Selected Papers from the 2011 Summit on Clinical Research Informatics

Over the past several years, a broad groundswell of activity has served to bring the biomedical informatics sub-domain of Clinical Research Informatics (CRI) rapidly to national prominence. Such increased recognition of the role and importance of CRI has been driven by policy and funding initiatives sharing a common focus on the fundamental re-engineering of our clinical and translational research enterprises in order to increase their quality, efficiency, and timelines [1–5]. A brief review of exemplary scholarly publications spanning the past eight years serves to illustrate this evolution, beginning in 2003 with an Institute of Medicine (IOM) sponsored report by Sung and colleagues that elucidated the “T1” and “T2” blockages impeding the translation of knowledge between basic science, clinical research, and clinical or public health practice, and noting the importance of biomedical informatics and information technology relative to overcoming such barriers [5]. This work was followed in 2005 by the publication of a second IOM-sponsored manuscript by Payne and colleagues that examined the critical role of biomedical informatics in enabling the efficient conduct of clinical and translational research and enumerating the major challenges facing the academic biomedical informatics community relative to those opportunities [4]. In 2006, Chung and colleagues examined the role of biomedical informatics in re-engineering the foundational workflows and information management activities incumbent to the modern clinical research environment [1]. Subsequently, in 2009, Embi and Payne published the findings of a study involving a representative sampling of the CRI community that served both to establish a formal definition of the field of CRI, and to provide a framework for grand research challenges facing the field [2]. Following these publications, in 2010 and 2011, a number of policy and perspective articles further catalyzed community-wide discussions of the future educational, research and practice agendas for the CRI sub-domain [6–8]. In parallel to the preceding series of publications, and under the auspices of the American Medical Informatics Association (AMIA), a series of activities conducted by both the association’s Clinical Research Informatics Working Group and Clinical Research Informatics Steering Task Force culminated in the creation in 2010 of a first-of-its-kind Summit on Clinical Research Informatics, incorporating a scientific program spanning a full spectrum of basic and applied CRI content. By co-locating and bridging the CRI-focused Summit with the complementary AMIA Summit on Translational Bioinformatics, 2010 saw the first combined AMIA Summits in Translational Science. In 2011, these Joint Summits became even more tightly integrated, expanding the opportunity for presentation of the best science from these overlapping informatics sub-disciplines. When taken as a whole, the preceding range of activities serves to illustrate the emergence and maturation of CRI as a robust biomedical informatics sub-discipline that continues to identify and pursue a broad spectrum of basic and applied science with the ultimate objective of improving human health through the facilitation of timely and high impact clinical research.

In this special supplement, we highlight a series of papers that are outstanding examples of the state-of-the-art in basic and applied CRI science, drawn from the submissions to the second AMIA Summit on Clinical Research Informatics held in 2011. These authors and their work were selected via a rigorous and multi-part peer-review process (including formal review of expanded papers through the JBI editorial process) conducted by the Scientific Program Committee for that same meeting. The papers exemplify the rigorous scholarly work underway as a result of the evolution and rapid growth of CRI. These publications reflect current trends and critical research challenges incumbent to the current state of clinical and translational research, and can be broadly situated in three complementary thematic groupings:

- The first of these thematic areas focuses on the critical issues facing the research community with regards to the discovery and re-use of data, information, and knowledge resources. This theme is manifest in three reports that explore critical applied CRI issues that must be addressed in order to overcome potential barriers to the satisfaction of investigator-focused information needs. In the first of these articles, Borlawsky and colleagues describe the design and usability of an ontology-anchored integrative query tool, known as Research-IQ, which utilizes a combination of knowledge engineering methodologies and semantic web technologies to facilitate the discovery of heterogeneous and distributed data, information, and knowledge resources with potential applications in a variety of clinical research use cases [9]. In the second article in this grouping, Kandula and colleagues describe a quantitative bootstrapping method that enables triangulation between ICD-9 codes and complementary structured data resources in order to build classification models that identify patient cohorts that can in turn be employed for study feasibility analyses and participant recruitment operations [10]. In a similar manner, in the third of these reports, Myers and Herskovik describe a set of probabilistic techniques that can be used to obtain discrete patient counts from a clinical data warehouse that contain synthetic or other derivative data types [11].

- The second thematic area is concerned with the use of data standards and semantic reasoning to enable data re-use in support of clinical research. The issues discussed in the two reports representative of this area provide insights to foundational informatics methods capable of addressing major challenges surrounding the variable semantics, codification, and granularity of data sets commonly encountered in the clinical research environment. In the first report, Jiang and colleagues describe the use of controlled terminologies and
ontologies to inform the definition of Common Data Elements (CDEs) for use in cancer research, with a specific emphasis on the use of the UMLS Semantic Network in order to automate or enhance the generation and semantic annotation of such definitional constructs [12]. In a similar manner, and in the second of these publications, Luther and colleagues discuss the use of a number of text mining methods in order to generate a clinical vocabulary for post-traumatic stress disorder (PTSD) related research, based on heterogeneous source documentation and analogous information sources [13].

• The third and final of the thematic areas represented in this special edition focuses on approaches to information systems architecture, integration, and usability in the context of clinical research and combined standard-of-care and clinical research settings. The two reports in this theme place a major emphasis on the integration of enterprise systems and clinical research data management platforms in order to increase overall efficiency and quality of data collection operations, as well as the formal evaluation of the usability of such tools. In the first of these reports, Elfadly and colleagues describe a set of architectural and technical approaches to the tight integration of research-oriented data capture tools and common electronic health record (EHR) systems to realize increased efficiencies in combined standard-of-care and research encounters, an area of intense interest in the clinical research community [14]. Following a complementary but distinct line of research, the second report by Franklin and colleagues describe the outcomes of a 2-year qualitative evaluation study concerning optimal support and training strategies for multi-user electronic data capture platforms, making significant contributions to our collective understanding of socio-technical factors surrounding such technology deployment scenarios [15].

When taken as a whole, the preceding body of work shows that CRI has emerged as an increasingly robust and mature field of basic and applied biomedical informatics research and development. This state of the field is indicated in large part by both the increasing diversity and breadth of research being reported relative to the formal evaluation of the usability of such tools. In the first of these reports, Elfadly and colleagues describe a set of architectural and technical approaches to the tight integration of research-oriented data capture tools and common electronic health record (EHR) systems to realize increased efficiencies in combined standard-of-care and research encounters, an area of intense interest in the clinical research community [14]. Following a complementary but distinct line of research, the second report by Franklin and colleagues describe the outcomes of a 2-year qualitative evaluation study concerning optimal support and training strategies for multi-user electronic data capture platforms, making significant contributions to our collective understanding of socio-technical factors surrounding such technology deployment scenarios [15].

References


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