Date: March 11, 2013

To: HL7 Workgroup Co-Chairs

From: CIC and Tooling Workgroup

Subject: MAX Project Requirements Gathering

The Clinical Interoperability Council (CIC) and Tooling Workgroups are co-sponsors of the Model Automated Exchange (MAX) toolkit project. The goal of the MAX toolkit project is to enable the import, export, and round-tripping of a user defined subset of model elements specified in a UML modeling tool. XMI is the default definitive means by which models and model packages are imported and exported by UML modeling tools.

MAX is intended to support capabilities not easily supported by XMI alone. Specifically MAX addresses the desire to limit a model import/export to a subset of model elements and element features that possibly span model package boundaries and the ability to import/export using a user defined data structure. In phase one of MAX the only UML modeling tool being addressed is Enterprise Architect from Sparx System and the only import/export dataset definition is MS Excel. We have define two major Use Cases as the minimum requirements for the initial release of MAX:

* **Cross-Reference model elements to reference documents**

Model elements are often cross-referenced to externally maintained reference documents as a means of providing requirements traceability or supporting evidence for modeling rationale. The most common means of accomplishing this is to create a spreadsheet. The use case to be satisfied by MAX is to enable the cross-references to be imported, exported, and round-tripped. It needs to support the ability to modify existing mappings during import (add or remove), support the ability to distribute mapping responsibilities to multiple members of the project team, and support a many to many mapping between model elements and reference items.

* **Maintain model element descriptive Text**

Model elements such as classes, attributes, and activities often have descriptive text that is best authored by subject matter experts. The goal of this use case is to support the ability to distribute the responsibility for authoring descriptive text among multiple parties and then import their work into the model and support the exporting of model descriptive text for review, comment, and publication. The use case to be satisfied by MAX is to enable element definitions to be imported, exported, and round-tripped. It needs to support the ability to modify existing definitions during import (add or remove) and support the ability to distribute authoring of definitions to multiple members of the project team.

We have identified the following functional capabilities as requirements for the MAX tool:

1. Allow users to declare model elements and element features to be exported
2. Allow users to declare inclusion/exclusion criteria for model elements to be exported
3. Retrieve declared model elements from an EA model
4. Allow users to declare the order in which model elements and features exported from EA will appear in the target CSV
5. Create a CSV export populated with data exported in accordance with declared export formatting instructions
6. Allow users to declare the order in which model elements and element features to be imported into EA appear within the source CSV
7. Create, update, or delete model elements in the EA model in accordance with the content of the source CSV

We currently have a working prototype that fulfills the functional capabilities requirements and are now seeking input from potential users of this tool regarding desired feature and usability requirements. We are particularly interested in learning about use case scenarios in which this tool might be applied, what is currently being done to address the use case requirements, and the strengths and weaknesses of the current solutions.

We will use your use case scenarios to further refine the functional requirements of MAX. Specifically, we seeking to discover

* what model elements and model element features are exported most often?
* what inclusion/exclusion criteria are typically used for exported model elements?
* what are the formatting requirements for model elements exported to excel?
* what model elements and model element features are imported most often?
* how important is the need to roundtrip model elements?
* what are round-tripping issues to be resolved and what are potential solutions?

We need your help. If you have a project which is using Enterprise Architect as a UML modeling tool, please share with us scenarios in which you find it necessary to export model elements from EA into a spreadsheet. The information we desire includes:

* Project name
* Project Insight Identifier
* Sponsoring workgroup(s)
* Project Contact
* Max Related Use Case Scenario
  + Import/export/roundtrip
  + Model elements/features involved
  + Export include/exclusion criteria
  + Import processing (create, update, delete)
* Current solutions
  + Method used
  + People / Roles involved
  + Strengths
  + Weaknesses
* MAX Feature Requests
  + Must have features
  + Nice to have features

We will be gathering these requirements throughout the month of March. Please provide your input as soon as possible but no later than April 12, 2013. A word document format can be used to submit your requirements directly to AbdulMalik Shakir ([AbdulMalik@ShakirConsulting.com](mailto:AbdulMalik@ShakirConsulting.com)), CIC Project Facilitator, with a copy to the Clinical Interoperability Council coChairs (addresses below). A sample submission from the Trauma Data Exchange DAM project is included with this note and can be used as an example when completing your particular use case. We will produce a summary of what we gather for review during the May working group meeting. Thank you for your assistance.

