Date: November 2, 2011

From: Jorge Herskovic
David Kreda

To: Chris Chute, Carl Gunter, Stan Huff, Josh Mandel, Tony Michalos, Tom Oniki, Guergana Savova, Elmer Bernstam, Jay Doughty, Lacy Hart, Ken Mandl, Rachel Ramoni, Jiajie Zhang, Debora Simmons, Jessica Nadler, Ross Martin, David Arney

Re: Pan-SHARP Medication Reconciliation Plan Proposal

This memorandum captures our Pan-SHARP discussions in Washington, D.C. at the AMIA Annual Symposium, occurring on October 25, 2011. This document supersedes all previous memos.

Timeline

2011			
Washington Plan Draft Distribution	Wed	Nov 02	This document circulated to the Medication Reconciliation Working Group (**MRWG)**
Feedback Request from MRWG	Tues	Nov 08	Jorge **Herskovic** / David **Kreda** will incorporate feedback, etc.
Final Proposal Distribution	Thu	Nov 10	Jorge **Herskovic**/ Jessica **Nadler** will circulate final document to SHARP **PI's** and **XO's,** as well as **MRWG** and ONC Observers
Target Approval Date	Fri	**Nov 18**	**CIRCLE THAT DATE !**
Team Virtual Kick-Off	Wed **or** Thu **or** Fri	Nov 30 Dec 01 Dec 02	Jessica **Nadler** to schedule final date to satisfy everyone's schedules
2012			
Team In-Person Kick-Off	Wed **or** Thu **or** Fri	Jan 18 Jan 19 Jan 20	Jessica **Nadler** to schedule final date/venue to satisfy everyone's schedules
Technical Demo (Mercury launch)		July	Exact timing TBD
2013			
Feature-complete Demo (Gemini launch)		July	Exact timing TBD

The target for a medication reconciliation (Med Rec) technical demo (the Mercury milestone, see below) is the next SHARP Fest on/about July 2012.

The Pan-SHARP project will have two deliverables: Mercury (technical demo showing feasibility) and Gemini (feature-complete version that is actually applicable to healthcare). This document covers these two iterations; further versions (Apollo) are possible but out of scope for this plan.

Pan-SHARP Success Criteria

How should the success of a Pan-SHARP project be judged? Here we propose criteria for the success of the Pan-SHARP endeavor.

Phase 1 – Mercury proof-of-concept (SHARPFest July 2012 deliverable)

- Construct a processing pipeline that is able to:
- Take data from different underlying systems (SHARPn)
- Translate it to a common representation (SHARPn)
- Expose it via the SMART API (SMART)
- Present it to the user for medication reconciliation (SHARPC)
- Do so securely and maintaining provenance information (SHARPS)
- Demonstrate effective collaboration among the SHARP programs

Phase 2 - Gemini (SHARPFest July 2013 deliverable)

- Feature-complete code release
- Proceed to lab User Experience (UX)/User Interface (UI) testing at UT-Houston
- Proceed to clinical testing at a site TBD
- Use of the code, in whole or part, by members of the Open Source community
- Adoption of SHARPC UI/UX design for Medication Reconciliation in a different commercial product

The Medication Reconciliation Opportunity

Justification: We believe that the driving clinical need is to prevent Adverse Drug Events (ADEs) and improper medication administration through the review and careful curating of medication lists.

Demo Use Case: To address the production of a reconciled medication list at the time of patient discharge.

User Story for Mercury: An adult inpatient in an internal medicine service is ready for discharge. The resident needs to prepare a discharge summary and final orders for the patient to take home. The resident needs to review the medications the patient was taking upon admission to the hospital, understand the evolution of the patient throughout the hospital stay,

review the patient's problem list, and produce a new list of medications for the patient to take home.

The resident runs a Med Rec Program that pulls information from the patient's admission information and his inpatient medication history inside the hospital. The Med Rec Program compares the admission medication list with the last known medication list and uses the results of the comparison to propose a final medication list.

The resident then edits this medication list and produces a print-out, including precise and visually clear instructions to aid compliance, for the patient and a secure email for the patient's Primary Care Provider (PCP).

