Solicitation:

ONCHIT-1

The Evaluation of a Standard Harmonization Process for Health Information Technology

Offeror:

Records For Living, Inc.
34 Church Street
Sudbury, MA 01776
(978) 460-0539
info@RecordsForLiving.com

Persons authorized to negotiate on the offeror's behalf and to sign the proposal:

Simone L. Pringle
President and Founder
(978) 460-0539
simone@RecordsForLiving.com

This page intentionally left blank.

Executive Summary

RFP ONCHIT-1 requests proposals to "develop, create prototypes for, and evaluate a process to harmonize industry-wide health IT standards development, maintenance and refinements over time."

It is our belief that standards harmonization efforts are most likely to succeed if they are based on the use of an infrastructure that supports continued standards evolution, while avoiding designs that generate ambiguity, redundancy and gaps. We propose a standards harmonization infrastructure that is based on a secure metadata-driven foundation, with support for reporting, auditing, versioning, and rich transformation semantics. It is fundamental to our Proposal that the metadata-driven foundation be a combination of metadata tools, technologies and governance processes and that these elements, in the context of standards harmonization, be designed to leverage certain existing mature industry solutions such as those that have been successfully used in the fields of database and data warehousing management. These metadata tools, technologies and related governance processes have evolved to support information models that transcend relational schemas as well as transformations that transcend traditional ETL (extract, transform and load) techniques.

The metadata-driven foundation is designed to bring to the standards harmonization effort those benefits attributed to the use of metadata technologies. Universally acknowledged benefits of metadata usage include support for traceability and data lineage; information lifecycle management; reuse of information assets; reduction of development, maintenance and deployment costs; improvements in data consistency and quality; elimination of ambiguity and inconsistency of metadata; and improved support for assimilation of new information models.

Our Proposal documents the several important parallels between standards harmonization efforts and the more traditional uses of metadata technology, illustrating how a metadata-driven foundation can improve the standards harmonization process.

This page intentionally left blank.

TABLE OF CONTENTS

This page intentionally left blank.

"If you wish to converse with me, define your terms."
Voltaire

1. Overview

Existing health care standards don't insure – or, in most cases – even permit interoperability. The RFP, driven by this fact, requests contractors to offer harmonization process solutions that will solve this problem and, in consequence, achieve interoperability.

> *"Interoperability, for the purposes of this contract, means the ability of different information systems, software applications and networks to communicate and exchange information in an accurate, effective, useful, and consistent manner." [Page 2, RFP ONCHIT-1]*

Our Proposal investigates the commonly agreed factors that prevent the realization of interoperability and, based on that investigation, suggests the use of metadata-driven infrastructures and processes as a solution. Because we assume the reader is familiar with the current state of metadata tools, techniques and governance processes, there is no effort made in this Proposal to provide an exhaustive review of referenced metadata-related technologies. Nevertheless we do provide enough information to allow the reader to correlate the use of specific metadata constructs with the context of standards harmonization.

2. Hindrances to Interoperability

Business processes can often be complex, with workflows that involve multiple users and systems. The term *business process* is being used here in a way that includes the normal set of activities that would support the natural course of delivering health care-related services.

It is not uncommon for multiple systems to be involved in the delivery of medical information pertaining to a particular business process, even in what may appear to be the simplest of scenarios. For instance, a highly automated medical system might interface with a claims processing service, an imaging archive, a clinical system, and a pharmacy all in connection with a single visit to the doctor. In this example, multiple standards will ordinarily have been used for information communication.

Typically, systems integrators are required to work the maze of standards, mapping, transforming and at times approximating information as it travels from one information system to another.

This impedance mismatch in communications between processes using disparate standards represent and reflect the most commonly existing barriers to interoperability, such as gaps and conflicts.

The amount of effort required to overcome such interoperability issues is typically replicated by every new system integration effort, compounding the original issue with ambiguity of usage, and absence of an agreed upon set of consistency checks and business rules. One example of this problem is in the use of HL7 v2.x, where the use of an evolving ad hoc methodology has made it impossible to create reliable conformance tests.

