INCREASE QUALITY AND REDUCE SDTM DEVELOPMENT TIME WITH A TEST DATA SIMULATOR

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June 2018
Agenda

- Challenges
- What is a Test Data Simulator (TDS)?
- How it Works?
- Scenarios
- Uploading Architect Loader Specification (ALS)
- Input Parameters
- Outputs with Sample
- Benefits
- Defensive Coding Technique - Sample

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Challenges

Name for Subject ID is never the same

Is Sex Male or Female, M or F, 1 or 2?

Adapted from slide courtesy of Armando Oliva, M.D. and Amy Malla, FDA

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What is a Test Data Simulator?

2016

- Client request for a SDTM and related Deliverables @ “First Patient First Visit”

Thought process to address the end go

- Through sufficient Data
- Additional Bonus –
  - Reduce Programming Time of SDTM
  - Defensive Programming
  - Downstream activities -

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How it works?

Download ALS from Rave → Upload to TDS → Generate Data for all forms in .csv file format

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Scenarios!!

- Screen Failures
- Subject screened, but not randomized
- Subject randomized, but did not receive study treatment
- Subjects being randomized, treated, completed
- Subject died
- Blinded studies, have define dummy information for DM, EX, SE & DS

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Uploading ALS

Test Data Simulator

Upload Rave Draft

C:\Users\bs1611\Desktop\TD

Browse... Upload

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Input Parameters

Note: All fields are Mandatory.

Number of Subjects

Study Start Date

Study End Date

FormOID

Informed Consent Date

Date of Birth

Subject ID

File Type

Age

FieldOID

Do you Require Additional Medical Coding

Submit  Cancel

Note: Select a Date field, if not select Birth Year
### Sample Outputs

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Size</th>
<th>Ratio</th>
<th>Packed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIMARY.csv</td>
<td>Microsoft Excel C</td>
<td>995</td>
<td>62%</td>
<td>292</td>
</tr>
<tr>
<td>ENROLL.csv</td>
<td>Microsoft Excel C</td>
<td>2,592</td>
<td>33%</td>
<td>1,209</td>
</tr>
<tr>
<td>VISITD.csv</td>
<td>Microsoft Excel C</td>
<td>28,272</td>
<td>90%</td>
<td>427</td>
</tr>
<tr>
<td>CONSENT.csv</td>
<td>Microsoft Excel C</td>
<td>8,949</td>
<td>91%</td>
<td>834</td>
</tr>
<tr>
<td>DEMOG.csv</td>
<td>Microsoft Excel C</td>
<td>2,866</td>
<td>53%</td>
<td>1,340</td>
</tr>
<tr>
<td>REG.csv</td>
<td>Microsoft Excel C</td>
<td>1,538</td>
<td>65%</td>
<td>531</td>
</tr>
<tr>
<td>NIS.csv</td>
<td>Microsoft Excel C</td>
<td>6,642</td>
<td>90%</td>
<td>660</td>
</tr>
<tr>
<td>MEDICN.csv</td>
<td>Microsoft Excel C</td>
<td>6,708</td>
<td>72%</td>
<td>1,367</td>
</tr>
<tr>
<td>DXMtx.csv</td>
<td>Microsoft Excel C</td>
<td>15,121</td>
<td>63%</td>
<td>5,543</td>
</tr>
<tr>
<td>DXTRT.csv</td>
<td>Microsoft Excel C</td>
<td>1,166</td>
<td>71%</td>
<td>343</td>
</tr>
<tr>
<td>SURG.csv</td>
<td>Microsoft Excel C</td>
<td>14,693</td>
<td>67%</td>
<td>4,086</td>
</tr>
<tr>
<td>RADTX.csv</td>
<td>Microsoft Excel C</td>
<td>11,554</td>
<td>84%</td>
<td>1,754</td>
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<tr>
<td>SYSTX.csv</td>
<td>Microsoft Excel C</td>
<td>30,703</td>
<td>69%</td>
<td>9,402</td>
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<tr>
<td>RECE.csv</td>
<td>Microsoft Excel C</td>
<td>13,158</td>
<td>88%</td>
<td>1,568</td>
</tr>
<tr>
<td>ECOG.csv</td>
<td>Microsoft Excel C</td>
<td>4,043</td>
<td>83%</td>
<td>702</td>
</tr>
<tr>
<td>IPREG.csv</td>
<td>Microsoft Excel C</td>
<td>7,187</td>
<td>61%</td>
<td>2,011</td>
</tr>
<tr>
<td>VS.csv</td>
<td>Microsoft Excel C</td>
<td>57,570</td>
<td>80%</td>
<td>11,532</td>
</tr>
<tr>
<td>VLS.csv</td>
<td>Microsoft Excel C</td>
<td>6,771</td>
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<td>903</td>
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<td>VEG.csv</td>
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<td>16,155</td>
<td>61%</td>
<td>6,373</td>
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<tr>
<td>ECGTIP1.csv</td>
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<td>14,394</td>
<td>65%</td>
<td>5,063</td>
</tr>
<tr>
<td>ECGTIP2.csv</td>
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<td>29,351</td>
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<td>10,005</td>
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<td>ECHO.csv</td>
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<td>2,024</td>
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<td>65,331</td>
<td>60%</td>
<td>25,143</td>
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<td>Microsoft Excel C</td>
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<td>60%</td>
<td>26,030</td>
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<tr>
<td>COAG.csv</td>
<td>Microsoft Excel C</td>
<td>14,593</td>
<td>59%</td>
<td>5,999</td>
</tr>
<tr>
<td>LURN.csv</td>
<td>Microsoft Excel C</td>
<td>7,689</td>
<td>83%</td>
<td>1,277</td>
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<tr>
<td>TSH.csv</td>
<td>Microsoft Excel C</td>
<td>14,208</td>
<td>62%</td>
<td>5,452</td>
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<td>PSA.csv</td>
<td>Microsoft Excel C</td>
<td>2,715</td>
<td>56%</td>
<td>1,191</td>
</tr>
<tr>
<td>CREATE1.csv</td>
<td>Microsoft Excel C</td>
<td>2,902</td>
<td>57%</td>
<td>1,257</td>
</tr>
<tr>
<td>CREATE2.csv</td>
<td>Microsoft Excel C</td>
<td>1,672</td>
<td>70%</td>
<td>500</td>
</tr>
<tr>
<td>AEL.csv</td>
<td>Microsoft Excel C</td>
<td>20,761</td>
<td>62%</td>
<td>11,202</td>
</tr>
<tr>
<td>JL.csv</td>
<td>Microsoft Excel C</td>
<td>1,490</td>
<td>66%</td>
<td>504</td>
</tr>
</tbody>
</table>

