

Pain Data Standards Review Comments

30-Mar-2012

| Reviewer Name        | Affiliation              | Domain | Section/<br>paragraph/<br>Page number | Variable Name | Suggested Change  | Rationale  | CDISC Response  | Date      |
|----------------------|--------------------------|--------|---------------------------------------|---------------|---|--|---|-----------|
| Endo Pharmaceuticals | Implementati<br>on Guide | All    | 1.4, page 5                           |               | Reference to Parkinson's guide needs to be updated.                               |  | Corrected   | 4/9/2012  |
| Alice Nila, MD       | CCT                      | All    | 6.4.5/ 6/11                           |               | Add: Phobias associated with pain (photophobia,phonophobia,osmophobia)            | Relevant to migrains Vs Cluster headach                                    | This Pain scale will need to be reviewed by the STANDRDS Committee for inclusion in a later version of the PAIN Standards.  | 4/30/2012 |
| Lisa Lyons           | Janssen                  | All    | All                                   |               | Should questionnaires without copyright agreements be deleted from the documents? |  | CDISC Operations decision to include the Non-Approved QS forms with generic terminology for QSTESTCD/QSTEST. This at lease provides the ability to pool on common tests, but the source and target of any data interchange needs to coordinate the standardization of all other relevant fields in order to unsure poolability.           | 4/9/2012  |
| Lisa Lyons           | Janssen                  | All    | All                                   |               | Can the Appendix 2 Mapping Strategy sections include the QSCAT variable?          | Need to refer to the example data for questionnaires with multiple QSCATs. | QSCAT is included in the CDISC Questionnaire Controlled Terminology and is maintained via NCI EVS. QSCAT is a single value for each individual QS instrument dataset. The NV domain example contains multiple QSCAT values and is included in Section 4: Mapping Strategy. All other QS forms have only one QSCAT value per rating scale. | 4/9/2012  |

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| Veronica Martin | GSK     | ALL | General                                     |  | The approach followed for the Pain standard is not consistent with the CDISC/SDTM model.                       | The QS domain was developed to handle all types of rating scales. I was not expecting CDISC to develop/create IG guides for each rating scale. My assumption was that the guidelines for QS would be enhanced for areas which are not currently covered by the domain or modified for the areas where the domain is not very clear. This exercise would be completed as the group gets more experience and exposure use the QS domain for all different types of rating scales. I don't think it is efficient use of resource producing IG guidelines for individual rating scales (there are thousands out there!) | The CDISC SDS strategic decision was to develop separate QS Supplements per QS form based on the need for specific controlled terminology (QSCAT/QSTESTCD/QSTEST) and detailed mapping documentation per rating scale with the use of rating scales across multiple Therapeutic Areas. Each document details the necessary mapping strategy for the pooling of the QS rating scale. The documentation is being stored in a separate location on the CDISC website (STANDARDS & INNOVATIONS/Implementations/Questionnaire) for access by any Therapeutic Area. | 4/5/2012 |
| Randall Austin  | GSK     | ALL | section 1, 3rd paragraph                    |  | "in many different therapeutic are implementations." should be "in many  | typo  | SRC decision to add correct HYPERLINK   | 4/9/2012 |
| Randall Austin  | GSK     | ALL | section 1, 3rd paragraph                    |  | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website,                               | changed to  | SRC decision to add correct HYPERLINK   | 4/9/2012 |
| Randall Austin  | GSK     | ALL | section 1, 4th paragraph                    |  | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies" | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference   | SRC decision to add correct HYPERLINK   | 4/9/2012 |
| Denis Michel    | Janssen | All | UG Appendix A                               |  | Change ACTION to ACTTION in Dennis Turk row. Remove initials (CK)  |   | Removed   | 4/9/2012 |
| Denis Michel    | Janssen | All | UG section 1.1/paragraph 3/page 4           |  | Should "concluded in mid-December 2010" be 2011?   |   | Corrected   | 4/9/2012 |
| Denis Michel    | Janssen | All | UG section 1.4/paragraph1/page 5            |  | Change reference "(SDTMIG-PARKINSON'S V1.0)"   | Change from Parkinsons to Pain  | Corrected reference to the "current SDYMIG"   | 4/9/2012 |
| Denis Michel    | Janssen | All | UG section 6.3.5/paragraph 1 table / page 8 |  | Change "Karnofsky Performance Scale" to Karnofsky Performance Status Scale                                     |   | Corrected   | 4/9/2012 |

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| Denis Michel    | Janssen                    | All | UG section 6.3.5/paragraph 1 table / page 8 |  | Correct spelling of "Opiods" to Opioids   |                             | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen                    | All | UG section 6.3.5/paragraph 1 table / page 8 |  | Change "Mini Mental Scale (MMSE)" to Mini Mental State Examination (MMSE)   |                             | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen                    | All | UG section 6.3.5/paragraph 1 table / page 8 |  | Change "EQ-5D (EQ5D)" to EQ-5D-3L   |                             | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen                    | All | UG section 6.4.5/paragraph 1 / page 9       |  | Reword sentence: "Due to the evolution of Pain/Analgesic studies using different data anchor terms across drug projects and studies."   | Incomprehensible            | Need clarification/suggestion on re-wording: Will remain as is, since this was the only question asked on this and others understood the concept.   | 4/30/2012 |
| Denis Michel    | Janssen, Johnson & Johnson | All | User Guide 1.1/Page 4                       |  | The STANDARDS Working Group Co-chairs <b>led</b> the overall WG....   | Grammar - "lead" to "led"   | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen, Johnson & Johnson | All | User Guide 1.1/Page 4                       |  | Many of <b>these</b> instruments required copyright permission  | Grammar - "this" to "these" | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen, Johnson & Johnson | All | User Guide 1.1/Page 4                       |  | concluded in mid-December, <b>2010 - Should this be 2011?</b>   |                             | Corrected   | 4/9/2012  |
| Denis Michel    | Janssen, Johnson & Johnson | All | User Guide Appendix A                       |  | Associate Director, <b>ACTTION</b> Executive Committee, University of Washington  | Correct ACTION to ACTTION.  | Corrected   | 4/9/2012  |
| Gary Cunningham | Teva                       | all |   |  | I don't think the use of QSSTRESC and QSSTRESN is correct in many of the example implementations. It seems that values are being assigned to all categorical responses, e.g. Yes = 1 , No = 2. This is only correct if the response truly is ordinal in nature and/or the response is scored for purposes of numeric analysis. A yes/no response that |                             | STRESN codes were only provided when indicated on the source standard CRF. The decode of all value lists were stored in QSORRES per the QS definition in the SDTMIG v3.1.2. See examples on pages 23, 24, 50 & 148. | 4/9/2012  |
| Gary Cunningham | Teva                       | all |   |  | There are several cases of the wrong variable names in the examples for QSSTNRLO and QSSTNRHI. In some  |                             | Corrected to QSSTNRLO & QSSTNRHI  | 4/9/2012  |