3. Evolution of Metadata Scope and Definition

Metadata technology has evolved tremendously over the years. Initially defined as, "data about data", metadata and the set of tools, techniques and processes that support it have evolved to include a broader usage.

In its original scope, metadata was typically used in the context of databases and data warehousing, capturing information such as:

- Definition of data elements
- Data types
- Valid domain values
- Source of data information
- Frequency of data updates
- Quality metrics
- Database schemas
- Data profiling

The benefit obtained by careful governance and usage of metadata information proved valuable enough to warrant expansion of the original scope to include:

- Messaging definitions
- Data transformations
- Business rules
- Use cases
- Business processes
- System configuration
- Application portfolio

A number of software systems exist today that support rich metadata environments with the full benefits of versioning, access control and extensive reporting. These benefits will be further explored later in our Proposal.

4. Standards Interoperability

The standards harmonization process includes a set of activities that supports the efforts of industry leaders to shift from the current state of affairs to a maintainable steady-state of governance activities that support standards interoperability.

Interoperability will be built on a foundation that includes:

- Specific portfolio of harmonized messaging and vocabulary standards
- Architectural message delivery standards
- Metadata-driven tools and techniques
- Metadata governance processes

4.1 Standards Portfolio

The standards harmonization effort will evolve in a number of different dimensions including changes in supported technologies, content, processes, and messaging and vocabulary standards. An example of a messaging standard that is likely to be harmonized in the near future is messaging standard in support of personal health record (PHR) information exchange. Efforts to specify PHR messaging standards are underway and would likely become a part of the harmonized standard landscape, once it is approved.

This Proposal suggests that an initial set of standards be considered in support of identified use cases. A good starting point is to leverage work already done by the Consolidated Health Informatics (CHI) group, identifying and adopting five standards (March 2003):

- LOINC: Laboratory Result Names
- Health Level 7 (HL7): Messaging standards for
    - Scheduling
    - Medical record/image management
    - Patient administration
    - Observation reporting
    - Financial management
    - Patient care
- NCPDP: Retail Pharmacy transactions
- IEEE 1073: Medical device connectivity
- DICOM: Inter-agency sharing of image data

In addition, vocabulary standards should be considered:

- UMLS
- SNOMED

Other standards can be considered, in particular as their relevance is identified by use cases. An additional source of standards to be considered as part of the initial harmonization efforts might include interfaces to commercial off the shelf (COTS) products, e.g. HealthFrame, LifeSensor and HealthTrio).

The harmonization process itself should support as many inclusions as is desired and driven by the use cases from a strictly procedural point of view. The impact on the effort would translate in increased cost of implementation as new metadata content will need to be supported.

4.2 Architectural message delivery standards

Content delivery includes the actual delivery of instances of standards-based messages, as well as metadata-derived harmonization content (mappings, transformations, gap analysis, etc). A number of delivery mechanisms should be supported for ready access of harmonization information, such as web services and remote messaging. Likewise, support for both point-to-point and broadcast communications are likely to be required.

It is desirable to keep mechanisms for data access, message delivery, and message structure largely orthogonal. Standards protocol efforts such as the Children's Hospital Informatics Program Personal Internetworked Notary and Guardian (PING), support secure transport protocols that support independence of delivery and structure.

Work in this area will likely require coordination with efforts done in the RFP relating to the prototype of a NHIN architecture (ONCHIT-3).

4.3 Metadata-driven Tools and Techniques

All information relating to data and messaging content, as well as transformational and mapping rules across standards, business rules and usage context will be tracked in the metadata system.

Key characteristics of the metadata-driven framework include:

- Being supported by COTS products that minimize effort that is not directly related to harmonization activities. Examples of such products include ASG-Rochade, Ab Initio, Informatica's Super Glue, Assential AuditStage, Hyperion, etc. The effort required to reproduce functionality supported by these products should not be underestimated. Much of HL7 efforts required to create the Reference Model Repository infrastructure are natively supported in these COTS solutions. In particular, as recently as in HL7 v2.x messages were created by a process that included editing of word processing documents by one team, that was followed by a separate process to produce metadata.

