Diabetes Data Strategy Project ('Diabe-DS')

Overview and Status Update

October 2010

HL7 Workgroup Sponsors

- EHR Workgroup (primary sponsor)
- Clinical Interoperability Council (co-sponsor)
- Patient Care Workgroup (co-sponsor)
- RCRIM (co-sponsor)
- Interoperability Workgroup (co-sponsor)

Project Goals

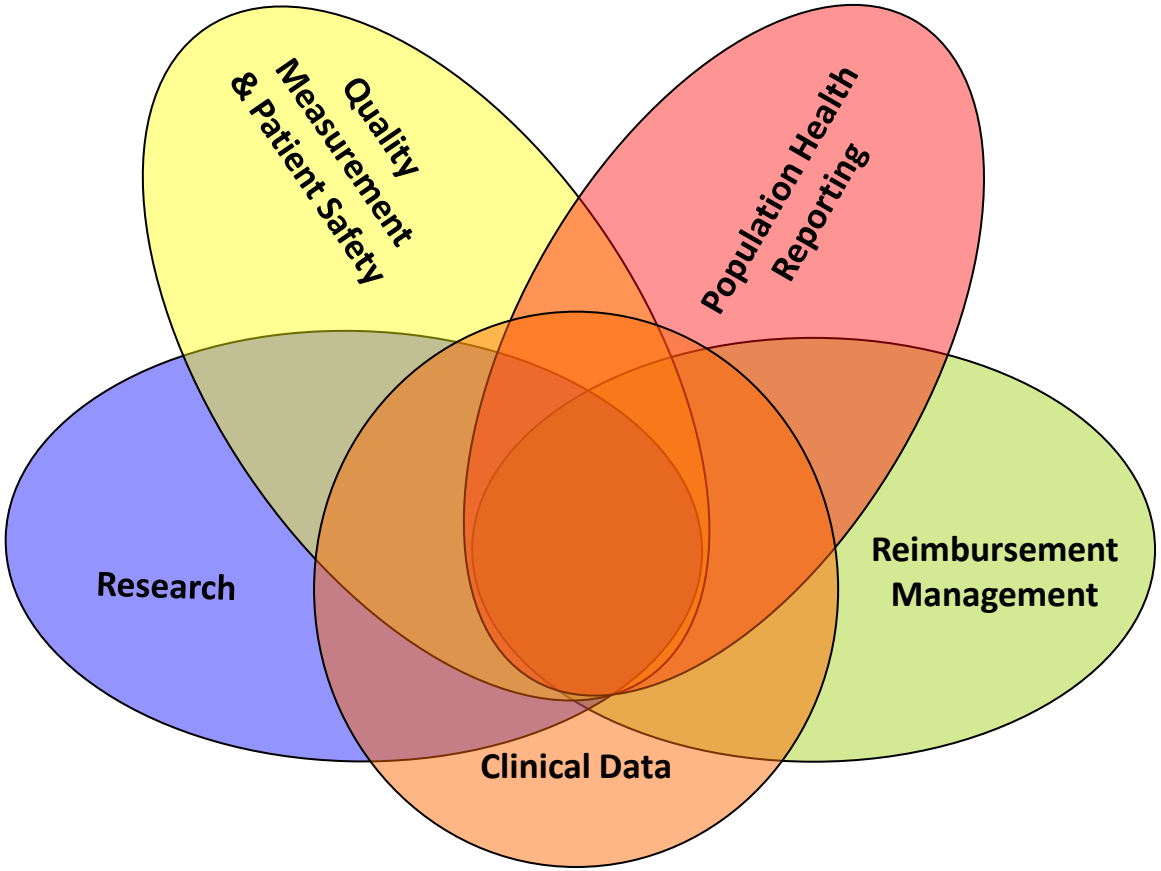
1. Develop a small set of data elements for the outpatient diagnosis of Type 1 Diabetes(T1D) that overlap* between electronic health record (EHR) and some secondary uses – like research and quality monitoring.
2. Look at how elements can be harmonized to support the "collect once, use many" paradigm.
3. Tie data elements and data use requirements to EHR system functions
4. Document the process, procedures, & lessons learned for subsequent projects.
5. Set the stage for T1D stakeholders to vet/enhance the elements to produce a true clinical T1D DAM.

* Because the goal was to pick research measures that were likely to have related content in the EHR, we did not produce a comprehensive set of research data elements for T1D.

Uses of Data Have Significant Overlap

Premise of project:

- Develop a process to identify a common set of data elements in the center of overlap for a given clinical domain/ therapeutic/disease area.
- Establish the framework to repeat the process in other domains.



Graphic by Don Mon, 5-2009

A Collaborative Team Effort

Project Facilitators

Rachel Richesson
Crystal Kallem
Don Mon

Project Team Members

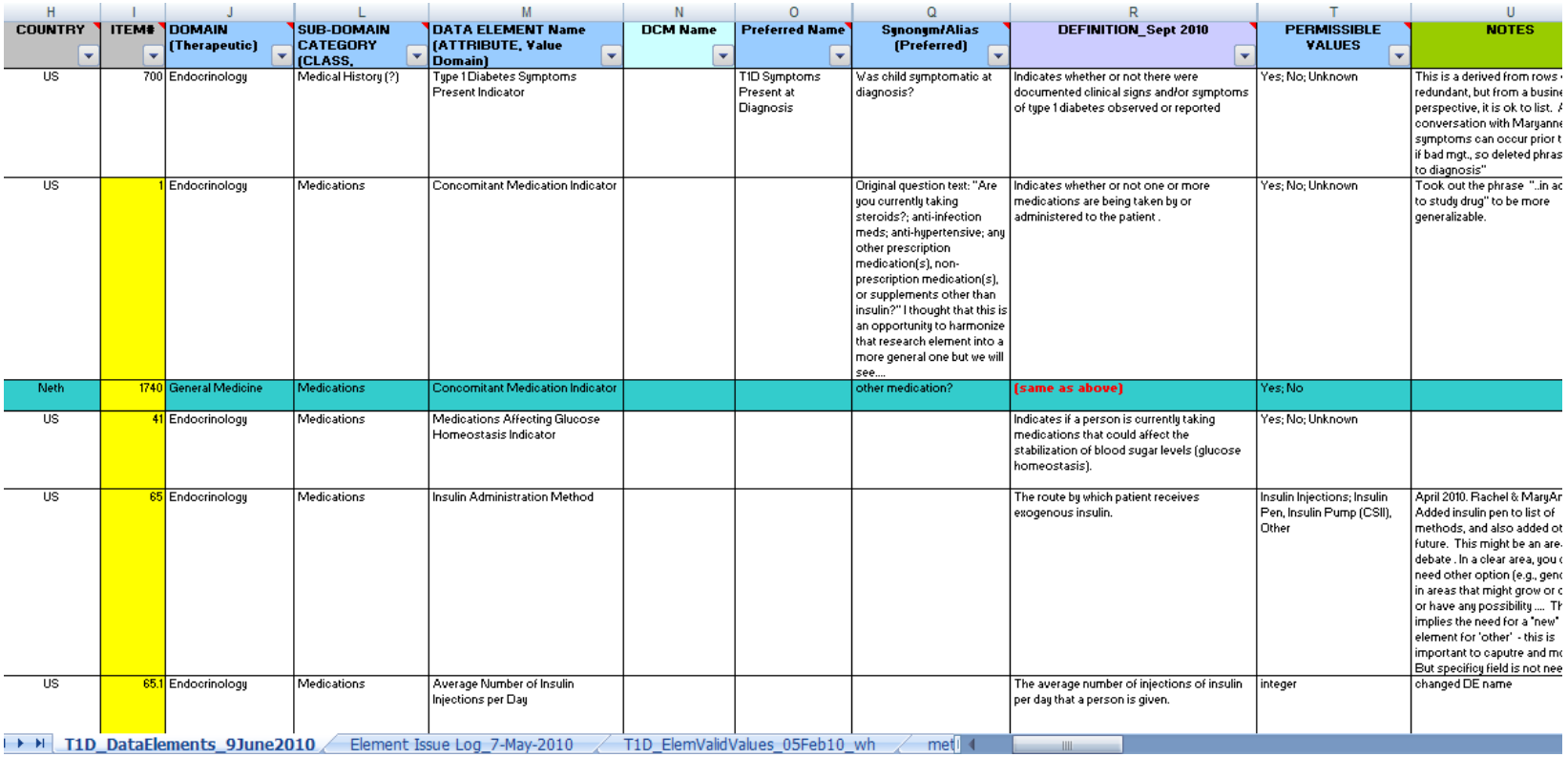
Luigi Sison	Pat Van Dyke	Donna DuLong
Wendy Huang	Gary Dickinson	Scott Bolte
Maryann Quinn	Kendra Vehik	William Goossen
Meredith Nahm	Michael Celeste	Kristi Eckerson
Joyce Niland	Joyce Bruno Reitner	Joy Kuhl
Steve Bentley	Mitra Rocca	Yong Choi
Jeff James	Steve Ward	Davera Gabriel
Pat Gunter	*…and new members continuing to jump in…*	