User Story for Gemini:

The Gemini iteration will enable alternate methods of input, such as entering information directly, or pulling data from prescription fulfillment repositories or devices directly. The user stories for Gemini will therefore be varied. For example,

1. The patient was referred to the hospital with a referral note containing medication information.
    a. Optionally, the patient has supplemented or contradicted some of this information. In this case, the resident's task is putting together this information with the new desired treatment to figure out the correct medication orders.
2. The patient brings a bag containing medications from her medicine cabinet at home to the PCP's office. The PCP wants to reconcile these with her own Active Medications list.
3. Data from the patient's wearable insulin pump is downloaded and reconciled with the original treatment plan by a diabetologist.
4. The patient's PCP receives a discharge summary from the hospital and must reconcile it with the medication list in his/her own Electronic Health Record (EHR).

Goals for Proposed Med Rec Process: Improved patient safety through fewer medication errors and fewer ADEs. The reconciliation process becomes faster and more accurate, making for more effective use of clinicians' time.

Key factors For Med Rec Success: As complete and accurate a medication history as possible, an accurate and updated problem list, and a clear and unambiguous hand-off medication document to the patient.

Desirable factors For Med Rec Software:

The end-user software should:

- be discoverable, i.e., the user should require little or no training to use it
- provide all relevant information and no more – accurate medication history [and problem history]
- label medications with provenance information when available and pass the original text through to the user interface for presentation to the user if necessary and/or desirable

- provide task-related cognitive cues (which do not violate the proximity-compatibility principle)
- provide a high data to ink ratio, i.e., low/no decorative overhead (see the SMART Reynolds Risk Score for an example)
- allow the user to be in control, i.e. every decision should be made by the clinician.
- be resilient, i.e. degrade gracefully because data can be incorrect, misleading, contain typos or unfamiliar terms, units, etc., and the back-end should pass data through unadulterated if it does not recognize medications or information
- have no impact on the integrity of the back-end system that is passing data to it; and
- be predictable, i.e. given same two inputs, then it should produce the same output

Technical Considerations

The proposed Pan-SHARP Med Rec project focuses on three core needs:

1. Sources of medication data
2. Reconciliation assistance algorithms
3. A user application for viewing and completing the reconciliation process

Medication lists may come from patient interview at admission, interview with family members, a PCP via a reference letter, other e-documents, actual physical medications presented by the patient, structured data from an e-pharmacy benefit manager or pharmacy fulfillment lists.

For the Mercury stage, we will assume that admissions medication lists will be obtained from a referral letter from the patient's PCP. We will extract medication information using NLP from letters, which may be presented by realistic mockups. Eventually, we want such lists to be obtained from diverse sources, for example:

- Manual input into the MR App for patient self-reporting
- Direct (structured) sourcing from the current EMR list of medications
- Other EMR-sourced lists of medications
- HL7 Feeds
- Other structured source data such as pharmacy benefits managers
- NLP of machine readable clinical notes

The front-end of the Med Rec Program, hereinafter the **MR App**, will operate as follows:

- It will permit the clinician to select among known medication lists identified by a title and date, for example, "Admission on October 10, 2011" or "Medications Dispensed in the last 24 hours." For the demo, the dispensing could be in-hospital or outpatient fulfillments; we will leverage any readily-available source of data.
- It will load medication lists and compute the overlap between them and propose a potential reconciliation strategy, e.g. identical medications should be continued, suggest potential matches based upon formulation, brand names, and treatment intent, etc.
- It will present the proposed reconciliation in an attractive way to the clinician who will make a final selection, including dosages

- It will produce an attractive, legible, easy-to-understand printout of the reconciliation results
- It will produce machine-readable output to conform to one or more machine-readable output specifications, one of which will be the SHARPn medication Core Clinical Element Model (CEM) and medication list Core CEM (when developed) (and may also include free text data as permitted by the extant specifications).
- It may provide certain additional services:
- Sending a Med Rec medication list via Direct (secure e-mail) to a clinician and/or patient in both human-readable (PDF) and machine-readable (CDA or other format) forms.
- Posting a Med Rec medication list result to the EHR

