Chapter 21
Future Directions in Clinical Research Informatics

Peter J. Embi

Abstract Given the rapid advances in biomedical discoveries, the growth of the human population, and the escalating costs of health care, there is an ever increasing need for clinical research that will enable the testing and implementation of cost-effective therapies at the exclusion of those that are not. The fundamentally information-intensive nature of such clinical research endeavors begs for the solutions offered by CRI. As a result, the demand for informatics professionals who focus on the increasingly important field of clinical and translational research will only grow. New models, tools, and approaches need to be developed to achieve this, and this innovation is what will drive the field forward in the coming years.

Keywords Clinical research informatics • Biomedical informatics • Phases of translation research • Electronic health records • Future trends • US policy initiatives • Health IT infrastructure

As evidenced by the production of this text and reflected in its chapters, clinical research informatics (CRI) has clearly emerged as a distinct and important biomedical informatics subdiscipline [1]. Given that clinical research is a complex, information- and resource-intensive endeavor, one comprised of a multitude of actors, workflows, processes, and information resources, this is to be expected. As described throughout the text, the myriad stakeholders in CRI, and their roles in the healthcare, research, and informatics enterprises, are continually evolving, fueled by technological, scientific, and socioeconomic changes. These changing roles bring new challenges for research conduct and coordination but also bring potential for new

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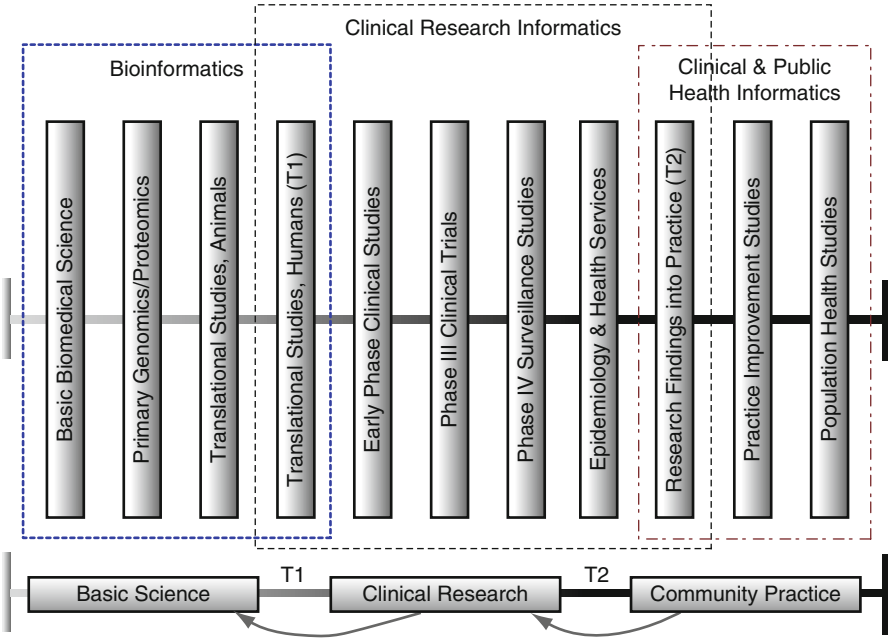

Fig. 21.1 Clinical and translational science spectrum research, and informatics. This figure illustrates examples of research across the translational science spectrum and the relationships between CRI and the other subdomains of translational bioinformatics, clinical informatics, and public health informatics as applied to those efforts (From Embi and Payne [1], with permission)

research efficiencies, more rapid translation of results to practice, and enhanced patient benefits as a result of increased transparency, more meaningful participation, and increased safety.

As Fig. 21.1 depicts, the pathway from biological discovery to public health impact (the phases of translational research) clearly is served by informatics applications and professionals working in the different subdomains of biomedical informatics. Given that all of these endeavors rely on data, information, and knowledge for their success, informatics approaches, theories, and resources have and will continue to be essential to driving advances from discovery to global health. Indeed, informatics issues are at the heart of realizing many of the goals for the research enterprise.

