11. Extension – Potential Financial Benefits

Estimating the financial value of using electronic health records (EHR) for clinical research is fraught with difficulties for a number of reasons, some of which are enumerated here.

1. Clinical research is a very large domain to consider and complicated array of public and private interests.
2. Business processes are not in place to develop a true accounting of costs in clinical research. The basic challenge in obtaining costs for clinical research processes is that there is not a clear delineation of cost accounting in many facets of research. In many cases, co-mingling of funding sources or cost-shifting from research to clinical care cost centers is sizeable. This practice is encouraged by federal-funding mandates that indicate that the full costs of clinical research projects are typically not covered by grants and contracts, including indirect costs. The result is that there are logistical and pragmatic challenges to full accountability of research costs.
3. Non-uniform health information systems used by organizations sponsoring systems creates an obstacle for obtaining reproducible data and financial models in clinical research.
4. There is no formal assessment of clinical information systems in the grant/contract review processes in many cases, thus there is no driver for standards adoption or certified systems requirements for the conduct of research.
5. In addressing publicly funded research projects, the HHS agencies have traditionally been reluctant to apply or enforce standards for information sets upon grantees or contractors unless clearly specified authority is provided. A noticeable policy exception for HHS has recently been seen with the phased e-government requirement for electronic submission of grant submissions. In the absence of business requirements for use of standards, the appreciation of value through the use of them is weakened.

This reality imposes limitations on the ability to estimate savings in terms of time and money. The following value proposition for the harmonization of standards for the use of EHR data to support clinical research makes several assumptions as a basis for a value discussion. First, the standards will address broad needs across the majority of clinical research, rather than disease process- or methodology-specific standards. Second, the standards will be adopted by a significant market-share of the field of clinical research, such that the value accrued by the facilitation of research processes is apparent to multiple stakeholder groups. Third, the implementation of the standards will not facilitate research at the expense of normal clinical care workflow and thus accrue costs outside research participation. Fourth, the standards will enhance the ability of institutions to comply with current regulations and research oversight, as well as readily adapt to future modifications.

This value discussion must also differentiate between the implementation of the standards and the implementation of health information technology (IT), as a whole. There is still significant paper involved in the provision of health care in the United States. The implementation of EHR and associated health IT is also valuable to many stakeholders. This value discussion necessarily focuses on the ability of health IT used in clinical care to support clinical research. While these are two separate value propositions, it is important to recognize that implementation of health IT *without* the standards to

utilize the data for clinical research represents a large opportunity cost incurred by retrofitting IT systems at a later date, rather than implementing a more functional system initially.

In this framework, there are clear benefits gained by shortening the timeframe for research results to inform clinical care decisions and improving the clinical research process. The Value Case for Use of Electronic Health Records in Clinical Research has already outlined the subjective value for various stakeholders in the clinical research community. With the caveat that the costs and how they are reported and interpreted vary widely across research studies and venues, the following is a discussion of the potential financial benefits of the ability to use electronic health records to support clinical research.

Clinical research includes, but is not limited to, interventional clinical trials, observational studies, epidemiology and so forth. Research information gathered could be used for numerous purposes, such as informative publications, government-sponsored research, applications to regulatory agencies for marketing approval of new therapies, population of patient registries, monitoring the safety of research participants, and informing patients of research opportunities.

The overriding assumption is that research benefits to health care consumers would accrue in a number of ways, but primarily the following:

- Improved clinical care decisions informed by the latest trusted research results/quality data
- Efficiencies in clinical research to provide access to safer and better therapies faster

It is important to recognize that the role of health care consumer is different than the role of clinical research participant, as research participants do not accrue value directly from their contribution to research. Aside from the health care consumer, who is the primary beneficiary of quality care based upon effective and efficient research, clinical research has three major 'actor' categories: the site, the sponsor and the recipient. Because of the various ways research is done, these categories are necessarily broad and encompassing.

- Site: investigators, study coordinators, research staff, sub-investigators and anyone conducting the research with subjects
- Sponsor: the individual (e.g. investigator-sponsored studies) or organization responsible for developing and conducting the research protocol in an ethical and appropriate manner, including the principle investigator, academic research organizations, biopharmaceutical companies or CROs
- Recipient: any individual or organization that receives the research results, including the sponsor, IRBs, DSMBs, regulatory agencies, registries, biosurveillance groups

The potential financial benefits include **reduced costs, reduced resource needs and faster cycle times** and **higher quality**. Faster cycle times can also translate into faster recouping of capital investments made in clinical research. Similarly, higher data quality can reduce the number of participants needed to reach a sound clinical decision, resulting in fewer subjects exposed to potentially risky experimental treatments and lower costs associated with the study.