Sampling of Data Elements

- Hunted and gathered
  - research forms
  - practice guidelines
  - quality measures
  - expert interviews
  - two outpatient diabetic clinic information systems
- Added elements from national efforts in The Netherlands and Canada

Data Element Spreadsheet

- 200+ data elements
- Sample of important data elements, but not an exhaustive or representative list



H	I	J	L	M	N	O	Q	R	T	U
COUNTRY	ITEM#	DOMAIN (Therapeutic)	SUB-DOMAIN CATEGORY (CLASS,	DATA ELEMENT Name (ATTRIBUTE, Value Domain)	DCM Name	Preferred Name	Synonym/Alias (Preferred)	DEFINITION_Sept 2010	PERMISSIBLE VALUES	NOTES
US	700	Endocrinology	Medical History (?)	Type 1 Diabetes Symptoms Present Indicator		T1D Symptoms Present at Diagnosis	Was child symptomatic at diagnosis?	Indicates whether or not there were documented clinical signs and/or symptoms of type 1 diabetes observed or reported	Yes; No; Unknown	This is a derived from rows redundant, but from a busine perspective, it is ok to list. A conversation with Maryanne symptoms can occur prior t if bad mgt., so deleted phras to diagnosis"
US	1	Endocrinology	Medications	Concomitant Medication Indicator			Original question text: "Are you currently taking steroids?; anti-infection meds; anti-hypertensive; any other prescription medication(s), non-prescription medication(s), or supplements other than insulin?" I thought that this is an opportunity to harmonize that research element into a more general one but we will see....	Indicates whether or not one or more medications are being taken by or administered to the patient .	Yes; No; Unknown	Took out the phrase "..in ac to study drug" to be more generalizable.
Neth	1740	General Medicine	Medications	Concomitant Medication Indicator			other medication?	(same as above)	Yes; No	
US	41	Endocrinology	Medications	Medications Affecting Glucose Homeostasis Indicator				Indicates if a person is currently taking medications that could affect the stabilization of blood sugar levels (glucose homeostasis).	Yes; No; Unknown	
US	65	Endocrinology	Medications	Insulin Administration Method				The route by which patient receives exogenous insulin.	Insulin Injections; Insulin Pen, Insulin Pump (CSII), Other	April 2010. Rachel & MaryAr Added insulin pen to list of methods, and also added ot future. This might be an are debate. In a clear area, you need other option (e.g., genc in areas that might grow or or have any possibility .... Th implies the need for a "new" element for 'other' - this is important to caputre and mo But specifiy field is not nee
US	65.1	Endocrinology	Medications	Average Number of Insulin Injections per Day				The average number of injections of insulin per day that a person is given.	integer	changed DE name

T1D_DataElements_9June2010 | Element Issue Log_7-May-2010 | T1D_ElemValidValues_05Feb10_wh | met

“Data Cleaning”

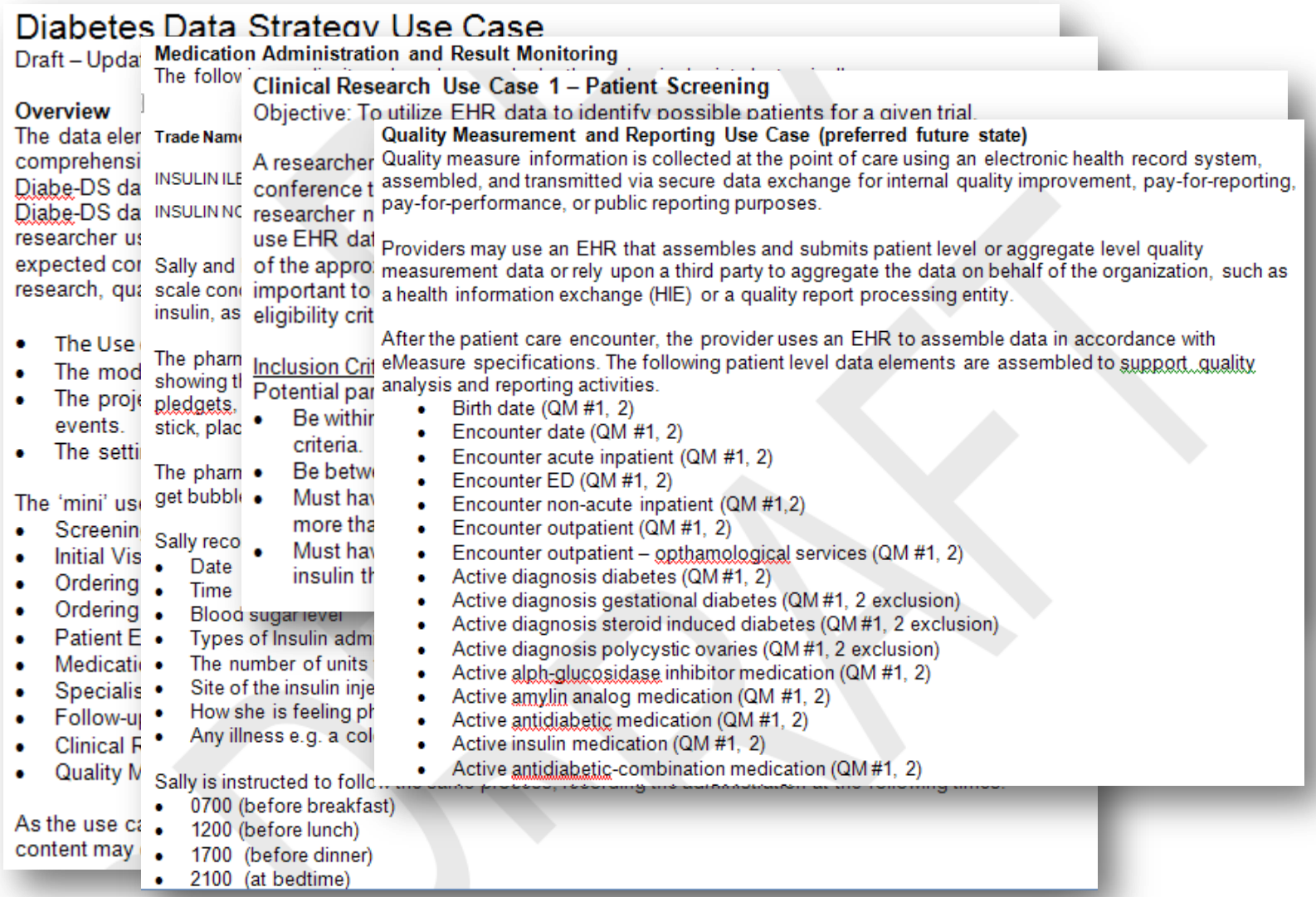
- Naming conventions for data elements
  - E.g., Hypoglycemia