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**Sample Requirements Documentation**

* **Project name:** Cardiovascular Data Standards (Duke, FDA, ACC/AHA, CDISC, NCI)
* **Project Insight Identifier:**
* **Sponsoring workgroup(s):** Clinical Interoperability Council Work Group (sponsor),
* **Project Contact:** Rebecca Wilgus ([rebecca.warlick@dm.duke.edu](mailto:rebecca.warlick@dm.duke.edu)) or Anita Walden ([anita.walden@dm.duke.edu](mailto:anita.walden@dm.duke.edu))
* **Max Related Use Case Scenario:**

We are using EA to build and model cardiology data standards. Data Elements are developed by SMEs, submitted to the informatics team and the modeling facilitator creates a relational model in Enterprise Architect (EA). Data elements are organized into Packages, classes and attributes with codelists specified as attributes of value domains. SMEs and various members of the project review, provide comments, and updates back to the modeling facilitator who manually updates the model. The manual entry/updating of data elements and the creating, updating and formatting of extracts/reports from EA is labor intensive. One way MAX could add value is to reduce the manual burden of updating data elements in the model by enabling updates to be loaded from the reviewer’s file directly into the model.

* + ***Import/export/roundtrip:*** 
    - Import
    - Export
    - Round Trip (ideally)
  + ***Model elements / features involved:*** 
    - **Package** – Name, Parent Package
    - **Class** – Name, Owning Package, Alias, Notes, tagged values
    - **Attribute** – Name, Owning class, Alias, Type, Notes, tagged values
    - **Value Domains (?)** - Name, Owning class, Alias, Type, Notes
    - **~~Attribute Constraint~~** ~~– Type, Name, Owning Attribute~~
  + ***Export include/exclusion criteria***
    - Filter by Attribute, Class, Type, Tagged Values (of classes and attributes).
  + ***Import processing (create, update, delete)***
    - Update and delete attribute for an existing class attributes, create new classes, & attributes, and delete any classes and attributes as instructed by the SMEs.
* **Current solutions**
  + ***Method used***
    - We export the database into ORACLE and write and run queries against it to parse, correlate and sort the data into a user-friendly report format. The output is exported into MSWord (or an RTF file). The model facilitator manually enters questions or comments for the reviewers into the RTF file using the ‘comment’ feature or highlighting text w/in the report or adding a question (in colored text) into the cell of the report. RTF file is emailed to SMEs. They review and provide feedback/answer questions using ‘tracked changes’. Each SME returns their comments to the model facilitator via email (so if we get 10 people to review, then we receive feedback in 10 files w/ changes tracked). The model facilitator collates and reconciles changes then inputs the updates in EA saving the updated file in an up-version. This enables the project team to preserve the original and all edited versions of the model.
  + ***People / Roles involved***
    - The model facilitator
    - Informatics/PL, and other team members
    - SMEs
  + ***Strengths***
    - Once the RTF template is defined it can be reused.
    - An RTF file is easy to edit, understand and track any manual changes (if you use Track Change).
    - SME’s prefer to review and edit ‘word’ documents; they do not like to review or edit text in spreadsheets.
    - Tracked changes make it easy to identify the revisions, new entries and deletions
    - It’s easy to generate a table of contents of the report output.
    - Queries can be customized to report specific sections of content in the model
    - Sort and display order of the output can be pre-specified
    - Report serves as a communication tool for questions from Proj Team to SME’s and from SME’s to Project team.
  + ***Weaknesses***
    - We have no automated means of importing changes to the model identified by the SMEs.
    - Any comments or questions provided by model facilitator(s) to SME’s must be copied/re-inserted every time the model is updated and/or the report is re-run and distributed.
    - It’s not obvious in EA which fields have been updated during any review cycle or who made the changes.
    - Manually updating the model is extremely time-consuming. It does not scale well for multiple review cycles
    - Many of the notes fields in EA exceed the field size in the native access back-end; the export process often truncates text that’s outbound to an Oracle table as well – thus the content of any Word or RTF file must be reviewed in great detail to be sure full content is available.
    - Formatting of special characters (< > = ) do not export consistently.
    - Report output is exported at the ‘field’ level; Each field must be formatted and sized individually in the template file; once the data is exported, the fields do not ‘autosize’ in the RTF file - so it’s often not obvious when edits are made to text that falls below the last line of type visualized in the field. Fields that are re-sized manually generally impact the formatting of output above and below the change.
* **MAX Feature Requests**
  + ***Must have features***
    - Must be able to identify which model elements and which element features are to be exported
    - Must be able to filter what gets exported based upon the value of model element features, including not exported features
    - Must allow new classes and attributes to be added as well as allow unwanted classes and attributes to be deleted; similarly, updates to text in any given cell must flow from the SME file to the model during the import
    - Ability to generate a Change Report from previous model to current model based on import updates.
    - Must enable update or removal of model element feature values upon import
    - Must maintain integrity across any associated diagrams (if changes are made to a class or attribute that is part of a diagram, those changes must be reflected in the diagram (ie if an attribute is moved to another class or a new class is added, the diagrams in EA must reflect those changes)
    - Must handle exceptionally large numbers of characters in any cell/field
    - Tool must work for all versions of EA; desktop version and enterprise versions.
  + ***Nice to have features***
    - Ability to same export selection criteria so that is can be reused within the same model or in different models. Similar to the way that RTF report templates can be saved and shared.
    - Ability to confirm a “deletion” or “change” before making the update to the model.
    - Ability to recognize changed, new and deleted data once it is back in the EA.
  + ***Questions***
    - How are deleted items in the spreadsheet handled when the spreadsheet is loaded back into EA?
    - Is there a “Roll Back” feature if can the model be versioned up on re-load?
    - Will the data in the model be globally overwritten or will only the changed information be updated?
    - Can MAX export/import to any formats other than EXCEL such that changes to information can be tracked and imported to EA?