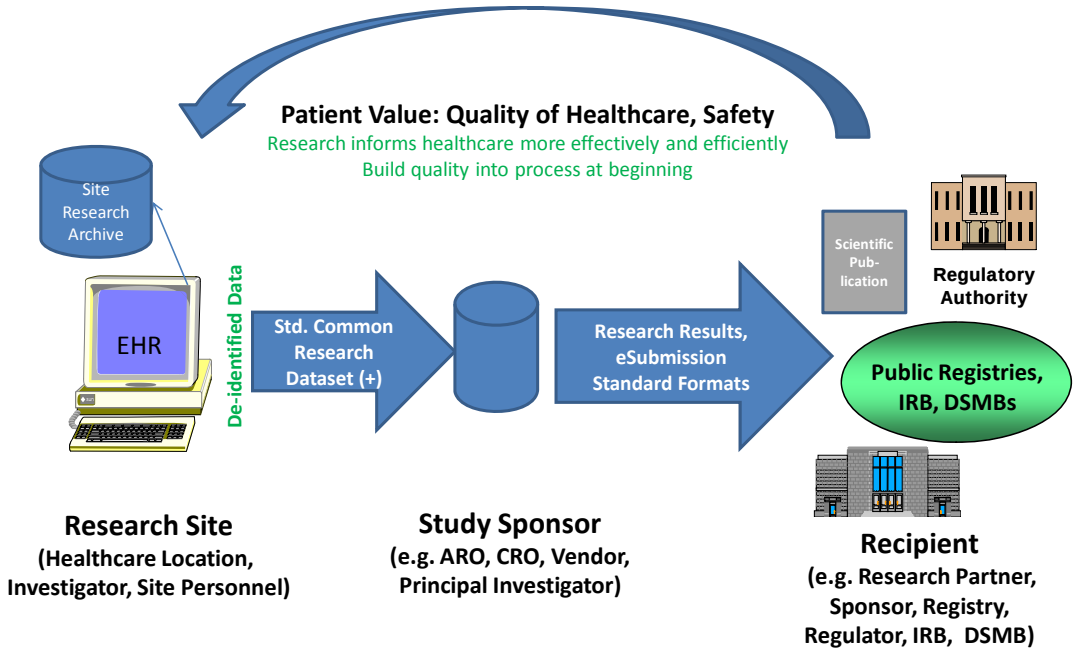
As a previously indicated limitation, there is scarce tangible data on the base costs and the impact of process-related improvements. Therefore, this discussion specifically relates to an individual clinical

study and benchmark industry data. Hence, the following estimates are based upon this data with respect to the impact of

a) eSource or Single Source (i.e. entering data once into an EHR vs. multiple times into a medical record and separately into an EDC system or a paper CRF)

b) using data interchange standards for data collection and transaction

The following figure indicates the three main categories of actors, with the subsequent tables referencing available figures on cost/time benefits.



Site

Inability to Transact Clinical Data to Research Systems	eSource (EHR as Source) with Standards
Site enters data two or more times	eSource would reduce cost and time for data entry by 50% or more eSource would reduce time to reconcile CRF with source data Improved quality of single data entry with 90% fewer errors and queries reduced by 80% [a] eSource would reduce cost to verify CRF with source Trial length has been reduced by 30% using eSource [a]

Site has different data entry and query resolution requirements for each study sponsor and their respective data collection tool (CRF, eCRF)	Standards for data collection would reduce training costs on different requirements per sponsor Standards for data collection would reduce errors made due to misunderstanding proprietary requirements Standard data collection fields would reduce time to start-up study eSource – use of EHR for study data would minimize customization requirements for EHR vendors to work with multiple sponsors, facilitating site data collection
Sites often do not do more than one study due to cumbersome research processes – data collection and query resolution	Standards and eSource reduce the burden on the site personnel Standards enable regulatory compliance (data archives and audit trails inherent in the standards-based systems) eSource and standards integrate workflow into normal clinical care processes

Estimated Savings: 30-50% of costs per study, primarily study coordinator time

For a "benchmark" clinical multicenter study with overall costs of ~ $10M, 40% would presumably be investigative site costs. Savings of 30-50% for this study would be $1.2-2 M; for a $1M multicenter study, the savings would be $120K-200K. At an individual site, a study coordinator could potentially have 30-50% more time to do additional activities and the site would presumably be willing to do more than one research study. This decreased burden of research processes would also eliminate a barrier for clinicians to participating in clinical research.

Sponsor

Inability to Transact Clinical Data to Research Systems	**eSource (EHR as Source) with Standards**
Over 50% of studies are still using paper CRFs; those that use eCRFs typically require the re-entry of data from EHRs or paper medical records into EDC systems	With eSource, errors of transcription would be decreased; CRAs or monitors query resolution time could be reduced with 80% fewer queries having been reported [a]

Study start-up time is on the order of 5 months [b]	eSource and standards can shorten this time by 70-90% since many CRF fields/forms are standard [c]
Integration of laboratory data may require transfer from central laboratory into sponsor database and to investigative sites	Standards for lab data have reduced set-up time for transfers by 90% [d]
Study conduct requires monitoring visits and query resolution through manual source data verification – currently takes ~ 4 months [b]	Duration of non-subject participation part of the study can be reduced by approximately 40% through online monitoring and/or eSource, eliminating the need to verify CRF data with source data [c] and reduced queries [a] Standards reduce training time for project team on study-specific data formats and query resolution requirements Time to database lock (sufficiently validated data to permit breaking blind) reduced by 60% [a]
Programming for analysis and reporting currently takes ~ 5 months [b]	Standards reduce programming set-up requirements for study-specific data formats by as much as 50% through use of macros [c]
Some organizations still have proprietary standards or use no standards, requiring repetition of protocol and CRF development, database development, edit check programming, validation, analysis and reporting for each study	A core set of industry data interchange standards allows standardized processes from study start-up through reporting. Overall savings of non-subject participation time has been estimated at 60% [c]