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| Gary Cunningham | Teva | all |  | QSSTNRC          | I'm not in agreement that QSSTNRC is being used appropriately. By definition, QSSTNRC modifies the variable QSSTRESC. So if QSSTRESC contains a "2", it does not seem appropriate for QSSTRNC to equal "Does not interfere - Completely interferes". There is no way that this helps to identify what a "2" means. The QS Team is looking into other alternatives. |  | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 6/4/2012  |
| Gary Cunningham | Teva | all |  | QSCAT            | I don't think that all of the QSCAT values agree with the latest QS terminology. This should just be verified.   |  | Reviewed to confirm that all QSCAT values supplied by the CDISC QS Terminology Team were used in all QS supplement documents.  | 4/9/2012  |
| Alice Nila, MD  | CCT  | All |  | Pain Measurement | Add: Edmonton Classification System for Cancer Pain  |  | This Pain scale will need to be reviewed by the STANDRDS Committee for inclusion in a later version of the PAIN Standards.   | 4/30/2012 |

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| E.Lombardi      | Synteract | All - general                        |                       |                       | clean up occurrences of boxes spilling onto two pages. See MNSI page 9 as an example  |  | Will check on the general WORD feature to avoid this in tables - revisions passed internal review  | 4/9/2012  |
| Randall Austin  | GSK       | ALL WITH SECTION 4: MAPPING STRATEGY | 4                     |                       | Rather than calling this a "mapping strategy", a better phrase may be "standard result translation", "standard result derivation" or "standard result mapping strategy" | "Mapping strategy" implies something like legacy terminology translation. All we have here is the relationship between ORRES and STRES, not a strategy. If you are really tied to "mapping strategy" then I suggest "standard result mapping strategy" | In preparing the initial QS specific rating scales, it was determined that users needed more detail information in order to produce consistent QS datasets per rating scale in order to ensure poolability of the scale. The mapping strategy provides those terminology level details. The Terminology team did not want to include the name "terminology" in the section, so it would not be confused with the CDISC controlled terminology stored in NCI EVS. Mapping Strategy was the suggested name for this section and it contains all the necessary QS specific information need to map this data consistently for poolability purposes. | 5/10/2012 |
| Gary Cunningham | Teva      | BPI                                  | 4                     |                       | All QSSTRNC values here differ from those in the example.   |  | User meant QSSTNRC. Corrected.   | 4/24/2012 |
| Gary Cunningham | Teva      | BPI                                  | Example and Section 4 | QSSTRESC and QSSTRESN | For all rows (items) where the response is character and is not used in the calculation of a score, QSSTRESC should equal QSORRES and QSSTRESN                          |  | Please reference IG 3.1.2 page 145   | 4/24/2012 |
| Gary Cunningham | Teva      | BPI                                  | Header Page 4         |                       | Delete "Short Form".  | Wrong questionnaire.   | Corrected.   | 4/24/2012 |
| Gary Cunningham | Teva      | BPI                                  | Row 23 Page 5         |                       | QSORRES says "Four" but QSSTRESC and QSSTRESN both show "5". Make consistent.   |  | 5/8/2012: QSORRES=Four Hours<br>Agreed with G. Cunningham that QSORRES should contain the actual text on the CRF and not separate out UNITS.   | 5/11/2012 |
| Brian Mitchell  | Covidien  | BPI Short                            | Appendix F            |                       | Relabel as Appendix 3   | consistency of numbering   | New template already removed the Appendix  | 4/24/2012 |

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| Gary Cunningham | Teva      | BPI Short Form | 4                  |     | All QSSTRNC values here differ from those in the example.   |  | User meant QSSTNRC. Corrected.  | 4/24/2012 |
| Gary Cunningham | Teva      | BPI Short Form | 3.2 Example Page 4 |     | For Row 1, QSSTRESC should equal "YES" and QSSTRESN should be missing. QSSTNRLO, QSSTNRHI, and QSSTRNC should all be missing.                         | Response is character in nature and not scored. Incorrect use of QSSTRESN and range variables. | STRESN codes were only provided when indicated on the source standard CRF. The decode of all value lists were stored in QSORRES. QSSTNRLO, QSSTNRHI, and QSSTRNC were replaced with the SUPPQS approach | 4/24/2012 |
| Gary Cunningham | Teva      | BPI Short Form | 3.2 Example Page 4 |     | For Row 6, QSSTRNLO and QSSTRNHI should be missing.   | Incorrect. Response is textual, with no range.   | Corrected.  | 4/24/2012 |
| E.Lombardi      | Synteract | BPI Short Form | page 4             | n/a | Example looks silly when header text flows onto multiple lines (see USUBJID as one example). Recommend removing variables which are not useful in the | legibility   | The dataset is for one subject at one visit. All expected columns are included in the example.  | 4/24/2012 |
| E.Lombardi      | Synteract | BPI Short Form | page 7+            | n/a | If the result mapping strategy matches exactly for multiple QSTEST/QSTESTCD then show each  | easier to follow   | Corrected.  | 4/24/2012 |

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| Amy Adyanthaya  | Millennium Pharma | BPI Short Form     | Question 2 on PDF/ General |       | Why is there no guidance to the mapping of the diagram on the pdf or in the IG? Shouldn't QSLOC, QSLAT & QSDIR be used? | MPI uses this scale and the MDs feel that the location may be relevant certain oncology indications.                      | 6/4/12 SRC agreement:<br>Describe the use of diagrams used in questionnaires below. Question # 2 on the CRF requests the subject to shade in the areas where you feel pain on a diagram of the body and put an X on the area that hurts the most. The diagram was not considered a data field by the Terminology Team based on the need to identify a CDISC controlled terminology anatomical location term. The CRF does not provide the facility to record this on the CRF. The best approach for this is if the diagram locations could be transformed into anatomical location terminology, so it could be controlled and consistent for analysis of this questionnaire. Some organizations do not database this question. There is no consistent method to convert to an anatomical location and this question was considered out of scope until this concept can be researched further.<br><br>The diagram was not | 5/8/2012  |
| Gary Cunningham | Teva              | BPI Short Form CRF |                            | QSCAT | Change "SHOT" to "SHORT".   | Typo.   | Corrected.   | 4/24/2012 |
| Susan Timinski  | Teva              | CGI                | CGI                        | QSCAT | Recommend to use severity and change in title.  | We use these scales a lot of and many people know them as CGI-C or CGI-S. It would be hard to implement this as just CGI. | The W. Guy 1976 version of the CGI CRF contains the three standard question on Severity, Global Improvement and Efficacy Index. The CDISC Terminology team made the decision to retain the questions as reported on the version of the CGI CRF.  | 4/30/2012 |

