**Introduction of Semantic Technology for SAS® programmers**

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**ABSTRACT**

There is a new technology to express and search the data that can provide more meaning and relationship – semantic technology. The semantic technology can easily add, change and implement the meaning and relationship to the current data. Companies such as Facebook and Google are currently using the semantic technology. For example, Facebook Graph Search use semantic technology to enhance more meaningful search for users.

The paper will introduce the basic concepts of semantic technology and its graph data model, Resource Description Framework (RDF). RDF can link data elements in a self-describing way with elements and property: subject, predicate and object. The paper will introduce the application and examples of RDF elements. The paper will also introduce three different representation of RDF: RDF/XML representation, turtle representation and N-triple representation.

The paper will also introduce “CDISC standards RDF representation, Reference and Review Guide” published by CDISC and PhUSE CSS. The paper will discuss RDF representation, reference and review guide and show how CDISC standards are represented and displayed in RDF format.

The paper will also introduce Simple Protocol RDF Query Language (SPARQL) that can retrieve and manipulate data in RDF format. The paper will show how programmers can use SPARQL to re-represent RDF format of CDISC standards metadata into structured tabular format.

Finally, paper will discuss the benefits and futures of semantic technology. The paper will also discuss what semantic technology means to SAS programmers and how programmers take an advantage of this new technology.

**WHAT IS SEMANTIC TECHNOLOGY?**

In dictionary, “Semantics” is the study of meaning. In data computing, Semantics means not only the meaning of data, but also the relationships between data. Semantic technology provides a new approach to modeling data. Its data model is very simple, consisting of subject, object and predicate/property as shown in Figure 1.

![Figure 1: Basic semantic data model](image)

Using this data model, semantic technology links together two entities (e.g., people, places, objects or things) based on the relationship between them to form a triple. It can also allow users to connect the data without transformations that could corrupt the original source of the data. With this triple model, programmers build a common vocabulary for describing an almost limitless number of facts and relationship of any data. This is one way to simplify and take an advantage of a big data.

**WHY SEMANTIC TECHNOLOGY?**

Semantic technology is a new way of modeling data. At its core, semantic technology exists because it adds contextual meaning around data so it can be better understood, searched, and shared. It also enables both people and machines to see and discover relationships in the data. For example, the phrase of “Kevin lives in Philadelphia” could be represented in RDF models. Figure 2 shows the RDF graphical representation of “Kevin lives in Philadelphia”. It shows how two entities, “Kevin” and “Philadelphia”, are linked with the relationship of “LiveIn”.

![Figure 2: single RDF data](image)

Semantic technology does not stop here. The programmers link the current data with other entities. For example, the phrase of “Philadelphia is in USA” could be added in the data in Figure 2. Figure 3 shows how programmers can add additional data to the existing data in semantic technology.
The power of semantic technology is that programmers can link the current data to endless entities with the relationship. For example, programmers can link “Kevin” to “PharmaSUG” with “Attend” relationship, “SAS program” with “skills” relationship, “Semantic Technology” with “skills” relationship and so on.

A log of linked open data such as DBPedia and GeoNames are published and ready to be used. Figure 4 shows some of public linked open data. Public open data continues to grow and gets used in many industries.

Programmers can use the currently available open linked data rather than create them from the scratch, which will save a lot of time. For example, if the programmers can link “Kevin” to “Philadelphia” of DBPedia in Figure 2, the programmer can access to all the published data of “Philadelphia” of DBPedia (http://dbpedia.org/page/Philadelphia).

Another advantage using semantic technology is that programmers can infer the another fact using connected data. Figure 5 shows how the programmers infer the new fact of “Kevin lives in USA” using two data of “Kevin lives in Philadelphia” and “Philadelphia is in USA”.

Figure 3: connected RDF data

Figure 4: Public linked data

Figure 5: Inferencing in Semantic technology
The semantic technology is adopted in data-driven companies like Google and Facebook for better, meaningful search.

FACEBOOK GRAPH SEARCH

Facebook Graph Search is a semantic search engine that was introduced by Facebook. It uses the semantic search to enhance its search engine. Users use Facebook Graph Search to find the information using both the contents of the users and their friends and their relationships.

For examples, if a user wants to find the restaurants that his friends like in Philadelphia in Facebook, Facebook Graph Search Engine will provide the list of restaurants that his friends liked in Philadelphia. As seen in Figure 6, if a user types “find the restaurants that my friends like in Philadelphia”, Facebook search engine finds the appropriate search phase based on its semantics, “restaurants that my friends like in Philadelphia”.