Estimated Savings: 60% of non-subject participation, primarily sponsor project team

For the Sponsor, the use of eSource and data interchange standards can reduce 60% of the time and cost of the non-patient participation portion of a 'benchmark' clinical study. If the study is $10M and 40% is for investigators, then we have a $3.6 M savings. The sponsor team would also have 60% more of their time/resources to do other activities.

Recipient

Inability to Transact Clinical Data to Research Systems	**eSource (EHR as Source) with Standards**
Sharing data with partners, within the project team (e.g. CROs, sites, contractors, vendors, technology providers) or outside (e.g. IRBs, Data	Data interchange standards enable the ready exchange of information without excessive mapping or programming. This can save

Safety Monitoring Board, study registries, regulatory authorities) requires set up, execution and validation of data transfer with associated mapping and programming	significant time and cost, on the order of weeks and between $10,000 and $40,000 per transfer [e]
If the recipient is internal and the studies are done by various vendors or CROs, integration of these data into a single warehouse or database can be time-consuming if not impossible.	Integrating data into a common repository can be far more efficient if the data are in the same format thus requiring far less programming [f] Integrated databases can be quite valuable, providing cross-study information that can eliminate the need for further studies (on the order of $25 M and over a year of resources doing another study [g]
If the recipient is a regulatory authority, it could take weeks or months to understand the submitted data and transform it into a format to use state of the art review tools.	Data in standard formats allows for the use of state of the art review tools, facilitating comprehension and review of information in integrated databases.

Estimated Savings: Depends on the recipient, but data transfer time and costs are minimized with industry standards and tremendous value comes in being able to readily integrate data across studies and employ review tools.

It is difficult to estimate the value of eSource and standards for the recipients since they vary so widely. It is always very difficult and sometimes impossible to integrate data from various studies into a common cross-study database if the data are not in a standard format and map data into standard formats to allow for such integration if and when the data are collected in proprietary or non-standard formats. Yet, aggregated data are incredibly valuable in understanding research results and ultimately for improving patient well-being and population health.

Research sponsors (e.g. academic institutions and government agencies as well as biopharmaceutical companies) and regulators need to be able to access aggregated information to make better decisions. According to Gartner, by 2010, a 30% improvement in clinical trial efficiency will save the industry $7.5 – 8.8 billion annually [c]. The clinical research endeavor is larger than the biopharmaceutical industry; national spending on medical research is on the order of $100 billion. Globally, this spending is far greater still.

Clinical Research and Electronic Health Records

Although the value case focus is initially for a core set of information to be exchanged between EHRs and research systems, depending upon the study, this core dataset could represent from 40-80% of the data required. This value case will provide a foundation for future value cases. These value cases will bring additional benefits to patients, sites, sponsors and recipients. They include:

- patient identification/recruitment, which will increase the opportunities for patients and sites to participate in research;
- pharmacogenomics, which will increase knowledge of patients that may or may not respond to particular therapies;
- compliance, which ensures ethical and well-conducted research studies; and
- safety monitoring, which improves the way that safety of therapies is ensured.

If EHR standards and interoperability specifications are developed without these research needs in mind, such opportunities will be lost.

Recent information indicates that the adoption of electronic health records is low, on the order of 2-20% depending on how one defines an EHR. However, there is a global swelling of interest in moving paper records into an electronic form within a number of countries, including the U.S. Although only about 50% of studies use eCRFs and there are not precise estimates for the resource, time and cost benefits, it is clear that there is sufficient evidence of the value of capturing data in an electronic format and for using standard exchange formats.

Much of the accrued value of more efficient health information exchange, however, is accrued by those furthest downstream. For example, the real net asset value of standards in clinical trials may in some settings be appreciated by the use of the data or clinical trial results in medical practice. In this situation, the knowledge benefits can be accrued and attributed to the research many years after the study in terms of health care savings, quality of life years saved, or other measures.

The primary goal is to ensure that there is convergence of these two worlds, clinical care and clinical research, with a wealth of common data, such that the standards selected are harmonized and enable an infrastructure that will ensure that the EHRs implemented support clinical research needs as well as clinical care requirements.

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[a] Case Study: J&J and Phoenix Data Systems (J. Andrus)

[b] Parexel Sourcebook and Tufts Center for Drug Development Benchmark Data

[c] Gartner Report: CDISC Standards Enable Reuse without Rework (C. Rozwell); Applied Clinical Trials articles

[d] Case Study: Covance Laboratory (P.Pochon)

[e] White Paper: Cost of Clinical Data Interchange (R. Kush)

[f] Case Study: Genzyme (S. Dubman)

[g] Case Study: GlaxoSmithKline (S. Bishop)