    ---Versus---
  - Hypoglycemia indicator
  - Hypoglycemia symptom
  - Hypoglycemia onset date
- Value set ‘quality’ (comprehensive, exhaustive, exclusive)
- Definition clarification

Analysis of Data Elements

- Organized by conceptual groups
- Resolution of similar elements
- Annotated by relationship to EHR standards
- Classified as “atomic” or “derived” elements

Use Case Development



Diabetes Data Strategy Use Case

Draft – Updat

Overview

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Medication Administration and Result Monitoring

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- Blood sugar level
- Types of Insulin admi
- The number of units
- Site of the insulin inje
- How she is feeling ph
- Any illness e.g. a col

Sally is instructed to follo

- 0700 (before breakfast)
- 1200 (before lunch)
- 1700 (before dinner)
- 2100 (at bedtime)

Clinical Research Use Case 1 – Patient Screening

Objective: To utilize EHR data to identify possible patients for a given trial.

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Quality Measurement and Reporting Use Case (preferred future state)

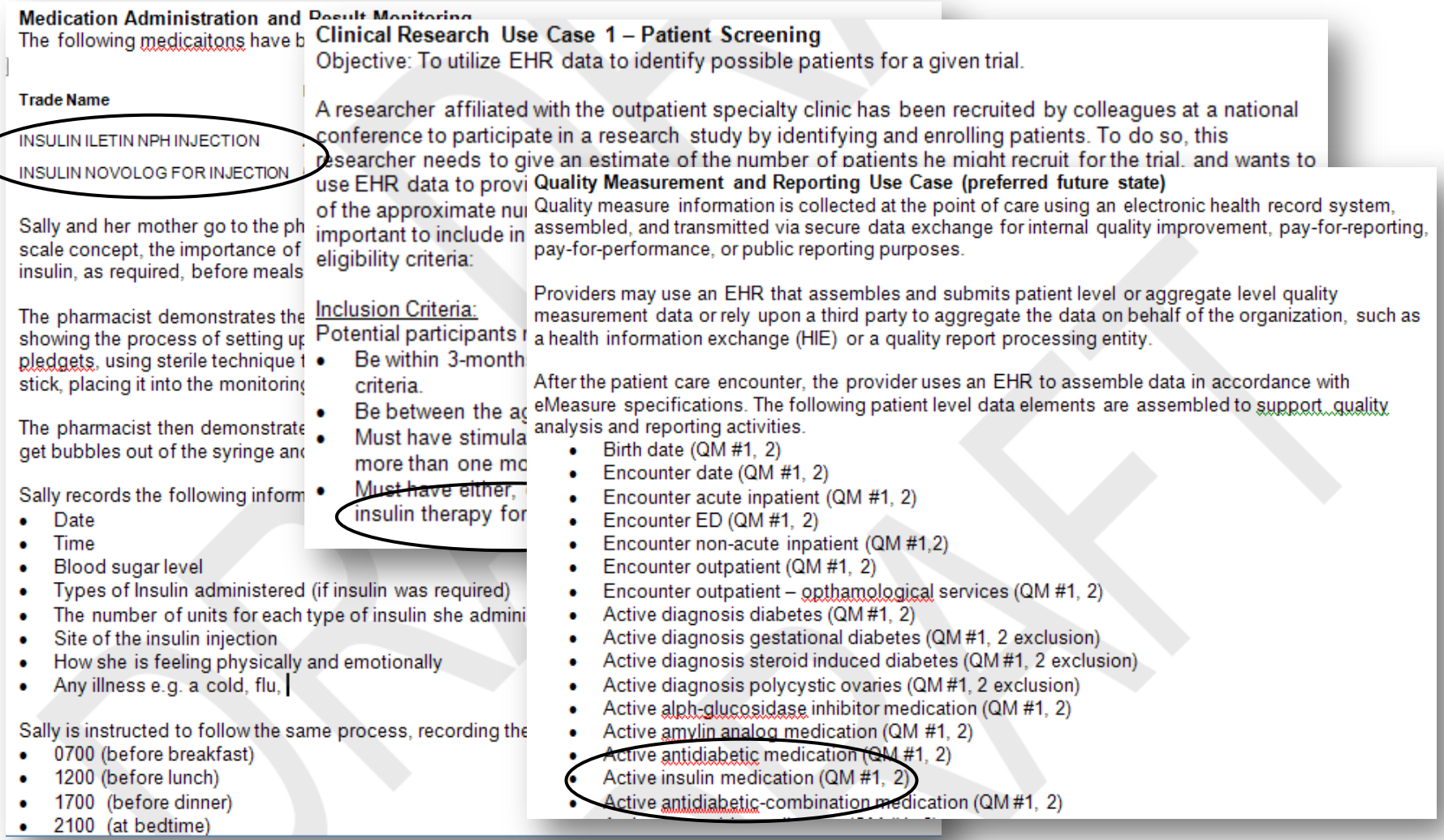
Quality measure information is collected at the point of care using an electronic health record system, assembled, and transmitted via secure data exchange for internal quality improvement, pay-for-reporting, pay-for-performance, or public reporting purposes.

Providers may use an EHR that assembles and submits patient level or aggregate level quality measurement data or rely upon a third party to aggregate the data on behalf of the organization, such as a health information exchange (HIE) or a quality report processing entity.

