Ethnic Bridging in Phase 1 Clinical Trials: A Strategy for Enhancing Asset Value and Accelerating Global Drug Development, New Webinar Hosted by Xtalks

Quicker drug development time means increased valuation of your asset due to the ability to achieve commercial milestones earlier than through regional-specific development program management. Join this webinar to hear about specific case studies and strategies on how to include ethnic bridging in your early clinical development plans to hasten regulatory acceptance of data worldwide.

TORONTO (PRWEB) January 17, 2019 -- The possibility that ethnic differences exist in different populations with regards to drug metabolism and distribution has been documented for many years. These observed differences may be manifest in alterations in safety, efficacy and/or labeled dosages, or in terms of adverse event profiles in patients residing in different geographic regions. This created the perceived necessity to fully and separately develop new medicines for each geographic market.

This development practice evolved into a trend such that drug development was initiated in the USA or Europe, and development in other geographic regions followed in such countries as Japan, South Korea and Taiwan. Development in Canada, Australia, New Zealand, South Africa and South America generally kept pace with development in the USA and Europe. Consequently, throughout the 1980s and early 1990s there was an acknowledged 7 to 10 year ‘drug approval lag’ in Japan, South Korea and Taiwan. Thus, these populations suffered delayed access to new therapies even though safety and efficacy had already been established in other regions of the world. Consequently, it was difficult to explain to the patients residing in these regions why they had to wait so many years beyond the rest of the world to get access to these medications.

The urgent need to rationalize and harmonize regulations was understood by regulators worldwide, as well as the global pharmaceutical industry. As a result, ICH E5 – Ethnic Factors in the Acceptability of Foreign Clinical Data (5 Feb 1998) was published and the concept of global clinical development was widely and rapidly adopted.

Join Dr. Melton Affrime, PharmD, President and Chief Scientific Officer at WCCT Global in a live webinar on Tuesday, February 5, 2019 at 2pm EST to hear about:

• Specific case studies where ethnic bridging has been used in early clinical development
• Strategies on how to include ethnic bridging in your early clinical development plans
• How ethnic bridging can hasten regulatory acceptance of data worldwide

For more information or to register for this event, visit Ethnic Bridging in Phase 1 Clinical Trials: A Strategy for Enhancing Asset Value and Accelerating Global Drug.

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