

OpenStudyBuilder DDF Connect-a-thon

OpenStudyBuilder as an ODM Study Definition solution
Connectathon Category: Process Automation

30th September

OPEN STUDY BUILDER



EVIDENTIQ
CLINICAL DATA SCIENCE GROUP



REDCAP
CLOUD

neo4j

ODM-XML as a Study Definition

Library / Concepts / CRFs

CRFs ?

CRF Templates Forms Item Groups Items CRF Tree ODM View Alias

Expand All Reorder content

Templates / Forms / ItemGroups / Items	Version	Status	Repeating	Mandatory	Link
^ T ODM version 1.3.2 DM with DoB	1.0	Final			+
^ F Informed Consent and Demography	1.0	Final	<input type="checkbox"/>	<input type="checkbox"/>	+
^ G Informed Consent	1.0	Final	<input type="checkbox"/>	<input type="checkbox"/>	+
: I Study ID	1.0	Final		<input type="checkbox"/>	
: I Date Informed consent obtained	1.0	Final		<input type="checkbox"/>	
: I Time informed consent obtained	2.0	Final		<input type="checkbox"/>	
^ G General Demography	1.0	Final	<input type="checkbox"/>	<input type="checkbox"/>	+
: I Date of birth	1.0	Final		<input type="checkbox"/>	
: I Age	1.0	Final		<input type="checkbox"/>	
: I Sex [read-only]	1.0	Final		<input type="checkbox"/>	
: I Race	3.0	Final		<input type="checkbox"/>	
: I Ethnicity	1.0	Final		<input type="checkbox"/>	

Simple CRF / ODM-XML View with blank and annotated CRF based on ODM-XML

Download as XML

One ODM-XML to rule them all...

```

<?xml version="1.0" encoding="utf-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" ODMVersion="1.3.2" FileType="Snapshot" FileOID="OID.1664369356550" CreationDateTime="2022-09-28T12:49:16.550695" Granularity="All">
  <Study OID="ODM version 1.3.2 DM with DoB-T.ODM-1-3-2-V1">
    <GlobalVariables>
      <StudyName>ODM version 1.3.2 DM with DoB</StudyName>
      <StudyDescription>ODM version 1.3.2 DM with DoB</StudyDescription>
      <ProtocolName>ODM version 1.3.2 DM with DoB</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions>
      <MeasurementUnit OID="years" Name="DictionaryTerm_000913">
        <Symbol>
          <TranslatedText xml:lang="en">years</TranslatedText>
        </Symbol>
      </MeasurementUnit>
    </BasicDefinitions>
    <MetaDataVersion OID="MDV.0.1" Name="MDV.0.1" Description="Draft version">
      <FormDef OID="F.DM" Name="Informed Consent and Demography" Repeating="No">
        <Description>
          <TranslatedText xml:lang="en">Informed Consent and Demography form</TranslatedText>
        </Description>
        <ItemGroupRef ItemGroupOID="G.DM.IC" Mandatory="Yes" OrderNumber="1" />
        <ItemGroupRef ItemGroupOID="G.DM.DM" Mandatory="Yes" OrderNumber="2" />
      </FormDef>
      <ItemGroupDef OID="G.DM.DM" Name="General Demography" Repeating="No" Purpose="Tabulation" SASDatasetName="DEMOG" Domain="DM">
        <Description>
          <TranslatedText xml:lang="en">General Demographic item group</TranslatedText>
        </Description>
        <ItemRef ItemOID="I.BRTHDTC" Mandatory="Yes" OrderNumber="1" />
        <ItemRef ItemOID="I.AGE" Mandatory="No" OrderNumber="2" />
        <ItemRef ItemOID="I.SEX" Mandatory="Yes" OrderNumber="3" />
        <ItemRef ItemOID="I.RACE" Mandatory="Yes" OrderNumber="4" />
        <ItemRef ItemOID="I.ETHNIC" Mandatory="No" OrderNumber="5" />
      </ItemGroupDef>
      <ItemGroupDef OID="G.DM.IC" Name="Informed Consent" Repeating="No" Purpose="Tabulation" SASDatasetName="DEMOG" Domain="DM">
        <Description>
          <TranslatedText xml:lang="en">Informed Consent item group</TranslatedText>
        </Description>
        <ItemRef ItemOID="I.STUDYID" Mandatory="Yes" OrderNumber="1" />
        <ItemRef ItemOID="I.RFICDAT" Mandatory="Yes" OrderNumber="2" />
        <ItemRef ItemOID="I.RFICTIM" Mandatory="No" OrderNumber="3" />
      </ItemGroupDef>
      <ItemDef OID="I.STUDYID" Name="Study ID" Origin="Protocol Value" DataType="string" Length="11" SASFieldName="STUDYID" SDSVarName="STUDYID">
        <Question>
          <TranslatedText xml:lang="en">Study ID</TranslatedText>
        </Question>
        <Description>
          <TranslatedText xml:lang="en">Study Identifier</TranslatedText>
        </Description>
      </ItemDef>
    </Study>
  </ODM>