After the patient care encounter, the provider uses an EHR to assemble data in accordance with eMeasure specifications. The following patient level data elements are assembled to support quality analysis and reporting activities.

- Birth date (QM #1, 2)
- Encounter date (QM #1, 2)
- Encounter acute inpatient (QM #1, 2)
- Encounter ED (QM #1, 2)
- Encounter non-acute inpatient (QM #1,2)
- Encounter outpatient (QM #1, 2)
- Encounter outpatient – opthamological services (QM #1, 2)
- Active diagnosis diabetes (QM #1, 2)
- Active diagnosis gestational diabetes (QM #1, 2 exclusion)
- Active diagnosis steroid induced diabetes (QM #1, 2 exclusion)
- Active diagnosis polycystic ovaries (QM #1, 2 exclusion)
- Active alph-glucosidase inhibitor medication (QM #1, 2)
- Active amylin analog medication (QM #1, 2)
- Active antidiabetic medication (QM #1, 2)
- Active insulin medication (QM #1, 2)
- Active antidiabetic-combination medication (QM #1, 2)

Commonalities Among Mini Use Cases



Medication Administration and Result Monitoring

The following medicaitons have b

Trade Name

INSULIN ILETIN NPH INJECTION

INSULIN NOVOLOG FOR INJECTION

Sally and her mother go to the ph
scale concept, the importance of
insulin, as required, before meals

The pharmacist demonstrates the
showing the process of setting up
pledgets, using sterile technique t
stick, placing it into the monitoring

The pharmacist then demonstrate
get bubbles out of the syringe and

Sally records the following inform

- Date
- Time
- Blood sugar level
- Types of Insulin administered (if insulin was required)
- The number of units for each type of insulin she admini
- Site of the insulin injection
- How she is feeling physically and emotionally
- Any illness e.g. a cold, flu,

Sally is instructed to follow the same process, recording the

- 0700 (before breakfast)
- 1200 (before lunch)
- 1700 (before dinner)
- 2100 (at bedtime)

Clinical Research Use Case 1 – Patient Screening

Objective: To utilize EHR data to identify possible patients for a given trial.

A researcher affiliated with the outpatient specialty clinic has been recruited by colleagues at a national conference to participate in a research study by identifying and enrolling patients. To do so, this researcher needs to give an estimate of the number of patients he might recruit for the trial, and wants to use EHR data to provi
of the approximate nu
important to include in
eligibility criteria:

Inclusion Criteria:

Potential participants r

- Be within 3-month
  criteria.
- Be between the ag
- Must have stimula
  more than one mo
- Must have either,
  insulin therapy for

Quality Measurement and Reporting Use Case (preferred future state)

Quality measure information is collected at the point of care using an electronic health record system, assembled, and transmitted via secure data exchange for internal quality improvement, pay-for-reporting, pay-for-performance, or public reporting purposes.

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- Active antidiabetic-combination medication (QM #1, 2)

Cross Referencing Scenarios to Data Requirements

Medication Administration and Result Monitoring
The following medicaitons have been order by the endocrinologist electronically:

Trade Name *[medication name (ID#)]*	RxNorm Code *[medication code (ID#)]*	Appl No	Strength *[dose amount (8.08)]*	Firm Name
INSULIN ILETIN NPH INJECTION	217707	017936	100UNT/ML	PHYSICIANS TOTAL CAR
INSULIN NOVOLOG FOR INJECTION	575679	020986	100UNT/ML	PHYSICIANS TOTAL CAR

Sally and her mother go to the pharmacy to pick up the medications. The pharmacist explains the sli scale concept, the importance of checking blood glucose before meals and the importance of giving insulin, as required, before meals and at bedtime.

The pharmacist demonstrates the technique for checking blood sugar. Sally does a return demonstra showing the process of setting up the monitor in preparation for the test, cleansing the skin with alcoh pledgets, using sterile technique to lance her fingertip, applying a drop of blood on the glucose monit stick, placing it into the monitoring device and reading the blood glucose result.

The pharmacist then demonstrates the technique for drawing up insulin, including mixing insulins, ho get bubbles out of the syringe and finally the injection itself. She is instructed on site rotation.

Sally records the following information in her recording chart during the instruction:

- Date *[administration datetime (ID#)]*
- Time *[administration datetime (ID#)]*
- Blood sugar level
- Types of Insulin administered (if insulin was required) *[insulin type (906); medication name(ID#); medication code (ID#); medication code system (ID#)]*
- The number of units for each type of insulin she administered *[administration dose amount (ID#)]*
- Site of the insulin injection *[administration body site (ID#)]*
- How she is feeling physically and emotionally
- Any illness e.g. a cold, flu,

Sally is instructed to follow the same process, recording the administration at the following times:

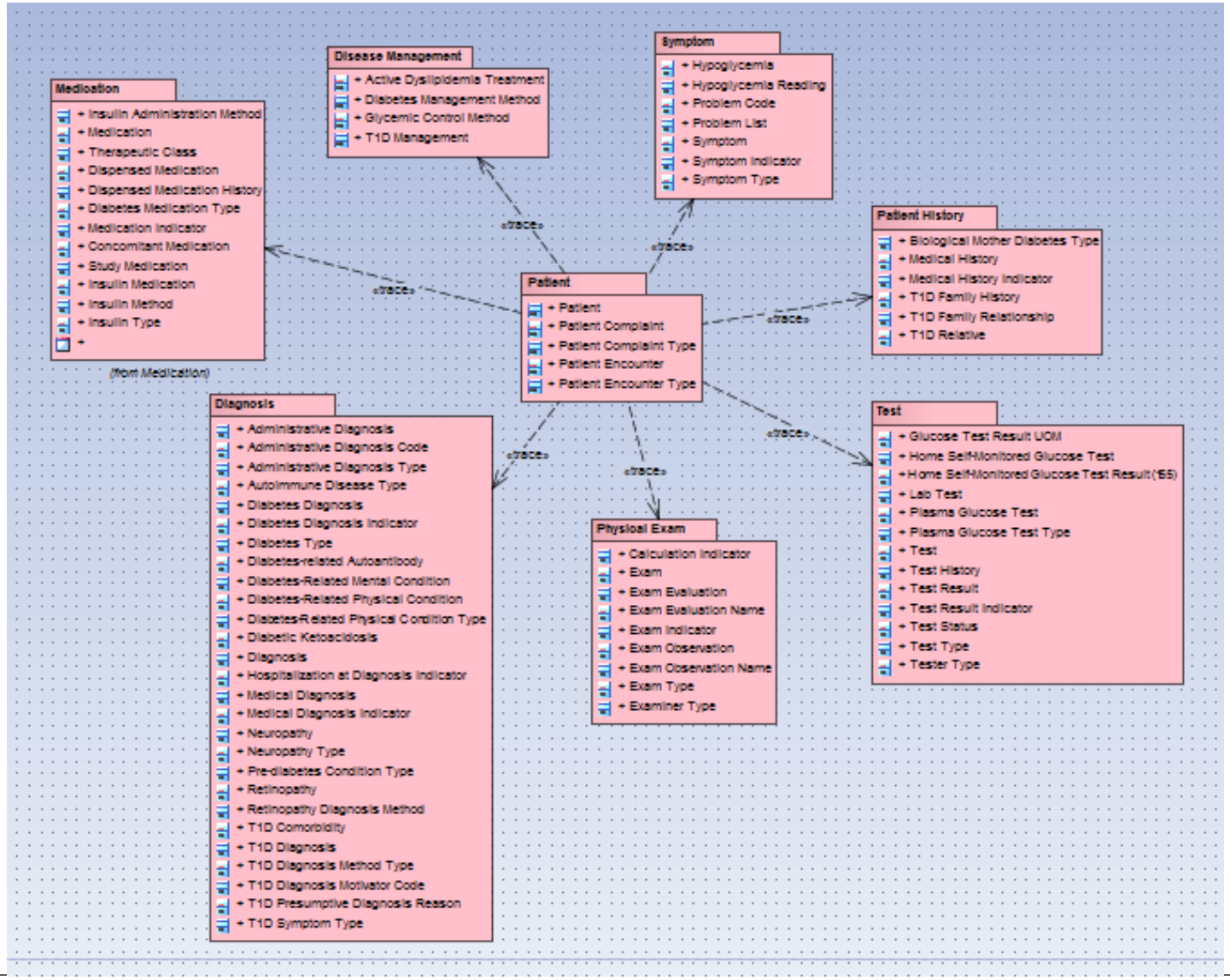
- 0700 (before breakfast)
- 1200 (before lunch)
- 1700 (before dinner)
- 2100 (at bedtime)

