Abdel Halim about NLSDays' super session : 'From Population to Precision'

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The Precision Medicine Revolution has shifted to an evidence-based and 'proactive' rather than 'reactive' approach and, with this shift, has come the understanding that simply having viable treatments is no longer enough. What are the challenges from an SME perspective?

– Directly after retrospective approval of HER2 testing (HercepTest) as a companion diagnostic (CDx) to select breast cancer patients for treatment with Herceptin (Trastuzumab) late 1990s, drug developers and regulators started to realize the critical value of precision medicine and CDx in drug development and post-approval patient management. There has been evidence that % of oncology drugs approved with CDx by FDA has significantly increased over the past 5 years. However, there are multiple significant challenges and limitations facing the drug-diagnostic co-development, of which are lack of early strategy/planning, misalignment between drug sponsor, IVD provider and testing lab, misalignment even with a drug development organization, immature biology, analytical and pre-analytical variables. Without good resolution/mitigation of these factors, unfortunately, most of the effort would go in vain.

You have experience in different aspects of biomarkers, precision medicine and IVD; from strategic planning to actualization and you have published a book within the field. What have you learned on your journey? What trends do you see?

– I have no doubt about potential values of biomarkers in drug development and post-approval patient treatment above and beyond patient selection. However, as hinted above, challenges and limitations are still unrecognized, underestimated or ignored. My book you referred to was a message to the industry but we need to make it a commitment to address these challenges. Regulators especially in the US became clearer on their expectations but majority are still practicing the old way, mainly for convenience, uncertainty, potential impact of DX on study timelines and/or untolerable CDx development spend before seeing a good clinical response. This makes implementation of early plans for prospective analyses infeasible but just replicates the Herceptin/HercepTest retrospective scenario with the high risk for unsuccessful bridging studies.

Any advice to SMEs?

– No hiding but proper early planning with proactive discussions of possible challenges. Selection of the right IVD partner with a good balance between single lab location (aka lab-developed test or LDT) and universal IVD kit. Enthusiasm is good but too much excitement may take things out of contexts.

What are you most excited to share at the NLSDays session? And as the moderator, what are you curious to hear from the other speakers?

– I'd share my thoughts about practicing CDx and enabling precision medicine in early phase clinical trials and to make it interactive informative session, I'd like other speakers to share their experiences.

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