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| Gary Cunningham | Teva     | CGI             | Page 4 third table    | QSSTRESC and QSSTRESN | Leading zeros should be removed from both variables.   | QSSTRESN is numeric, so a leading zero isn't possible. QSSTRESC is supposed to equal QSSTRESN. | Corrected the Mapping strategy section by removing the leading zero's.   | 4/30/2012 |
| E.Lombardi      | Syneract | CGI, WPAI, MNSI |                       |                       | As per previous comment above, I believe a table with full CT for QSTEST/QSTESTCD is helpful in addition to the examples provided.   |  | The QS Controlled terminology for QSTESTCD/QSTEST is published and maintained in NCI EVS for user access; This eliminates the need to maintain the controlled terminology within the QS documents.   | 4/30/2012 |
| Gary Cunningham | Teva     | COMM            | Example and Section 4 | QSTESTCD = "COMM118"  | Suggest that QSORRES be set to missing and that the categorization, e.g. "> or = 9" be placed in QSRESCAT. That is more appropriate than using QSSTRESC. Furthermore, on Page 6, the values under QSSTRESN are not even possible. QSSTRESN is numeric. |  | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |
| E.Lombardi      | Syneract | COMM and SOAPP  | page 4                | n/a                   | The QSDRVFL would only be used if this value is not collected on the CRF.  | per SDTM.IG  | The scores are not fields listed on these two CRFs. The CRF only provide instructions for the scoring. This is why it is a derived field in the QS dataset. COMM118 and SOAPR126 TESTCD's are derived fields and the QSDRVFL will be added to the data example table.  | 4/24/2012 |

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| E.Lombardi        | Syneract | COMM and SOAPP | page 5                 | n/a | Is there a reason there is no QSTEST/QSTESTCD CT list provided? I realize all the CT is available in the example but I think it's preferred that a table be presented   |  | The QS Controlled terminology for QSTESTCD/QSTEST is published and maintained in NCI EVS for user access; This eliminates the need to maintain the controlled terminology within the QS documents.  | 4/30/2012 |
| E.Lombardi        | Syneract | COMM and SOAPP | page 5 / page 6        | n/a | Typo where text says "QSSTREC"  |  | Corrected.  | 4/24/2012 |
| Gary Cunningham   | Teva     | C-SSRS         | If yes, specify fields |     | I'm not particularly fond of making the specify fields separate records and QSTESTCDs/QSTESTs. It seems to me they modify the corresponding Yes/No question and belong on the same record. I understand though that SDTM does not have a variable or mechanism to handle this currently, however. Perhaps SDTM could add a SPECIFY variable to the model. |  | This was a QS and CDISC Terminology Team decision based on the importance of these questions in the copyrighted questionnaires. These pre-specified questions and they felt it best to retain the test fields in the QS dataset than having to join the values from a SUPPQS dataset.   | 5/10/2012 |
| Gary Cunningham   | Teva     | C-SSRS         |                        |     | See Row 3 above.  |  | QSCAT is included in the CDISC Questionnaire Controlled Terminology and is maintained via NCI EVS. QSCAT is a single value for each individual QS instrument dataset. The NV domain example contains multiple QSCAT values and is included in Section 4: Mapping Strategy. All other QS forms have only one QSCAT value per rating scale. | 4/9/2012  |
| Rajinder Randhawa | GSK      | EQ5D3L         | 3.1.2                  |     | replace "the current Copyright approval status" with "the current copyright   | typo --- copyright should not be capitalized | Corrected   | 4/30/2012 |

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| Rajinder Randhawa | GSK | EQ5D3L | Example table            |                                | Remove columns for QSORRES, QSSTRESC, QSSTRESN  | Users will incorrectly assume that they should put the word "Copyright" in these fields. Remove the columns entirely and put a note in the introduction that says QSORRES etc. aren't shown in the table but should be populated with values from the questionnaire, per the SDTM IG QS guidance. | The dataset is for one subject at one visit. All expected columns are included in the example. This data example was updated to indicate that "Due to the copyright for this questionnaire not being approved, the data values for the expected fields QSORRES, QSSTRESC and QSSTRESN cannot be displayed and will need to be populated by the sponsor, based on their copyright approval. Based on the values were set to XXX." | 4/30/2012 |
| Rajinder Randhawa | GSK | EQ5D3L | Example table            |                                | There are no supplemental variables indicated to store the information about question 6 which is a visual analogue scale. | This should be part of the standard as the information is part of the scale i.e. min score/label, max score/label, VAS unit   | This can not be done, based on this not being copyright approved with CDISC. Fields can be mapped and stored as SUPPQS in real Life sponsor specific implementation, if copyright approval is obtained.  | 4/30/2012 |
| Rajinder Randhawa | GSK | EQ5D3L | section 1, 3rd paragraph |                                | "in many different therapeutic are implementations." should be "in many   | typo  | Corrected  | 5/5/2012  |
| Rajinder Randhawa | GSK | EQ5D3L | section 1, 3rd paragraph |                                | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies"            | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference   | SRC decision to add correct HYPERLINK  | 4/9/2012  |
| Rajinder Randhawa | GSK | EQ5D3L | section 1, 4th paragraph |                                | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under Standards > Questionnaires"        | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference   | SRC decision to add correct HYPERLINK  | 4/9/2012  |
| Rajinder Randhawa | GSK | EQ5D3L | section 2, 3rd paragraph |                                | replace "the generic method we used " with "the generic method that was used "  | Grammar --- maintain consistency with the 3rd-person tense of the rest  | Corrected  | 5/5/2012  |
| Alice Nila, MD    | CCT | FA     | 6.3.5/6.3.5.1/8          | Disease Specific Pain Measures | Add: Cancer-Pain  | Cancer pain not only affects quality of life, but some studies have shown that pain is an important predictor for survival  | Cancer pain was considered by the STANDARDS Working Group, but based on the instrument inclusion criteria, there were not at least two example CRF's for this to be included in the Pain Standard v1,0.  | 5/5/2012  |