Class	ITEM#	DATA ELEMENT NAME	Atomic or Reuse Element	Data Element in EHR Direct or Derived	Related Atomic Data Element(s) in EHR? (yes, should be, no)	Atomic Combination (for Derived Elements)
Active Medication	239	Other medication indicative of diabetes active	Reuse	Derived	Yes	
Administration	TBD	Administration Body Site	Atomic	Direct		
Administration	TBD	Administration Datetime	Atomic	Direct		
Administration	TBD	Administration Dose Amount	Atomic	Direct		
Administration	TBD	Administration Dose Unit of Measure	Atomic	Direct		
Administration	TBD	Administration Entity Name	Atomic	Direct		
Administration	TBD	Administration Entity Role	Atomic	Direct		
Administration	TBD	Administration Entity Type	Atomic	Direct		
Administration	TBD	Administration Route	Atomic	Direct		
Administration	TBD	Administration Status	Atomic	Direct		
Administration	TBD	Post-Administration Condition	Atomic	Direct		
Administration	TBD	Pre-Administration Condition	Atomic	Direct		
Administration	TBD	Reaction/Tolerance	Atomic	Direct		
Concomitant Medication	1	Concomitant Medication Indicator	Reuse	Derived		

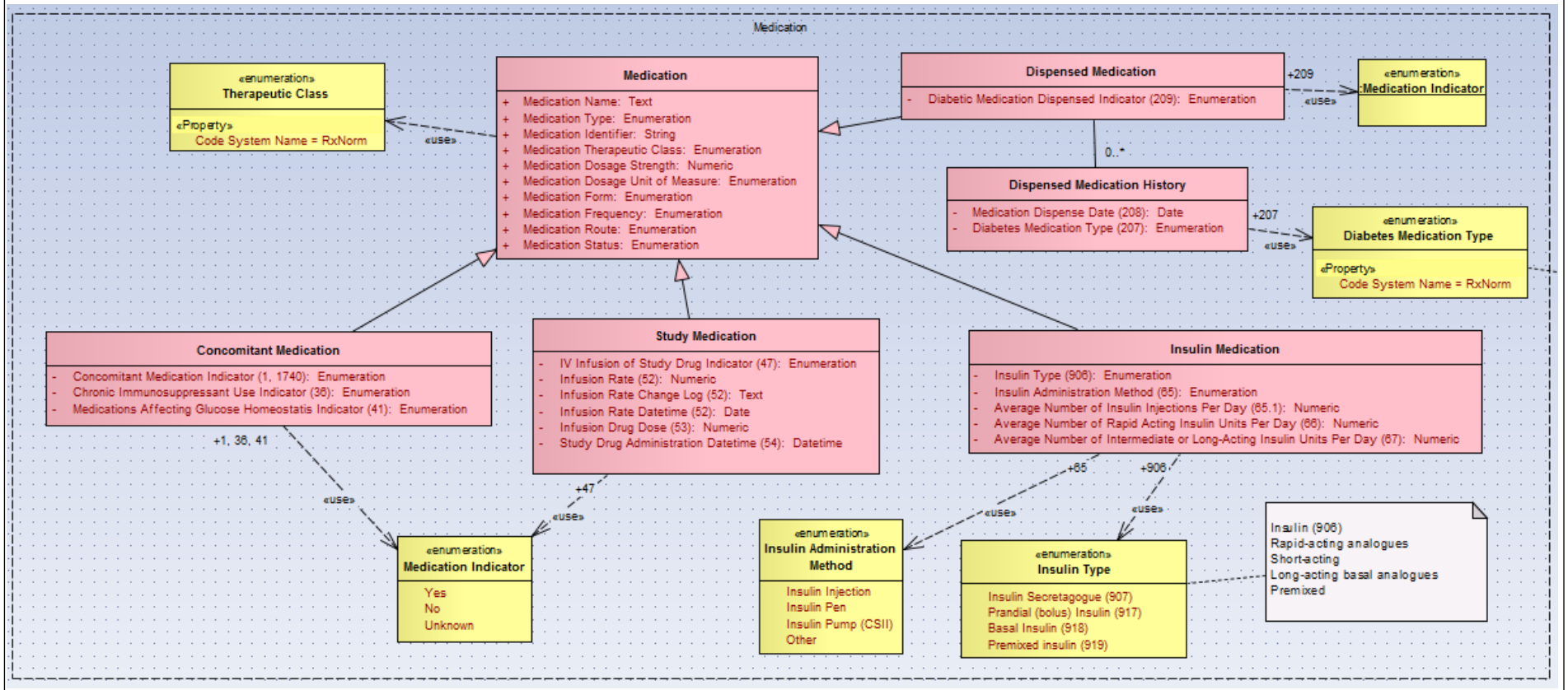
Data Modeling

- Modeling the data elements
  - Creates a graphical depiction of data elements
  - Helps identify atomic data elements and relationship to reuse elements
  - Demonstrates how patterns can be identified in support of future large scale harmonization efforts
  - Exploring relationship to existing standards (e.g., DCM, HITSP C154 and other specs, BRIDG, etc.)

