Office of the National Coordinator for Health Information Technology
Strategic Health IT Advanced Research Projects (SHARP)

Progress Report
Program: AREA 4- Secondary Use of EHR Data (SHARPn)
Award Number: 90TR0002
Prime DUNS: 006471700
Principal Investigators: Christopher Chute, MD, DrPh, Mayo Clinic;
                    Stan Huff, MD, Intermountain Healthcare
Program Manager: Lacey Hart, MBA, PMP®

Collaborators:
• Agilex Technologies
• CDISC (Clinical Data Interchange Standards Consortium)
• Centerphase Solutions
• Deloitte
• Group Health, Seattle
• IBM Watson Research Labs
• University of Utah
• Harvard Univ. & i2b2
• Intermountain Healthcare
• Mayo Clinic
• Minnesota HIE (MNHIE)
• MIT and i2b2
• SUNY and i2b2
• University of Pittsburgh
• University of Colorado

1) Program Background
AREA 4- Secondary Use of EHR Data (SHARPn) is a collaboration of 14 academic and industry partners to develop tools and resources that influence and extend secondary uses of clinical data. The program proposed to assemble modular services and agents from existing open-source software to improve the utilization of EHR data for a spectrum of use-cases and focus on three themes: Normalization, Phenotypes, and Data Quality/Evaluation. The program was assembled into six projects that span one or more of these themes, though together constitute a coherent ensemble of related research and development. Finally, these services will have open-source deployments as well as commercially supported implementations. The six projects are strongly intertwined, mutually dependent projects, including: 1) Semantic and Syntactic Normalization 2) Natural Language Processing (NLP) 3) Phenotype Applications 4) Performance Optimization 5) Data Quality Metrics 6) Evaluation Frameworks. The first two projects align with our Data Normalization theme, with Phenotype Applications and Performance Optimization spanning themes 1 and 2 (Normalization and Phenotyping); while the last two projects correspond to our third theme.
2) 2010 Progress Report - Executive Summary

The SHARP Area 4 program (SHARPn) made progress in the spring ramping up resources, refining scope and chartering the six subprojects. The Area was represented by the PI, Dr. Christopher Chute and Program Director, Lacey Hart at the SHARPfest meeting in Washington DC on June 2-3 where collaborations with other SHARP Program areas occurred. The program was highlighted at the Minnesota eHealth Summit June 16-17 in both breakout sessions and poster session. An annual meeting was held in Rochester Minnesota on June 21-22 with over 60 attendees in person and several key stakeholders teleconferenced in. Presentations, demos and posters presented at the event have been publically posted to the program Wiki site: http://sharpn.org. The Advisory Committee and project leads are organized and the chartered subproject teams are meeting weekly moving through the planning phase to a project execution phase at a rapid pace.

The SHARPn project teams continued moving from planning to execution and members were actively engaged in collaborations. A cross-SHARP program synergy assessment was conducted with cross-SHARP area tasks mapped and plans for resourcing scoped. The Data Normalization project team released a Clinical Element Model Library and web search tool: http://intermountainhealthcare.org/cem. The clinical Natural Language Processing (NLP) group released new NLP annotator software cTAKES; this includes an updated medication annotator that will allow researchers to extract drug mentions from clinical free text. It also includes a dependency parser, a foundational component that analyzes syntactic structure. This building block enables the development of future cTAKES components that utilize grammatical context to extract events, attributes, and relations from clinical documents. The Highthroughput Phenotyping (HTP) team completed evaluation results available for 13 algorithms from the electronic Medical Records & Genomics (eMERGE) Network with respect to data elements used, terminologies used, and phenotyping logic for representation of the algorithms. Preliminary draft of a manuscript for submission to the 2011 AMIA Annual Symposium is available.