Policy Trends

It should therefore come as no great surprise that recent years have seen the emergence of several national and international research and policy efforts to foster advances in CRI by supporting CRI professionals' efforts to address the inherent

challenges and opportunities that motivate the subdiscipline. Focused on accelerating and improving clinical research capacity and capabilities in the biomedical sector, a range of initiatives funded by US health and human service agencies are helping to advance the field. These include initiatives by the US National Cancer Institute (NCI), such as the Cancer Biomedical Informatics Grid (caBIG) [2–5], to the National Institutes of Health's (NIH) Clinical and Translational Science Award (CTSA) [6, 7] programs [8, 9]. In recent years, the CTSA program in particular has had fostered significant growth in both the practice and science of CRI as well as fostering professional development of CRI, given one of its major emphases the advancement of CRI, and the closely related domains of translational research informatics and translational bioinformatics. Further, other NIH institutes like the National Library of Medicine, as well as funders like the Agency for Healthcare Research and Quality (AHRQ), are also driving advances in research data methods and techniques for CRI-related efforts, including comparative effectiveness and health services research.

In addition to such initiatives focused on advancing the science and practice of CRI, investments by institutions and by the government through the US Department of Health and Human Services (DHHS), the US Office of the National Coordinator for Health IT (ONC), and the US Centers for Medicare and Medicaid Services (CMMS) are serving to incentivize the adoption and "meaningful use" of electronic health records (EHRs). Such movement toward more widespread health IT infrastructure, while initially focused primarily on improving patient care, is meant ultimately to lead an interoperable infrastructure that will enable a national health information network in the United States. Once in place and enabled via appropriate health information interchange standards, such a network is envisioned to leverage the reuse of data and information from clinical care for improvements in public health and research – to create the learning health system [10]. Just as biomedical informatics approaches and resources are essential to realizing the potential of such systems for enhancing clinical care, so too will CRI methods, theories, and tools be critical to realizing the potential of such a system for enabling discovery through acceleration and enhancement of clinical research.

Data Management and Quality

Indeed, fully leveraging our healthcare and research investments to advance human health will require even more emphasis on making sense of the ever increasing amounts of data generated through healthcare and research endeavors. It is work in the field of CRI that will enable and improve such research activities, from the translation of basic science discoveries to clinical trials, to the leveraging of healthcare data for population level science and health services research. Importantly, these advances will require increased effort not just to the development and management of technologies and platforms but also to the foundational science of CRI in an increasingly electronic world [11]. By facilitating all of the information-dense

aspects of clinical research, CRI methods and resources enable the conduct of such research programs to generate new and impactful knowledge. In fact, the truly "meaningful use" of EHRs will allow the systematic collection of essential data that will drive quality improvement research, outcomes research, clinical trials, comparative effectiveness research, and population level studies to a degree not heretofore feasible. However, realizing this promise will require the attention and efforts of experts focused on advancing the domain of CRI.

As the preceding chapters also demonstrate, advances in CRI have already begun to enable significant improvements in the quality and efficiency of clinical research [8, 9, 12]. These have occurred through improvements in processes at the individual investigator level, through approaches and resources developed and implemented at the institutional level, and through mechanisms that have enabled and facilitated the endeavors' multicenter research consortia to drive team science. As research becomes increasingly global, initiatives like those mentioned above provide opportunities for collaboration and cooperation among CRI professionals across geographical, institutional, and virtual borders to identify common problems, solutions, and education and training needs. Increasingly, investigators and professionals engaged in these groups are explicitly self-identifying as CRI experts or practitioners, further evidence for the establishment of CRI as an important, respected, and distinct informatics subdiscipline.