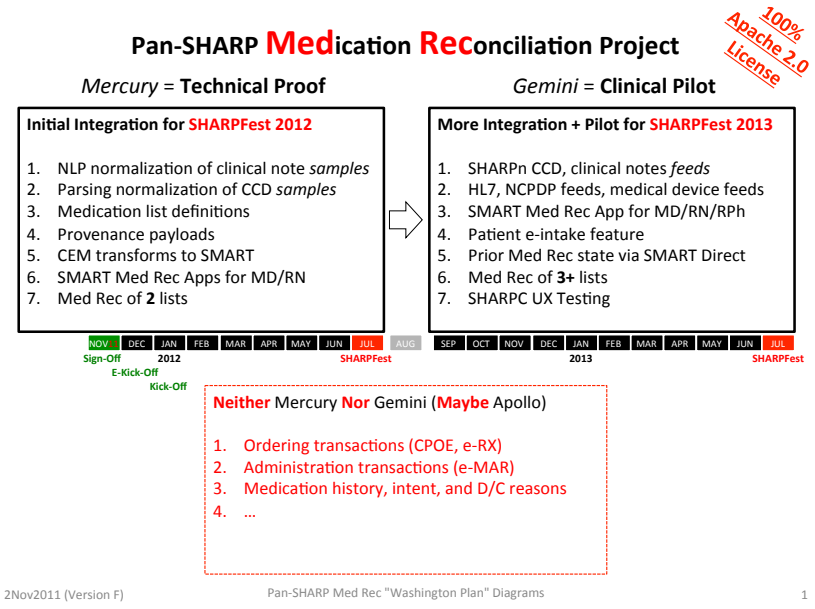


Figure 1 - Proposed timeline and general overview of Pan-SHARP deliverables

Pan-SHARP Bill-of-Materials

We identify two deliverables: the first is Mercury, the proof-of concept, which leverages a lot of existing assets; the second deliverable, Gemini, entails turning the proof-of-concept into a full-featured solution. The required components for each follow:

July 2012 Mercury (Figure 2)

- 2 SHARPC (SMART) MR Apps [same data, different front-end user paradigms]
- 1 SMART Medication List Object
- 1 SHARPC Med Rec back-end reconciliation algorithm
- 1 SMART Container populated by 30 patient records from SHARP.N Pipeline
- 1 SHARPn Software component to translate CEM XML to SMART RDF
- *Optional*: 1 SMART Direct App Implementation