![Facebook Graph Search](image1)

**Figure 6: Facebook Graph Search**

Figure 7 provides the results of search using Facebook Graph Search.

![Facebook Search Results](image2)

**Figure 7: Search results from Facebook Graph Search**

Figure 8 shows how Facebook Graph Search uses semantic technology to find the information that I requested in Facebook.
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**INTRODUCTION OF RESOURCE DESCRIPTION FRAMEWORK (RDF)**

Resource Description Framework (RDF) is a standard data representation of Semantic Technology maintained by [www.w3c.org](http://www.w3c.org). RDF has two data structures: RDF graphs and RDF datasets.

- RDF graphs are sets of subject-predicate-object.
- RDF datasets are collections of RDF graphs.

For example, in “CDISC standards RDF representation”, rdf.cdisc.org/std/sdtmig-3-1-3-1-3.ttl is a RDF dataset (Appendix 1 include SDTM DM portion of sdtmig-3-1-3.ttl) and the triple, the label of DM.AGE is “Age”, is an example of RDF graph.

```xml
<?xml version="1.0"?>
<rdf:RDF xmlns:rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
         xmlns:mms="http://rdf.cdisc.org/mms#">
  <rdf:Description rdf:about="http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE">
    <mms:dataElementLabel>"Age"^^xsd:string</mms:dataElementLabel>
  </rdf:Description>
</rdf:RDF>
```

In above RDF graph (triple), the data is consisted of the following:
- subject is <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE>
- predicate is mms:dataElementLabel
- object is "Age"^^xsd:string

**RDF REPRESENTATION**

There are mainly three RDF representations: RDF/XML, turtle, and N-triple. Below examples provide three different RDF representation of the triple, the label of DM.AGE is “Age”.

**In RDF/XML**

```xml
<?xml version="1.0"?>
<rdf:RDF xmlns:rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
         xmlns:mms="http://rdf.cdisc.org/mms#"/>
```

**In turtle**

```turtle
@prefix xsd: <http://www.w3.org/2001/XMLSchema#> .
@prefix mms: <http://rdf.cdisc.org/mms#> .
<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE> mms:dataElementLabel "Age"^^xsd:string .
```

**In N-triple**

```turtle
```

Figure 10 shows the graphic representation of the given triple.
INTRODUCTION OF CDISC RDF


Programmers can download RDF representation of CDASH, SDTM, SEND, ADaM and CT from GitHub project. Code 1 is the RDF representation of DM.AGE in SDTMIG 3.1.3.

```
<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE>
  rdf:type mms:Column ;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
  mms:dataElementDescription "Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns)."^^xsd:string ;
  mms:dataElementLabel "Age"^^xsd:string ;
  mms:dataElementName "AGE"^^xsd:string ;
  mms:dataElementType "xsd:positiveInteger"^^xsd:anySimpleType ;
  mms:ordinal "17"^^xsd:positiveInteger ;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtmig-3-1-3#Classifier.ExpectedVariable> ;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtmig-3-1-3#Classifier.RecordQualifier> ;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Numeric> ;
```

Code 1: DM.AGE RDF representation(turtle) in SDTMIG 3.1.3

Table 1 shows how RDF triple can be represented as typical tabular structures.

<table>
<thead>
<tr>
<th>RDF type</th>
<th>mms:context</th>
<th>mms:dataElementDescription</th>
<th>mms:datElementLabel</th>
<th>mms:datElementName</th>
<th>mms:ordinal</th>
<th>cdiscs:dataElementCompliance</th>
<th>cdiscs:daElementRole</th>
<th>cdiscs:dataElementType</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dataset. Column</td>
<td>DM</td>
<td>Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns)</td>
<td>Age</td>
<td>AGE</td>
<td>Positive Integer</td>
<td>n/a</td>
<td>Classifier.ExpectedVariable</td>
<td>Classifier.RecordQualifier</td>
</tr>
</tbody>
</table>

INTRODUCTION OF SPARQL

Simple Protocol RDF Query Language (SPARQL) is a standard query language that can convert RDF graph format to structured tabular format. SPARQL is also maintained by www.w3c.com. The paper will use TopBraid to represent the graph format of RDF CDISC Standards metadata to a tabular format.

