SL-5  The translational knowledge cycle: innovations in moving science from discovery to application

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The current era of ‘big data’, the promise of the sequenced genome, advances in green chemistry—all contribute to unique opportunities to apply innovative science to improve human and environmental health. Traditional scientific disciplinary lines are being replaced with interdisciplinary approaches. As a result, there is a growing interest in collaboration across groups that were once competitive. These collaborations take the form of public-private and private-private partnerships and are creating a new and energized research environment. However, these new approaches must seek to meet challenges of emerging and chronic diseases, growing environmental impacts associated with population growth and industrialization, and economic and resource limitations for novel research.

HESI, a global scientific foundation based in Washington, DC, has initiated a new program called CITE (Combining Interdisciplinary and Translational Expertise). This effort has engaged participants from a broad range of disciplines (agricultural sciences, environmental sciences, drug development and safety, chemical development and safety, economics, foundation management, entrepreneurship, regulatory science, philanthropy, and academic research management among others) to identify opportunities to move science from discovery to application more efficiently. This presentation will identify some of the opportunities for improving this process that were identified through the HESI CITE initiative and the next steps that will be taken to address these recommendations. The discussion will also include examples of how HESI’s current scientific portfolio and process help to optimize the flow and management of knowledge as part of translational science implementation.

SL-6  Advancing regulatory science to enhance medical product development and public health

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The FDA’s new initiative on advancing regulatory science embraces the increased adoption of emerging technologies such as pharmacogenomics (PGx) and bioinformatics in regulatory application. These technologies are complex in nature and individual groups often do not have the resources to pursue biological qualification of biomarkers and validation of these technologies individually, thus slowing the realization in regulatory application. The FDA has developed the Voluntary eXploratory Data Submission (VXDS) program as a framework outside traditional regulatory interactions for sponsors and FDA to develop expertise, tools, and processes appropriate for regulatory interpretation of PGx data, and ultimately determine the utility, shortcomings, and needs for development and application of PGx. The program identifies considerable work in progress and controversies to be resolved before consensus is achieved on the most appropriate and valid methods at a refined and advanced level. The VXDS is thus being undertaken in parallel with ongoing research aimed at determining the best scientific practices in using exploratory data. An important parallel research effort is the MicroArray Quality Control (MAQC) project that is an FDA-led, community-wide effort aimed at developing consensus among stakeholders for optimizing the reproducibility of technologies, standardizing data analysis practices, and allowing re-analysis of the data by sharing the results across the research community. Both VXDS and MAQC programs have had to grapple with formidable difficulties in data management, analyses, and interpretation, resulting in the establishment of the new Division of Bioinformatics and Biostatistics at the FDA’s National Center for Toxicological Research (NCTR), which has developed a suite of bioinformatics tools including ArrayTrack as an efficient and adaptable bioinformatics environment to support regulatory science. Realizing that we are entering the 21st century as consumer products are increasingly globalized, regulatory science needs a strategy to develop a global path to expedite the translation of basic science innovation to regulatory application. With this goal in mind, we established the Global Summit on Regulatory Science (GSRS) which fosters the development of sustainable regulatory systems that promote global public health through scientific exchange, training and research collaborations. Importantly, we have developed a Global Coalition of Regulatory Research Scientists (GSRSR); this is an international coalition with an objective of facilitating education, scientific training and scientific exchange in the field of regulatory science. All these aforementioned efforts are designed to enhance our capability to expedite the translation of cutting edge technologies into comprehensive approaches to advance regulatory science and public health.