Moving into 2011, the SHARPn team faces two significant scope decisions which it will review with the Project Advisory Committee: PCAST report alignment and persistence layer standardization.
3) Research Update: Cross-integrated suite of project and products

a) Clinical Data Normalization & Evaluation Framework

In 2010, the two defined projects of Clinical Data Normalization and Evaluation Framework that represent the ‘bookends’ of the program were combined for scope synergies and resource sharing.

i) Aims: Build a generalizable data normalization pipeline, establish a globally available resource for health terminologies and value sets, and establish and expand modular library of normalization algorithms. Iteratively test normalization pipelines, including NLP where appropriate, against normalized forms, and tabulate discordance. Use cohort identification algorithms in both EMR data and EDW data. (normalize against CEMs).

ii) Progress:
(1) Designation of Clinical Element Models (CEMs) as canonical form.
(2) Collaborations with cNLP and HTP teams to utilize use case scenario’s (PAD, CPNA, etc) for Clinical Element Model (CEM) normalization.
(3) Exploration into generalizable CEM models – diagnosis, medications, labs.
(4) Several communications and meetings with SHARPn High throughput Phenotyping team to discuss the feasibility of the RDF representation.
(5) Development of processes/tools to identify relevant existing CEM models within CEM libraries
(6) Development of processes to identify missing CEMs for data (and classes of data) in use-cases.
(7) Collaboration with SHARP Area 3 in modeling discussions and CEM application.
(8) Defined a template for modeling CEMs using OWL.

iii) Milestones Reached:
(1) The Data Normalization project team released a Clinical Element Model Library and web search tool: http://intermountainhealthcare.org/cem.
(2) Preliminary analysis of the benefits on RDF representation of CEM.
(3) A preliminary high-level architectural plan (Step-based knowledge acquisition) for integrating UIMA, BPEL, and NHIN CONNECT has been developed and discussed within the HTP team, as well as, Data Normalization and Infrastructure teams.
(4) Selected representative models as the study cases for OWL representation.
(5) Defined CONNECT software environment (C32 specs; CEM subsets formulate XML docs (part of meaningful use).

iv) Next Steps:
(1) In collaboration with the Regenstrief Institute, this team will implement Regenstrief HOSS Pipeline into SHARP 4 computing environment and move to UIMA platform conversion for this pipeline.
(2) Formalize Meaningful Use vocabularies into LexGrid server
(3) Design other components of Data Normalization framework (Terminology Services - NHIN connections).
(4) Maintain collaboration with Area 3 with CEM models and persistent layer cohesion.
b) Clinical Natural Language Processing (cNLP)

i) Aims: Information extraction (IE): transformation of unstructured text into structured representations and merging clinical data extracted from free text with structured data.

ii) Progress & Milestones Reached:
1. Detailed project plan finalized
2. Aligned Clinical Element Models (CEM) and their application to NLP. Developed a prototype annotation schema as a starting point for mapping cTAKES NLP output to CEMs.
3. Started cross-site discussions associated with the Common UIMA type system which is a critical component for the software.
4. Developing guidelines for the deidentification process. Created a Knowtator project for that task and provided training and support for the data deidentification during the reported period.
5. Developed methodology for the design of the clinical narrative data for the NLP project. The corpus will consist of two layers: seed and stratified. This will be the corpus to be annotated with gold standard annotations on which machine learners will be built.
6. Began work on the common evaluation workbench in UIMA to be used by all co-investigators throughout methodology development and evaluation. The workbench will be extensible, modular, and self-contained (i.e., a single application that is installed on the user’s hard drive with all necessary related software or tools).
7. Created SVN repositories that will be used to share code and annotated data among programmers and annotators
8. Built two complementary de-identification systems that combine the strengths of existing de-id systems, referred to as base de-id systems, for better combined performance.
9. Built a semi-supervised learning framework that improves bootstrapping performance by "budgeting" the limited number of annotated training samples.
10. Began to develop a module that generates synthetic data as a replacement for PHI identified by the de-id module. This creates narrative medical texts that read naturally and retain much of the original’s linguistic structure and complexity, but without allowing identification of the original patients. This tool will also be available to others in the project.
11. Built and evaluated new methods to recognize co-reference among non-identical textual descriptions of the same clinical entity.
12. Provided medication extraction capabilities for the medication SMaRT app
13. Design, implementation and porting of cTAKES annotators for smoking status, side effects and coreference in progress.

iii) Next Steps:
(2) De-identification of the seed corpus is underway to be shared across sites by end of January, 2011.