In above RDF representation of DM.AGE, if a programmer wants to see only the description of DM.AGE, he can use SPARQL as the following.

```
PREFIX mms: <http://rdf.cdisc.org/mms#>
SELECT ?o
WHERE { <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE> mms:dataElementDescription ?o }
```

Above SPARQL in TopBraid will provide below response.

"Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns)."
Figure 11 shows how programmers can use SPARQL to obtain the label of DM.AGE from sdtmig-3-1-1.ttl dataset using TopBraid.

Figure 11: SPARQL query and its results in TopBraid.

PHUSE SEMANTIC TECHNOLOGY WORKING GROUP

PhUSE semantic technology working group is working on how semantic technology can support the clinical data life cycle from protocol to submission. Programmers can find more information in PhUSE wiki in http://www.phusewiki.org/wiki/index.php?title=Semantic_Technology.

Currently there are 4 active sub-groups:

- Analysis results and metadata in RDF – develops standards models and technical standards for the storage and usage of analysis results data and metadata using RDF data cube and R package.
- Clinical program design in RDF – develops a RDF model to capture, retain, reuse and share the design of clinical programs.
- Regulations in RDF – develops a searchable resource by extracting and linking structured information from regulations, guidance and regulatory processes.
- Use cases for linked data – develops use cases for linked data solutions in clinical data life cycle.

APPLICATION IN CLINICAL DATA LIFE CYCLE

Below use cases are possible practical applications in healthcare industry.

End to End Clinical Trial Artefacts Development

In current drug development, all the clinical trial artefacts are developed separately and in sequence. Protocol document is developed, then SAP, EDC, SDTM, ADaM, TFL and CSR are developed one after another. For example, when a clinician writes protocol, he or she does not really know how data are collected, prepared, analyzed and submitted. He simply passes on protocol to next people. Clinicians, data manager, programmers, statisticians and medical writers independently create their own clinical trial artefacts looking at the previous clinical trial artefacts. If clinical trial artefacts are linked through semantic technology, all parties will be able to clearly see a whole picture of what should be done in each stream. And using this data, clinical artefacts could be automatically created in each work stream without much of human involvement. Figure 12 shows how that once “Cheson 2007 criteria” is selected in protocol, all “Cheson 2007 criteria” driven clinical artefacts are defined and selected in each work stream.
Figure 12: End to End clinical trial artefacts using semantic technology

Traceability of clinical trial data
Figure 12 also shows the traceability of data and documents from protocol to analysis. The data point level traceability can be achieved as well. For example, programmers can add another triple to provide the traceability from SDTM DM.AGE to ADaM ADSL.AGE. As seen below, one line of triple can add the traceability from SDTM DM.AGE to ADaM ADSL.AGE.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE> mms:TracedFrom <http://rdf.cdisc.org/std/adamig-1-0#Column.ADSL.AGE>

Real world data application with clinical trial data
If clinical trial data is represented in triples, programmers can link a real world patient to clinical trial subjects with the same profiles. Figure 13 shows how “patient” and “subject 1” can be linked through common profiles such as male, colon cancer and age. In near future, once programmers have genetic makeups for patient and clinical trial subject, this linkage becomes a lot more powerful and effective. Using the inference of semantic technology, a patient could see how his symptom could be improved with the certain treatments and choose the best treatments. This will provide a data-driven personalized treatment.

Figure 13: Real world data application with clinical trial data

FUTURE AND BENEFITS
Semantic Technology has existed about 15 years since it was introduced by Berners Lee, who is the founder of internet. Semantic technology has evolved over time and now, it is considered as one of hot emerging technology. Semantic technology is here to stay and will play a major role in data-driven environment. Now, we see its real world
implementation in a data-driven companies like Facebook and Google, we also start seeing its implementation in our industry.

Unfortunately, SAS does not provide semantic-based procedures and functions yet. However, some programmers develop GitHub projects to implement semantic concepts in SAS environment (e.g., https://github.com/MarcJAndersen/SAS-RDF-writer). If SAS programmers understand its concepts and technologies and can bring semantic data in SAS environment, they can provide a great value to customers and sponsors.

CONCLUSION

Semantic technology provides another way to represent and understand data. Its data model allows programmers to connect to a limitless data, both in inside organization and outside organization such as DBPedia and OpenData. Understanding the benefits and potential of semantic technology, programmers will be able to view the contextual meaning of information and provide more accurate, relevant answers to the problems.