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| Alice Nila, MD | CCT     | FA | 6.4.5 /paragraph 1/<br>9                    | Frequency of Pain                      | Add: Pain frequency  | The pain frequency is associated with psychosocial distress;US Headach Consortium Guidelines for Migraine Treatment-goals of long-term treatment : Reduce migraine frequency and severity                          | Pain Frequency is included in the Pain Intensity and Pain Relief questionnaire as an optional field. The capture of this should be clarified on the CRF for accurate data capture.  | 5/5/2012 |
| Denis Michel   | Janssen | FA | UG section 6.4.5/<br>Page 9                 | All                                    | VAS, NRS, and VRS can be Findings incorporated into QS domain, consistent with other pain scales in the efficacy analysis. | VAS, NRS, and VRS are pain scales analyzed consistent with other pain scales in efficacy analyses. FA is used for findings about events or interventions. These pain scales are more appropriate to the QS domain. | 5/21/12 SRC Decision: these type of scales are now populated in the QSMETHOD field and the QS domain is now used for Pain Intensity, Pain Relief and General Clinical Global Impressions><br><br>This topic was reviewed with CDISC SDS technical team members, who determined that these data items were groups of questions mainly used for efficacy analysis and did not fit the QS concept, being a standard fixed set of numbered questions. The general pain concepts are asked in a varied number of ways with a number of optional fields to be included. Draft v1.0 for public review revised the capture of these general pain concepts for Pain Intensity, Pain Relief and General Clinical Global Impressions from the FA domain to be part of a Physiology Nervous System Findings domain after a F2F review with the SDS team. This NV domain will be reviewed again with the SDS QS Team for | 5/5/2012 |
| Denis Michel   | Janssen | FA | UG section 6.4.5/Examples 1-6 / pages 13-19 | QSDTC, QSDY, QSTPT, QSTPTREF, QSEVLINT | Should these be FA prefixed variables, instead of QS?  | Domain is FA, but variables have QS prefix   | Corrected in the new QS domain for these pain variables   | 3/3/2012 |

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| Alice Nila, MD       | CCT | FA |  | Frequency of Pain | Add: Time of pain- morning/evening- for Fibromyalgia; Measures of frequency of pain: days, 1-3 months, years  | Because there is no Pain Assessment Scale for frequency of pain, it can be captured only as a frequency for specific disease. Significant individual variability in pain threshold and susceptibility to chronic pain due to variation within   | Pain Frequency is included in the Pain Intensity and Pain Relief questionnaire as an optional field. The capture of this should be clarified on the CRF for accurate data capture.  | 5/5/2012  |
| Endo Pharmaceuticals |     | FA |  |                   | Why are questionnaires split into two separate domains QS and FA ? It appears that the differentiation is validated vs non validated scales. Can this be clarified in the Implementation guide? | During drug development questionnaires often go through a validation process which will take them from FA Domain (non-validated) to a QS domain (validated). How should this be handled? We anticipate that this will cause difficulties in data handling , pooling, integration etc. | 5/21/12 SRC Decision: these type of scales are now populated in the QSMETHOD field and the QS domain is now used for Pain Intensity, Pain Relief and General Clinical Global Impressions><br><br>This topic was reviewed with CDISC SDS technical team members, who determined that these data items were groups of questions mainly used for efficacy analysis and did not fit the QS concept, being a standard fixed set of numbered questions. The general pain concepts are asked in a varied number of ways with a number of optional fields to be included. Draft v1.0 for public review revised the capture of these general pain concepts for Pain Intensity, Pain Relief and General Clinical Global Impressions from the FA domain to be part of a Physiology Nervous System Findings domain after a F2F review with the SDS team. This NV domain will be reviewed again with the SDS QS Team for | 5/21/2012 |

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| Endo Pharmaceuticals |  | FA |  |          | If it is true pain scale why would it go into FA and not QS? FLAC, VAS, NIPS |  | <p>5/21/12 SRC Decision: these type of scales are now populated in the QSMETHOD field and the QS domain is now used for Pain Intensity, Pain Relief and General Clinical Global Impressions&gt;</p> <p>This topic was reviewed with CDISC SDS technical team members, who determined that these data items were groups of questions mainly used for efficacy analysis and did not fit the QS concept, being a standard fixed set of numbered questions. The general pain concepts are asked in a varied number of ways with a number of optional fields to be included. Draft v1.0 for public review revised the capture of these general pain concepts for Pain Intensity, Pain Relief and General Clinical Global Impressions from the FA domain to be part of a Physiology Nervous System Findings domain after a F2F review with the SDS team. This NV domain will be reviewed again with the SDS QS Team for</p> | 5/21/2012 |
| Endo Pharmaceuticals |  | FA |  | FARESCAT | How are different types of averages differentiated (computed vs reported) ?  |  | <p>The use of the --RESCAT field can not be used as indicated in the example. It will be replace with the need to add separate QSTESTCD's for each type of pain Intensity: AVERAGE, WORST LEAST, MINIMUM, MAXIMUM. The questions asks the subject to interpret each of these test questions, so they are not derived.</p>   | 5/7/2012  |

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| Endo Pharmaceuticals |      | FA |  |  | Is FA Domain used for derived/computed scores?   |  | The original FA domain uses was changed to the QS domain. Derived scores not entered on the CRF, but computed from CRF scores are indicated with the QSDRVFL=Y to differentiate it from an entered score on the CRF.   | 5/5/2012  |
| Endo Pharmaceuticals |      | FA |  |  | Page 3 of the SDTMUG "With regards to clinical trials of Pain, this guide describes the explicit implementation of a subset of the domains whose general implementation is described in the current version of the Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG v3.1.2). This document demonstrates the SDTM domains, showing rules and examples on implementing these domains specifically for trials of Pain." |  | Any CDISC TA Data Standard will state refer to the TA working group's decision on which Questionnaire's are included in the data standard, Many Questionnaire's are used across TA's, so they were developed individually and then referenced for the appropriate TA as it is developed. | 4/30/2012 |
| Endo Pharmaceuticals |      | FA |  |  | HAMD 17 is a validated instrument, it is included in QS in the SDTMUG , however HAMD 29, which encompasses HAMD 17 is not included in QS. If HAMD 29 was used would the 17 items   |  | HAMD29 was not requested by the PAIN STANDARDS Working Group. It may be requested for a future version or another TA.  | 4/30/2012 |
| Endo Pharmaceuticals |      | FA |  |  | If a validated instrument is utilized in a patient population other than the one it was validated in , would the questions be  |  | Would be developed in QS and used in the appropriate TA.   | 4/30/2012 |
| Susan Timinski       | Teva | FA |  |  | FA domain has become just a place for anything and everything. Suggest using another domain.   | Collection of data using FA makes it impossible to consider SDTM like the RAW data. We attempt to use xxCAT or xxSCAT as our form names in EDC which align with the protocol and submission data. This would be hard to implement. | The original FA domain used was changed to the new QS domain after the PAIN Standard public review comments were addressed. See ENDO response on line 61 for more details.   | 5/5/2012  |

|                      |     |        |     |  |   |  |   |           |
|----------------------|-----|--------|-----|--|---|--|---|-----------|
| Endo Pharmaceuticals |     | FA, QS |     |  | What about assessments not part of version 1.0 (above and beyond the current 16), where would they go FA, QS? How is this determined. |  | Copyrighted and most public domain questionnaires will be mapped to the QS domain as indicated in the SDTMIG v3.1..2. General grouped efficacy questions will be evaluated by the TA Standards development team as to the need to map them to another FINDINGS type domain. | 5/5/2012  |
| Rajinder Randhawa    | GSK | FPSR   | 3.1 |  | replace "following assumptions apply " with "following assumption applies "   | only one item is listed so "assumption" should be singular | Corrected.  | 4/24/2012 |
| Rajinder Randhawa    | GSK | FPSR   | 3.2 |  | replace "Section 4: Mapping Strategy. " with "Section 4: SDTM Mapping Strategy."  | the section name is not correct in this paragraph          | Corrected.  | 4/24/2012 |