It is important to note that while a number of mature metadata tools are available in the market; specific criteria must be met to provide appropriate support to the standards harmonization effort. In particular, versioning and access control are considered key criteria. Additionally, rich transformation semantics support will improve the quality of the communication reports. There is great variability among tools on the level of support of these specific criteria.

- Automated discovery of metadata content. This is particularly important as a productivity enhancement to the process. If messaging and vocabulary standards definitions are available in industry standard formats such as XML (eXtensible Markup Language) schema, it is possible to reduce efforts and the opportunity for data entry errors by automating the process of boot-strapping standard information in the metadata repository.

- Full versioning support that allows the standardization team to produce consistent, point-in-time interoperability designs.

- The ability to track the portfolio of supported messaging and vocabulary standards (with specific standard version information), the mappings and transformations across standards, definition information (including data types, size, etc), and mappings to use cases.

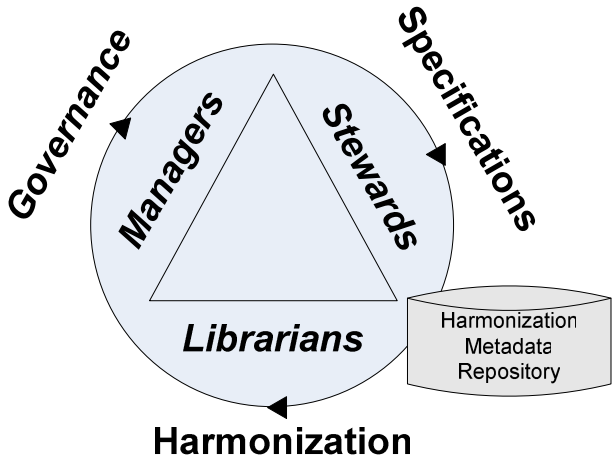
- The ability to produce full audit trails and other analytical reports that support the governance processes.

- Support for automated generation of code and technical specification and documentation. It is a common practice to define standards using a generic, abstract interfacing specification (for instance, using an interface definition language). The abstract interface specification will typically need to be converted into implementation and channel-specific artifacts (XML schema, programmatic API, etc). The generational efforts that lead to the creation of implementation-specific artifacts are typically guided by standardized mappings, and would typically be a time-consuming activity to be created and later maintained. Leveraging metadata-aware technologies in the generation and maintenance of artifacts saves time, increases productivity, encourages standardization and reduces the chance for errors.

- Ability to interoperate with value-added (EMR systems, rules engines, forms, etc) metadata-aware COTS products that will facilitate the adoption and compliance with standards. Examples of such tools include offerings by Accenx Technologies, Ripple Systems and Symmetry Technology Labs.

4.4 Metadata Governance Processes

The governance process includes a set of roles (managers, stewards, librarians, users) and procedures that work together to ensure the quality of the harmonization effort, ensuring consistency and reducing gaps and conflicts.



Standards harmonization managers are members of the steering committee whose job it is to control the focus of each harmonization effort "release", i.e. targeted use cases, portfolio standard, specific functional subset, etc. The steering committee will be provided with metrics (reports) that will be used to gauge the level of success of each harmonization effort (identified gaps, conflicts, and resolution to gaps and conflicts).

Standards harmonization stewards include modelers responsible for

- documenting the data in information models and automated processes that create, read, update, delete, and archive data (source of the content in the repository);
- ensuring that data about information models (and any changes to them) is provided to the metadata repository or maintain the content in the repository itself;
- applying standard naming conventions;
- identifying the taxonomic classifications that apply to the information elements;
- working with standards representatives to identify (and eliminate, if appropriate) redundant or duplicate data;
- working with each other to promote reuse of repository contents; and
- working with the Repository Manager to identify impacts of changes to the data structures and ensure that all affected parties are notified.