REFERENCES

https://www.w3.org/2001/sw/ W3C Semantic Web Activity Homepage
Semantics for Dummies by Allen Taylor
Facebook Graph Search Wikipedia in https://en.wikipedia.org/wiki/Facebook_Graph_Search
https://github.com/MarcJAndersen/SAS-RDF-writer by Marc Andersen
Semantic Web for Working Ontologist by Dean Alleman and James Hendler
https://github.com/phuse-org/rdf.cdisc.org PhUSE Semantic Technology Working Group CDISC Standards

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mms:ordinal "24"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "*****"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RequiredVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTMIG 4.1.2.1, SDTMIG 4.1.2.4"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGE>
  rdf:type mms:Column ;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
  mms:dataElementDescription "Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTETHDTC may not be available in all cases (due to subject privacy concerns)."^^xsd:string ;
  mms:dataElementLabel "Age"^^xsd:string ;
  mms:dataElementName "AGE"^^xsd:string ;
  mms:ordinal "17"^^xsd:positiveInteger ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Numeric> ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.AGEU>
  rdf:type mms:Column ;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
  mms:dataElementDescription "Units associated with AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTETHDTC may not be available in all cases (due to subject privacy concerns)."^^xsd:string ;
  mms:dataElementLabel "Age Units"^^xsd:string ;
  mms:dataElementName "AGEU"^^xsd:string ;
  mms:dataElementType "xsd:positiveInteger"^^xsd:anySimpleType ;
  mms:ordinal "18"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "(AGEU)"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.VariableQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;