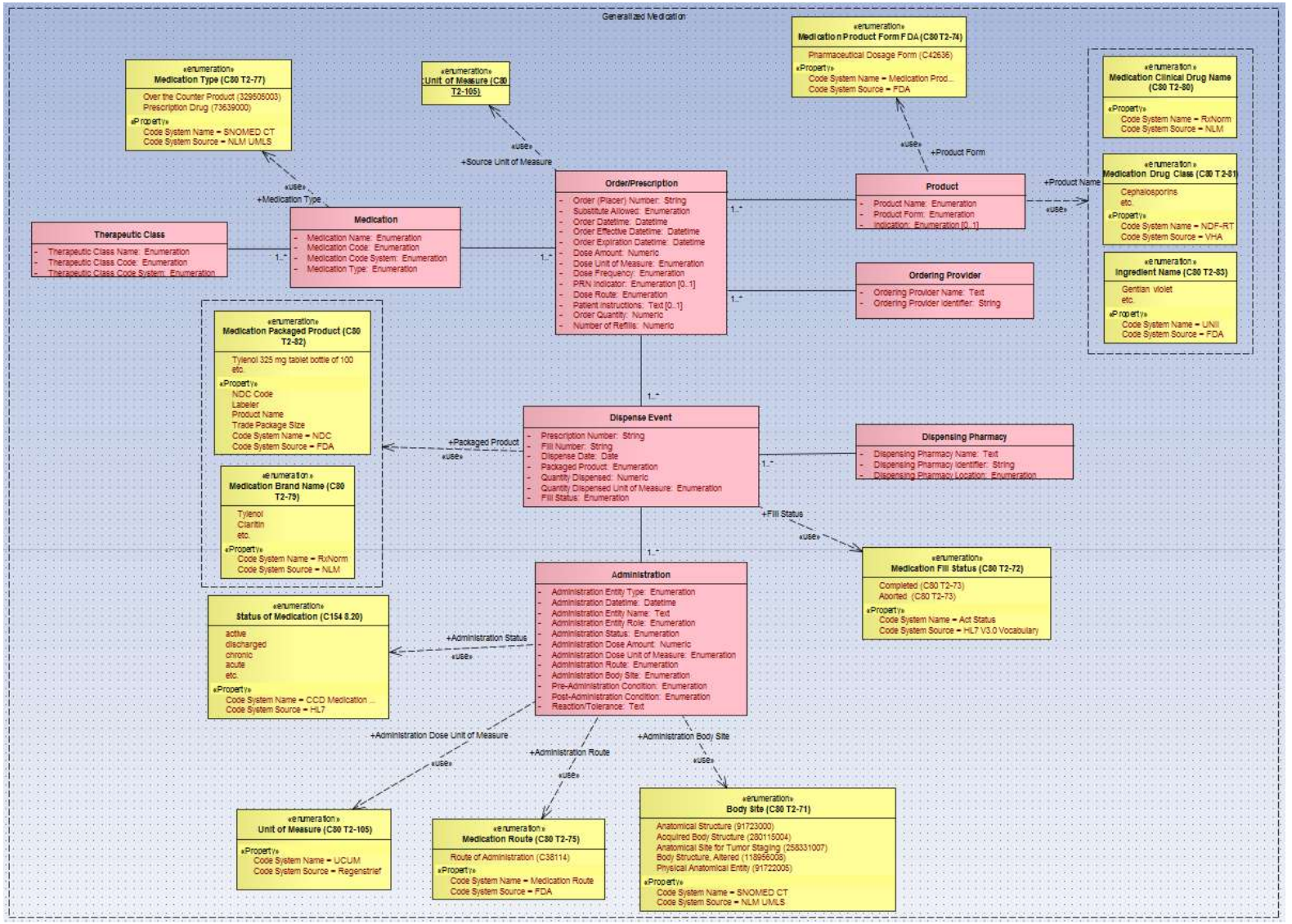
Modeling the Data Elements



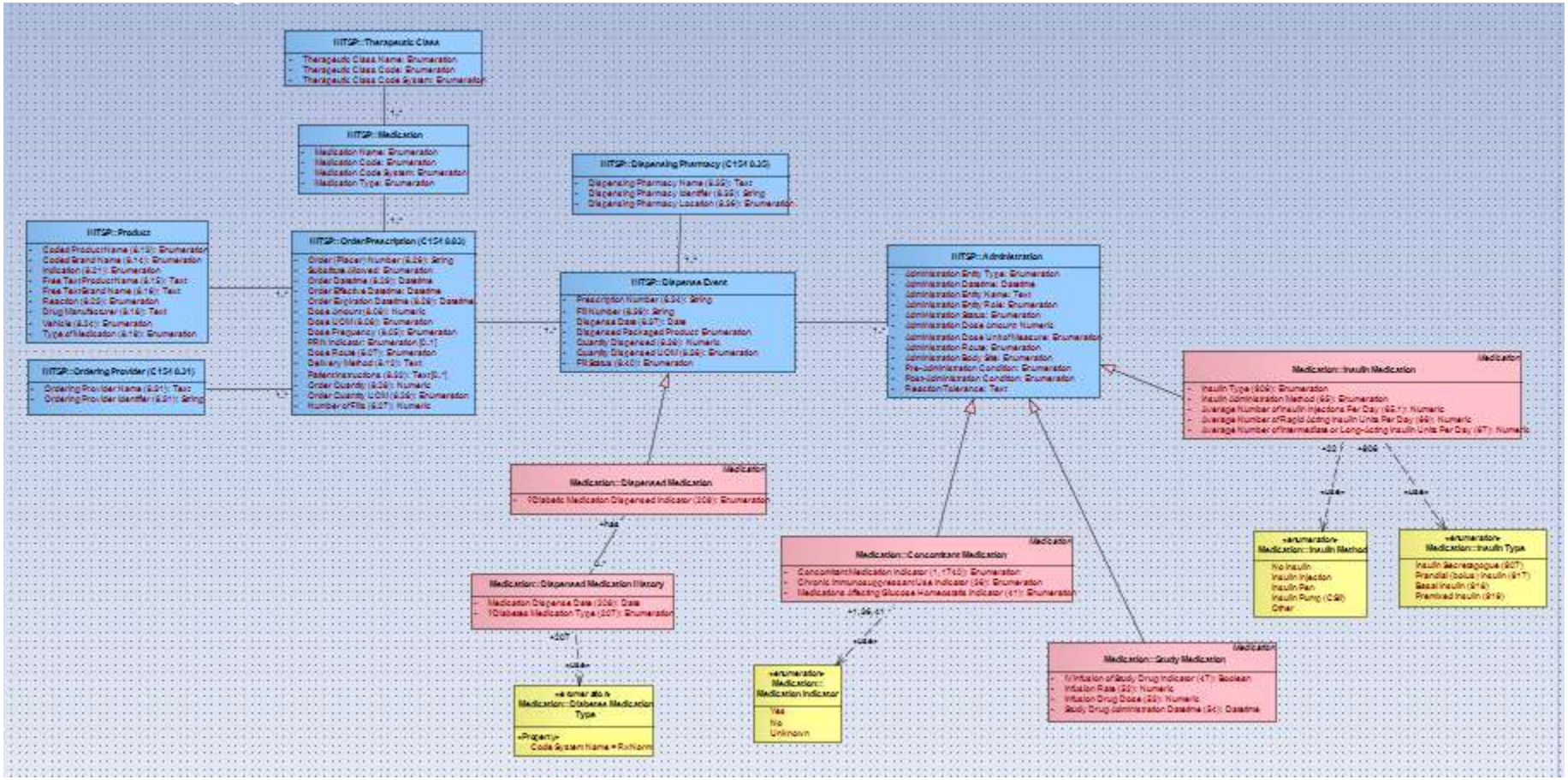
T1D Medication Elements



HITSP (hybrid) Medications



T1D/HITSP Merged - Medications

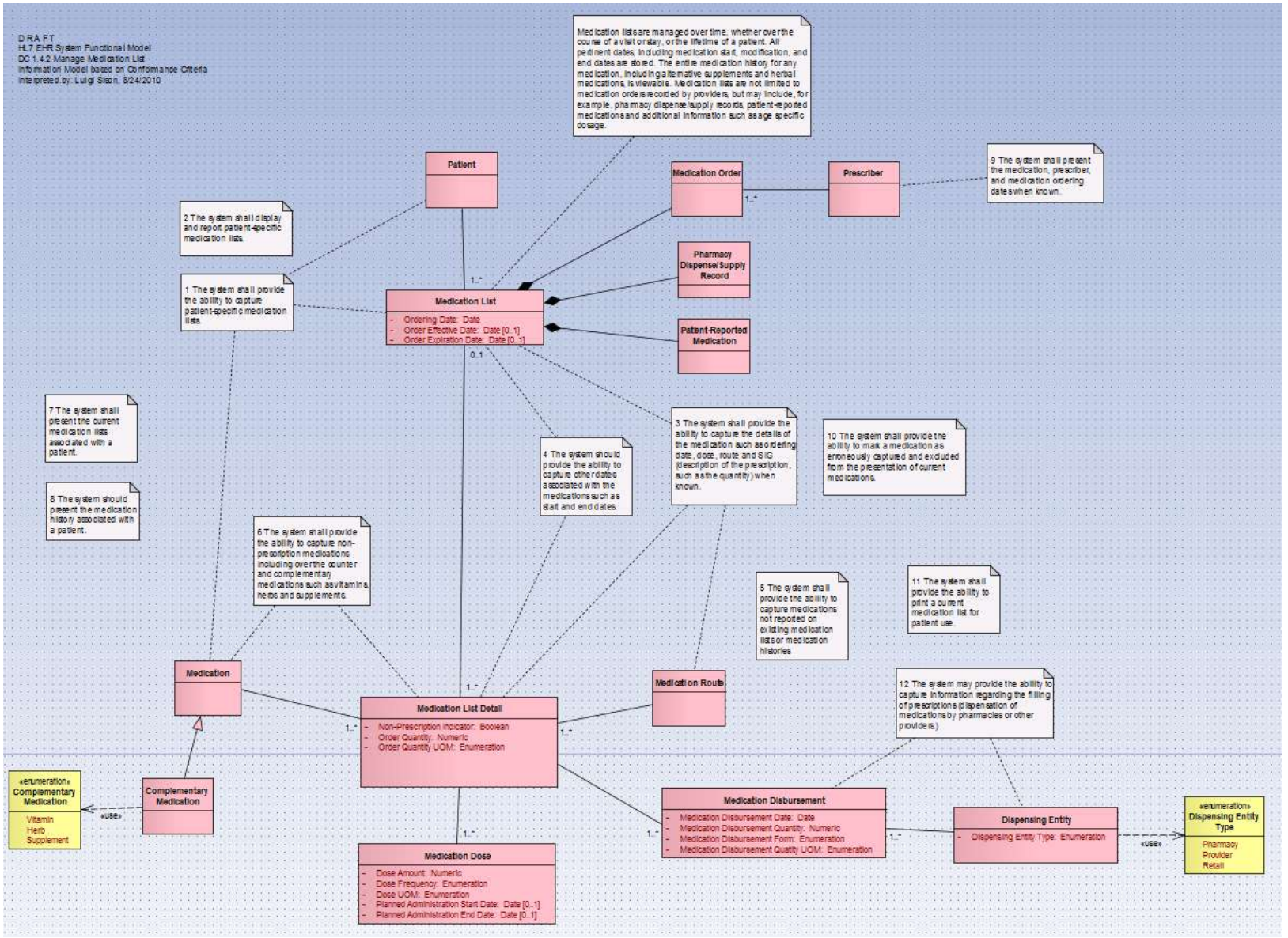


Data Mapping to EHR-S FM

- Early stages of mapping the atomic and T1D data elements to the EHR-S FM
- Prototype to test the feasibility and support future EHR WG data profile development

ID#	Type	Name	Statement/Description	See Also	Conformance Criteria	Row #	HITSP C154 Data Element Name/ID/Definition	Diabe-DS Data Element Name/ID/Definition	Corresponding RIM Objects (may not be all inclusive)
							Administration Timing (8.03) A Sig Component defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time		
					4. The system **SHOULD** provide the ability to capture other dates associated with medications such as start and end dates.	131	**Order Expiration Date/Time (8.29)** The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance.		
							Medication Administration Date/Time (associated with HITSP C34) Date/time that medication was administered in a controlled setting such as ED, ambulatory surgical centers, inpatient NOTE: Also a **Medication Date/Time** element associated with TN906. Definition is less specific – "Date and time that the medication was administered."	**Study Drug Administration Date (54)** The date that a study drug was administered to a study participant.	

Data Mapping to EHR-S FM



