On the Horizon:
New Trial Summary Dataset (TS)

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Presenting....

Overview
• What is it?
• Where did it come from?
• Who uses it?

Technical Specifications
• Structure
• Terminology
• Implementation Rules
What is TS?

It’s about the trial, not about the subjects.
It’s data...or is it metadata? Anyway, it’s summary information.
It’s the trial plan (mostly*); a mechanism for:
  Finding studies in a warehouse.
  Conveying the essence of a trial
It’s family with ClinicalTrials.gov
Multi-Drug Resistant Tuberculosis in Kor

This study is currently recruiting participants.

Verified on February 2011 by National Institutes of Health Clinical Center.

First Received on June 19, 2006. Last Updated on February 12, 2011.

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>National Institute of Allergy and Infectious Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaborators:</td>
<td>International Tuberculosis Research Center, National Masan Tuberculosis Hospital, Korean Center for Disease Control and Prevention</td>
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<td>Information provided by:</td>
<td>National Institutes of Health Clinical Center</td>
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<tr>
<td>ClinicalTrials.gov Identifier:</td>
<td>NCT00341001</td>
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</table>
Where did it come from?
Who uses it?

JANUS, ClinicalTrials.gov and
The Backstory

Helena Sviglin, FDA
Technical Highlights: Changes

• Structure change: four new variables
• Required and conditionally required content: the old version outlined what could be done, this one tells us what must be done
• New concepts:
  – Null flavors
  – Parameter (TSPARM) level metadata within the dataset instead of in the define.xml
  – The concept of Required applies to parameters (rows) in addition to variables (columns)
Structure Changes

- **TSVAL1..n**: Accommodates values >200 char, like CO
- **TSVALNF**: Parameter Null Flavor
- **TSVALCD**: Parameter Value Code
- **TSVCDREF**: Name of the Reference Terminology
- **TSVCDVER**: Version of the Reference Terminology
Structure Changes: TSVALNF

TS has a lot of required content and when it’s missing the reason needs to be explained; hence Flavors of Null. Flavors of Null is an existing HL7 concept; the TS team notes its novelty in SDTM and suggests testing it in TS. The Flavors of Null code list has 15 values used to express why a required parameter is not valued. Examples UNK (Unknown), NA (Not applicable), NI (No information), OTH (Other), PINF (Positive Infinity – in other words no upper limit)
Structure Changes:
TSVALCD, TSVCDREF, TSVCDER

Together these variables document coded parameter values:

TSVALCD  Parameter Value Code
TSVCDREF  Name of the Reference Terminology
TSVCDVER  Version of the Reference Terminology

If TSVALCD and TSVCDREF are mutually dependent (if one is filled the other must be), but TSVCDVER appears to be optional
Structure Changes:
TSVALCD, TSVCDREF, TSVCDER

SDTM V3.1.2 reserves space for synonyms of collected terms derived from external code lists. Terms are stored in the domain; dictionary refs in the define. See Events (--TERM/--BODSYS/--DECOD) and Interventions (--TRT/--DECOD/CLAS/CLASCD). This is different.

The new TS specs require a dictionary term and support dictionary documentation in the dataset for any term. There is no need to provide dictionary info in define.xml for TSPARM value-level metadata (or is there?)

External dictionaries, for example:
- DUNS, for the sponsor name
- SNOMED, for medical terminology
- UNII, for ingredients
- CDISC for CDISC published controlled terminology
- ...plus ISO8601, which is a format, not a dictionary
# Structure Changes: Null Flavors

<table>
<thead>
<tr>
<th>TSPARMCD</th>
<th>TSPARM</th>
<th>TSVAL</th>
<th>TSVALNF</th>
<th>TSVALCD</th>
<th>TSVCDREF</th>
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<tr>
<td>AGEMIX</td>
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</table>
## Structure Changes:
Coded Data with an External Reference

<table>
<thead>
<tr>
<th>TSPARMCD</th>
<th>TSPARM</th>
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<th>TSVALCD</th>
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Some new, some old. Use both the TS standard and CDSISC controlled terminology publications. They are harmonized right now but CT will accumulate before TS changes again.

TS now specifies *attributes* for TSPARMs, i.e. value-level metadata, including:

- Short name
- Long name
- Required/Conditionally Required/If Applicable
- Code List and Type (implied)
- Usage notes
Other Content Specifications

Chris Tolk, CDISC