

## *The Value of CDISC: Results of a Brief Survey*

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### **Abstract**

Advice is based on wisdom that comes from experience, and success is the result of collaboration. Collaboration and advice are key factors that further maintain innovation and assure fruitful outcomes. Being a global organization, CDISC is dedicated to working for global societies and with regulatory authorities to ensure the existence of standards that keep our patients safe and our researchers informed. CDISC standards save time and money and help prevent loss of data and serious errors. For this reason, CDISC conducts surveys of its stakeholders to collect valued feedback from its most loyal audiences; their opinion is extremely valid as it sheds the light on the existing strengths and weaknesses of CDISC and helps discover any potential opportunities for improvement.

A survey to assess how CDISC provides value to its stakeholders was conducted at two of our major annual events, the CDISC North American Interchange 2010 (known also as the CDISC International Interchange) and the CDISC European Interchange 2011. Out of a total of over 540 attendees there was excellent information provided through this mechanism, although we were disappointed many did not participate. Participants came from biopharmaceutical organizations and clinical research organizations, technology service providers, academic institutions, government, hospital, laboratory and non-profit organizations, the majority from the first two.

The results of these surveys indicate that our respondents greatly appreciate the importance of CDISC through its global standards as these standards are open and freely available via the CDISC website. Open standards is one of the many valuable aspects that distinguish CDISC from other standards development organizations. Respondents strongly stressed the value that CDISC provides to their organizations through its documentation and implementation guides, the platform-independent interoperability and semantics which allow robust tools, networking, information sharing, collaboration, education and training, regulatory interactions, as well as the CDISC Health Care Link initiative. Respondents to the survey also had the opportunity to provide input as to how CDISC can provide greater value in the future.

The following article summarizing the survey results sheds the light on the value and impact of CDISC standards and innovations on the global medical research and healthcare industry. CDISC is addressing a number of the suggestions for providing additional value through its 2012 strategic goals, educational courses and other means. The input from those who took the time to complete this survey is very much appreciated.

## Introduction

The word '**value**' in English is defined as relative worth, merit, or importance. John Perry Barlow, lyricist of the band 'The Grateful Dead' wrote "...here's the thing: if I give my song away to 20 people and they give it to 20 people, pretty soon they know me, and my **value** as a creator is dramatically enhanced". In another interview with Wired Magazine he stated: "The best way to raise demand for your product is to give it away". (Joshua Green, March 2010, *The Atlantic*, "Management Secret of the Grateful Dead"). Oddly enough, the Dead's influence on the business world may turn out to be a significant part of its legacy. The Dead were masters of creating and delivering superior customer value. One idea was to focus intensely on its most loyal fans.

This premise of creating value by giving products away is analogous to the practice of the Clinical Data Interchange Standards Consortium (CDISC). While other standards developing organizations (SDOs) in the related area of healthcare still require fees or membership to access their standards, CDISC has held strongly with the belief that these should remain open and free to encourage adoption and participation--and to create value. That being said, the organization must then find other streams of revenue to cover operating costs to enhance and maintain the standards. In an effort to better understand the ways CDISC advocates feel CDISC provides value and where CDISC can perhaps provide additional value, a short 'value survey' was developed. This survey was conducted at the two largest CDISC conferences (called Interchanges) to reach a number of the "most loyal fans" of CDISC. This manuscript outlines the methodology and findings of that survey.

## Methodology

The value survey was distributed to the attendees of two CDISC Interchanges, the CDISC North American Interchange, held in Baltimore in October 2010, and the CDISC European Interchange, held in Brussels in April 2011. It contained seven questions, three of which could essentially be considered demographics of the attendee. Specifically, the demographic questions included: a) organization type; b) primary role of the attendee at his/her workplace, and c) ways the attendee currently participates with CDISC. The other four questions were open-ended and required a written response. Two of the questions asked about the positive value CDISC provides and another question collected feedback on any additional value CDISC could provide. The last question asked attendees if they were interested in participating in ways other than those through which they currently participate.

