Nonclinical (SEND) Fit for Use Workstream

The CDISC SEND (Standard for Exchange of Nonclinical Data) team, in collaboration with the PhUSE Nonclinical Test Submissions Workgroup and the FDA CDER Office of Computational Science (OCS), conducted a workstream for piloting SEND V3.0 that was opened to the public to participate. Participants (nonclinical submitting organizations, sponsors or their delegates) have concluded submitting data, receiving pilot feedback, and determined content and deliverables to be shared broadly on this wiki site, which is open to all (ie, publicly accessible).

One of the main tenets of the Fit for Use Pilot was that feedback provided back to each participant would be shared with the public broadly, via the CDISC and PhUSE organizations working processes. Learning from this pilot is being used to inform industry CDISC and PhUSE team efforts. These teams are open to all who are interested in data standards and implementation.

Learning has also been incorporated in version 3.3 of the Study Data Technical Conformance Guide.

To meet the main tenet of "shared learning", the following deliverables are available below:

Presentations (in .pdf format):

- CDISC-PhUSE Fit for Use Pilot, October 2016
- SEND Challenges, Tabular Examples from Fit for Use, October 2016
- INDUSTRY FEEDBACK, March 2017
- INDUSTRY FEEDBACK: Domain / Data File Level Learning,
Actual Feedback files (in zipped files to be extracted):

– Informational packages that include the actual (redacted) feedback from the FDA to individual sponsor participants, April 201
Pilot Charter, at initiation:
This is a public-facing wiki site for sharing lessons learned from the "Fit for Use" SEND Pilot described in the attached charter, version 1.0: The Fit for Use Pilot Work Stream Charter v1 2Sept 2016.docx.

### Pilot Content, or Coverage of the pilot relative to SEND standard v3.0*

<table>
<thead>
<tr>
<th>Row</th>
<th>Study Type</th>
<th>GLP</th>
<th>Non GLP Study?</th>
<th>Was the Tu mor r. sub mitted?</th>
<th>W as the SD &amp; De fin e to TF dom ai n of SE ND?</th>
<th>W as the Pe of the rep ors sub mitted?</th>
<th>Specie s</th>
<th>Study Dura tion</th>
<th>M ul ti pl e Tre a men ts and F re quency</th>
<th>Domains included</th>
<th>Housing of animals on study</th>
<th>Study Design comments</th>
<th>Describe any data that was not captured in SEND format</th>
<th>Was the protocol / amm edme nts/ devia tions and final repor t included in your pilot subm ission?</th>
<th>Additional comments provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Repeat Dose</td>
<td>GLP</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>monkey</td>
<td>4 week</td>
<td>sub cuta neo us daily dosing</td>
<td>BW, EX, BG, PC, PP, EG, LB, RELREC, CO, CL, DM, DS, MA, MI, OM, TE, TA, TS, TX, group</td>
<td>study duration changed for some animals, single study animals also served as tk animals</td>
<td>ADA</td>
<td>final report included</td>
<td>no additional comments</td>
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<tr>
<td>2</td>
<td>Repeat Dose</td>
<td>GLP</td>
<td>No</td>
<td>Yes</td>
<td>dog</td>
<td>1 month with recovery</td>
<td>BW, CL, CO, DM, DS, EG, EX, LB, MA, MI, OM, PC, PP, RELREC, SC, SE, SUPPCl, SUPPEX, TA, TE, TS, TX, single housed</td>
<td>Dosing remained constant; no satellite animals; single supplier</td>
<td>We supplied dried blood spot analysis in SEND that was not in the study report, but nothing in the study report was missing in SEND</td>
<td>Full study report with protocol amendment, deviation(s), etc included</td>
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<tr>
<td>3</td>
<td>Repeat Dose</td>
<td>GLP</td>
<td>No</td>
<td>Yes</td>
<td>rat</td>
<td>4 week, QD week</td>
<td>TE, TS, CD, DM, SE, TA, TX, EX, DS, BG, BW, CL, FW, LB, MA, MI, OM, PC, SUPPMa, SUPPMI, single</td>
<td>Study design was composed of 5 groups with 10/sex/group in the main study and 6 satellite animals/sex/group for TK. Dosing in the 600 mg/kg (high dose) group discontinued on Days 11 and 6, respectively in males and female rats. These animals were continued on study without any further dosing.</td>
<td>We actually submitted 4 studies conducted on the same compound to the pilot. One was fully reviewed, the three others were checked for fitness.</td>
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<tr>
<td>4</td>
<td>Repeat Dose</td>
<td>GLP</td>
<td>No/A</td>
<td>Yes</td>
<td>dog</td>
<td>4 week, oral y via gav age, 4 week, once daily</td>
<td>BW, BG, CL, CO, DM, DS, EG, EX, LB, MA, MI, OM, PC, PP, RELREC, SE, SUPPPG, SUPPPB, SUPPCl, SUPPDS, SUPPLB, SUPPMA, SUPPCL, SUPPDS, SUPPPM, SUPPYY, TA, TE, TF, TS, TX, group</td>
<td>Satellite groups used for TK, pooled samples</td>
<td>Two studies submitted, rodent reviewed in full, 90-day dog was checked for fitness only</td>
<td>Full study report included</td>
<td>Additional comments provided</td>
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<td>5</td>
<td>Repeat Dose</td>
<td>GLP</td>
<td>No</td>
<td>Yes</td>
<td>rat</td>
<td>3 Month, QD, oral</td>
<td>BW, BG, CL, CO, DM, DS, EX, FW, LB, MA, MI, OM, PC, POOLDEF, PP, RELREC, SUPPBG, SUPPPBw, group</td>
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<td>Yes</td>
<td>No</td>
<td>mo</td>
<td>day</td>
<td>28-</td>
<td>day</td>
<td>28-</td>
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<td>day</td>
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<td>rec</td>
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<td>Yes</td>
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<td>Yes</td>
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<td>day</td>
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<td>day</td>
<td>rec</td>
<td>eve</td>
<td>ry</td>
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</table>

