The importance of adopting standards to support the exchange of data for global biopharmaceutical research and development has never been more important, and interest in this area has never been higher. Since the establishment of the Clinical Data Interchange Standards Consortium (CDISC) in 1997, we have seen significant momentum toward adoption of CDISC standards among sponsors, as evidenced by growing membership in this nonprofit organization, vastly increased attendance at standards-related training courses, and especially a rapidly increasing community of highly motivated participants contributing to standards development efforts. The US Food and Drug Administration (FDA) has done much to build some of this momentum by specifying the use of certain standards in several different areas and in recognizing the establishment of standards as one of their critical path objectives. However, sponsors have also been motivated to increase their adoption of data standards, not only to improve interactions with partners and to realize substantial cost and time savings in their research processes but also to improve team communication and data quality and to develop valuable repositories of knowledge. In addition, standards to enable the interchange of information between research and health care are of strategic interest to biopharmaceutical product development companies and academic research institutions to facilitate the investigator role in clinical research.

Meanwhile, the global standards-development landscape has become increasingly complex, involving an ever-broadening cast of stakeholders with many different objectives. Since its initiation, CDISC has enjoyed a niche for standards development within the clinical research domain, and since 2001, the efforts of CDISC have become closely aligned with the relevant activities within the primary health care standards development organization, Health Level Seven (HL7). These standards-development organizations are also represented within government initiatives such as the movement toward electronic health records now under way in many countries, and they are both committed to harmonizing the clinical research standards with relevant health care standards.

At the same time, the pace of technology advancement continues to accelerate, and the process of creating standards has become more rigorous and sophisticated using advanced modeling concepts. Perhaps, most importantly, the focus of standards development efforts has moved beyond the original goal of establishing simple syntactic data interchange standards toward full semantic as well as syntactic interoperability, a large part of which is based on defining a robust set of controlled terminology, “the words that populate the structures.” To achieve
this, the US National Cancer Institute (NCI) has contributed its terminology services and tools (supporting a global collaboration among HL7, CDISC, NCI, and FDA); HL7 has provided its modeling methodologies and the opportunity to interact with many other related health care standards activities; and the International Standards Organization is helping to make these developing and production data standards more globally accepted. However, these are just a few of the players in a deeply intertwined web of standards development. To facilitate coordination of the applicable standards-development achievements and ongoing efforts on a global basis, an inventory of standards has been compiled by Hammond, McCourt, and Kush; this resource, organized by categories, identifies the contributions of more than 50 organizations and over 100 distinct standards of relevance to our industry (1).

As the landscape has expanded, the footing has grown more challenging; yet, the potential impact and benefits of standards have also moved proportionately higher. Truly this is a most interesting, exciting, and critical time for all those who share the vision of establishing industry-wide standards to promote interoperability and improve the biomedical research process, for the betterment of therapies that are more effective and safer for the global population. As we navigate this path, CDISC has emerged as a leading voice of data standardization within the biopharmaceutical development and clinical research communities. CDISC has released a number of production standards to meet current needs and continues to lead a full portfolio of standards-development activities.

In this special section of the Drug Information Journal, we will explore a subset of the many facets of this dynamic world of standards development, particularly those most relevant to clinical or biomedical research. One article, “Toward a Comprehensive CDISC Submission Data Standard,” describes how CDISC production standards support the regulatory submission and review process and how they are evolving into a more cohesive collection of integrated standards that may eventually encompass the full range of safety and efficacy review for the approval to market new therapies. This article speaks to the FDA implementation of the data components of the ICH eCommon Technical Document. Another article, “A Standard Computable Clinical Trial Protocol: The Role of the BRIDG Model,” discusses the ongoing efforts to define a standard structured protocol representation that is both human and machine readable. This would enable the ready reuse of protocol information downstream for trial registries, IRBs, clinical study reports, project management, and other areas that make use of information in the study protocol. This article also introduces a biomedical research domain analysis model as the key reference framework for all research standards-development activities and describes how this model will provide the means to ensure harmonization and end-to-end integration of all of the CDISC standards. By directly linking these research standards with the relevant health care standards, it will truly become a “bridge” between these two worlds of clinical research and clinical care. The effect of interoperable standards between clinical research and health care for investigative sites is considered in a third article, “Data Standards: At the Intersection of Sites, Clinical Research Networks, and Standards Development Initiatives.” This article addresses work that is being done to achieve the National Institutes of Health Roadmap and to provide means to facilitate investigative site participation in clinical research. These efforts are producing therapeutic area-specific standards for areas such as cardiology and infectious diseases, in particular, tuberculosis.

The final article in this section, “Controlled Terminology for Clinical Research: A Collaboration Between CDISC and NCI Enterprise Vocabulary Services” describes the current focus on defining the controlled terminology that will be instrumental to enhancing the standards so that the ultimate mission can be reached—the realization of full semantic interoperability among systems to support health care and related areas of medical research. The articles in this section are but a sample of some of the impressive
progress to date and challenges being addressed in the world of standards. We hope that you will find this set of articles enjoyable and informative. The work does not stop here, as these and many more ongoing efforts continue to progress toward delivering a complete, integrated set of data standards across clinical research and related areas of medical research and health care for the betterment of the public health.

REFERENCE