cdiscs:references "SDTMIG 4.1.2.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.ARM>
  rdf:type mms:Column ;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
  mms:dataElementDescription "Name of the Arm to which the subject was assigned."^^xsd:string ;
  mms:dataElementLabel "Description of Planned Arm"^^xsd:string ;
  mms:dataElementName "ARM"^^xsd:string ;
  mms:ordinal "23"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "*****"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RequiredVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.SynonymQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTMIG 4.1.2.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.ARMCD>
  rdf:type mms:Column ;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
  mms:dataElementDescription "ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-character abbreviations for each treatment and separating hyphens, the length of ARMCD values would be 20."^^xsd:string ;
  mms:dataElementLabel "Planned Arm Code"^^xsd:string ;
  mms:dataElementName "ARMCD"^^xsd:string ;
  mms:ordinal "22"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "*****"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RequiredVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTMIG 4.1.2.1"^^xsd:string ;
<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.BRTHDTC>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Date/time of birth of the subject."^^xsd:string ;
mms:dataElementLabel "Date/Time of Birth"^^xsd:string ;
mms:dataElementName "BRTHDTC"^^xsd:string ;
mms:dataElementType "xsd:dateTime"^^xsd:anySimpleType ;
mms:ordinal "16"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.COUNTRY>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Country of the investigational site in which the subject participated in the trial."^^xsd:string ;
mms:dataElementLabel "Country"^^xsd:string ;
mms:dataElementName "COUNTRY"^^xsd:string ;
mms:dataElementType "xsd:string"^^xsd:anySimpleType ;
mms:ordinal "26"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 3166"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RequiredVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.DMDTC>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElement <http://rdf.cdisc.org/std/sdtm-1-3#DataElement.Timing.--DTC> ;
mms:dataElementDescription "Date/time of demographic data collection."^^xsd:string ;
mms:dataElementLabel "Date/Time of Collection"^^xsd:string ;
mms:dataElementName "DMDTC"^^xsd:string ;
mms:dataElementType "xsd:dateTime"^^xsd:anySimpleType ;
mms:ordinal "27"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.TimingVariable> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.DMDY>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElement <http://rdf.cdisc.org/std/sdtm-1-3#DataElement.Timing.--DY> ;
mms:dataElementDescription "Study day of collection measured as integer days."^^xsd:string ;
mms:dataElementLabel "Study Day of Collection"^^xsd:string ;
mms:dataElementName "DMDY"^^xsd:string ;
mms:dataElementType "xsd:integer"^^xsd:anySimpleType ;
mms:ordinal "28"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 3166"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.TimingVariable> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Numeric> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.DOMAIN>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Two-character abbreviation for the domain."^^xsd:string ;
mms:dataElementLabel "Domain Abbreviation"^^xsd:string ;
mms:dataElementName "DOMAIN"^^xsd:string ;
mms:dataElementType "xsd:string"^^xsd:anySimpleType;
    mms:ordinal "2"^^xsd:positiveInteger;
    cdiscs:controlledTermsOrFormat "DM"^^xsd:string;
    cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RequiredVariable>;
    cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.IdentifierVariable>;
    cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
    cdiscs:references "SDTM 2.2.4, SDTMIG 4.1.2.2, SDTMIG Appendix C2"^^xsd:string;
    .
    <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.DTHDTC>
    rdf:type mms:Column;
    mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
    mms:dataElementDescription "Date/time of death for any subject who died, in ISO 8601 format. Should represent
    the date/time that is captured in the clinical-trial database."^^xsd:string;
    mms:dataElementLabel "Date/Time of Death"^^xsd:string;
    mms:dataElementName "DTHDTC"^^xsd:string;
    mms:dataElementType "xsd:dateTime"^^xsd:anySimpleType;
    mms:ordinal "11"^^xsd:positiveInteger;
    cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string;
    cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable>;
    cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
    cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
    cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
    .
    <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.DTHFL>
    rdf:type mms:Column;
    mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
    mms:dataElementDescription "Indicates the subject died. Should be Y or null. Should be populated even when the
    death date is unknown."^^xsd:string;
    mms:dataElementLabel "Subject Death Flag"^^xsd:string;
    mms:dataElementName "DTHFL"^^xsd:string;
    mms:dataElementType "xsd:string"^^xsd:anySimpleType;
    mms:dataElementValueDomain sdtmct:C66742;
    mms:ordinal "12"^^xsd:positiveInteger;
    cdiscs:controlledTermsOrFormat "(NY)"^^xsd:string;
    cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable>;
    cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
    cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
    cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
    .
    <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.ETHNIC>
    rdf:type mms:Column;
    mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
    mms:dataElementDescription "The ethnicity of the subject. Sponsors should refer to "Collection of Race and
    Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity
    (http://www.fda.gov/cder/guidance/5656fnl.htm)."^^xsd:string;
    mms:dataElementLabel "Ethnicity"^^xsd:string;
    mms:dataElementName "ETHNIC"^^xsd:string;
    mms:dataElementType "xsd:string"^^xsd:anySimpleType;
    mms:dataElementValueDomain sdtmct:C66790;
    mms:ordinal "21"^^xsd:positiveInteger;
    cdiscs:controlledTermsOrFormat "(ETHNIC)"^^xsd:string;
    cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable>;
    cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
    cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
    .
    <http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.INVID>
    rdf:type mms:Column;
    mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
    mms:dataElementDescription "An identifier to describe the Investigator for the study. May be used in addition to
    SITEID. Not needed if SITEID is equivalent to INVID."^^xsd:string;
    mms:dataElementLabel "Investigator Identifier"^^xsd:string;
    mms:dataElementName "INVID"^^xsd:string;
    mms:dataElementType "xsd:string"^^xsd:anySimpleType;
    mms:ordinal "14"^^xsd:positiveInteger;
    cdiscs:controlledTermsOrFormat "(INVID)"^^xsd:string;
    cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable>;
    cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
    cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
    .
<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.INVNAM>
rdf:type mms:Column;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
  mms:dataElementDescription "Name of the investigator for a site."^^xsd:string;
  mms:dataElementLabel "Investigator Name"^^xsd:string;
  mms:dataElementName "INVNAM"^^xsd:string;
  mms:dataElementType "xsd:string"^^xsd:anySimpleType;
  mms:ordinal "15"^^xsd:positiveInteger;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable>;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.SynonymQualifier>;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RACE>
rdf:type mms:Column;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
  mms:dataElementDescription "Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race.
(http://www.fda.gov/cder/guidance/5656fnl.htm) See Assumption below regarding RACE."^^xsd:string;
  mms:dataElementLabel "Race"^^xsd:string;
  mms:dataElementName "RACE"^^xsd:string;
  mms:dataElementTypeValueDomain sdtmct:C74457;
  mms:ordinal "20"^^xsd:positiveInteger;
  cdiscs:controlledTermsOrFormat "(RACE)"^^xsd:string;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable>;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
  cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFENDTC>
rdf:type mms:Column;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
  mms:dataElementDescription "Reference End Date/time for the subject in ISO 8601 character format. Usually equal to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects."^^xsd:string;
  mms:dataElementLabel "Subject Reference End Date/Time"^^xsd:string;
  mms:dataElementName "RFENDTC"^^xsd:string;
  mms:ordinal "6"^^xsd:positiveInteger;
  cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable>;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
  cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFICDTC>
rdf:type mms:Column;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
  mms:dataElementDescription "Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent."^^xsd:string;
  mms:dataElementLabel "Date/Time of Informed Consent"^^xsd:string;
  mms:dataElementName "RFICDTC"^^xsd:string;
  mms:ordinal "9"^^xsd:positiveInteger;
  cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable>;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier>;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
  cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
.