**Comment:** I see a couple of challenges for our group in using a tool like MAX – at least the way it’s currently described.

1 - Our WG’s don’t like to review and comments to text in spreadsheets. It looked like that was the primary format for MAX exports. I also appreciate that it’s hard to load databases from word documents which are the file format our reviewers provide their feedback in. Seems like an ongoing challenge will be to find a format that’s both acceptable to clinicians and suitable for database loads.

2. We will receive feedback files from many reviewers and it’s not clear to me yet if the feedback in those files will have to be manually collated and put into a single file before using MAX to import to EA or if MAX will somehow handle sequential, incremental loads i.e., load changes from multiple files to any given field in EA w/o overwriting the original content or comments from files loaded previously. For example, if 10 reviewers provide different comments on the same field in EA – it’s important to us that the comments from all reviewers be loaded into that field. My preference is that MAX be able to handle multiple loads and that the loads into each field be cumulative not an overwrite.

3. One of the most labor intensive parts of the feedback cycle is manually entering questions/comments into report output for reviewers to consider during their reviews. There’s currently not a field in EA to use as a ‘communication field’ so, comments/questions can’t really be t’d up in the model and exported along w/ the data elements each time the report is generated. We also have no way to accumulate questions/comments from the project team about any given field over time… we have to go thru each prior report to find out if we’ve asked about the element before and if so, what were the responses… It’s a lot of work that’s being done outside of the model. We end up maintaining a master spreadsheet plus the EA model and for each review cycle, producing multiple reports – each version requiring the manual work of entering comments/questions. The attached file is one version of a report that went to our WG’s in a recent review cycle. The highlighted text was added to draw reviewer attention to specific content after the report was produced. It took 4 or 5 versions to get the report output right, and unfortunately, I ended up putting these comments into each version (not realizing we’d need to modify the report so many times before it went out for review…). Ideally, there would be a field somewhere to put questions/comments so that they could be exported as part of the report that’s produced from the model - so, either a field in EA, or a field in an external table somewhere that could be joined to the EA tables in a way that the report output would contain the data elements and the questions/comments (and responses to prior questions). When reviewers respond, it would be ideal if their responses could be uploaded into the same file where the questions from us are stored so we accumulate a review history for each data element.