A total of 129 out of 460 attendees (24%) at these two interchanges handed in a completed survey. There were 84 surveys completed by attendees of the North American Interchange, also known as CDISC International Interchange, while the other 45 questionnaires received were filled out by attendees of the CDISC European Interchange.

The demographics questions had choices and were tallied based on the selected responses; however, the open-ended questions required reading each response thoroughly and making judgment calls as to how these responses could be categorized. Open-ended questions were often not easy to categorize because of the fact that many responses discussed multiple topics. In fact, some of the responses were categorized as many as four times. Thus, common themes were identified to classify the compiled list of responses from these questions. .

The methodology to categorizing a response was simple: if it specifically mentioned the name of the category or if it could be inferred that the person's response was in reference to a category, then that response was marked. For example, one category that showed up a few times in the analysis was *efficiency* (working with standards made their work efficient). A response of , "Increased efficiency and data quality through standardization." was also categorized under *efficiency*. Other times, it was necessary to infer that a response referred to efficiency. For instance, another answer for the same question mentioned above was, "Streamline processes." The word 'efficiency' is not used directly, but we can assume that *streamlining processes* brings *efficiency*.

Since some answer choices were marked more than once, the total number of tallied responses does not equal the total number of responses given by respondents of both interchanges. Therefore, a figure of 55% for responses listing *Standards* as what brings most value to their companies, indicates that slightly over half of the total number of responses tagged fit into this category.

This report lists the current ways through which Interchange attendees are involved with CDISC, but does not include how they may wish to participate in the future.

## Results

### Demographics of Respondents

Slightly over half of the respondents were from biopharmaceutical organizations. Clinical research organizations and technology service providers each accounted for another 20% of the attendee population. The remaining 7% were from the following types of organizations, in order from greatest to least: academic institution, government, hospital or laboratory, clinical laboratory, and non-profit organization (NPO). Figure 1 below shows the results for the question on Organization Type:

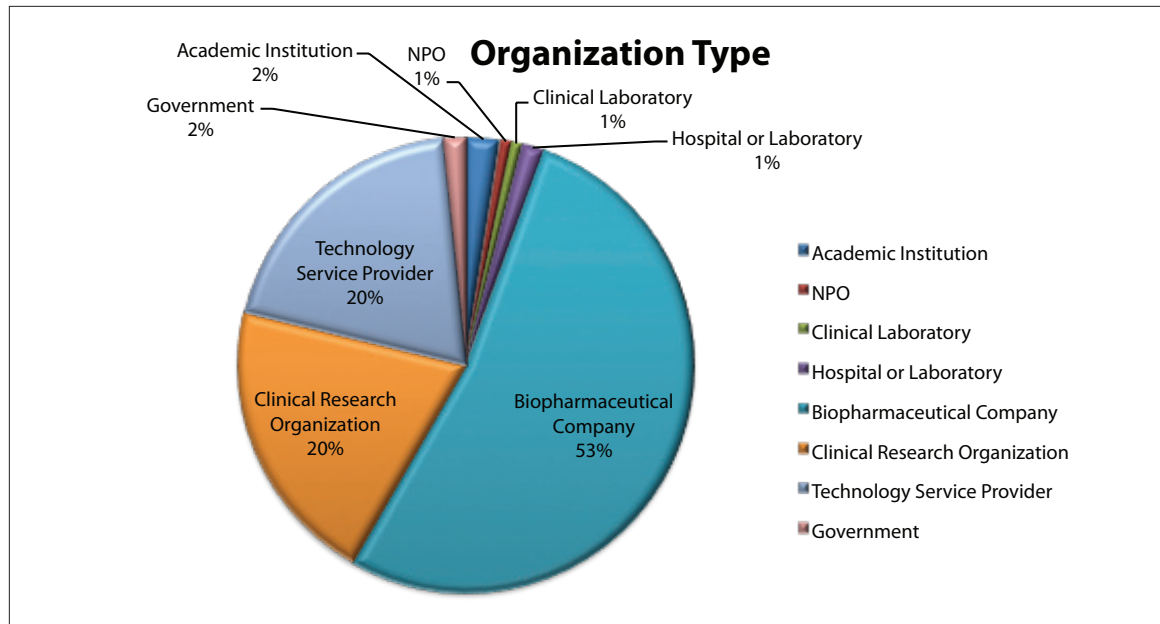


Figure 1

The two primary roles of those attendees who provided feedback were programming and data management; specifically, 36% percent of the respondents were programmers and 28% were data managers. The next three primary roles of the Value Survey respondents for both interchanges were: project/program managers (13%), statisticians (10%), and information technologists (8%). Other primary roles of the attendees were monitoring and FDA personnel. One category listed on the survey questionnaire that was not selected in either interchange was marketing and communications. Figure 2 below shows the statistics for the primary roles of respondents.

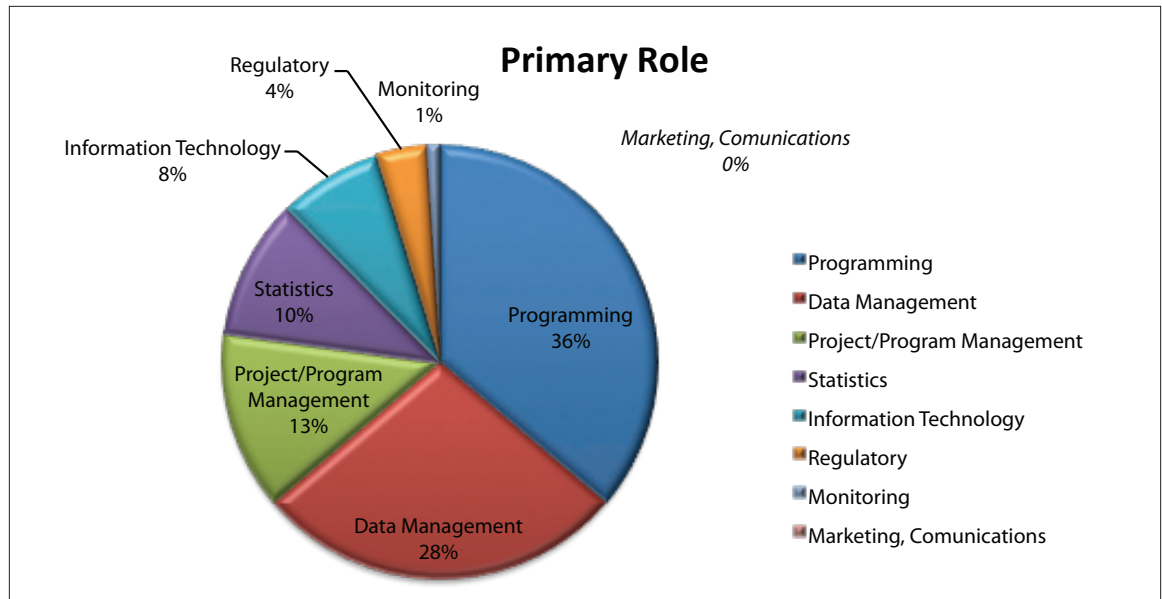


Figure 2

The last question categorized in this analysis as demographics of the respondent requested feedback on how the attendee was currently involved with CDISC activities. Almost 93% of the respondents participated in more than one CDISC activity, and 75% of them were involved in more than one CDISC area. Many of the attendees were CDISC standards implementers, from an organization that had a CDISC membership, course attendees, or a CDISC Team Leader or Team Member. There is no correlation between the respondents' type of organization or primary role in which they participated with CDISC. Figure 3 below shows the ways respondents participate with CDISC.

