstract

Companion diagnostics provides a powerful means to use specific biomarkers to stratify patients into responders and non-responders, thus facilitating the administration of the proper drug at the proper dose to the proper patient subpopulation. Moreover, such stratification reduces healthcare costs by avoiding the administration of expensive drugs to non-responders while at the same time decreasing potential adverse drug reactions and their associated hospitalization costs. The development and FDA clearance of companion diagnostics must now adhere to new guidelines established by the Agency to assure co-development and contemporaneous regulatory submissions of both a drug and its companion diagnostic. The costs and risks associated with the potential failure of a drug trial during any of its clinical trial phases complicates the decision making process regarding the initiation of development efforts for the associated companion diagnostic. While a failed drug trial will render its associated companion diagnostic of no value, a failed diagnostic trial could potentially sideline and prevent an innovative new therapeutic from reaching the intended patient population. Coupled with these significant risks are the new challenges associated with the rapidly changing reimbursement landscape in the U.S. Not only have the former molecular diagnostic "stacking" CPT codes been replaced by corresponding "bundled" codes, but the reimbursement rates have declined on average by 25-35 percent and in some cases even more. Many of these challenges can be overcome by the availability of fully automated molecular diagnostic platforms that can be rapidly configured to detect and quantitate the biomarkers of interest.

Biography

Richard holds a Ph.D. in Molecular Biology and is Senior Vice President for Scientific Affairs at Rheonix, Inc. where he oversees regulatory and reimbursement issues. He is also an Adjunct Professor at Cornell University (Dept. of Biological& Environmental Engineering), has been awarded over $5.5 Million of grant funding as Principal Investigator, published 40 peer-reviewed scientific papers, and led the commercialization of over 40 biotech products, including FDA approved diagnostics. In 1988 he testified before President Reagan's AIDS commission regarding the prevalence of HTLV-1 antibodies in the US blood supply, urging the commission to mandate nationwide blood screening, which was implemented within one year.

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