Object Management Group

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Clinical Observations (COBS)

Request For Proposal (RFP)

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Submissions due: May, 18, 1998

Objective of this RFP

This RFP solicits proposals for reporting and managing clinical observations. Clinical observations constitute a significant proportion of the information recorded about any patient. Examples of clinical observations include the following: laboratory results; vital signs; subjective and objective observations and assessments generated during a patient encounter; observations and measurements provided by a specialist such as radiologist or pathologist who interprets images and other multi-media data. Interoperable specifications that support the workflow involved in collecting and reporting clinical observations are sought in this RFP. The specifications should leverage extant standards such as HL7 and DICOM Structured Reporting (Supplement 23) and other appropriate standards.

For further details see Chapter 6 of this document.

6.0 Specific Requirements on Proposals

This RFP solicits proposals for reporting and managing clinical observations. Clinical observations constitute a significant proportion of the information recorded about any patient. Examples of clinical observations include the following: laboratory results; vital signs; subjective and objective observations and assessments generated during a patient encounter; observations and measurements provided by a specialist such as radiologist or pathologist who interprets images and other multi-media data. Interoperable specifications that support the workflow involved in collecting and reporting clinical observations are sought in this RFP. The specifications should leverage extant standards such as HL7 and DICOM Structured Reporting (Supplement 23) with in the United States and other appropriate standards in Europe and else where **(***reviewers please help fill these in***).**

6.1 Problem Statement

The context in which information systems tracking observations need to be deployed is currently characterized by: 1) heterogeneous environments consisting of multiple vendor proprietary subsystems 2) partial support of HL7 standards or extensive use of the "Z" segement, a user definable structure for message transmission 3) support for DICOM standards in the case of image modalities. The challenge faced by the information system staff at hospitals and other healthcare centers is to make these clinical observations available to the right people in a timely and secure fashion.

Depending on the type of information being collected or processed, the workflow that needs to be supported can be different, although the basic information types may be the same. For instance, in the case of radiology readings, the modus operandi in most institutions is to rely heavily on a dictation-transcription process to generate the reports. In reality, the process has to support a variety of business and legal functions including: verification and sign-off of reports by an appropriate provider, and routing of the results to an appropriate set of people from referring to attending to consulting physicians. The process can be very involved as is typically the case for dealing with pathological reports and observations. Pathology, additionally, has claims attachment processing in the workflow where observations may be included at a time after the observation was made. Within a hospital stay the Nurse becomes the primary care giver and must be able to access observations from laboratory and imaging areas but also adds observation reports to the patient's records such as vital signs, I/Os, etc.

The focus of standards groups have typically been in modeling the data set that

is relevant for any specific type of observation. They typically ignore the complexity of supporting the process of providing care and the tracking and supporting of who needs what information, when and for what purpose. These become important issues as we look forward to enforcing complex security constraints and provide patient privacy and confidentiality protection.

Furthermore, the manual, paper based processes of the past have often failed to capture and record all of the events which constitute a clinical observation (e.g. the relationship between detailed macroscopic and microscopic observations and electropheresis measurements in pathology and the final report/diagnosis) resulting in a reduction in healthcare quality and increased liability to the provider. The paper based patient record also suffers from only being accessible from one place at a time. Patients may be seen by multiple doctors within a short time and the paper record often lags the patient going from one office to another. As primary care physicians consult with specialists the need to view the patient record remotely and immediately increases.

6.2 Scope of Proposals Sought

As part of this RFP, proposals are sought that provide clear, unambiguous, mechanisms to support reporting a wide variety of observations. The observations may be reported using unstructured reporting mechanisms to well structured elements. The proposals should address how the process of collecting, managing, reporting, dispatching, signing, verifying of such clinical observations are handled by the proposed mechanisms.

6.3 Relationship to Existing OMG Specifications

Technology submissions should take advantage of existing OMG specifications where appropriate. The following services are anticipated to be appropriate for use by this facility:

CORBA Services:

- Security - It is expected that the OMG Security Service will be utilized for security capabilities.

- Secured Time - It is expected that responses will use CORBA Time services for time continuity.

- Transactions - It is expected that the OMG Object Transaction Service (OTS) will be utilized for transaction management.

- Objects by Value - Work in progress on the OMG Objects by Value RFP may prove useful in responses to this submission.

In addition, submitters should be aware that RFP's are currently outstanding for technology adoption in the following areas. Submitters are encouraged to follow this work, because technology may be adopted in this space before submissions are due for this RFP.

Other relevant OMG Work in progress:

- Electronic Healthcare Claims Facility
- Electronic Payment Facility
- Insurance Party Management
- Notifications
- Messaging
- Patient Identification Services (PIDS)
- Lexicon Query Services (LQS)

6.4 Related Documents and Standards

Some groundwork in this area has already been laid by other standards organizations, particularly:

- DICOM: Structured Reporting - Supplement 23
- HL7: Observations
- GEHR
- IEEE 1073
- ***** Please help to identify others *****

DICOM in particular provides a model for the relationship between multi-media data items (e.g. images) and the expert observations and interpretations recorded against these items. Both DICOM and HL-7 are very important standards in clinical medicine and it is highly recommended that responders coordinate closely with these bodies.

