July 18, 2016

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

athenahealth

311 Arsenal Street
Watertown, MA 02472

Re: Use of Electronic Health Record Data in Clinical Investigations

Submitted electronically via www.regulations.gov

Dear Dr. Califf,

athenahealth appreciates the opportunity to comment on the Food and Drug Adminstration ("FDA") Draft Guidance for the Use of Electronic Health Record Data in Clinical Investigations.

We provide electronic health record ("EHR"), practice management, care coordination, patient communication, population health, data analytics, and related services to physician practices and hospitals. Working with a network of over 78,000 healthcare professionals in all 50 states, all of our providers access our services on the same continuously-updated, network enabled, cloud-based platform. Our clients enjoy an ever-increasing level of connectivity to the rest of the healthcare ecosystem, conducting 17 million transactions daily with over 131,000 end points over 278,000 interfaces and 175 application program interface endpoints. As actively participating members in multiple private sector interoperability initiatives, including the CommonWell Health Alliance, Carequality/the Sequoia Project, and the Argonaut Project, we see in real time the benefits from seamless information flow across the entire continuum of care.

athenahealth supports the goals of the guidance, particularly the use of EHR data in clinical investigations and promoting interoperability between EHRs and electronic systems that support clinical investigations. Clinical trials offer a significant benefit to the care of patients as a treatment alternative for physicians. However, there are many challenges that physicians face when engaging in clinical trials which often prevents participation and discourages them from engaging in multiple clinical trials, to the ultimate detriment of patient health.

As you know, physicians face challenges in collecting and reporting data in clinical trials because the systems used to capture data for clinical trials and EHR systems remain separate. As a result, treating physicians that are also participating in a clinical trial are

forced to 'swivel' back and forth between their EHR and electronic data capture ("EDC") system, which leads to additional time, work, and potential error in the documentation related to a clinical trial. To the extent data collected directly in the EHR can be used as supporting documentation in the trial, transmitted through a standard interface from the EHR to the EDC, duplication of data entry can be avoided. This in turn would improve efficiency in the trial and help to mitigate inaccuracies in the data captured, thus reducing patient safety risk and improving both the care delivered and the clinical trial. Additionally, interoperation between EHRs and EDCs would allow for more complete and accurate treatment of a patient, by providing treating physicians with the most up to date findings related to their patients, at the point of care.

However, we urge FDA to resist the impulse to regulate this degree of interoperation through a heavy-handed approach. The benefits of connecting EHRs and EDCs are apparent to all stakeholders, and with EHR adoption reaching ubiquitous levels, we believe that market forces will be sufficient to drive progress in this area. FDA's focus should be ensuring that its rules and sub-regulatory guidance clearly contemplate interoperation between EHRs and EDCs, that existing regulations applicable to EHRs are taken into account (such as the Office of the National Coordinator for Health IT ("ONC") Certification Program), and that it does not place unnecessary burdens on the exchange of information between EHRs and EDCs.

Specifically, as an ONC certified EHR, we agree that the attributes that are required of source data systems (attributable, legible, contemporaneous, original and accurate) are considered and reviewed as a part of the ONC Health IT Certification Program. Any additional EHR certification for the purpose of interoperating with EDCs would be unnecessary, and we encourage FDA to finalize this aspect of its guidance as proposed.

Finally, as the agency continues to assess the role of EHRs in clinical trials, we urge FDA to consider the significant challenge that the healthcare industry faces in the identification and recruitment of patients for clinical trials. We believe that there is additional opportunity to leverage the use of EHR data for the identification and recruitment of patients in clinical trials, as EHRs provide a more longitudinal view of a patient's past medical history and would enable treating physicians to much more readily identify patients that qualify for trials based on their medical history. Use of EHR data in recruitment would bring efficiency to the process of launching a clinical trial, and it would also improve the overall success of the trial, as patients may be less likely to drop out or be disqualified from participating due to conditions that are discovered further into the trial process. FDA should ensure that its policies encourage a 21st century approach to clinical trials, including recruitment.

We look forward to continuing to work with your agency on promoting the use of EHR data in clinical trials.

Sincerely,

Stephanie Zaremba
Director, Government and Regulatory Affairs
athenahealth, Inc.