(3) Organizing a Security Roundtable for Cloud-Deployed NLP, May 23-24, 2011 in Seattle, WA. Participation from SHARP 1, 2 and 3 is expected.

(4) Participating in the organization of the 2011 i2b2/VA challenge, an annual shared-task that is in preparation and will take place in November 2011. SHARP NLP team has contributed the ODIE corpus to this event.

(5) First release of NLP results and analysis workbench.

(6) Document outlining SHARP adopted standards and conventions.

(7) Research refactoring cTAKES with UIMA FIT and additional cTAKES release.

(8) Share synthetic data generator and de-identifier tool with collaborating sites.

(9) First release of NLP code repository.

c) High throughput Phenotyping (HTP)

i) **Aims**: To develop techniques and algorithms that operate on normalized EMR data to identify cohorts of potentially eligible subjects on the basis of disease, symptoms, or related findings.

ii) **Progress**:

(1) HTP is focusing on identification and modification of existing, and where applicable, creation of new CEMs (Clinical Element Models) for Electronic Health Record (EHR) based phenotyping algorithms.

   (a) Identification of existing, and relevant, CEMs for Peripheral Arterial Disease (PAD), Type 2 Diabetes (T2D), Hypothyroidism, and Community Acquired Pneumonia.

   (b) Several communications and meetings with SHARPn Data Normalization team to modify existing CEMs, or create new CEMs, where necessary.

   (c) Categorization of CEMs (phenotype-independent vs. phenotype-specific) to facilitate future implementation of the CEM browser.

   (d) Resource Description Framework (RDF) based representation of CEMs.

(2) Focus on a formal definition of the CEM using semantic web specifics.

   (a) Identifying representative models from the CEM repository at Intermountain Healthcare.

   (b) Several communications and meetings with SHARPn Data Normalization team to discuss the feasibility of the RDF representation.

(3) HTP is focusing on leveraging the CDISC protocol representation model for structured modeling of phenotyping algorithms.

(4) Investigating how Business Processing Execution Language (BPEL) and Service Oriented Architecture technologies can be integrated with open-source Unstructured Information Management Architecture (UIMA) developed by IBM.

(5) Addressing issues relevant to variation and heterogeneity of EHR data across institutional boundaries for any given disease or phenotype.

(6) HTP is studying the financial aspects of manual phenotyping Vs. electronic phenotyping using the proposed SHARPn tools and technologies.
iii) **Milestones Reached:**

1. Identification and documentation of CEMs for 3 different phenotyping algorithms (PAD, T2D, Hypothyroidism) in the SHARPn wiki.
2. Preliminary analysis of “gap” between existing CEMs, and what is required for the phenotyping algorithms.
3. Identification and documentation of CEM use cases in the CEM library.
4. Preliminary analysis of the benefits on RDF representation of CEM.
5. Evaluation results available for 13 eMERGE algorithms with respect to data elements used, terminologies used, and phenotyping logic for representation of the algorithms. Preliminary draft of a manuscript for submission to the 2011 AMIA Annual Symposium is available.
6. Preliminary representation of the eMERGE PAD algorithm using CDSIC protocol representation model as well as a “process oriented” representation of the PAD algorithm has been developed. This representation is based on IHE’s Retrieve Process for Execution (RPE) methodology.
7. Project plan to test market value of new EHR based algorithms for cohort identification to facilitate clinical trials; Identification of market metrics for cohort identification based on false positives, and false negatives.