Interoperability & Lifecycle Models

ONC/AHIC Year 4 Clinical Research Use Case			Action Record(s) per Action			Action Record Lifecycle Event ("X" if applicable to Action) See Key for Services per Event P = Persistence Services, T = Transactional Services (traditional														INPUT Data needed to Begin Action
						P	T	T	T	P	P	P	P	P	P	P	P	P	P	P	
Sequence	Scenario, Event, Action	From Action Library: Action ID	Action shall/should/may have an Action	Combine with other Actions (list)	2+ Action Records (#)	Originate and Retain	Transmit, Disclose	Receive (no retention)	Receive and Retain	Amend	Translate	Verify	Attest	Access, Use	Converge	De-identify or Alias	Re-Identify	Archive	Lose or Destroy	Deprecate	
7.0	**Core Research Data Element Exchange**																				
7.1	**Study Sponsor Perspective**																				
7.1.1	**Event: Complete and Communicate Study Design**																				
7.1.1.1	**Action:** Develop study design and protocol.																				
7.1.1.2	**Action:** Working with the Principal Investigator.																				
7.1.1.3	**Action:** Sponsor sends design and protocol to investigative site and Reviewer(s).																				
7.1.2	**Event: Send case reporting form (CRF Template) from centrally hosted server**																				
7.1.2.1	**Action:** Sponsor sends CRF to the Investigative Site data manager.																				
7.1.3	**Event: Receive, validate and tabulate CRF study data**																				