```

REDCap Cloud Integration – Using the ODM-XML file

Instrument View (Informed Consent and Demography)

Instrument Definition Instrument Variables Response Sets

Section 1

General Demography	
Date of birth* <i>(date_of_birth)</i>	<input type="text" value="14"/>
Sex _____* <i>(sex_read_only_)</i>	<input type="radio"/> Male <input type="radio"/> Female
Ethnicity <i>(ethnicity)</i>	<input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> Hispanic or Latino
Race* <i>(race)</i>	<input type="radio"/> Black or African American <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="radio"/> White <input type="radio"/> Asian <input type="radio"/> American Indian or Alaska Native
Age <i>(age)</i>	<input type="text" value=""/> years

Informed Consent	
Study ID* <i>(study_id)</i>	<input type="text"/>
Date informed consent obtained* <i>(date_informed_consent_obtained)</i>	<input type="text" value="14"/>
Time informed consent obtained <i>(time_informed_consent_obtained)</i>	<input type="text" value="12:00 AM"/>

EvidentIQ Integration – Using the same ODM-XML!

The screenshot displays a web-based data entry interface for a clinical trial. On the left is a vertical navigation menu with icons for home, a plus sign, a clipboard, messages, charts, an envelope, a group of people, a calendar, a truck, a document, and a camera. The main content area is divided into two sections: 'Informed Consent' and 'General Demography'. The 'Informed Consent' section contains three text input fields: 'Study ID *' with the value '001', 'Date informed consent obtained *' with the value '9/29/2022', and 'Time informed consent obtained' with the value '8:06 AM'. Each field has a circular refresh icon and a plus icon. Below these is a radio button. The 'General Demography' section contains five fields: 'Date of birth *' with '9/1/1992', 'Age' with '30' and 'years', 'Sex [read-only] *' with 'Male', 'Race *' with 'Asian', and 'Ethnicity' with 'Not Hispanic or Latino'. Each field has a plus icon. A 'Save' button is located at the bottom right of the form.

Baseline Visit
C. 2

Informed Consent and Demography

Informed Consent

Study ID *

Date informed consent obtained *

Time informed consent obtained

General Demography

Date of birth *

Age years

Sex [read-only] *

Race *

Ethnicity

Save

OpenStudyBuilder as an ODM Study Definition solution

Connectathon Category: Process Automation



- ✓ Managing the Study Definition specification
- ✓ Delivering an ODM specification for EDC
- ✓ Link the CRF metadata with the Protocol one

Watch also the other videos:

- OpenStudyBuilder as a DDF compatible SDR solution
- OpenStudyBuilder integration to Protocol and SDTM Study Design datasets

Visit our GitLab site for more information:

<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>

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