December 28, 2015

Stephen Ostroff, MD
Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Ostroff:

On behalf of the Healthcare Information and Management System Society (HIMSS), we are pleased to provide written comments to the Using Technologies and Innovative Methods To Conduct Food and Drug Administration-Regulated Clinical Investigations of Investigational Drugs; Establishment of a Public Docket [Docket No. FDA-2015-N-3579], which was published in the Federal Register on October 29, 2015. HIMSS appreciates the opportunity to leverage our members’ expertise in developing these comments, and we look forward to establishing a dialogue with the Food and Drug Administration (FDA) on the continued advancement and improvement of incorporating technologies and innovative methods into clinical research.

HIMSS is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). HIMSS leads efforts to optimize health engagements and care outcomes using IT. The organization produces health IT thought leadership, education, events, market research, and media services around the world. Founded in 1961, HIMSS encompasses more than 61,000 individuals, of which more than two-thirds work in healthcare provider, governmental, and not-for-profit organizations across the globe, plus over 640 corporations and 450 not-for-profit partner organizations, that share this cause.

As a cause-based organization focused on health IT as an enabler of healthcare transformation, HIMSS is supportive of ensuring that technology and innovative methods are used to carry out clinical investigations. HIMSS is committed to finding the right technologies that support clinical research, but also are integral to new, innovative care delivery processes. We recognize that technology and evidence-based medicine are helping our nation to transition from a fee-for-service system to a value-based care system, but also supports the clinical research enterprise.

A critical piece of that transition is the ability to securely exchange timely health information between settings and providers of care, with patients and family members, and using that information to achieve improved outcomes as well as maximizing value for patients. The ability to securely and efficiently exchange health information is also a key tenet for successful clinical trials.

HIMSS strongly discourages any federal agency from dictating specific technology tools that providers should be using in a particular care delivery model or to conduct research. Each provider will approach its IT structure differently, and should have the flexibility to implement the solutions that they require. Most technologies will have cross-functional purposes that support clinical research as
well as innovative care delivery so there should be flexibility in adapting different technologies for different purposes.

Such enabling technologies and services for clinical research include electronic health records (EHRs), telehealth services (including remote patient monitoring), health information exchange services, and tools in patient engagement, population health management, and data aggregation and analytics. Providers may use all of these tools or just some of them—in either case, it should be up to each provider to determine its technology requirements and decide which technologies they should use for their particular circumstances.

There exist a range of relevant IT tools that providers can use to perform their duties. The applicability of the tools for care delivery are often one-in-the-same with the tools for the administration of clinical research. FDA needs to understand the statutory or regulatory requirements for IT’s use in care delivery to ensure that it is not negatively impacting the use of IT tools in the clinical research space, and vice-versa. The agency should also expand its collaborations with other agencies on the use of IT tools to ensure that the interconnectedness of technology for research and care delivery can be maintained and promoted.

HIMSS has prepared comments on the following specific issues in support of FDA’s request for comments:

1. **What technologies, communication infrastructure, or innovative methods are being used to conduct clinical investigations?** FDA is aware of several groups conducting and interested in conducting clinical investigations using mobile technology and remote methods for data collection. FDA requests feedback on experiences with implementing such methods or models (for example, lessons learned), as well as information supporting the use of any suggested technologies, methods, or models, including any characteristics that would make the technology more or less desirable for use in clinical trials.

There are numerous examples across the healthcare continuum where innovative technologies, such as remote patient monitoring, are already an integral part of clinical research, and these present opportunities to build a stronger infrastructure for both care delivery and research endeavors going forward. These examples include:

- **CHRISTUS Health** has been engaged in a remote patient monitoring pilot program through their St. Michael Health System in Texarkana, Texas. The project began with a focus on congestive heart failure patients, and tried to answer the question of whether remote patient monitoring improves care transitions efficiencies for 90-days post discharge from a healthcare facility. The research project supplied each patient with a Home-Based Wireless Kit, that included a tablet, weight scale, blood pressure cuff, pulse oximeter, daily alarm reminder, and videoconference capability.

  With the early success of the program, the diagnoses covered was expanded to include heart failure, myocardial infarction, coronary artery disease, hypertension, pneumonia, chronic
obstructive pulmonary disease, respiratory failure, diabetes, and sepsis. The research has produced results that demonstrate a significant decrease in the 30-day related readmissions rate as well as the average inpatient admissions rate, with great patient satisfaction scores.

