

▶ Continuing Efforts Toward Data Standardization

PAULA BROWN STAFFORD, President of Clinical Development at Quintiles and Chair of the CDISC Board of Directors, shares her thoughts on data standardization.



Paula Brown Stafford

➔ **PV: Why is data standardization so important?**

BROWN STAFFORD: Lack of standardization often leads to undesirable outcomes. One simple example that is often cited in such discussions is the fact that electrical outlets in different countries for example, the United States and countries in Europe, require different plugs, and hence an electrical device purchased in one country may well not work in another. Fortunately, this particular issue is easily remedied by using a converter, a device that effectively facilitates standardization and interoperability.

The benefits of standardization are well exemplified in the modern airline industry. Planes can take off, fly to a destination, land and refuel, take off again, and fly to their next destination all over the world. Standardized human factors, such as detailed systems of required practices and multiple checks for correct land-land and land-air communication, and mechanical factors, such as widgets successfully fit into other widgets worldwide, facilitate the operation of an efficient and extremely safe industry.

However, clinical research data standardization is nowhere near as advanced. In our data-powered future, we are going to have to share and combine data to improve the efficiency of drug development to better serve patients, and that requires data standards. Right now, the lack of standardization when managing multiple, complex data streams is evident in multiple ways, including different SOPs driving data collection, different data formats, and different nomenclature and terminology.

➔ **PV: What are some of the key organizations in this space?**

BROWN STAFFORD: Important players include the FDA, the Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute (C-Path), and Health Level Seven International (HL7). CDISC is a nonprofit organization comprising about 300 supporting member organizations and is the common language for clinical research.

CDISC's goal is to develop and support platform-independent data standards to permit information system interoperability and, therefore, in-

form patient care and safety through higher quality medical research. Located in Tucson, C-Path was founded in 2005 as an independent, nonprofit organization dedicated to bringing scientists from the FDA, industry, and academia together to improve the path for innovative new drugs, diagnostic tests, and devices to reach patients in need. HL7 is also a nonprofit organization, with its members representing more than 90% of the information systems vendors serving healthcare.

Following close cooperation with CDISC, the FDA, and the National Cancer Institute, the BRIDG (Biomedical Research Integrated Domain Group) model of biomedical research is gaining adoption and supporting global harmonization. This model provides data interchange between clinical research environments and patient care, bearing witness to the evolution of the CRO industry from one purely focused on biopharmaceutical drug development to one also focused on medical research and patient care.

➔ **PV: Tell us about the new CFAST Initiative.**

BROWN STAFFORD: The FDA, CDISC, and C-Path are collaborating on efforts to support development of therapeutic area standards. One exciting new development is the creation of the Coalition for Accelerating Standards and Therapies, known as CFAST. As Dr. Rebecca Kush, CDISC president and CEO, stated recently, CFAST is a major new initiative that will allow the biopharmaceutical industry to speed the delivery of new therapies for patients in various ways. These include helping us gain more knowledge from past research by more extensive integration, standardization, analyses of existing data sets, and improving the overall clinical research process for future trials, from protocol design through execution, analysis, and communicating the results, while all the time remaining cognizant of the benefits of data standardization.

Collecting optimum quality data is always critical, but it's just the first step. Data lead to information, which in turn leads to knowledge, understanding, and ultimately better decision-making. Whether we're thinking about regulatory agencies, which use data to make marketing approval deci-

sions, or doctors and their patients, who use data to decide on a case-by-case basis which treatment option is best for each patient, standardized data will lead to better decision-making. The official launch of CFAST will be on October 24 at the CDISC International Interchange in Baltimore.

➔ **PV: Tell us about the FDA's list of disease and therapeutic areas that could benefit from further standardization.**

BROWN STAFFORD: Last fall, the FDA released a list of 55 therapeutic areas broken down into a three-tiered structure. The agency has a tentative five-year timeline to accomplish standardization across all of these by 2017. One of the first projects was the Alzheimer's disease data repository, developed through the CDISC process and posted to the CDISC website in October 2011. There are standards currently in development for a number of other therapeutic areas, including tuberculosis, pain, Parkinson's disease, and oncology.