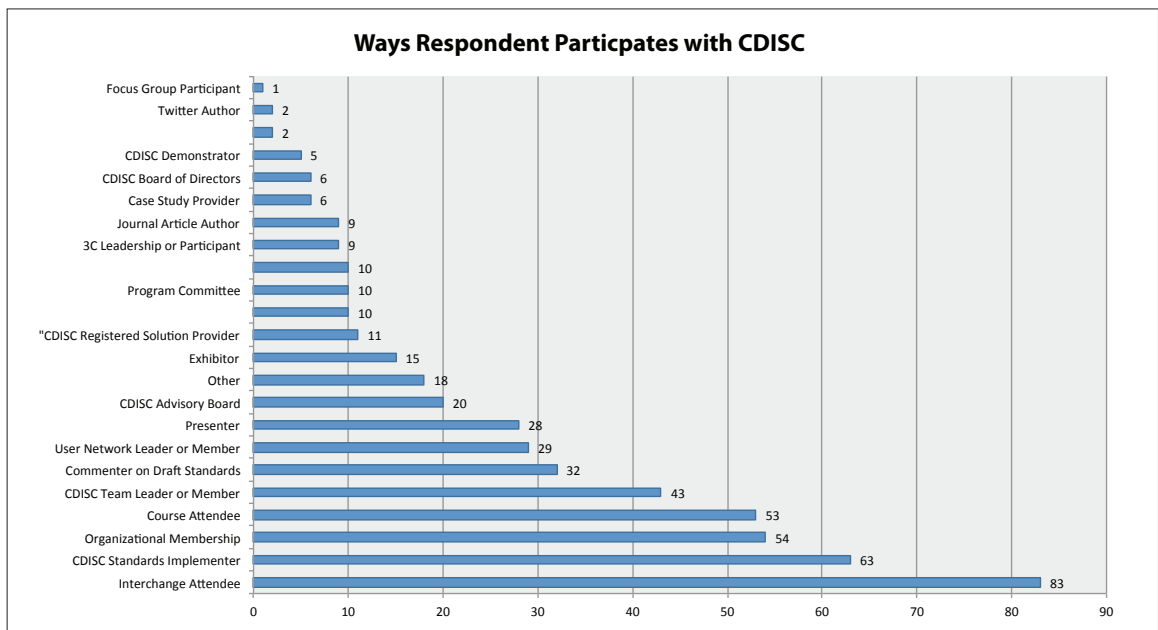


Figure 3

**Where CDISC Provides Most Value**

The key question of the survey was, “CDISC currently provides the most value to me through the following:” Answers were provided in free text. A total of 128 (>99%) respondents (from the EU and NA Interchanges) answered this question. Nine categories seemed to fit the responses. Not surprisingly, the majority cited that they primarily value the standards that CDISC has developed through its consensus-based approach; this category is listed as Open Standards in the following figure (30%). Eighteen percent value collaboration and information sharing. Ten percent value networking and the opportunity to work with FDA more closely, another ten percent value CDISC documentation and implementation guides. The remaining 32% cited CDISC value through five categories: Semantics/Interoperability, Efficiencies, Regulatory Interactions, Education and Healthcare Link. Education Opportunities, implementation of CDISC standards, regulatory interactions, efficiency and collaboration were repeated numerous times through the feedback provided. Figure 4 below demonstrates the data for this question:

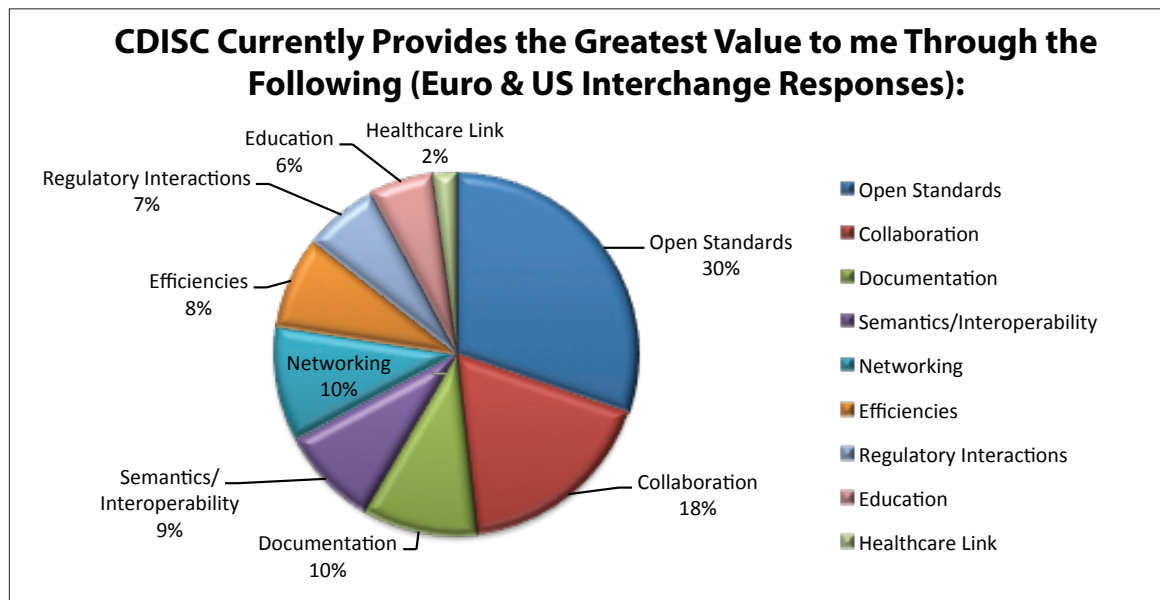


Figure 4

There was additional text in these responses that indicated how the standards provide value. For example, a respondent from the European Interchange mentioned that SDTM and ADaM standards are “easy to follow” while another respondent from the EU Interchange wrote that ADaM and SDTM “(streamline) the process of data analytics and the exchange with partners and external providers.”

The North American and European Interchange respondents provided different feedback. While there was a good turnout for all the CDISC Educational courses offered at both Interchanges, the value of training and education received by Interchange attendees was cited more frequently by those of the North American Interchange. Another point of difference was the value that the North American Interchange attendees put on collaboration and information sharing. There were a few responses related to the collaboration from the European Interchange attendees, but the percentage of respondents citing this as a value of CDISC was much higher for the North American Interchange. An attendee at the North

American Interchange stated the following about information sharing and collaboration: “(The) ability to contribute ideas, hear ideas, and participate in discussions in a win-win collaborative mode [sic].”

### Additional Value

Another question on the survey was, “*CDISC should also provide additional value through other means including:*”. Over half of the respondents asked for additional standards to be developed, which is one of the key strategic goals for 2012 where CDISC is working on developing new standards for various therapeutic areas. The results are displayed in figure 5 below in both sections Standards-All as well as Developing Additional Standards. The remaining feedback, twenty-three percent, pointed out the need for additional collaborative efforts while 20% were interested in seeing the development and advancement of CDISC standards tools and research projects. The remaining 5% mentioned that additional efforts should be made to improve training. Figure 5 below portrays these statistics:

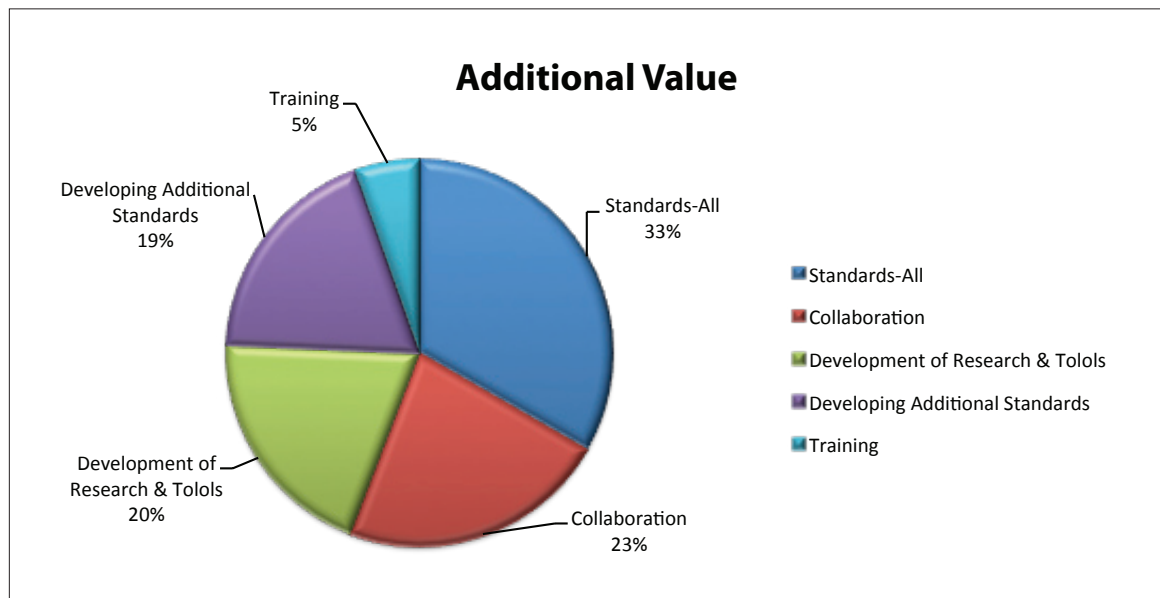


Figure 5

Additional collaboration was another significant value requested by survey respondents, for example, a respondent from the North American Interchange mentioned that CDISC could provide additional value through “facilitating connections between members.” Similar feedback was displayed by the European Interchange attendees. One of the attendees requested “more one day events to meet and share knowledge”. One of our strategic goals for 2012 is to provide a CDISC Day event in various regions of the world to spread the knowledge about CDISC and shed the light on our work and progress.

### Value in ~10 Words

The survey ended with a very interesting question: “*How would you sum up what CDISC brings that you feel is useful for you/or your organization in about 10 words*”. This question had quite

stimulating feedback. The categories were similar to the prior question on how CDISC brings the most value; however, this question forced brevity and the responses do not deserve only to be ‘categorized’. Hence, following is a representative sampling of the responses, which point to the importance of CDISC and global healthcare and medical research:

- “Standards, Expertise, Vision, Opportunity to network, value in terms of efficiency”
- “Globalization of CDISC standards working with other regulatory agencies for worldwide adoption”
- “Enhances data quality by facilitating cross-functional collaboration in medical research”
- “Developing, promoting, and making standards available as well as helping to build a more transparent communication system with regulatory authorities (FDA)”
- “Modernizing clinical research for improved medical care”
- “CDISC provides a common language for diversified companies/agencies and even for individuals with different backgrounds, education, and experience”

Figure 6 below portrays the main outcome of this question listed in four summarized categories: Harmonization, Efficiency/Simplification, Collaboration and Regulatory Interactions.