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| A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | AA | AB | AC | AD | AE | AF | AG | AH |
| 1 | project | study | ident | site | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study | study |
| 2 | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World | TDS-TestStudy | 1985 | 100 | SITE1 | 2793 | World |

**DEMOG:**

- AE:

**AE:**

- AE:

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Generate Once !!!

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Benefits

SDTM Ready Before FPFV
Enables Standard Macro
Reduce TAT/Development Time

Increase Data Quality
Fast DB Lock
Facilitates Programming
Helps in Defensive Programming

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Sample - Defensive Programming

1. Increase Quality and Reduce SDTM Development Time with a Test Data Simulator June 2018

```sas
data dm;
  set raw; demog;
  if strip(gender) eq '' then put 'DM issue: Gender is missing for Subject: ' subjectid;
  else if upcase(strip(gender))='M' then sex='M';
  else if upcase(strip(gender))='F' then sex='F';
  else put 'DM issue: Please note for subject: ' subjectid ' Gender is: ' gender;
run;
DM issue: Gender is missing for Subject: IN004
DM issue: Please note for subject: IN005 the Gender is: n
NOTE: There were 7 observations read from the data set WORK.DM.
NOTE: The data set WORK.DM1 has 7 observations and 5 variables.
NOTE: DATA statement used (Total process time):
  real time 0.00 seconds
  cpu time 0.00 seconds
```
Summary

Why did we build it?

What does it generate?
- Vital Signs
- Concomitant Meds
- Adverse Events
- Medical Hx
- Demographic
- ...and much more clinical data

How does it work?
- Generates Data
- Validates all logic and input
- Data for all forms & all visits
- Reads ADR

Benefit and how?
- SDM Ready Before FPFV
- Reduce TAT/Development Time
- Fast DB Lock
- Enables Standard Macro
- Facilitates Programming
- Helps in Defensive Programming
- Increase Data Quality

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Questions?

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