**7 Repeat GLP Non GLP Dose**
- **Non GLP Dose**
  - **GLP:** No
  - **Non GLP Dose:** Yes
  - **mal e rat:** Yes
  - **dog:** Yes
  - **3 week:** 7 day
  - **Oral:** Gav
  - **age:** (gav) 4 week
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX
  - **Socially housed:** Standard, male only
  - **MICRONUCLEUS:** Yes
  - **Dog/Beagle:** Single supplier, main study animals also funded TK
  - **24 on study:** (3/sex/group)
  - **Multiple Suppmi:** SUPPMA, SUPPPM, TA, TE, TS, TX
  - **No - Final:** Report only states the final methodology

**8 Rep GLP Dose**
- **Non GLP Dose:** NA
  - **Gav:** Yes
  - **dog:** Yes
  - **4 week:** 14 day
  - **Oral:** Gav
  - **age:** (gav) 4 week
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, FW, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX, VS
  - **Group except during feeding:** Standard, males only
  - **Standard design:** ECG

**10 Rep GLP Non GLP Dose**
- **Non GLP Dose:** No
  - **age:** 26 week
  - **tran sge ncy:** No
  - **dog:** Yes
  - **4 week:** 12 days
  - **Oral:** Gav
  - **age:** (gav) 4 week
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, FW, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX, VS
  - **Group:** females only
  - **Full study report with protocol amendment:** No
  - **deviation:** No

**11 Car cino gen icity**
- **Non GLP Dose:** NA
  - **dog:** Yes
  - **4 week:** 26 week
  - **Oral:** Gav
  - **age:** (gav) 26 week
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, FW, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX, VS
  - **Group:** females only
  - **Full study report with protocol amendment:** No
  - **deviation:** No

**12 Rep GLP Non GLP Dose**
- **Non GLP Dose:** No
  - **dog:** Yes
  - **4 week:** 12 days
  - **Oral:** Gav
  - **age:** (gav) 4 week
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, FW, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX, VS
  - **Group:** females only

**13 Rep GLP Non GLP Dose**
- **Non GLP Dose:** No
  - **dog:** Yes
  - **4 week:** 13 days
  - **Oral:** Gav
  - **age:** (gav) 13 days
  - **daily dosi:** no rec
  - **Period:** with 28 day rec
  - **Supp:** BG, BW, CL, CO, DM, DS, EX, FW, LB, MA, MI, PC, PP, RELREC, SE, SUPPMA, SUPPPM, TA, TE, TS, TX, VS

*The contents of this table were provided very early in the pilot effort to demonstrate the amount and coverage of data provided in the pilot; an individual row(s) does not necessarily align with any other feedback posted at this site.

Please provide any comments you have regarding this wiki site below.