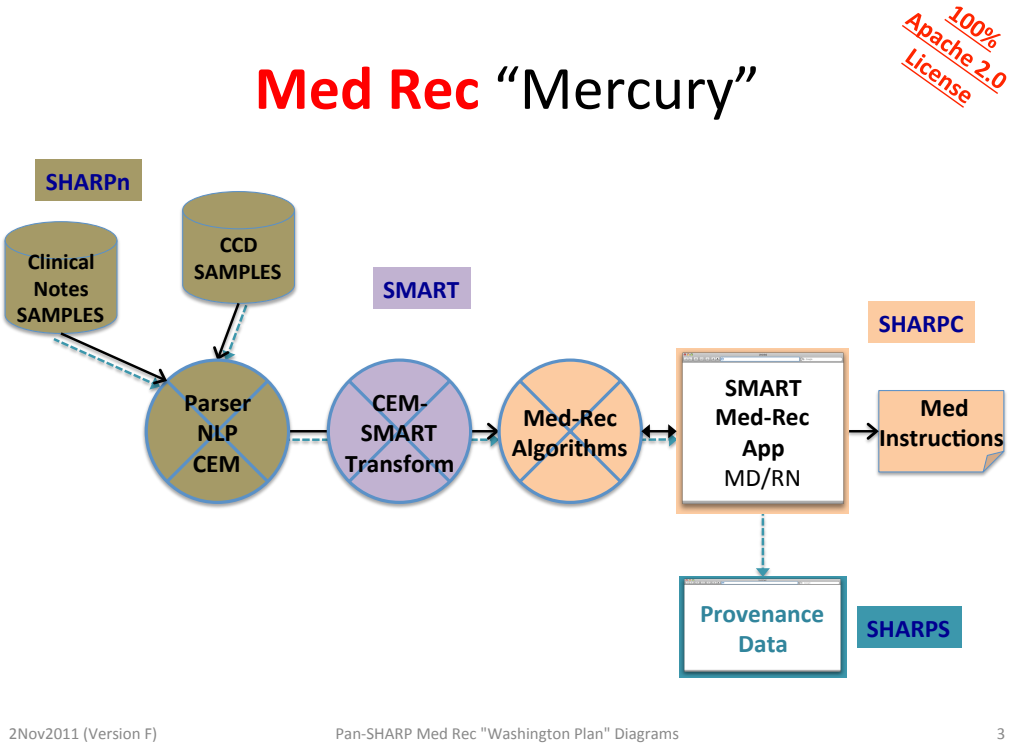
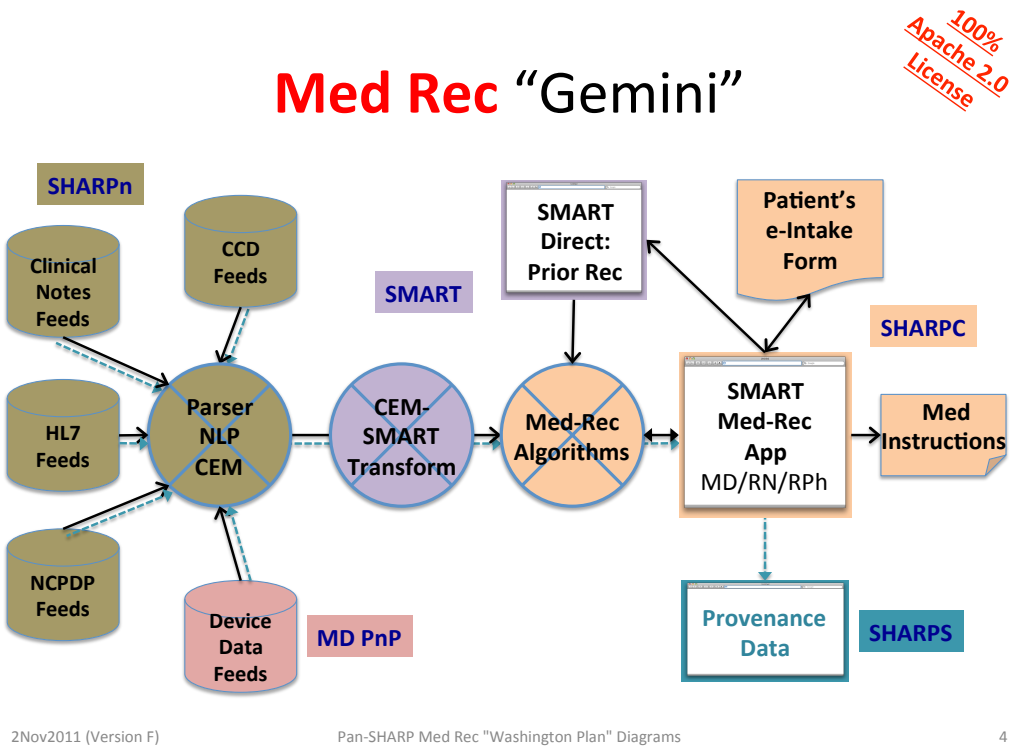


Figure 2 - Mercury workflow proposal. Preprocessed samples are used as data sources. Provenance information is maintained across the entire process by using SHARP.S metadata headers.

July 2013 Gemini



(Figure 3)

- 1 SMART Medication List Write API [writes Med Rec results out to host EMR]
- 1 SMART Application Internal State Write API [persists MR Apps user preferences]
- 1 SHARPn Pipeline that accepts clinical note text to produce medication CEMs
- 1 SHARPn Normalization process to translate HL7 messages into medication CEMs
- 1 SHARPS security configuration for vouchsafing services, storage, messaging
- 1 MD SHARP MD PnP (medical device plug-n-play) data feed from an insulin pump

