

February 3, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of National Coordinator for Health IT
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. DeSalvo:

On behalf of Anolinx, LLC, we are pleased to provide written comments to the [Federal Health IT Strategic Plan for 2015-2020](#) published on www.healthit.gov.

Anolinx™ is a specialized clinical research organization (CRO) that helps large pharmaceutical manufacturers make more informed decisions regarding the design and conduct of clinical trials and other research. Anolinx™ also assists in the accelerated development of new medicines by analyzing identified and de-identified electronic health/medical records (EHR/EMR) for a variety of clinical research projects, such as:

1. Data-driven patient identification and recruitment
2. Site identification
3. Protocol design and feasibility assessment
4. Pharmacoepidemiology
5. Outcomes research
6. Patient registries

Utilizing our proprietary processes and tools, including advanced informatics and analytics, Anolinx is able to identify patients in our data sources that cannot typically be found in other administrative claims and health-care data. Some CROs are limited to using billing codes (such as ICD-9) to identify patients; however, our clients are often interested in studying patients with a unique medical condition, a sub-type of a given medical condition or patients with other qualifiers (e.g., moderate-severe disease). Anolinx is able to search the clinical documents available in EHR/EMR data to accurately identify these patients and related outcomes of interests.

By taking real world health care data and applying our proprietary processes, tools and technology, we enable our clients to make more informed decisions as they design and conduct clinical trials and develop new medicines. We identify potentially eligible patients more quickly for clinical trials by exploring, describing and quantifying patient populations. We are then able to carefully study treatment and referral patterns, compare patient populations, determine unmet medical needs and define baseline rates of outcomes of interest, including potential adverse events.

Anolinx welcomes the opportunity to comment specifically on the following four topics related to the use of electronic health records to further clinical research and clinical trials:

1. ***Goal 5: Advance Research, Scientific Knowledge, and Innovation***

Anolinx is delighted that ONC and contributing federal agencies acknowledge the value of electronic health information technology in support of research and innovation. Anolinx has validated the 2008

study conducted by the Center for the Study of Drug Development at Tufts University and has demonstrated the value of health IT in clinical and drug research to reduce the overall cost of drug development and time-to-market for new pharmaceuticals. We have, therefore, paid particular attention to the language relevant to clinical trials:

Electronic health data can be used to substantially improve the efficiency, effectiveness, and reach of clinical trials. Researchers can use data to identify target populations, make informed sample size estimations, recruit potential trial participants, collect more baseline data, and, within the framework of integrated health care systems or payer programs, streamline follow-up. Furthermore, conducting clinical trials within the context of existing electronic health data makes it possible to enroll a much greater proportion of potentially eligible individuals increasing the likelihood that trial results are generalizable.

RECOMMENDATION #1: Given our experience of supporting clinical trials and research by leveraging electronic health data and expert informatics, Anolinx recommends that the strategic plan add to the Goal #5 summary that an additional value of electronic health data is to reduce the cost and decrease time to market for new pharmaceuticals.

2. *Objective 5A: Increase access to and usability of high-quality electronic health information and services*

Anolinx strongly supports the Federal Health IT Strategic Plan subgoal to make data more available for use in clinical research and drug trials. We note that strategies for this goal include:

2. Collaborate with private and academic research activities on strategic dataset releases, appropriate data dissemination, data discovery and location mechanisms, and education to support innovative data use

RECOMMENDATION #2: Given Anolinx experience with our customer base of pharmaceutical manufacturers, we recommend that Objective 5A, Strategy 2, be amended to include pharmaceutical manufacturers and CROs as collaborative members, including funding and resource contributors.

3. *Objective 5B: Accelerate the development and commercialization of innovative technologies and solutions*

Anolinx strongly supports the federal objective to accelerate the development and commercialization of innovative technologies and solutions, and in particular appreciates that strategies include:

1. Fund organizational learning and research, and promote innovation for new health IT products and solutions, including mobile applications, that incorporate privacy protections, wearable technologies, advances in big data, computation and analytic methods, and other scientific

RECOMMENDATION #3: In recognition of current research utilizing mobile and remote monitoring devices to gather data for clinical studies, Anolinx recommends amending Objective 5B Strategy 1 to include the use of innovative technologies in support of clinical trials and research.

4. *Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find, and use electronic health information*

Serving as conduits at the intersection between the healthcare community and Life Sciences industries, Anolinx acts as advocate for the pharmaceutical industry and healthcare organizations in the use of electronic health records for clinical trials and research. Anolinx strongly supports the strategic plan objective to increase external use of electronic health record data by multiple constituencies:

Interoperable exchange of health information allows individuals, providers, public health departments, and payers to find, securely exchange, and use vital health information, enhancing care delivery, public health, and research, and empowering individuals to make informed choices regarding their health.

Strategies:

- 1. Establish rules of engagement and a governance mechanism related to standards, data policy, and operations, for electronic health information exchange to facilitate security and interoperability across all types of entities and networks that provide exchange services and safeguards for appropriate levels of information access*
- 2. Work with partners to reduce regulatory and business challenges that impact health information exchange*
- 3. Promote the coordination of care for individuals across the care continuum through innovative care and payment models, shared care plans, and value-based purchasing*
- 4. Ensure health IT products and services support the privacy, technical, and vocabulary standards necessary for capturing, finding, exchanging, and using standard health information across the health care and long-term services and supports continuum, and with individuals and public health entities*
- 5. Encourage electronic information sharing between public and private health providers and payers to promote care continuity*

RECOMMENDATION #4: Amend Objective 2A to include CROs and pharmaceutical manufacturers amongst the partners for development of governance and information sharing goals.

Anolinx appreciates the opportunity to submit comments on this draft Strategic Plan. We look forward to dialogue with CMS, and welcome any questions you may have. For more information, please contact Dr. Aaron Kamauu, Chief Executive Officer, 1-888-968-5469, akamauu@anolinx.com.

Sincerely,

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