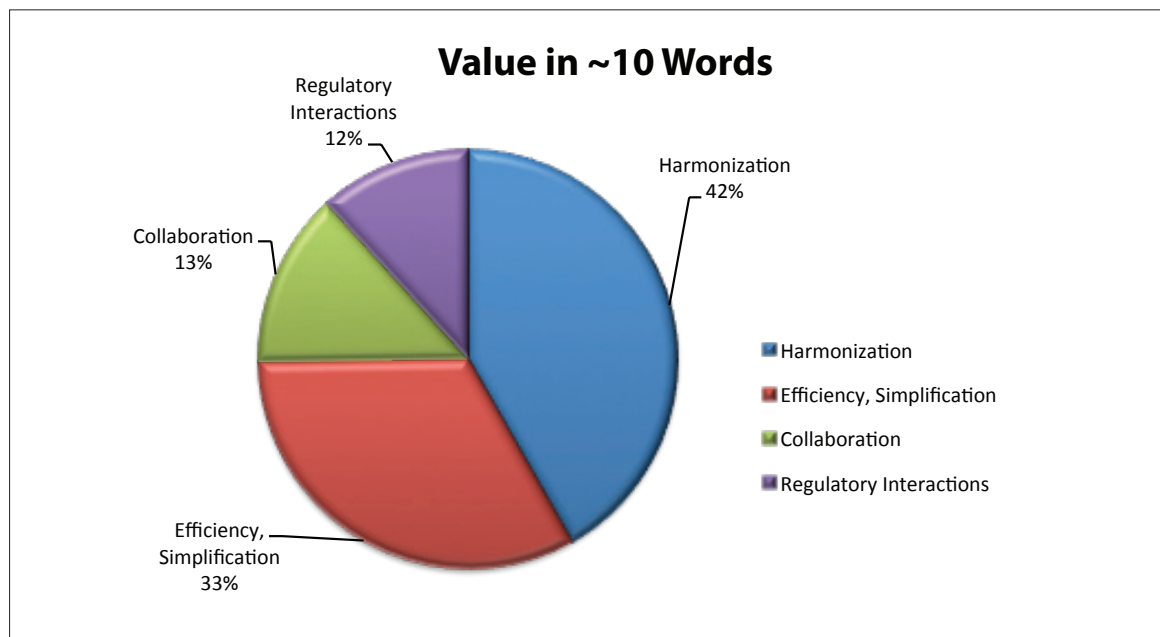


Figure 6

## Discussion

Many of the statistics in this article can be a bit misleading. For instance only 9 attendees who came from an academic institution, government authority, hospital or laboratory, clinical laboratory, or NPO filled out the survey. Very few of our members (10%) work in the industries mentioned above. Thus it is not a question as to why very few respondents filled out a survey or even why few people from these organizations attended our interchanges. The question we should be asking ourselves is why five industries that we serve (out of 13) make up a little over 10% of our membership list.

What's also worth noting is that many of the attendees of both interchanges are programmers (36%) or data managers (28%). The primary roles with the next largest numbers are project/program managers (13%), statisticians (10%), and information technologists (8%). This data alone would be startling until one realized that our two most popular standards are SDTM (Study Data Tabulation Model) and ADaM (Analysis Data Model). SDTM involves methods to collect large sets of data and ADaM's role is to analyze the collected data.

## Conclusion

It is quite encouraging for CDISC to learn how its mission is valued and supported globally through various regions of the world. CDISC will keep expanding its global participation and influence on the international healthcare industry. CDISC has indeed reached Africa, Asia, Australia and Europe in addition to the U.S. . The CDISC vision is to inform patient care and safety through higher quality medical research. The input from valued Interchange attendees help CDISC learn more about our strengths in addition to means through which CDISC can provide additional value in the future. With that being mentioned, one of the most noteworthy CDISC key strategic goals for 2012 is developing additional standards related to therapeutic areas for regulated clinical research and clinical trials, a goal through which we hope to address one of the key areas noted by the Interchange attendees.

We are pleased to realize that CDISC is valued through its open standards that are freely available to everyone, with its collaboration, networking opportunities, regulatory interactions, process efficiencies and its Healthcare Link initiative. Communications and sharing knowledge, education around the theory and application of the CDISC standards as well documentation such as the implementation guides are other means through which provides value to its "most loyal fans".

## Acknowledgements

This article portrays information and feedback from many of our CDISC most loyal fans. The survey was conducted in an effort to maintain, improve and expand the CDISC mission and to provide more value to our stakeholders. The participation of all who completed the survey is very much appreciated.

**About CDISC**

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.

**[www.cdisc.org](http://www.cdisc.org)**

*The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research.*

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