Standards librarians will be responsible for

- managing the repository tools;
- administering security and access control for the metadata repository;

- working with stewards to identify impact of changes to the contents of the repository and ensuring that appropriate collateral materials are generated; and
- managing the change control process including the execution of consistency check reports.

Standards users will:

- rely on harmonization artifacts for current state of harmonization, and notification of changes and evolution of standards harmonization (reports);
- provide feedback to governance team when practical use of the harmonization effort is ambiguous, missing or insufficient.

Governance processes will support:

- the scope specification for each harmonization effort (use cases, standards portfolio, functional subsets);
- data collection and maintenance for harmonization metadata;
- making sure that metadata maintenance tools are leveraging latest technology advances, in line with the harmonization project needs and cost allocation;
- synchronizing the content of potentially distributed repositories;
- capacity planning; and
- change management and versioning.

The process of standards harmonization is an evergreen set of activities that include metadata population, analysis, stewardship and general governance.

5. Metadata Reporting

Metadata reporting in effect facilitates data mining of metadata, providing efficient insight into the relationships and dependencies of information and the context in which it is used (transformations, messages, business processes, etc).

Robust support for extracting metadata information is critical for the following analysis activities:

- Addition of new information elements, or modification of existing elements, while preventing redundancy.
    - Metadata reporting will support the process of verifying that new elements aren't already part of the standard or that changes won't cause overlaps with other existing elements.

- Addition of new information elements, or modifications of existing elements, while preventing ambiguity.
    - Metadata will support definitional content to be tracked for new and modified elements, as well as usage context that disambiguates elements.

- Addition of new information elements, or modifications of existing elements, while identifying gaps.
    - The introduction of information elements may highlight gaps between standards that will need to be addressed by the metadata stewardship team.

- Deprecation/removal of information elements, with understood effect on upstream and downstream dependencies.
    - Metadata tools will support reporting on upstream dependencies (i.e. transformations and processes that produce the information element). This will support impact analysis on the removal of information elements, as well as potentially support changes to how new element(s) will be used as a replacement of the one being deleted.
    - Metadata tools will support reporting on downstream dependencies (i.e. transformations and processes that originate from the information element). This will support impact analysis on the removal of information elements, as well as potentially support changes to how new element(s) will be used as a replacement of the one being deleted.

- Reports that capture metrics on standard harmonization
    - Elements that have not been successfully mapped in the metadata system either due to conflicts or gaps can be identified in the reports, providing a metric of the level of harmonization achieved by any particular version of the standard system.

- Fully versioned support for consistent point in time view of standard interoperability information.
    - The standards governance team will frequently make changes to the interoperability metadata, introducing, changing or removing information at the same time that relationships, dependencies and definitions are being updated. The governance team should be able to produce consistent, transactional views of the interoperability metadata, similar to the ability that software development teams have of producing consistent code releases that can be unit tested and checked-in for use by a larger audience.

6. Standards Harmonization Process

The standards harmonization process consists of a number of different tasks, all of which will tend to evolve to support additional standards, governance representation, changes to content, resolution of issues, etc.

At a high-level the standards harmonization process includes:

- creation and maintenance of a *Harmonization Steering Committee*;

- selection of S*tandards Portfolio*;
- *functional partitioning* of services;
- selection of *Use Cases*;
- population of *harmonization metadata repository;*
- creation of *conformance tests and environment*;
- creation of *standards-neutral reference information model*;
- harmonization metadata governance processes; and
- generation of external and internal *communication artifacts*.

6.1 Creation of Harmonization Steering Committee

This is a role that is likely to be filled by members of the American Health Information Community (AHIC), or other appropriate long-term governance body.

It is critical for adoption and support of harmonization efforts, that SDOs have appropriate representation both at technical and strategic levels (e.g. licensing, review of recommendations, etc).

It probably suffices for an evaluation implementation of the harmonization process to include individuals who have experience with the chosen standards and who can articulate the identified areas of decision-making that will be required to support the continued harmonization effort.