Successes / Opportunities

- LOTS of interest in the project
- Engaging a very diverse group of volunteers – various perspectives; including clinicians
- Identifying some gaps in HITSP constructs
- Process supports a patient-centric view

Challenges / Lessons Learned

- Industry is a sea of change - working with a lot of moving parts
  - Related topics/issues discussed throughout HL7
  - Meaningful Use
  - Quality measures in flux
  - Adding new content as it comes along
- Managing scope creep is difficult
- Need for consistency /best practices for naming variables/questions/data elements

Next Steps

- Engage with public health
- Continue prototype analysis
- Document the process, methodology, and outcome
- Summarize/publish prototype results
- Determine how to advance/expand the work
- Formally engage various T1D experts and stakeholders
  - Coordinate with CIC, CIIC and Child Health WG to engage with professional groups (e.g., ADA, endocrinology, pediatrics) to endorse EHR standard elements (which also support data reuse)

“Two Pager” about the Project

The Diabe-DS Proof-of-Concept for “Collect Once, Use Many” Project: A Strategy for Defining Common Data Elements to Support Clinical Care and Secondary Use

A pilot demonstration project sponsored by the HL7 EHR Workgroup
Team member list attached

Overview

The objective of the Diabe-DS (Diabetes Data Strategy) proof-of-concept project is to demonstrate a repeatable process that identifies important data elements for clinical care and secondary use. The process provides a framework for the “collect once, repurpose many times” paradigm, which is vital to support the next generation of clinical and translational research.

The project focuses on Type 1 Diabetes (T1D) assessment in an ambulatory setting to document the process and produce artifacts.

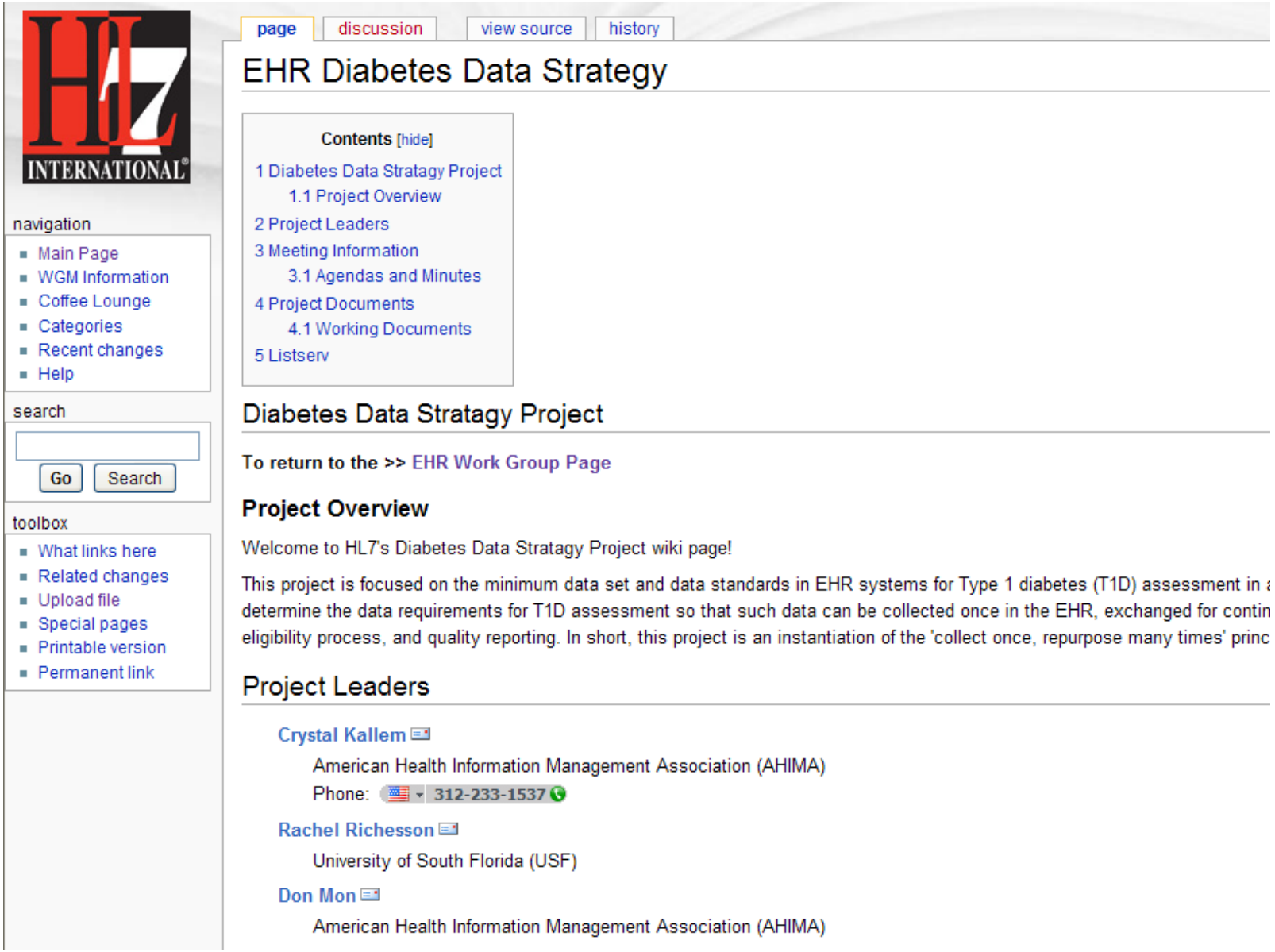
Background

There are several data standards and reporting requirements for healthcare organizations to consider in the collection of healthcare data. The standards and requirements are vast in scope (most cover all disease areas) and therefore complex to implement. The healthcare industry needs clinical content data standards (e.g., data elements, definitions and value sets, information models) which can support both patient care and secondary data uses, such as quality measurement and a spectrum of clinical research and population health activities. These clinical content data standards will likely be developed in disease- or therapeutic-specific contexts, but need to be harmonized with complex national and international data standards and specifications. The learning curve and technical skills required for a disease-specific content data standards project are significant – especially in the context of a focused domain – and the potential for duplication of effort and for conflicting data standards across clinical content areas is very real. This creates a need for a standards-based process that specifically includes: a thorough review of existing standards (of many types), an analysis of the data requirements for both patient care and secondary uses, and formal linkage of these requirements and data standards to Electronic Health Record (EHR) information models and functional specifications.

Methods

The Diabe-DS (Diabetes Data Strategy) project was formed in early 2009 by the HL7 EHR Working Group and includes representatives from academic medical centers, research

Follow the Project on the EHR WG Wiki



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EHR Diabetes Data Strategy

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Diabetes Data Stratagy Project

To return to the >> EHR Work Group Page

Project Overview

Welcome to HL7's Diabetes Data Stratagy Project wiki page!

This project is focused on the minimum data set and data standards in EHR systems for Type 1 diabetes (T1D) assessment in a determine the data requirements for T1D assessment so that such data can be collected once in the EHR, exchanged for contin eligibility process, and quality reporting. In short, this project is an instantiation of the 'collect once, repurpose many times' princ

Project Leaders

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