|                   |      |      |                          |  |   |  |  |           |
|-------------------|------|------|--------------------------|--|---|--|--|-----------|
| Rajinder Randhawa | GSK  | FPSR | 4                        |  | Where did the variables QSSTRNC, QSSTRELO QSSTREHI come from - it's not on the QS domain Version 3.1.2.   | There are new variables in the FPSR guideline yet they are not part of the QS domain/Findings class definition or the guidelines.  | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 5/11/2012 |
| Rajinder Randhawa | GSK  | FPSR | Example                  |  | reword or remove the statement "Values for QSORRES are for prospective data collection. Sponsors mapping legacy data should retain legacy values for QSORRES. " | the phrase "prospective data collection" is very confusing. I think you mean, "going forward, use these terms but don't retrospectively change what you've already done." That doesn't need to be said because Original Result is by definition the collected result. Mapping legacy data is a controversial topic in its own right and this document doesn't need | Values for QSORRES are for prospective data collection. The prospective approach is the CDISC agreed method.   | 4/24/2012 |
| Gary Cunningham   | Teva | FPSR | Page 4                   |  | Incorrect variable names. Should be   |  | Corrected.   | 4/24/2012 |
| Rajinder Randhawa | GSK  | FPSR | section 1, 3rd paragraph |  | "in many different therapeutic are implementations." should be "in many   | typo   | Corrected.   | 4/24/2012 |

|                   |           |        |                          |     |   |  |   |           |
|-------------------|-----------|--------|--------------------------|-----|---|--|---|-----------|
| Rajinder Randhawa | GSK       | FPSR   | section 1, 3rd paragraph |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies"  | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference  | Corrected.  | 4/24/2012 |
| Rajinder Randhawa | GSK       | FPSR   | section 1, 4th paragraph |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under Standards > Questionnaires"  | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference  | Corrected.  | 4/24/2012 |
| E.Lombardi        | Synteract | HAMD   | page 4                   | n/a | confirm example matches CT described below! Note row 2 has QSORRES =  | example should follow CT to prevent user confusion   | Corrected.  | 4/24/2012 |
| E.Lombardi        | Synteract | HAMD   | page 4                   | n/a | confirm example matches CT described below! Note row 3 has QSORRES =  | example should follow CT to prevent user confusion   | To be Corrected to "gestures"   | 5/11/2012 |
| E.Lombardi        | Synteract | HAMD   | page 5                   | n/a | add QSTESTCD to mapping strategy section  | clarity/ease of use  | Corrected. Add QSTESTCD for all   | 4/24/2012 |
| E.Lombardi        | Synteract | HAMD   | page 6                   | n/a | Change "HAMD1-Insomnia Early Hours Morning" to "HAMD1-Insomnia Early Hours - Morning". The last - should have   | inconsistency  | Corrected.  | 4/24/2012 |
| Rajinder Randhawa | GSK       | HAMD17 | 3.1                      |     | replace "following assumptions apply " with "following assumption applies "   | only one item is listed so "assumption" should be singular   | Corrected.  | 4/24/2012 |
| Rajinder Randhawa | GSK       | HAMD17 | 3.1                      |     | replace "The patient is instructed " and "for groups of patients " with "The subject is instructed " and "for groups of subjects "                              | Clinical studies are not necessarily conducted on "patients". Using the word "subjects" includes patients as well as any other classes of study participants.  | Corrected. Made change on "HAMD 17 is a multiple choice questionnaire that clinicians may use to rate the severity of a <b>subject's</b> major depression. It consists of 17 questions, all of which contribute to the total score. " | 4/24/2012 |
| Rajinder Randhawa | GSK       | HAMD17 | 3.2                      |     | replace "Section 4: Mapping Strategy. " with "Section 4: SDTM Mapping   | the section name is not correct in this paragraph  | Corrected.  | 4/24/2012 |
| Rajinder Randhawa | GSK       | HAMD17 | 3.2                      |     | reword or remove the statement "Values for QSORRES are for prospective data collection. Sponsors mapping legacy data should retain legacy values for QSORRES. " | the phrase "prospective data collection" is very confusing. I think you mean, "going forward, use these terms but don't retrospectively change what you've already done." That doesn't need to be said because Original Result is by definition the collected result. Mapping legacy data is a controversial topic in its own right and this document doesn't need | Values for QSORRES are for prospective data collection. The prospective approach is the CDISC agreed method.  | 4/24/2012 |
| Rajinder Randhawa | GSK       | HAMD17 | section 1, 3rd paragraph |     | "in many different therapeutic are implementations." should be "in many   | typo   | Corrected.  | 4/24/2012 |

|                   |                   |           |                          |                   |  |   |  |           |
|-------------------|-------------------|-----------|--------------------------|-------------------|--|---|--|-----------|
| Rajinder Randhawa | GSK               | HAMD17    | section 1, 3rd paragraph |                   | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies"     | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference | Corrected.   | 4/24/2012 |
| Rajinder Randhawa | GSK               | HAMD17    | section 1, 4th paragraph |                   | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under Standards > Questionnaires" | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference | Corrected.   | 4/24/2012 |
| Amy Adyanthaya    | Millennium Pharma | KPS Scale |                          | QSSTRNLO/QSSTRNHI | Why isn't there mapping guidance on these as there is for the BPI?   |   | QSSTRNLO and QSSTRNHI were replaced with the use of SUPPQS in the data example. See explanation in the assumptions section.<br><br>In KPSS, has a value set in increments of 10 from 0-100 with 10 specific scores each with a separate meaning; It is not analogous to a VAS or Numeric rating scale with range of scores with beginning and ending data anchors; mapping strategy is correct | 5/11/2012 |
| Amy Adyanthaya    | Millennium Pharma | KPS Scale |                          | QSSTNRC           | Why isn't there mapping guidance on this as there is for the BPI?  |   | QSSTNRC was removed from the data example and will not be used. See SUPPQS for explanation in the assumptions section.<br><br>In KPSS, has a value set in increments of 10 from 0-100 with 10 specific scores each with a separate meaning; It is not analogous to a VAS or Numeric rating scale with range of scores with beginning and ending data anchors; mapping strategy is correct      | 5/11/2012 |
| Rajinder Randhawa | GSK               | KPSS      | 3.1                      |                   | replace "following assumptions apply " with "following assumption applies "  | only one item is listed so "assumption" should be singular  | Corrected.   | 4/24/2012 |