- At the Scripps Translational Science Institute, several clinical trial projects are underway in digital medicine. Some of the examples include:
  - **Using wireless monitoring to understand the body’s response to meditation**
    The study is trying to offer advanced insight into the body’s response to meditation by wirelessly and unobtrusively monitoring heart and brain activity during meditation.
  - **Wireless monitoring for disease wellness and prevention**
    The study aims to evaluate the impact of using a smartphone enabled “Wireless Monitoring System” in conjunction with a disease wellness and prevention program on the healthcare costs and resource utilization of chronically ill individuals with diabetes, hypertension, and cardiac arrhythmia. The equipment used consists of a combination of current wireless medical devices designed for use in the management of these conditions, a smartphone, and an online software platform to analyze disease data and enable care coordination.
  - **Comparative Effectiveness of Pocket Mobile Echocardiography vs. Transthoracic Echocardiography**
    The investigators are evaluating the effectiveness of a hand-held echo (HHE) device in detecting cardiac pathology in both an inpatient and outpatient clinical setting as compared to a comprehensive traditional transthoracic echocardiography (TTE) evaluation.
  - **Genomic Risk Markers for Atrial Fibrillation Following Extended Cardiac Rhythm Monitoring**
    Scripps is conducting a multicenter, nationwide study of individuals presenting with symptoms suggestive of, but not yet diagnosed as atrial fibrillation. Individuals received a patch for two weeks of rhythm monitoring plus genetic testing to identify novel markers for atrial fibrillation risk.
  - **Wearable Sensors for Objective Measures of Post-Traumatic Stress Disorder**
    The pilot study, in collaboration with the Navy, is to intensively monitor sleep quality, activity and autonomic nervous system function of servicemen/women using an innovative wristband sensor that continuously monitors measures of stress, activity and sleep quality.
  - **Pilot Study in the Home Diagnosis of Sleep Apnea**
    The home monitoring under this study will explore potential findings supportive of sleep apnea while monitoring at home during routine sleep over 5 to 7 nights, wearing a device the size of a Band-Aid, via adhesive to their chest over a period of 10 days.
  - **Pilot Study for Monitoring Patients with Heart Failure**
    The study proposes to utilize a novel, wearable device which has multiple sensors embedded in a “wrist-watch” in order to explore its monitoring capabilities in individuals with congestive heart failure.
Overall, remote patient monitoring technologies are being documented as an efficacious tool for clinical research and ensuring access to high quality healthcare.

We would also like to highlight the HIMSS Value Suite as another potential vehicle for FDA to learn more about how technologies are being used to conduct clinical investigations. Although the Value Suite is focused on how organizations have realized the full value of health IT, many of the case studies have material applicability to clinical research.

2. What are ways FDA could encourage adoption of these technologies and innovative methods in the conduct of clinical investigations?

In previous HIMSS public comments on the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework, we addressed several regulatory topics which are applicable in the context of technologies and innovative methods that help conduct clinical research.

The FDASIA Report proposes a framework that is intended to promote innovation and protect patient safety. The specific principles from this framework that are applicable to FDA’s request for public comments include:

- **Leverage private sector knowledge, experience, and expertise**
  HIMSS supports the idea of leveraging the existing knowledge base from the private sector for the promotion of new technologies in clinical research. As we have articulated in this letter, there are numerous examples of how new technologies are being employed in the clinical research setting. HIMSS suggests specifically leveraging not-for-profit organization research and resources as part of this approach. One tactic to supporting non-federal sector efforts could be the establishment of a core council or councils selected from key stakeholder groups relevant to clinical research and health IT policy activities, to ensure that FDA is receiving regular feedback on how this space is evolving and if additional policy levers need to be pulled in the future.

- **Facilitate, rather than impede, innovation**
  In order to sustain rather than stifle innovation in the drive to use technologies and innovative methods in clinical research, there must be an acceptable level of clarity and predictability in terms of regulation and/or oversight. We recognize that the nature of health IT and its role in clinical research is constantly evolving, and that future regulatory action and oversight might be appropriate. With this possibility in mind, it is essential that the Department of Health and Human Services (HHS), FDA, and other agencies involved provide clarity and consistency, especially in relation to potential regulation in this space.

  For any final regulatory guidance, we encourage FDA to call for and incorporate detailed stakeholder input and careful study, to ensure that it is striving to provide clarity to stakeholders and reduce their uncertainty. HIMSS welcomes the opportunity to work with FDA to strike an appropriate balance.
• **Create/support an environment of learning and continual improvement**

Any sort of learnings that come from the private sector, other government agencies, or other collaborative efforts needs to be shared amongst all stakeholders. FDA will need to institute policies to ensure that this information is shared appropriately and encourage clinical investigators and other stakeholders to incorporate these advances into their research processes.