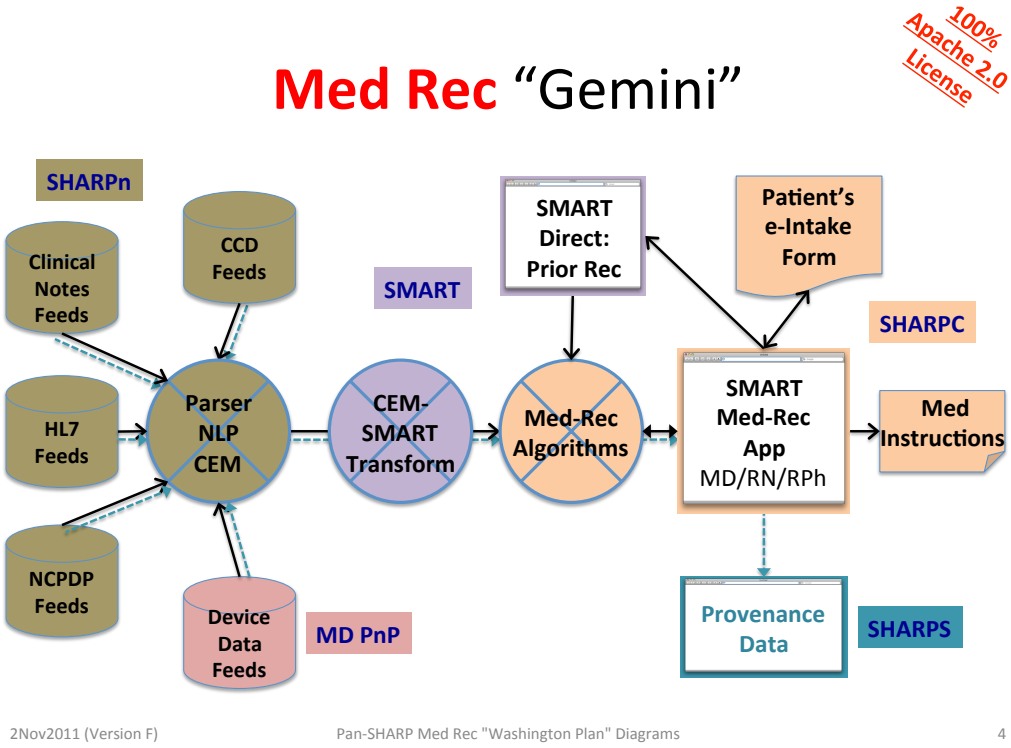


Figure 3 - Gemini workflow proposal

The target IP framework for the deliverables is the Apache 2.0 license. We expect to license 100% of the Pan-SHARP project under Apache 2.0.

Challenges/Gap Analysis For Proof-of-Concept

We list known or suspected challenges to completing the Gemini stage:

- MR Apps' UX are too limited today, e.g. no manual data entry, only two lists at a time
- MR Apps support for variable data entry, e.g. turning "Tylenol" alone into a full CEM
- MR algorithm risk averseness may be considered unhelpful
- Evaluation of NLP via SHARPn Pipeline using real-world data from multiple institutions
- Missing medication data model mapping CEM to SMART
- Missing component to expose CEMs via the SMART API
- Lack of a well-defined "Medication List" data type in CEM and SMART
- Lack of SMART write-support
- Lack of real world EMR support for medication lists
- Lack of real world access to machine-readable admission notes
- Distributed SHARP workforce and competing/pre-existing plans