The steering committee will also be responsible for continued fine-tuning of governance processes, including but not limited to specification of additional communication artifacts, and performance metric reports.

6.2 Initial Standards Portfolio

Initial set should be selected in a manner that is expected to meet immediate industry needs for harmonization. A list similar to the one collected in the *Standards Portfolio* section is probably an adequate starting point.

It should be noted that licensing considerations may play a key role in determining which standards are used in the initial harmonization efforts. Please see the *metadata initialization* section below for licensing concerns.

6.3 Selection of Use Cases

Use cases should initially target areas where bootstrapping is simplest, with limited known issues with gaps and conflicts among selected standards.

Use cases will be used to identify portions of the selected standards that will be harmonized, following the steps below. In other words, use cases will be used to select, as is today, the subset of the standards (specific messages, vocabularies, etc) that will be harmonized, initially.

Use cases themselves become a part of the descriptive metadata content, providing upstream dependency information to harmonized content.

It is possible here again to leverage the efforts of the CHI, and consider an initial set of use cases to support:

- Order entry
- Scheduling
- Medical record/image management
- Patient administration
- Observation reporting
- Financial management
- Patient care
- Public health notification
- Lab test result name
- Lab test ordering
- Lab test result value
- New prescriptions
- Prescriptions changes
- Prescription refill requests
- Prescription fill status notifications
- Prescription cancellation notifications
- Instrument data exchange
- Imaging content exchange

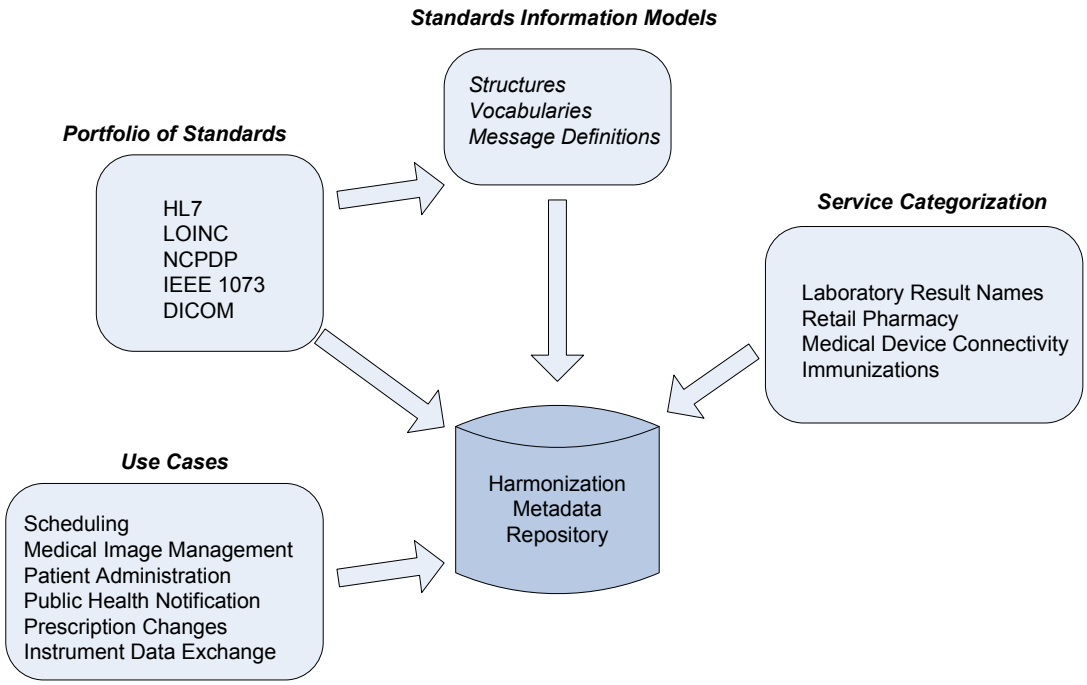
6.4 Functional Partitioning of Services

From a management and taxonomy point of view, it is useful to group functional service clusters and to identify how standards meet the needs of each functional category. The CHI had created a system of domains and sub-domains that could be leveraged as the initial taxonomy. In addition to the five domains supported by the previously identified standards, the following domains should be considered:

- Immunizations
- Medications
- Interventions and Procedures
- Nursing
- Disability
- Population Health
- Genes and Proteins

6.5 Population of Harmonization Metadata Repository

The first overall step in the standards harmonization process is to populate the metadata repository with an initial set of applicable standards-based messaging and vocabulary information. Note that the standards portfolio information itself is part of the metadata content stored in the repository. This is critical, as the harmonization effort evolves to support additional standards.



This is an area where tool supported automation can improve productivity and reduce the chance of data entry errors. The idea is to populate the metadata repository with known standard metadata content such as object models (including definitions, data types, business rules, constraints, etc) using documentation techniques already supported by the standards. Typically, this information can be imported to the metadata repository from UML models, XML schemas, etc.

There is a potential licensing issue here, with standards bodies resisting the centralization of their metadata content. Hopefully a special licensing agreement can be reached with the American Health Information Community (AHIC), which might include limitations to direct access to this metadata content by external parties. Information that is the outcome of the harmonization process, such as business rules and guidelines around gap, ambiguity, redundancy and conflict resolution would be permitted publication, as part of the federal government's harmonization efforts.

6.6 Standards-neutral harmonization information model

It may be tempting to adopt any one standard's object/information model. There are a number of concerns when one considers this approach, however:

- The harmonization process would tend to be mostly phrased from one of the standard's point of view, causing potential concerns with other standards organizations, including potentially licensing concerns.

- Conflicts and gaps that require (or would be better served by) changes to the information model would cause a branching out of the information contained in the harmonization metadata system vis-à-vis that contained in the actual "reference standard". Optionally, the harmonization effort could be at the mercy of revisions to the "reference standard" but that is not likely to be an adequate alternative.

- Some standards have existed for a number of years, prior to certain technological and architectural advances that would have allowed for improved modeling. The creation of a state of the art model would help leverage modern technologies even if certain models may have become somewhat outdated.

- Existing standards may rely on a particular set of codes that does not support cross-referencing and code simplification efforts (e.g. UMLS). A standard-neutral information model would be more attune to the industry's need to consolidate around vocabularies.

A standards-neutral information model would give the standards harmonization team the flexibility to articulate, define and document a model that best handles the information that needs to be exchanged over all harmonized standards.

This information can be of great benefit to standards bodies both as documentation and as potential options in their future revisions.

Finally, the existence of a standards-neutral information model provides a "one-off" mechanism for mapping diverse informational content as opposed to potentially requiring many-to-many mappings.

The down-side of creating a standards-neutral information model is that more modeling and analysis is required initially, but we believe future benefits in the harmonization effort (outlined above) outweigh this down-side.

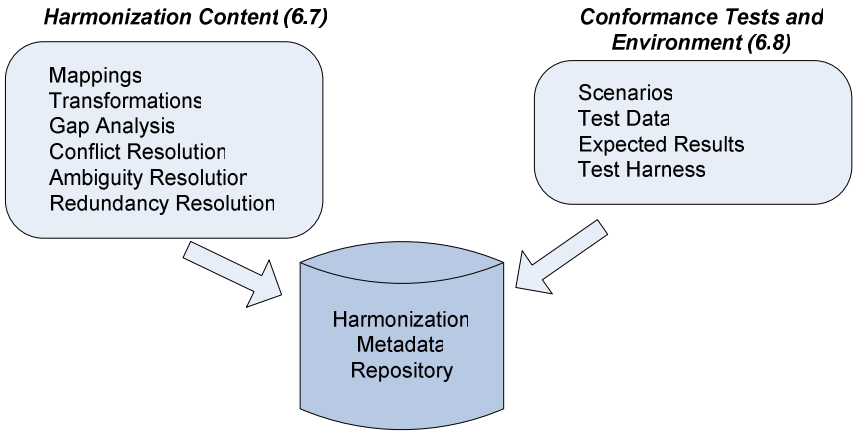
Note that use of a standards-neutral information model or not is an issue that is orthogonal to the use of a metadata-driven foundation.