iv) **Next Steps:**

1. Preliminary representation of RDF-based CEMs.
2. Collaboration with data normalization team for representation of patient-specific instance data conformant to the selected CEMs for PAD, T2D, and Hypothyroidism. Collaboration for the semantic definition of CEM using semantic web notations.
3. Recommendations and suggestions to CDISC on evaluation of the protocol representation model.
4. Prototype tooling for natural language processing based extraction of inclusion and exclusion criteria and its representation using the CDISC representation model.
5. Library of phenotyping algorithms to identify cohorts of patients with diseases and conditions of interest for clinical trials, quality improvement, disease registry, CMS etc.
6. Execution and evaluation of the approach for testing market value of new EHR based algorithms for cohort identification to facilitate clinical trials.
7. Manuscript publication/white paper determining economic value and financial aspects for EHR derived phenotyping.
8. Manuscript publication/white paper on CEM analysis.
d) Infrastructure & Scalability
   i) **Aims:** Consult on pipeline design / architectures / configuration; Work with team leads to identify “fit” (or not) of UIMA into subprojects; Develop and deploy virtual machine images that can dynamically scale in cloud computing environments.

   ii) **Progress:**
       1. Motivated by the on-going high-level integration discussions, the IBM team is starting some investigations on improving UIMA consumability by WebServices/SOA infrastructures.
       2. Ordered/received/installed/setup program-wide sharable computing infrastructure.
       3. Decided on initial high-level architectural componentry, and are in the process of installing this on the new infrastructure.
       4. Holding many high level discussions across all teams to determine use of this resource within the project.
       5. Defined CONNECT software environment (C32 specs; CEM subsets formulate XML docs (part of meaningful use).
       6. A preliminary high-level architectural plan (Step-based knowledge acquisition) for integrating UIMA, BPEL, and NHIN CONNECT has been developed and discussed within the HTP team, as well as, Data Normalization and Infrastructure teams.

   iii) **Next Steps:**
       1. Design and development of a detailed architectural plan integrating BPEL, UIMA, and NHIN CONNECT technologies along with other tools.
       2. Preliminary plan for the design and implementation of a SHARPn workbench based on open-source Eclipse platform.
       3. Research refactoring cTAKES with UIMA FIT and additional cTAKES release.

e) Data Quality
   i) **Overview:** Develop statistical profiles of: a) malformed data (failing transformation checks), b) non-semantic data (failing vocabulary profiles), c) inconsistent data (failing phenotype specific profiles), and d) conflicting data (lab or medicine characteristics incompatible with diseases, and the presence of negation and assertion for the same elements). These profiles will include frequencies, proportions, and variance measures. Create statistically based confidence measures that will be reported to the UIMA pipeline, enabling users to dynamically parameterize thresholds for rejection of spurious data.

   ii) **Progress:** Actively participated with Area 4 project areas (Data Normalization, HTP, and cNLP) meetings to:
       1. Quantify data quality and clarify how data quality issues can be identified.
       2. Integrated across projects to gather requirements and standards to establish data quality plan and metrics.
       3. Provided recommendation and methods to improve data quality and/or possible outcomes.
(4) Development of a study design for EHR data comparison and analysis at 2 different academic medical centers: Mayo Clinic and Intermountain Healthcare/University of Utah. Joint IRB under submission and review.

iii) Next Steps:
(1) Compare expected quality of data to actual data quality
(2) Evaluation of variation of EHR data for T2D at Mayo Clinic an Intermountain Healthcare/University of Utah.
(3) Manuscript publication/white paper on data variation and heterogeneity.
(4) Replication study design with University of Texas collaboration.

