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The need for innovation

THE FUTURE OF R&D — Last month I had the pleasure of being invited to the R&D Leadership Summit, the theme of which was "driving innovation, change and performance." This invitation-only event, organized by The Conference Forum, with support from RPS, drew more than two dozen high-level R&D executives ranging from large pharmaceutical companies to small biotech startups. The unique setting allowed these individuals to explore a number of themes in an open and candid format, which was a refreshing change from the staid and almost-robotic rhetoric one hears at some other conferences.

The general consensus was that the industry, in terms of its R&D operations, is in trouble unless companies can find a way to reduce their fixed costs, re-energize their pipelines, and find a path to innovation, which was the hallmark of the industry some 20 years ago. One CEO of a well-known specialty pharmaceutical company stated that the industry needs to reduce its fixed costs by 30% in order to be successful in the future. Others discussed the fact that simply buying biotech companies (where as much as two-thirds of the new products are) for their late-stage products is no longer the answer to stalled pipelines, and innovation will have to come from some type of disruption.

Dr. Peter Coor, co-founder and managing general partner of Celtic Therapeutics Management, who opened the two-day conference, stated that despite an increase in biomedical discoveries, pharmaceutical productivity is decreasing and the number of NMEs is at an all-time low. This long-term decline in productivity, combined with a loss in revenue due to patent expirations of $200 billion globally by 2015, has big pharmaceutical companies looking for ways to fill the ever-increasing gap.

Dr. Coor as well as other experts outlined several scenarios to improve the current outlook, one of which, is for pharmaceutical companies to acquire ownership of potential new products, rather than equity in companies, thereby not adding to what some say are already overburdened infrastructures. Another is for pharma to define and execute sophisticated clinical strategies for those products. To that point, this would require a review of the protocol development process, which has become so complex that it is inhibiting study start-ups, limiting trial recruitment, causing inefficiencies in the CRO landscape, and negatively impacting Phase II and Phase III development (where it gets really expensive).

Some of the experts during the conference agreed that new clinical technologies can help lower costs and improve efficiencies, but the real change has to be a cultural one. Pharmaceutical companies need to dramatically transform the culture, size, and incentives of their internal R&D structures.

This month we look at how some these technologies, such as EDC, have accelerated study start-up, reduced data errors, led to fewer queries and faster database lock. We also explore why technology adoption continues to lag in other areas of clinical trials, especially when it comes to optimizing the business processes and the operations associated with trial execution.

We will continue to keep our finger on the pulse of clinical development and look forward to the days of innovation disruption to come.

Regards,

Taren Grom
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Their Word...

DENISE MYSHKO
Managing Editor

Implementing integrated technologies on the operational side of trials can lead to more efficient processes and better decision-making.

ROBIN ROBINSON
Senior Editor

The industry is discovering the benefits of using patient communities for market research.

KIM RIBBINK
Features Editor

With its world renowned healthcare system and competitive R&D environment, France is an attractive market for the biopharmaceutical industry.

CAROLYN GRETTON
Contributing Editor

Medical affairs is evolving into a global group that provides a critical conduit between a wide range of internal stakeholders and external clients.

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