The following are the responses to the Clinical Observations RFI issued by CORBAmed in June 1997. Submitters should reference these for important evaluation criteria that may be applied by members of the CORBAmed task

force.

- corbamed/97-08-07, 97-08-06, 97-08-05 (CHIME and The Gehr Architecture

- corbamed/97-09-05 (Joint Response from Philips Medical Systems, Baptist Health Systems or South Florida, CareFlow|Net, Inc. and Kurzweil)

- corbamed/97-08-08 (Yale University School of Medicine)

- corbamed/97-08-09, 97-08-04, 97-08-10 (Protocol Systems and University of Michigan Health Services)

- corbamed/97-09-04 (HL7 SGML/XML SIG)

- corbamed/97-09-06 (American Association For Medical Transcription)

- corbamed/97-09-07 (DICOM Working Group 8)

- corbamed/97-09-08 (HL7 IMSIG)

6.5 Mandatory Requirements

This RFP solicits proposals for OMG IDL specifications of a Healthcare Clinical Observations (COBS) that will facilitate the management of clinical observations.

The following are the mandatory requirements for COBS:

- The COBS submission shall allow clinical observation data to be requested, archived, indexed or sent as needed.

- The COBS submission shall support structured reporting. Such structure shall be based on extant standards where they exist.

- The COBS submission shall support a publish/subscribe mechanism where clients can to be notified when certain observations are available, have changed or meet a particular criteria. Subscriptions to events must be able to be controlled by entities separate from the receiver of the event.

- The COBS submission must allow for data access/transmission as both unstructured and structured types. (E.g. they could be MIME-tagged blobs.)

- The COBS submission shall provide a mechanism for clients to access data filtered by the observations of interest and the time of interest.

- The COBS submission shall provide a mechanism for querying for what observations data is available for a person over a time of interest by the client.

- The COBS submission shall support a wide variety of data types that can be extended by individual implementations and standardization. The submission shall support the following data types either implicitly or explicitly: events/episodes; measurements; waveforms; text; images; audio; video; structured reports.

- The COBS submission shall provide a mechanism for implementations to expose what observations and data types they support in order to allow dynamic discovery of capabilities.

- The COBS submission shall provide a mechanism for implementations to expose the time scale of data available for query access.

- The COBS submission shall utilize the same representation for observations for pull (query) and push (registration/notification) access.

6.6 Optional Requirements

The following are optional requirements that a submission may decide to address but are not required to.

- The COBS submission may provide a standard set of data types to be used for observations data. As noted under Mandatory Requirements the data types must be extendible.

- The COBS submission may provide a general filtering mechanism for querying clinical observation data known by a service.

6.7 Issues to be discussed

How does the submission relate to DICOM Structured Reporting.

Describe possible approaches to integrate the use of the submission along with HL7 and DICOM capabilities.

Does the submission differentiate between observations data and other aspects of patient records? Describe why they should or should not be considered different.

6.8 Evaluation Criteria

The proposals will be evaluated on their completeness and their ability to

address the mandatory requirements. A submitter should give justification for any mandatory requirements not met.

Can the submission be used for a large variety of healthcare information systems that deal with observation data? Does this include Electronic Medical Record (EMR) systems?

Does the submission facilitate the communications of clinical data that is needed for workflow pertaining to capturing, managing, reporting, dispatching, signing, notification, and verification?

Is the submission useful for both intra-enterprise and inter-enterprise communications of observations data?

Is the submission independent of whether the integration of patient data is done at desk top applications, by a back end server, or a Clinical Data Repository (CDR)? Does it preclude any of these?

Has the submission met these requirements with a minimal number of interfaces and IDL type definitions?

Is the submission useful for a wide variety of business processes that handle observation data?

Does the event subscription part of the submission inter-operate with Event Services specification, and/or the Notification Service?

Does the submission reuse other OMG specifications where appropriate? In particular does it use or at least is it orthogonal to the Person Identification Service (PIDS) and Lexicon Query Service (LQS)?

Can the submission be used to create services that can be efficient where bandwidth limitations exist? Can it be used to for real time applications? Can it be used for continuous data channels?

6.9 RFP Timetable

The timetable for this RFP is given below. Note that the TF may, in certain circumstances, extend deadlines while the RFP is running, or may elect to have more than one revised submission step. The latest timetable can always be found in the Member Services section of OMG's Web page (URL http://www.omg.org/).

Event or *Activity*	**Actual Date**
TC votes to issue RFP	December 5, 1997
LOI to submit to RFP due	March 23, 1998
Voter registration closes	June 1, 1998
Initial submissions due	May 18, 1998
Revised submissions due	August 24, 1998
TF votes to select specifications	September 17, 1998
TC votes to recommend specifications	September-October, 1998
BOD votes to adopt specifications	November, 1998