4) Program Outputs
a) Products
   i) Practical Modeling Issues tutorial released on SHARPn.org wiki.
   ii) The Data Normalization Team released the Clinical Element Model (CEM) Search Tool. Website: [http://intermountainhealthcare.org/cem](http://intermountainhealthcare.org/cem)
   iii) NLP released cTAKES 1.1. This is the first cTAKES release from efforts completed through the ONC-funded SHARP project. The new software includes an updated medication annotator that will allow researchers to extract drug mentions from clinical free text. This was first developed under a grant from the AT&T Foundation. It includes features such as: Frequency, Dosage, Strength, Form, Route, Duration and Drug change status. This version of cTAKES also includes a dependency parser — a foundational component that analyzes syntactic structure. This building block enables the development of future cTAKES components that utilize grammatical context to extract events, attributes, and relations from clinical documents. Click here to download: [https://cabigkc.nci.nih.gov/Vocab/KC/index.php/OHNLP_Documentation_and_Downloads](https://cabigkc.nci.nih.gov/Vocab/KC/index.php/OHNLP_Documentation_and_Downloads)
   iv) Phenotyping library of algorithms (stage 1) available in the SHARPn wiki.

b) Publications and Presentations
   i) Recent/accepted/published
      (1) Chute CG et al. Strategic Health IT Advanced Research Project (SHARP) Area 4: Secondary Use of EHR Data. CTSA-VA Informatics Symposium on Enhancing Clinical Phenotyping, Bethesda, MD.

   ii) Planned
(2) Presentation of COH/CDISC work on ASPIRE (Agreement on Standardized Protocol Inclusion Requirements for Eligibility).

5) Events

June 2-3, 201: 0SHARPFest, Washington DC
The Area was represented by the PI, Dr. Christopher Chute and Program Director, Lacey Hart where collaborations with other SHARP Program areas occurred.

June 16-17, 2010: Minnesota eHealth Summit, Minneapolis MN
The SHARPn program was highlighted at the Minnesota eHealth Summit with Dr. Christopher Chute presiding in informational breakout sessions and Lacey Hart in the poster session.

June 21-22, 2010: SHARPn Face-to-Face, Rochester MN
An annual meeting was held in Rochester Minnesota with over 60 attendees in person and several key stakeholders teleconferenced in. Presentations, demos and posters presented at the event have been publically posted to the program Wiki site: http://sharpn.org.

August 26, 2010: SMArt Developers Meeting, Boston, MA
SHARPn Project leads attended the SHARP Area 3 Developer’s Meeting at the SMArt (Subsitutable Medical Apps, reusable technologies) headquarters at the Center for Biomedical Informatics.

September 3, 2010: Mayo Clinic On-Site Visit, Rochester MN
Dr. Friedman visited Mayo Clinic, the SHARPn coordinating center and engaged with all of the program members via teleconference for an AREA 4 progress update.

October 24, 2010: University of Illinois
Dr. Christopher Chute visited and presented to the University of Illinois and SHARP Area 1 program.

November 1-2, 2010: IBM Watson J Research Lab, New York, NY
Marshall Schor hosted fellow SHARPn technical staff at the IBM Watson J Research Lab in New York for a UIMA deep-dive tutorial and planning session for SHARPn application. Attendees included Calvin Beebe, Sridhar Dwarkanath and Jeff Ferraro.

November 11-12, 2010: Regenstrief Institute, Indianapolis, IN
Dr. Christopher Chute, Dr. Stan Huff, Calvin Beebe, Sridhar Dwarkanath met with Dr. Marc Overhedge and the Regenstrief Institute technical team to begin a collaboration with SHARP Area 4. Particular focus was on the benefits of learning from Regenstrief’s HOSS Pipeline transforms and SHARP 4’s ability to migrate the pipeline into the UIMA Infrastructure.
November 13-17, 2010: AMIA 2010 Annual Symposium, Washington DC
Several SHARPn program resources attended the AMIA Annual Symposium. Dr. Christopher Chute presented with the other SHARP PIs regarding the program and others within the program had papers accepted.

December 13-15, 2010: All ONC Grantee Meeting, Washington DC
Dr. Christopher Chute and Lacey Hart represented SHARPn at the All ONC Grantee meeting. Dr. Christopher Chute presented at a break-out session.