➔ **PV: What do you see as some of the biggest challenges related to creating standards for clinical research?**

BROWN STAFFORD: One of the biggest challenges I see is that there are almost too many different groups addressing standardization, leading to a potential dilution of each message. We need to simplify the standardization process. This is why I believe CDISC and the initiatives discussed here can lead the way, playing a central and unifying role.

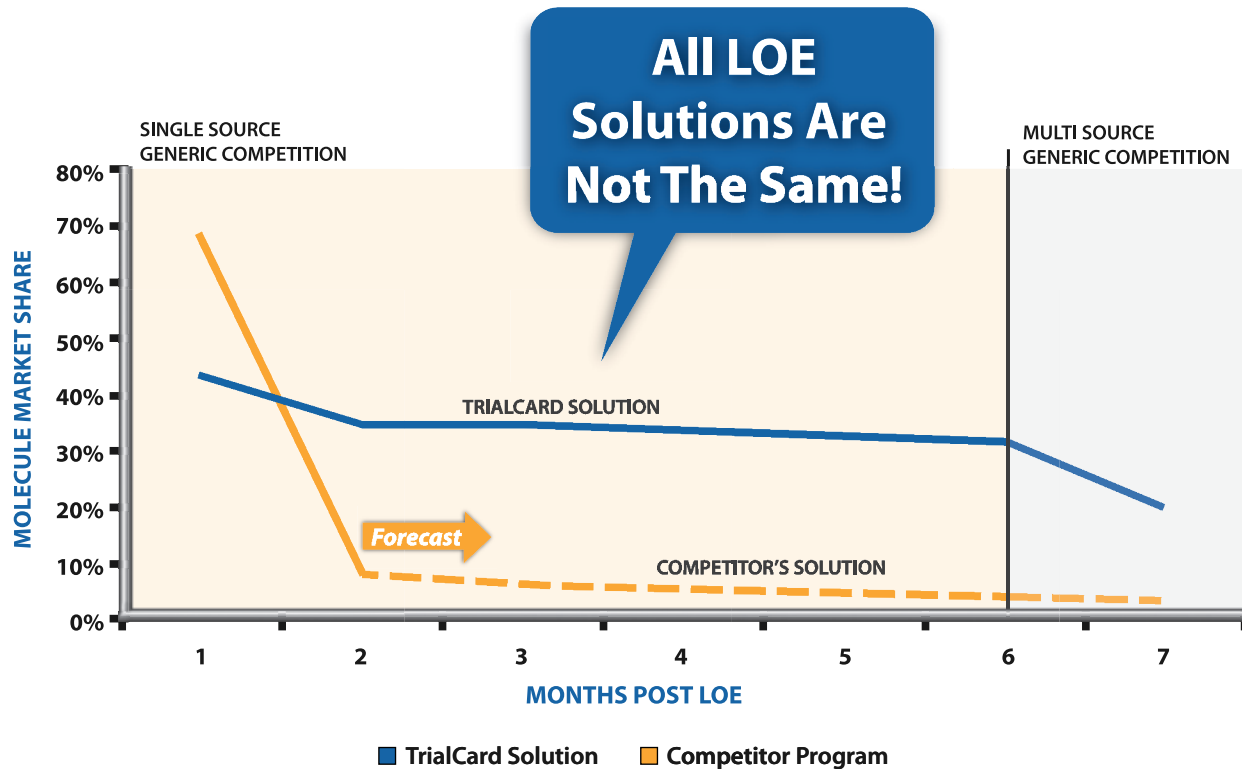
➔ **PV: Given the benefits of standardization that you've described, how can the CRO industry best advance and enhance standardization?**

BROWN STAFFORD: Quintiles and other large CROs interact with multiple biopharmaceutical sponsors, and I believe that each CRO has a role to play in educating sponsors about data standardization, and encouraging them to become active participants in collaborative ventures such as those discussed here. It's important to note that the FDA welcomes all stakeholder input as it considers how best to further data standardization and obtain maximum patient benefit from such initiatives, and all CROs can play an important role by adopting the use of standards on behalf of our sponsor companies. **PV**

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