|                   |          |      |                          |     |   |  |  |           |
|-------------------|----------|------|--------------------------|-----|---|--|--|-----------|
| Rajinder Randhawa | GSK      | KPSS | 3.2                      |     | reword or remove the statement "Values for QSORRES are for prospective data collection. Sponsors mapping legacy data should retain legacy values for QSORRES. "   | the phrase "prospective data collection" is very confusing. I think you mean, "going forward, use these terms but don't retrospectively change what you've already done." That doesn't need to be said because Original Result is by definition the collected result. Mapping legacy data is a controversial topic in its own right and this document doesn't need | Values for QSORRES are for prospective data collection. The prospective approach is the CDISC agreed method. | 4/24/2012 |
| Rajinder Randhawa | GSK      | KPSS | 3.2                      |     | replace "Section 4: Mapping Strategy. " with "Section 4: SDTM Mapping   | the section name is not correct in this paragraph  | Corrected.   | 4/24/2012 |
| Rajinder Randhawa | GSK      | KPSS | Example 1                |     | replace the SUBJID in the paragraph with "2324-P0001" to match the example  | The example USUBJID needs to be consistent between the paragraph and   | Corrected.   | 4/24/2012 |
| E.Lombardi        | Syneract | KPSS | page 5                   | n/a | My last Karnofsky experience was a couple years ago. The QSORRES results seem to be slightly different in syntax in some cases. The only difference worth mentioning is that I think "Requires occasional assistance, but is able to care |  | QSORRES Results are matched with the CDISC approved version  | 4/25/2012 |
| Rajinder Randhawa | GSK      | KPSS | section 1, 3rd paragraph |     | "in many different therapeutic are implementations." should be "in many   | typo   | Corrected.   | 4/24/2012 |
| Rajinder Randhawa | GSK      | KPSS | section 1, 3rd paragraph |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies"  | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference  | Corrected.   | 4/25/2012 |
| Rajinder Randhawa | GSK      | KPSS | section 1, 4th paragraph |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under Standards > Questionnaires"  | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference  | Corrected.   | 4/25/2012 |
| Randall Austin    | GSK      | MMSE | 3.2                      |     | replace "CDISC not receiving Copyright permission " with "CDISC not receiving   | typo --- copyright should not be capitalized   | Corrected.   | 4/25/2012 |
| Randall Austin    | GSK      | MMSE | 3.1.2                    |     | replace "the current Copyright approval status" with "the current copyright   | typo --- copyright should not be capitalized   | Corrected.   | 4/25/2012 |
| Randall Austin    | GSK      | MMSE | Example table            |     | Remove columns for QSORRES, QSSTRESC, QSSTRESN  | Users will incorrectly assume that they should put the word "Copyright" in these fields. Remove the columns entirely and put a note in the introduction that says QSORRES etc. aren't shown in the table but should  | Corrected.   | 4/25/2012 |
| Randall Austin    | GSK      | MMSE | Example, 2nd sentence    |     | replace "for one visits " with "for one visit "   | typo   | Corrected.   | 4/25/2012 |
| Randall Austin    | GSK      | MMSE | section 2, 3rd paragraph |     | replace "the generic method we used " with "the generic method that was used "  | Grammar --- maintain consistency with the 3rd-person tense of the rest   | Corrected.   | 4/25/2012 |

|                |          |      |   |                  |   |  |   |           |
|----------------|----------|------|---|------------------|---|--|---|-----------|
| Randall Austin | GSK      | MNSI | 3.1   |                  | replace "following assumptions apply " with "following assumption applies "   | only one item is listed so "assumption" should be singular   | Corrected.  | 4/25/2012 |
| Randall Austin | GSK      | MNSI | Example   |                  | reword or remove the statement "Values for QSORRES are for prospective data collection. Sponsors mapping legacy data should retain legacy values for QSORRES. " | the phrase "prospective data collection" is very confusing. I think you mean, "going forward, use these terms but don't retrospectively change what you've already done." That doesn't need to be said because Original Result is by definition the collected result. Mapping legacy data is a controversial topic in its own right and this document doesn't need | Values for QSORRES are for prospective data collection. The prospective approach is the CDISC agreed method.  | 4/24/2012 |
| Randall Austin | GSK      | MNSI | Example introduction  |                  | replace "transformed into a Standard Numeric " with "transformed into a   | typo --- capitalization of Standard and Numeric appears to be random   | Corrected.  | 4/25/2012 |
| Randall Austin | GSK      | MNSI | Example introduction and row 22, 28   |                  | Include the "specify" text in the original result field   | the instruction to leave QSORRES null for Specify responses violates basic SDTM IG rules about QSORRES. If QSORRES is null then STAT must be NOT DONE. Instead, for "Specify" questions, the text response should be put in QSORRES. Dummy up a specify response in the example so users will know to include  | Updated the data example with QSORRES="text" values and described this is being done to indicate a value will be used in the real-life situation and this will not be left NULL and then in conflict with the QSSTAT logic. | 4/25/2012 |
| Randall Austin | GSK      | MNSI | Example table   |                  | replace "Uncheck" with "Unchecked" or something better  | Why is "Uncheck" inconsistent with "Checked"? Either the pair should be "Unchecked" and "Checked" or "Uncheck" and "Check". Inconsistency is odd. Even better would be to use the standard Y and N terminology --- I have never seen the terms check/uncheck used as the database representation of the sort of result being collected here. Also note             | Corrected.  | 4/25/2012 |
| Anthony Chow   | Allergan | NV   | "Nervous System Findings Domain for Pain 2012-03-05.docx", Section 5, page 16 | QNAM of "PRLOCn" | Consider the use of --DIR (Directionality) instead  | Both SEND and Controlled Terminology have introduced --LAT (Laterality) and --DIR (Directionality) variables   | This approach was changed to create separate records for each unique location. The Pain Intensity and Pain Relief supplements were updated to describe this.  | 5/5/2012  |
| Anthony Chow   | Allergan | NV   | "Nervous System Findings Domain for Pain 2012-03-05.docx", Various locations  | NVEVLINT         | Change "-PT0H" to "PT0H"  | Having "-PT0H" is like saying -0, which can be confusing to general readers. "PT0H" would be a fine notation and fit the examples' intents and purposes  | Corrected   | 5/6/2012  |