6) Partnerships / Relationships / Alliances
Clinical and Translational Science Awards (CTSA), Mayo Clinic
Collaboration with Mayo Clinic CTSA for development of EHR-derived phenotyping algorithms for drug induced adverse events and side effects.

Consortium for Health Informatics Research (CHIR)
cNLP Team collaboration with CHIR grant at the VA, Salt Lake City around the common evaluation workbench.

electronic Medical Records & Genomics (eMERGE) Network
Collaboration with the eMERGE Network and the SHARPn HTP project team occurred with respect to data elements used, terminologies used, and phenotyping logic for representation of the algorithms. The eMERGE Network is a national consortium formed to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research. Participants in the consortium network include: Group Health Cooperative with the University of Washington, Marshfield Clinic, Mayo Clinic, Northwestern University and Vanderbilt University.

Harvard, SHARP Area 3 Collaboration
Collaboration has occurred with SHARP 3 by providing medication extraction capabilities for the medication SMaRT app. This app was demoed at the SHARP meeting at the Fall AMIA symposium. An additional i2b2 and SMArt platforms collaboration with SHARP Area 3 is anticipated in the adoption of RDF-based representation of CEMs, and algorithms for cohort identification.

NIH Pharmacogenomics Research Network (PGRN)
A collaboration with the pharmacogenomics network for ontology resource to facilitate adoption of standardized terminologies for phenotyping.

ONC Beacon Community Program
Collaborations with the Minnesota, Indiana and Utah Beacons are underway. ONC Beacon’s provide an applied population laboratory for High-throughput data normalization and phenotyping developed in SHARP Area 4.
Regenstrief Institute
A collaboration between the Regenstrief Institute and SHARPn was forged. The SHARPn team will gain benefits of learning from Regenstrief's HOSS Pipeline transforms and the SHARP 4 Data Normalization team will undertake the migration of the HOSS pipeline into the UIMA Infrastructure, providing performance testing.

Texas State University
The SHARPn - Data Quality project team has established a joint collaboration with Dr. Susan Fenton at the Texas State University for data quality replication studies. Dr. Fenton has worked in the health information management field for more than 20 years, including as a researcher and practice leader at the American Health Information Management Association. Dr. Fenton's research interests are health information workforce development, clinical classifications, and data quality.

7) Operational Activities
   a) Started with early with face-to-face collaboration; cross-knowledge pollination.
   b) The first stages of post award are complete including comprehensive project planning to refine objectives of the program, refined work by breaking it down into smaller tasks, sequencing and scheduling, optimization of resources, reviewed aggressive risk planning and defined a change control process.
   c) SHARPn program organization is implemented with fostered social connections across projects. Individual project efforts synergized with timelines in synch; use cases vetted and determined for the first six months of focus.
   d) Dr. Christopher Chute and Lacey Hart participate in the SHARP PI monthly teleconferences. Lacey Hart participates in the weekly Program Official teleconferences.
   e) Project managers are responsible for day-to-day management, execution, and delivery of project team deliverables. Measures are monitored and documented as achievement of milestones by target dates and accomplishment of tasks in accordance with defined expectations. The project managers track progress (scope, resources and costs), proactively manage risk, track lessons learned and report to the stakeholders.
   f) All subcontracts for SHARPn are completed. Data Use Agreements are underway.
   g) IRB & Data Sharing issues have been raised with best practice sharing and inventory of existing agreements between institutions reviewed.
   h) A cross-SHARP program synergy assessment was conducted with cross-SHARP area tasks mapped and plans for resourcing scoped.
8) Personnel / Hiring (ARRA Report)
Budgeted Personnel have remained consistent with justification approved. No significant changes forecasted for the first half of 2011.

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9) Grants Management (ARRA Report)
Expenditures have remained consistent with work scope approved. No significant changes forecasted for the first half of 2011.

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