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The challenge of genetic diversity in clinical trials: Is precision medicine up to the challenge?

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Abstract

Precision Medicine is a drug development paradigm that has evolved within oncology where cancer-causing genetic mutations have been known or suspected for some time, and where the toxicity and poor efficacy of non-specific chemotherapeutics promoted the search for targeted, less toxic therapies against these mutations. While programs like trastuzumab for HER-2 over-expression in breast cancer, crizotinib for ALK fusion proteins in NSCLC, and vemurafinib for BRAF V600E mutations in melanoma are shining success stories for Precision Medicine, there are surprisingly few others. It has become very apparent that despite the application of Precision Medicine the response rates in oncology clinical trials have not approached 100% or even come close. The leading hypothesis is that intra-tumor genetic diversity of distinct subpopulations of cells is the key driver for resistance and the disappointing results with targeted therapies. The recent tumor sequencing work to date suggests that how, when and where tumor samples are collected and analyzed need to be thoughtfully planned and implemented in clinical trials in order to maximize the utility of this genetic diversity information for patient selection criteria or for post-hoc subgroup analysis. While oncology has been the original playground for Precision Medicine, examples of other diseases/therapeutic areas where these patient selection criteria are likely to be very beneficial in improving the successes of clinical trials will also be briefly discussed. The future of Precision Medicine is promising, and if implemented carefully and consistently should improve clinical trial success rates and deliver more effective treatments for physicians and patients.

Biography

Paul Frohna has a PhD in Pharmacology from the University of Pennsylvania and an MD (Internal Medicine) from Georgetown University in Washington, DC. Dr. Frohna has been conducting translational research in the biotech industry for more than 14 yrs having served in roles from Medical Director to Chief Medical Officer at companies like Genentech, CV Therapeutics, Fibrogen and ProFibrix. Dr. Frohna is currently the CMO at ProFibrix, Inc. and an industry consultant providing services in translational medicine, clinical pharmacology, and clinical trial design (www.frohnabiotechconsulting.com). He has designed clinical programs in regenerative medicine, hematology, oncology, immunology, neurology and cardiology.