Multidisciplinary Collaboration

CRI professionals come to the field from many disciplines and professional communities. In addition to the collaborations and professional development fostered by such initiatives as the CTSA mentioned above, there is also a growing role for professional associations that can provide a professional home for those working in the maturing discipline. The American Medical Informatics Association (AMIA) is one such well-recognized organization. Working groups focused on CRI within organizations like AMIA have seen considerable growth in interest and attendance over the past decade. More recently, scientific conferences dedicated to CRI and the closely related informatics subdiscipline of translational bioinformatics (TBI) have been launched by AMIA to great success among the informatics and clinical/translational research communities. AMIA's journal, JAMIA, has also recently acknowledged the importance of CRI, with the addition of editorial board members and allotted journal space to the important topics in CRI, as have others. Given its growth, it is likely that journals specifically focused on this domain will emerge in the years to come. In addition, other important informatics groups and journal, such as International Medical Informatics Association (IMIA), and non-informatics associations and journals (e.g., DIA, The Society for Clinical Trials, and a myriad of professional medical societies) also increasingly provide coverage of and opportunities for professional collaboration among those working to advance CRI. Efforts like these continue foster the maturity and growth so critical to advancing the field.

Challenges and Opportunities

Despite these many advances, significant challenges and opportunities remain to be addressed if this relatively young discipline is to evolve and realize its full potential to accelerate and improve clinical and translational science. Indeed, as reported in 2009 by Embi and Payne, the challenges and opportunities facing CRI are myriad. In that manuscript, these were placed into 13 distinct categories that spanned multiple stakeholders groups (Fig. 21.2) [1].

This conceptualization of CRI activities includes those related to: education and original (informatics) research, research support services and activities, and policy leadership. The stakeholders for all of these span the individual, institutional, and national levels, and include those with clinical research as well as informatics perspectives and priorities. These broad groups of stakeholders and the wide range of diverse CRI activities should all be considered as the field evolves and as research agendas, educational and training efforts, and professional resources are developed.

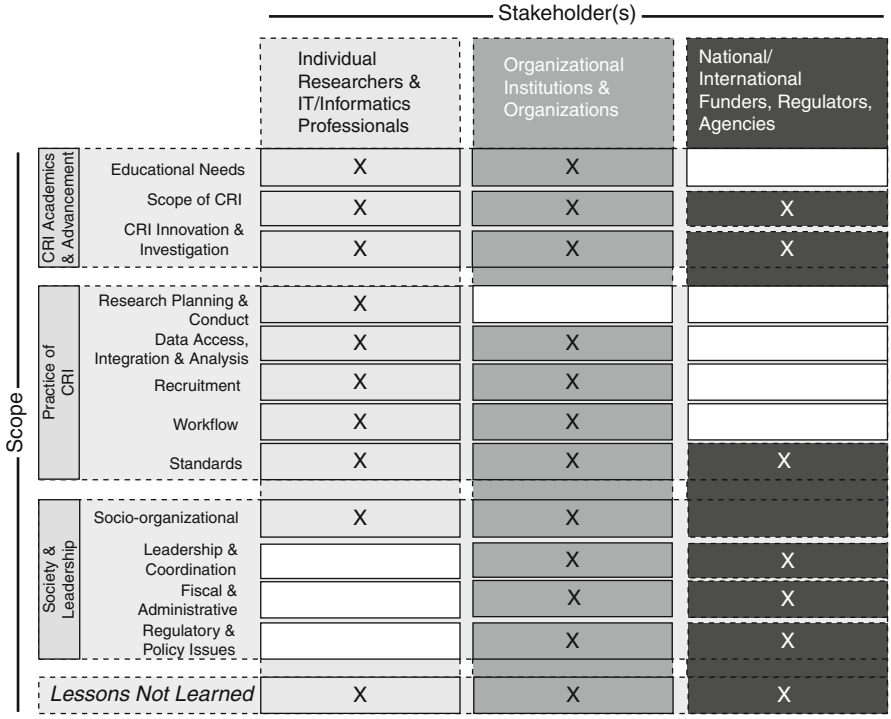

Fig. 21.2 Major challenges and opportunities facing CRI. This figure provides an overview of identified challenges and opportunities facing CRI, organized into higher-level groupings by scope, and applied across the groups of stakeholders to which they apply (From Embi and Payne [1], with permission)