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFPENDTC>
rdf:type mms:Column;
  mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM>;
  mms:dataElementDescription "Date/time of reference to the investigator for a site. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race.
(http://www.fda.gov/cder/guidance/5656fnl.htm) See Assumption below regarding RFPENDTC."^^xsd:string;
  mms:dataElementLabel "Investigator Reference Date/Time"^^xsd:string;
  mms:dataElementName "RFPENDTC"^^xsd:string;
  mms:ordinal "15"^^xsd:positiveInteger;
  cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string;
  cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.PermissibleVariable>;
  cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.SynonymQualifier>;
  cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character>;
  cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string;
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mms:dataElementDescription "Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up date recorded for lost to follow up, or death date."^^xsd:string ;
mms:dataElementLabel "Date/Time of End of Participation"^^xsd:string ;
mms:dataElementName "RFPENDTC"^^xsd:string ;
mms:ordinal "10"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFSTDTDC>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects."^^xsd:string ;
mms:dataElementLabel "Subject Reference Start Date/Time"^^xsd:string ;
mms:dataElementName "RFSTDTDC"^^xsd:string ;
mms:ordinal "5"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFXENDTC>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing)."^^xsd:string ;
mms:dataElementLabel "Date/Time of Last Study Treatment"^^xsd:string ;
mms:dataElementName "RFXENDTC"^^xsd:string ;
mms:ordinal "8"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.RFXSTDTC>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC."
"^^xsd:string ;
mms:dataElementLabel "Date/Time of First Study Treatment"^^xsd:string ;
mms:dataElementName "RFXSTDTC"^^xsd:string ;
mms:ordinal "7"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "ISO 8601"^^xsd:string ;
cdiscs:dataElementCompliance <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable> ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;
cdiscs:references "SDTM 2.2.5, SDTMIG 4.1.4.1"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.SEX>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Sex of the subject."^^xsd:string ;
mms:dataElementLabel "Sex"^^xsd:string ;

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mms:dataElementName "SEX"^^xsd:string ;
<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.SITEID>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Unique identifier for a site within a study."^^xsd:string ;
mms:dataElementLabel "Study Site Identifier"^^xsd:string ;
mms:dataElementName "SITEID"^^xsd:string ;
mms:dataElementType "xsd:string"^^xsd:anySimpleType ;
mms:ordinal "19"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "(SEX)"^^xsd:string ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.RecordQualifier> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;

cdiscs:references "SDTM 2.2.4"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.STUDYID>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElement <http://rdf.cdisc.org/std/sdtm-1-3#DataElement.Identifier.STUDYID> ;
mms:dataElementDescription "Unique identifier for a study."^^xsd:string ;
mms:dataElementLabel "Study Identifier"^^xsd:string ;
mms:dataElementName "STUDYID"^^xsd:string ;
mms:dataElementType "xsd:string"^^xsd:anySimpleType ;
mms:ordinal "1"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "(STUDYID)"^^xsd:string ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.IdentifierVariable> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;

cdiscs:references "SDTM 2.2.4"^^xsd:string ;

<http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.DM.SUBJID>
rdf:type mms:Column ;
mms:context <http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.DM> ;
mms:dataElementDescription "Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF."^^xsd:string ;
mms:dataElementLabel "Subject Identifier for the Study"^^xsd:string ;
mms:dataElementName "SUBJID"^^xsd:string ;
mms:dataElementType "xsd:string"^^xsd:anySimpleType ;
mms:ordinal "4"^^xsd:positiveInteger ;
cdiscs:controlledTermsOrFormat "SUBJID"^^xsd:string ;
cdiscs:dataElementRole <http://rdf.cdisc.org/std/sdtm-1-3#Classifier.TopicVariable> ;
cdiscs:dataElementType <http://rdf.cdisc.org/std/schema#Classifier.Character> ;