BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Cytel champions precision oncology master protocol trial designs

05 March 2020 | News | By Hithaishi CB

The new paper provides a valuable resource for increasing master protocol trial literacy among the many clinicians and researchers who may not be familiar with these innovative trial types

A new paper authored by statistical experts at Cytel has been published in the world-renowned journal CA: A Cancer Journal for Clinicians. The open-access paper, titled ‘An Overview of Precision Oncology Basket and Umbrella Trials for Clinicians,’ provides a valuable resource for increasing master protocol trial literacy among the many clinicians and researchers who may not be familiar with these innovative trial types. Such trials offer considerable potential value in more rapidly bringing new oncology therapeutics to patients. However, there is a critical need for improved understanding in order to optimize their use. To further address this need, Jay Park, Director at Cytel and lead author on the article, will host a free 60-minute webinar on March 19, to expand on the contents of the article, discussing the unique features of umbrella and basket trials and outlining the key considerations for their successful design and implementation.

“There is an important role that data scientists have to play in popularizing these quantitative methods,” notes co-author

Edward Mills, Vice President of Real World Evidence and Senior Principal Scientist at Cytel. “At first glance these methods might appear to be overwhelming to trial investigators. We need to show the power of these strategies in the hands of experienced problem-solvers.”

An increased ability to classify tumours at the genomic level has led to an ever-greater need for highly targeted cancer therapies. As such, there has been a rapid rise in the use of biomarker-guided trials under the master protocol framework in recent years — including both basket and umbrella trials. A master protocol refers to a single, overarching trial design that has been developed to evaluate multiple hypotheses with the aim of improving trial efficiency. Such trials enable expedited development timelines, reduced costs and improved patient safety. However, current understanding of such trials is not widespread among clinicians and researchers outside of the National Cancer Institute and a select number of organizations in the private sector, slowing their adoption.

“With such a wide spectrum of cancer subpopulations, it’s simply not feasible to pursue targeted therapies using traditional clinical development approaches,” explains Cyrus Mehta, President and Co-founder of Cytel. “Under the master protocol framework, we have an economically streamlined and statistically rigorous way to examine multiple interventions across multiple disease sub-types in parallel. Such approaches show promise in ensuring cancer patients receive the most efficacious new medicines in the shortest possible time.”

Commenting on the importance of greater trial literacy in this space, Yannis Jemiai, Chief Scientific Officer at Cytel, commented, “We’re seeing a growing number of master protocol trials being utilized globally, primarily in the oncology and rare disease fields. However, to effectively implement such trials and capitalize on their myriad benefits, a solid understanding of their statistical underpinnings and potential risks is essential. The recent publishing of a paper on this topic is part of Cytel’s wider campaign to share our in-depth knowledge and generate more widespread understanding of these trial paradigms so that clinical development can be accelerated through their use.”

In line with this, on March 19, (12pm EST), Jay Park will present a free 60-minute webinar titled, ‘Key Design Considerations for Basket Trials and Umbrella Trials,’ where attendees will have the opportunity to gain a deeper understanding of how basket and umbrella trials operate. This webinar will introduce these two master protocol types and explore their extension to trial design in various contexts from the HIV epidemics in global health to expedited oncology trials.