Among the many challenges to be overcome in order to realize the promise of CRI is the need to address the severe shortage of professionals currently working to advance in the CRI domain. As with many biomedical informatics subdisciplines, training in CRI is and will remain interdisciplinary by nature, requiring study of topics ranging from research methods and biostatistics, to regulatory and ethical issues in CRI, to the fundamental informatics and IT topics essential to data management in biomedical science. As the content of this very book illustrates, the training needed to adequately equip trainees and professionals to address the complex and interdisciplinary nature of CRI demands the growth of programs focused specifically in this area.

Furthermore, while there is certainly a clear need for more technicians conversant in both clinical research and biomedical informatics to work in the CRI space, there remains a great need for scientific experts working to innovate and advance the methods and theories of the CRI domain. In recent years, the National Library of Medicine, which has long supported training and infrastructure development in health and biomedical informatics, recognized this need by clearly calling out clinical research informatics as a domain of interest for the fellowship training programs it supports. While most welcome and important, the availability of such training and education remains extremely limited. Significantly, more capacity in training and education programs focused on CRI will be needed to establish and grow the cadre of professionals focused in this critical area if the goals set forth for the biomedical science and healthcare enterprise are to be realized. This will require increased attention by sponsors and educational institutions.

In addition to training the professionals who will focus primarily in CRI to advance the domain, there is a major need to also educate current informaticians, clinical research investigators and staff, and institutional leaders concerning the theory and practice of CRI. Programs like AMIA's 10×10 initiative and tutorials at professional meetings offer examples like a course focused in CRI that help to meet such a need [13]. Such offerings help to ensure that those called upon to satisfy the CRI needs of our research enterprise are able to provide appropriate support for and utilization of CRI-related methods or tools, including the allocation of appropriate resources to accomplish organizational aims.

As the workforce of CRI professionals grows, the field can be expected to mature further. While so much of the current effort of CRI is quite appropriately focused on the proverbial "low hanging fruit" of overcoming the significant day-to-day IT challenges that plague our traditionally low-tech research enterprise, significant advances will ultimately come about through a recognition that biomedical informatics approaches are crucial centerpieces in the clinical research enterprise. Indeed, just as the relationship between clinical care and clinical research is increasingly being blurred as we move toward the realizing of a "learning health system," so too are there corollaries to be drawn between the current formative state of CRI and the experiences learned during the early decades of work in clinical informatics. Those working to lead advances in CRI would do well to heed the lessons learned from the clinical informatics experiences of years past. Future years can be expected to see CRI not only instrument, facilitate, and improve current clinical research processes,

but advances can be expected to fundamentally change the pace, direction, and effectiveness of the clinical research enterprise and discovery. Through CRI advances, discovery, quality improvement, and the systematic generation of evidence will become as routine and expected a part of the healthcare system and practice in the years to come as advances in clinical informatics in years past have helped foster the systematic application of evidence into healthcare practice.

Conclusion

In conclusion, the future is bright for the domain of CRI. Given the rapid advances in biomedical discoveries, the growth of the human population, and the escalating costs of healthcare, there is an ever increasing need for clinical research that will enable the testing and implementation of cost-effective therapies at the exclusion of those that are not. The fundamentally information-intensive nature of such clinical research endeavors begs for the solutions offered by CRI. As a result, the demand for informatics professionals who focus on the increasingly important field of clinical and translational research will only grow. New models, tools, and approaches need to be developed to achieve this, and this innovation is what will drive the field forward in the coming years. It is a great time to be working in this critically important area of informatics study and practice.

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