|                 |                   |    |                                       |             |  |   |  |          |
|-----------------|-------------------|----|---------------------------------------|-------------|--|---|--|----------|
| Amy Adyanthaya  | Millennium Pharma | NV | 3.1/item 5/page 4                     | QSLAT/QSDIR | Why aren't these variables included with QSLOC?  |   | These new variables being added by the Terminology Team in SDTMIG v3.1.3   | 5/6/2012 |
| Gary Cunningham | Teva              | NV | all                                   |             | All of the examples have the wrong variable names for NVSTNRLO and                           |   | Corrected  | 5/5/2012 |
| Veronica Martin | GSK               | NV | Example 1 - Pain intensity VAS 100 mm |             | Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels. | Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPPQUAL with SUPPQUAL variables to capture:<br>- VAS minimum value<br>- VAS minimum label<br>- VAS maximum value<br>- VAS maximum label | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 6/4/2012 |
| Veronica Martin | GSK               | NV | Example 1 - Pain intensity VAS 100 mm |             | Clarify where the values for NVEVLINT have come from   | I can't tell where the values for NVEVLINT for this example have come from?<br><br>What does NVEVLINT of -PT0H  | Revised -PT0H to -PT24H to indicate the initial Hour result. -PT24H indicated the past 24 hours. These are in ISO 8601 format.   | 5/6/2012 |

|                 |     |    |                                       |  |  |   |   |          |
|-----------------|-----|----|---------------------------------------|--|--|---|---|----------|
| Veronica Martin | GSK | NV | Example 1 - Pain intensity VAS 100 mm |  | Clarify where NVLOC = BACK has come from   | There is no mention of location in the description of the example. Please provide a visual example of a pain intensity VAS 50 mm scale  | Location is described in the assumptions section and was added to the example description.  | 5/6/2012 |
| Veronica Martin | GSK | NV | Example 2 - Pain intensity VAS 50 mm  |  | Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels. | Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPQUAL with SUPQUAL variables to capture:<br>- VAS minimum value<br>- VAS minimum label<br>- VAS maximum value<br>- VAS maximum label | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 6/4/2012 |
| Veronica Martin | GSK | NV | Example 2 - Pain intensity VAS 50 mm  |  | Clarify where the values for NVEVLINT have come from   | I can't tell where the values for NVEVLINT for this example have come from?<br><br>What does NVEVLINT of -PT0H  | Revised -PY0H to -PT24H to indicate the initial Hour result. -PT24H indicated the past 24 hours. These are in ISO 8601 format.  | 5/6/2012 |

|                 |     |    |  |  |   |  |   |          |
|-----------------|-----|----|--|--|---|--|---|----------|
| Veronica Martin | GSK | NV | Example 2 - Pain intensity VAS 50 mm                     |  | Clarify where NVLOC = BACK has come from                | There is no mention of location in the description of the example. Please provide a visual example of a pain intensity VAS 50 mm scale | Location is described as an optional field in the Assumptions section for use with Pain Intensity and Pain Relief. Also added to the example description. | 5/6/2012 |
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | Provide an example of an 11-point numeric rating scale. | To understand how an 11-point numeric rating scale differs from other rating scales.   | Example 3 demonstrates an 11-Point numerical rating scale. It indicates the values range from 0-11 with the text anchors populated in NVSTNRC             | 5/6/2012 |
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | Clarify where NVLOC = BACK has come from                | There is no mention of location in the description of the example. Please provide a visual example of an 11-point numeric rating scale | Location is described as an optional field in the Assumptions section for use with Pain Intensity and Pain Relief. Also added to the example description. | 5/6/2012 |
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | Add NVORRESU and NVSTRESU                               | If it is a numeric rating scale - is there not a unit associated with the numeric value (i.e. Such as COUNT)?                          | There is no unit values indicated in the 11-Point rating scale  | 5/6/2012 |

|                 |     |    |  |  |  |   |   |          |
|-----------------|-----|----|--|--|--|---|---|----------|
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels. | <p>Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPPQUAL with SUPPQUAL variables to capture:</p> <ul style="list-style-type: none"> <li>- VAS minimum value</li> <li>- VAS minimum label</li> <li>- VAS maximum value</li> <li>- VAS maximum label</li> </ul> | <p>6/4/12 SRC agreement: QSSTNRC, QSSTRNLO &amp; QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:</p> <p>QNAM=RNGTXTLO<br/> QNAM=RNGTXTHI<br/> QNAM=RNGVALLO<br/> QNAM=RNGVALHI</p> <p>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.</p> <p>*****<br/> *****<br/> *****</p> <p>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous</p> | 6/4/2012 |
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | Clarify where the values for NVEVLINT have come from   | <p>I can't tell where the values for NVEVLINT for this example have come from?</p> <p>What does NVEVLINT of -PT0H</p>   | <p>Revised -PY0H to -PT24H to indicate the initial Hour result. -PT24H indicated the past 24 hours. These are in ISO 8601 format.</p>   | 5/6/2012 |

|                 |     |    |  |  |  |   |  |           |
|-----------------|-----|----|--|--|--|---|--|-----------|
| Veronica Martin | GSK | NV | Example 3 - Pain intensity 11-point numeric rating scale |  | NVRESCAT is missing                            | Not consistent with the model which has been defined. According to the details of the example - AVERAGE should be mapped to NVRESCAT. | The use of the --RESCAT field can not be used as indicated in the example. It will be replaced with the need to add separate QSTESTCD's for each type of pain Intensity: AVERAGE, WORST LEAST, MINIMUM, MAXIMUM. The questions ask the subject to interpret each of these test questions, so they are not derived. | 5/12/2012 |
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale                  |  | Provide an example of an 4-point verbal scale. | To understand how an 4-point verbal rating scale differs from other rating scales.  | Example 4 is a 4-Point verbal rating scale. It differs based on the number of values in the value set and the code list for the values.  | 5/6/2012  |

|                 |     |    |   |  |  |   |  |          |
|-----------------|-----|----|---|--|--|---|--|----------|
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |  | Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels. | Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPPQUAL with SUPPQUAL variables to capture:<br>- VAS minimum value<br>- VAS minimum label<br>- VAS maximum value<br>- VAS maximum label | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 6/4/2012 |
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |  | Clarify where the values for NVEVLINT have come from   | I can't tell where the values for NVEVLINT for this example have come from?<br><br>What does NVEVLINT of -PT0H  | Revised -PY0H to -PT24H to indicate the initial Hour result. -PT24H indicated the past 24 hours. These are in ISO 8601 format.   | 5/6/2012 |