In addition, the idea for incentives for sharing and exchanging health information should be explored further in the clinical research context. In *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* from the Office of the National Coordinator (ONC) for Health IT, HHS committed to a natural lifecycle of policies to drive interoperability beginning with incentives, followed by payment adjustments and then conditions of participation in Medicare and Medicaid programs.

Overall, data is fundamental to the premise of care transformation and clinical research as well as foundational to the success of a learning health system. Data support analytics, knowledge, and improvements. Ensuring data quality takes time and effort. HIMSS recommends that FDA work with other government agencies to make resources available to ensure high quality and timely data is provided in the clinical research setting. Additionally, because these data issues are both critical and universal to all providers, HIMSS suggests that FDA work with partners to provide and make available technical resources and education to interested providers and researchers, which go a long way toward helping to spread data best practices that promote clinical research.

3. **Identify any clinical, cultural, business, regulatory, or other barriers perceived by stakeholders that serve as a disincentive to the use of technology to facilitate the conduct of clinical investigations.**

   a. **What challenges do stakeholders anticipate in adoption of these technologies or methods? Are there challenges in complying with regulatory requirements surrounding the conduct of clinical investigations that use such technologies or methods?**

HIMSS focuses its efforts on ensuring that health IT and patient engagement techniques help deliver better care and outcomes to all our patient populations. We support the idea that employing new technologies in care practices would afford physician investigators the opportunity to use those same technologies for clinical research purposes. Remote patient monitoring is one of those areas that can significantly improve care delivery while also assisting in clinical research. We will continue to advocate for the expansion of the role of telehealth technologies and services, and we encourage FDA to consider how it can support telehealth and remote patient monitoring to ensure that it continues to become an even greater part of the care delivery infrastructure and tool for more effective clinical research.

HIMSS has consistently highlighted the need for expanded flexibility to aid telehealth providers and complement face-to-face interactions which support population care. We have also pushed to expand the definition of telehealth beyond a synchronous audio-visual interaction. The Centers for Medicare & Medicaid Services (CMS) have demonstration projects underway to test interventions that use EHRs, remote monitoring, and mobile diagnostic technology as part of strategies to increase quality of care and decrease costs. HIMSS notes Medicare covers telehealth services in certain cases, but several
other issues come into play when discussing these services that impact the creation and promotion of the infrastructure to help the clinical research enterprise.

For example, eligible originating sites for telehealth services can only be at approved medical facilities, which limit the reach of telehealth into patient homes. Those patients who receive care primarily in the home would benefit from access to telehealth services at their residences. HIMSS notes the opportunity to include the patient home or residence as an extension of an originating site. Given the broad advances in technology, focus on patient-centered care, and the concept of the medical home, an opportunity is available to assess technology and consumer access to such advances. By including other appropriate sites within the definition of originating sites, the stage is set for ensuring continuity of care, and not just episodic fee-for-service models, while also promoting clinical research. HIMSS recommends removing the eligible originating site requirements or substantially expanding the options.

In addition, many new platforms that enable remote patient monitoring rely on store and forward practices. The store and forward restrictions under Medicare overlook the value of information (such as patient-generated and remote patient monitoring data) that is not gathered during a telehealth visit. Moreover, patient-generated health data is routinely highlighted as an enabler of engaged, patient centric models of healthcare. There is an opportunity to gain better historical information, improve patient outcomes, and enable an expansion of clinical research opportunities by relaxing the remote patient monitoring store and forward exclusions.

Moreover, the idea of open data sources also needs to be considered a priority in this context. HIMSS would like to encourage the establishment of more open databases to help further and promote clinical research. In terms of patient engagement and activation, it is also important to ensure that there is patient access to and portability of information from clinical trials. As more people share their personal health information with or participate in clinical research, there should be some assurances put in place for patients to be able to access and use any information derived from those trials in the development of their own care plans.

HIMSS is committed to being a resource to FDA on the continued advancement and improvement of incorporating technologies and innovative methods into clinical research. We look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, Senior Director of Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

Dana Alexander RN, MSN, MBA, FAAN, FHIMSS
Vice President, Clinical Transformation
Divurgent
Chair, HIMSS North America Board of Directors

H. Stephen Lieber, CAE
President & CEO
HIMSS