Mercury Proof-of-Concept Alternatives for Data Integration

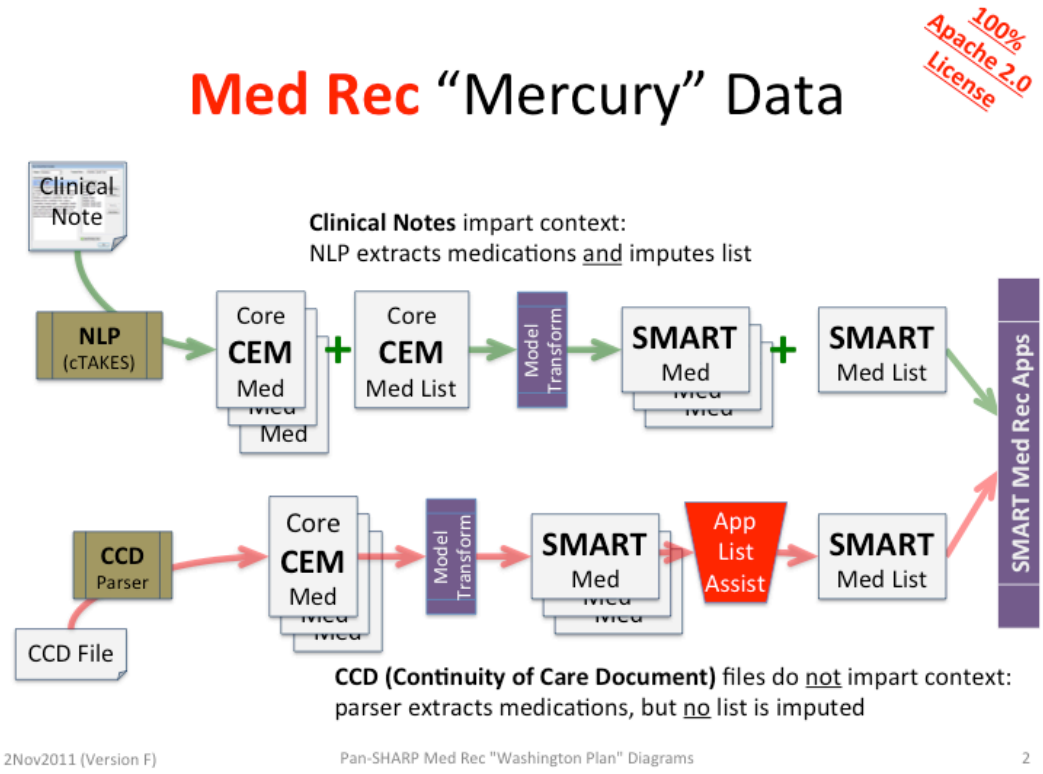


Figure 4 - Proposed data flow for Mercury

Integrating data (SHARPn) for the proof-of-concept could be pursued in several ways:

1. **SHARPn Standalone Pipeline (On-Demand Processing)**

- MR App gets a list of available clinical notes from the container
- MR App or user chooses a note
- MR passes note text to an independent installation of Pipeline
- MR App obtains a SMART-formatted Medication List object with med results

2. **SHARPn Pipeline Data Pre-Population**

- Pipeline pre-processes notes via NLP and HL7 meds + problems messages
- Pipeline generates 1 static file generated per patient converted into SMART RDF
- Sample SMART container loads the data (including multiple explicit med lists)
- MR App can query the sample container for the samples

3. **SMART API Layering on Top of SHARPn Pipeline CEM Store**

   The SHARPn pipeline currently feeds a "CEM store" that holds data.

Could the SMART API be layered on top of this kind of CEM store, exposing the underlying data as SMART RDF?

Team Specific Questions

- SHARPn
  - What are the semantics of mapping HL7 messages (and other discrete medication administration data) to produce a medication list?
  - What technologies do we have available for Pan-SHARP consumption now, and over the next six months, i.e., NLP Pipeline and SHARP.N Pipeline?
  - What corpus of Mayo clinical notes (real source, wholly de-identified) would SHARP.N be willing to share with the Pan-SHARP project?
  - What subset of Tracer Shot data (from Mayo or Intermountain Health) would be potentially available in the near-term to Pan-SHARP?
  - What are the characteristics – fields in the CEM, med list, doses, units, routing, etc. – of these data in the real world?
- SHARPC
  - How do users respond to the UX/UI designs?
  - Are there other interaction models worth exploring (besides drag-drop and columnar lists)?
- SMART
  - What does the SMART container vs. the SMART App do, i.e., what are the limits of the API that may or may not require other, non-SMART service calls
  - What is required for app storage to store medical data of App setting in the absence of a Write API?
  - What are the CEM to SMART data model mapping issues?
  - How to define a Med List object?
  - How to refine a Medication object or declare this out of scope, e.g. it may be over-fitting to support NLP-specific references to “original text”, certainty, etc.

Project Leadership and Management

The project will be overseen by a product manager and a project manager, coming from two of the four SHARPs and one SHARP-affiliated research teams, namely:

Dr. Jorge Herskovic (SHARPC) will be the Product Manager

Dr. Jessica Nadler (consultant for SHARPn) will be the Project Manager