Proposal Revision

Revision to Proposal titled: "**Adding PROM data to CDM**"
Initial proposal requested by: Colin Orr and Catherine Kerr; ICON plc
Revising party: Joshua Ransom, Anna Corning, Emelly Rusli, Rayhnuma Ahmed, Aaron Stern; SHYFT Analytics

Reference from original proposal: ICON plc is developing a platform to ingest, store and analyse the outcome measures and is using the OMOP Common Data Model to store the data. The current CDM satisfies many of the requirements, but there are some gaps, specifically:

1. We need to store data relating to each PROM (Patient_reported Outcome Measure) questionnaire that is completed by a patient. We propose introducing a new **SURVEY** table. Each row in the table represents an instance of a completed survey and serves to link a number of question and responses together in the **RESPONSE** table as well as providing additional information about the survey itself.
2. The patient responses are stored as key-value pairs in the **RESPONSE** table, and we need to be able to group responses together according to the survey they belong to. We also need to know the timing of the response in relation to the treatment the patient received - for example, 'baseline', or 'six month follow-up', so that we can compare outcomes. We propose adding the **SURVEY** and **RESPONSE** tables to fit these requirements.
3. Patient responses will be stored in the **RESPONSE** table as either: RESPONSE_AS_CONCEPT_ID, RESPONSE_AS_NUMBER, and/or RESPONSE_AS_STRING. We require an extension to the concept table to include the following domain/vocabulary additions:

Domain	Vocabulary
Survey	LOINC (PhenX and EQ-5D are both captured within this existing vocabulary), OMOP Custom (including ICHOM?) *each survey included may require end user license agreements
Question	LOINC (PhenX and EQ-5D are both captured within this existing vocabulary), OMOP Custom (including ICHOM?) *each survey included may require end user license agreements

4. QUESTION_CONCEPT_ID and QUESTION_SOURCE_VALUE may be used to record individual questions or groupings of questions that represent a survey Section (these relationships could be managed within the FACT_RELATIONSHIP table as well)
5. *Reference from original proposal: …Extensions to the concept table will include the ICHOM Data Dictionaries for each Standard Set. This requires new concepts for each data point in each Standard Set AND a concept for each allowable value for each data point. The ICHOM vocabulary will grow with each Standard Set that is defined by ICHOM. Each Standard Set is likely to generate 500 to 1,000 concepts and the objective is for 50 Standard Sets, thus requiring in the order of 50,000 new concepts.*

SURVEY table
(other potential table name options: PRO, PATIENT_REPORTED_OUTCOME, PROM, others?)

Field *Proposed revision*	Required	Type	Description	Field *Reference from original proposal, if revised*
SURVEY_OCCURRENCE_ID	Yes	integer	Unique identifier for each completed survey	SURVEY_ID
SURVEY_CONCEPT_ID	Yes	integer	A foreign key that refers to a survey Concept identifier in the Standardized Vocabularies	
PERSON_ID	Yes	integer	A foreign key identifier to the Person in the PERSON table about whom the survey was completed	
VISIT_OCCURRENCE_ID	No	integer	A foreign key to the visit in the visit table during which the treatment was carried out that relates to this survey	
SURVEY_DATE	Yes	date	Date on which the survey was completed	
ASSISTANCE_CONCEPT_ID	No	integer	A foreign key that refers to a data source Concept identifier in the Standardized Vocabularies Example: Yes = concept_id 45877994; LOINC concept_code LA33-6 No = concept_id 45878245; LOINC concept_code LA32-8	ASSISTED_IND_CONCEPT_ID

Field *Proposed revision*	Required	Type	Description	Field *Reference from original proposal, if revised*
ASSISTANCE_SOURCE_VALUE	No	varchar (10)	The assistance identifier as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference. Example: ICHOM code representing whether patient required assistance to complete the survey - 1=Completed without assistance, 2=Completed with assistance	ASSISTED_IND
SURVEY_RECORDER_CONCEPT_ID	No	integer	A foreign key that refers to recorder Concept identifier in the Standardized Vocabularies Example: Research Associate = concept_id 4074477; SNOMED concept_code 224614003 Patient = concept_id 4023409; SNOMED concept_code 116154003	DATA_SOURCE_CONCEPT_ID

Field *Proposed revision*	Required	Type	Description	Field *Reference from original proposal, if revised*
SURVEY_RECORD ER_SOURCE_VALU E	No	varchar (10)	The observation code as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference. Example: ICHOM code representing role of person who completed the survey - e.g. 1=Administrative, 2=Clinician, 3=Patient-reported	DATA_SOURCE
TIMING_CONCEPT _ID	No	integer	A foreign key that refers to a timing Concept identifier in the Standardized Vocabularies Example: 3 month follow-up = concept_id 44789369; SNOMED obs concept_code 200521000000107	
TIMING_SOURCE_ VALUE	No	varchar (100)	The timing value as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference. Example: Text string representing the timing of the survey - e.g. 'BASELINE'	

Field *Proposed revision*	Required	Type	Description	Field *Reference from original proposal, if revised*
COLLECTION_METHOD_CONCEPT_ID	No	varchar (10)	A foreign key that refers to a collection method Concept identifier in the Standardized Vocabularies Telephone Reported = concept_id 4084141; obs SNOMED concept_code 281313006 Etc.	
COLLECTION_METHOD_SOURCE_VALUE	No	varchar (50)	The collection type as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference. Example: ICHOM code representing method of capturing responses in survey - e.g. 1=Paper, 2=Telephone, 3=Electronic Questionnaire	COLLECTION_METHOD
DURATION_TIME	No	varchar (50)	Time taken to complete survey HH:MM:SS	DURATION
SURVEY_SOURCE_VALUE	No	varchar (100)	The survey name/title as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference.	

Please note: the SURVEY_ID field was removed from this revised proposal as the CDM does not generally specify a field for the source data unique identifier.

SURVEY_RESPONSE or **RESPONSE table**
(discussed table name QUESTION but decided against this option as it does not specify the outcome of those questions)

Field	Required	Type	Description
RESPONSE_OCCURRENCE_ID	Yes	integer	Unique identifier for each response.
PERSON_ID	Yes	integer	A foreign key identifier to the Person in the PERSON table about whom the response was recorded.
SURVEY_OCCURRENCE_ID	Yes	integer	A foreign key to SURVEY table about which survey the question and response occurred.
QUESTION_CONCEPT_ID	Yes	integer	A foreign key that refers to a question Concept identifier in the Standardized Vocabularies
QUESTION_SOURCE_VALUE	No	varchar(255)	The question as it appears in the source data. This code is mapped to a Standard Concept in the Standardized Vocabularies and the original code is, stored here for reference.
RESPONSE_DATE	Yes	date	Date on which the response was recorded
RESPONSE_DATETIME	No	datetime	Date and time on which the response was recorded
RESPONSE_AS_CONCEPT_ID	Yes	integer	Foreign key that refers to a response Concept identifier in the Standardized Vocabularies
RESPONSE _AS_STRING	No	varchar(255)	The response stored as a string. This is applicable to questions where the result is expressed as verbatim text.
RESPONSE _AS_NUMBER	No	float	The response stored as a number. This is applicable to questions where the result is expressed as a numeric value.