6.7 Harmonization Metadata Governance Processes

Once metadata information has been captured from the desired standards and the standard-neutral portion of the model has been created, it is possible to start the actual harmonization effort.

In this portion of the effort it is also possible to leverage metadata tools and information contained in the standards documentation to automate some of the harmonization - in particular, cases where models may be identical, e.g. U.S. address/location information.

Standards harmonization processes would mimic equivalent metadata lifecycle management to support the addition, modification and removal of metadata content. The governance process would rely on a system of checks and balances, whereby the work of stewards rolls up for the review and approval of librarians, and that work in turn is available for review and approval by the steering body, based on the achievement of previously specified objectives and confirmed by reported metrics.



During this phase of the work mappings and transformations are generated by the harmonization metadata stewards. Gaps, conflicts, ambiguities and redundancies are identified and resolved. Resolutions and their documentation become an intrinsic part of the harmonization metadata repository. Harmonization work will be externalized in the form of metadata based reporting.

6.8 Conformance Tests and Environment

It is the stated objective of the metadata-driven approach that it support standards harmonization, eliminating ambiguity, redundancy, gaps and conflicts. It is imperative that vendors and systems integrators have the benefit of a mechanism to validate their implementations vis-à-vis compliance with harmonized standards.

Each release of harmonized standards should include tests that verify consistent usage of standards specifications. Conformance tests should at a minimum attempt to test conformity to use cases specified as in scope for this release.

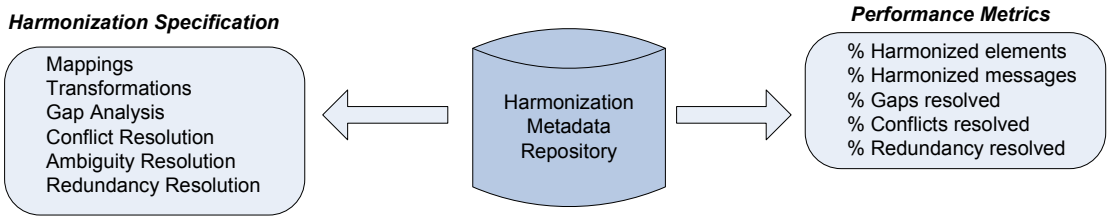
In order to support conformance and to facilitate testing, it is useful for the standards harmonization team to provide an externally available test environment. This environment at a minimum should contain fabricated data that can be used in conformance testing efforts, known to produce certain specific structures and values.

6.9 Generation of Communication Artifacts

A key aspect of governance is the ability to communicate to parties internal and external to the harmonization process. The list of communication artifacts is expected to be continually refined, but is likely that they would initially include communication artifacts such as:

- Documentation on current harmonization specifications
  - Information mappings and transformations across standards
  - Resolutions to gaps and overlaps
  - Standard-specific harmonization information
  - Functional category-specific harmonization information

- Performance metrics
  - Percentage of harmonized data elements
  - Percentage of harmonized messages
  - Percentage of harmonized vocabulary elements
  - Percentage of gaps in data element harmonization
  - Percentage of gaps in message harmonization
  - Percentage of gaps in vocabulary harmonization
  - Percentage of conflicts in data element harmonization
  - Percentage of conflicts in message harmonization
  - Percentage of conflicts in vocabulary harmonization
  - Use case coverage



7. Conclusion

This report has drawn parallels between the objectives and requirements of a standards harmonization process and functionality supported by metadata tools, techniques and governance processes.

The comparative analysis is not designed to be exhaustive but merely illustrative of a potential opportunity to use mature, well tested and documented strategies in the context of standards harmonization.

If this proposal is put into practice, there will be an evolving effort to better expand on the details that usage of a metadata-driven foundation in this context requires.