|                 |     |    |   |        |  |   |  |           |
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| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |        | Clarify the rationale for why a numeric value is stored as the standardized value rather than the textual value. | The only reason for storing a standardized value in --STRESC/--STRESN is because the numbers are used for a total score. The SDTM IG does not require an original value to be converted to a numeric number. If the original value is TEXT it can remain as text in --STRESC. | STRESN codes were only provided when indicated on the source standard CRF. The decode of all value lists were stored in QSORRES per the QS definition in the SDTMIG v3.1.2. See examples on pages 23, 24, 50 & 148.  | 4/9/2012  |
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |        | NVRESCAT is missing  | Not consistent with the model which has been defined. According to the details of the example - AVERAGE should be mapped to NVRESCAT.   | The use of the --RESCAT field can not be used as indicated in the example. It will be replaced with the need to add separate QSTESTCD's for each type of pain Intensity: AVERAGE, WORST LEAST, MINIMUM, MAXIMUM. The questions ask the subject to interpret each of these test questions, so they are not derived. | 5/12/2012 |
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |        | Clarify where the values for NVEVLINT have come from   | I can't tell where the values for NVEVLINT for this example have come from?<br><br>What does NVEVLINT of -PT0H  | Revised -PY0H to -PT24H to indicate the initial Hour result. -PT24H indicated the past 24 hours. These are in ISO 8601 format.   | 5/6/2012  |
| Veronica Martin | GSK | NV | Example 4 - 4-Point Verbal rating scale |        | Clarify where NVLOC = BACK has come from   | There is no mention of location in the description of the example. Please provide a visual example of a 4-point verbal rating scale   | Location is described as an optional field in the Assumptions section for use with Pain Intensity and Pain Relief. Also added to the example description.  | 5/6/2012  |
| Veronica Martin | GSK | NV | Example 5 - 6-Point Verbal rating scale |        | the same comments as for Example 4 : 4-point verbal rating scale   |   | See comments on 4-Point rating scale   | 5/6/2012  |
| Diane Wold      | GSK | NV | Example 6                               | TPTREF | Populate with name of reference time point, not a date/time  | See, for example, the CDISC note for LBTRTREF, which says, "Name of the fixed reference point referred to by VSELTM, VSTPTNUM, and VSTPT. Examples: PREVIOUS DOSE,  | Propose setting QSTPTREF=Initial Dosing to indicate the hours readings are based from that point in time. Revised.   | 5/10/2012 |

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| Veronica Martin | GSK | NV | Example 6    |  | Provide more information about the example | Very difficult to tell if the example (i.e. the source) has been mapped correctly to SDTM without actually seeing what is contained in the source itself. Would be better to provide the source data that is being used to populate the SDTM dataset. Without that I can't tell if the SDTM variables are being used correctly. | 5/21/12: This example is now split across the Pain Relief and General Clinical Global Impressions supplements with detailed explanations.<br><br>Example 6 was based on a legacy CRF that combined these general pain intensity, pain relief and general clinical global impressions. This was a proprietary CRF, so it could not be referenced with the example. I have provided the following detailed explanation: "This example is based on a legacy sponsor specific CRF, in which the Pain Intensity measure is taken prior to dosing and then at hourly readings, the results are obtained for Pain Intensity, Pain Relief and Starting Pain ½ Gone. At the end of the hourly readings, the following questions were asked for "Was there meaningful pain relief", "Time to Meaningful pain relief", "Was there Perceptible pain relief", and the "Time to perceptible pain relief". In addition the General Clinical | 5/21/2012 |
| Veronica Martin | GSK | NV | Introduction |  | Is the nervous system domain NS or NV?     | Clarify the correct name for the nervous system domain  | NV is the controlled terminology for the Physiology domain based on the Nervous System body system. This is a draft domain expected to be included in SDTMIG v3.1.4 in late 2012.  | 5/6/2012  |

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| Veronica Martin | GSK | NV | SDTM mapping strategy |  | Clarify the purpose of the SDTM mapping strategy | <p>I have not seen this being used before. What is the intended purpose of the SDTM mapping strategy and how does this fit in with the overall CDISC model? I don't believe it is necessary to provide an SDTM mapping strategy - I believe the SDTM IG already provides very good guidelines on how to populate --ORRES , --STRESC and --STRESN for the QS domain.</p> | <p>In preparing the initial QS specific rating scales, it was determined that users needed more detail information in order to produce consistent QS datasets per rating scale in order to ensure poolability of the scale. The mapping strategy provides those terminology level details. The Terminology team did not want to include the name "terminology" in the section, so it would not be confused with the CDISC controlled terminology stored in NCI EVS. Mapping Strategy was the suggested name for this section and it contains all the necessary QS specific information need to map this data consistently for poolability purposes.</p> | 5/10/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 10 & Example 1 | STNRLO, STNRHI | Remove VAS endpoint information from these variables. Propose a representation in metadata or in new variables. | STNRLO and STNRHI are intended to hold normal ranges, with the interpretation that any value between these values is "normal." The use of these variables to hold the codes and decodes for the extreme ends of a VAS scales is not consistent with the intended meaning of these variables. | <p>6/4/12 SRC agreement: QSSTNRC, QSSTRNLO &amp; QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:</p> <p>QNAM=RNGTXTLO<br/> QNAM=RNGTXTHI<br/> QNAM=RNGVALLO<br/> QNAM=RNGVALHI</p> <p>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.</p> <p>*****<br/> *****<br/> *****</p> <p>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous</p> | 6/4/2012 |
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| Veronica Martin | GSK | NV | Section 3.1/Point 2 |  | Add further clarification as to when the NV domain should be used rather than QS. | The following have been listed as examples of data capture formats : visual analog scale, numerical rating scale, verbal rating scale. These are not very good examples of things to map to the NV domain. For example we have VAS scales which have been mapped to QS (i.e. SFMP2). Please provide more clarity as to when NV domain should be used. | 5/21/12 SRC Decision: these type of scales are now populated in the QSMETHOD field and the QS domain is now used for Pain Intensity, Pain Relief and General Clinical Global Impressions><br><br>This topic was reviewed with CDISC SDS technical team members, who determined that these data items were groups of questions mainly used for efficacy analysis and did not fit the QS concept, being a standard fixed set of numbered questions. The general pain concepts are asked in a varied number of ways with a number of optional fields to be included. Draft v1.0 for public review revised the capture of these general pain concepts for Pain Intensity, Pain Relief and General Clinical Global Impressions from the FA domain to be part of a Physiology Nervous System Findings domain after a F2F review with the SDS team. This NV domain will be reviewed again with the SDS QS Team for | 5/21/2012 |
| Veronica Martin | GSK | NV | Section 3.1/Point 4 |  | Provide further clarification/guidance on NVRESCAT                                | It is not clear from the instructions provided as to how the values are determined. For example for a VAS scale how can you determine if a value is MIN or MAX? Is it possible to include examples of scales where the values for NVRESCAT are clearly shown on the scale for least, worst, minimum, maximum?   | The use of the --RESCAT field can not be used as indicated in the example. It will be replace with the need to add separate --TESTCD's for each type of pain Intensity: AVERAGE, WORST LEAST, MINIMUM, MAXIMUM. The questions ask the subject to interpret each of these test questions, so they are not derived.   | 5/12/2012 |

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| Veronica Martin | GSK | NV | Section 3.1/Point 6 |  | Remove reference to NVTPT and NVTPTREF | <p>NVTPT and NVTPTREF aren't supposed to be ISO8601 values. They are supposed to be clear text notations of the time points, e.g. "20 MIN POST-DOSE". The ISO date/time associated with NVTPTREF is supposed to go into NVRFTDTC and the ISO date/time of NVTPT should go into NVDTC. This is not the correct implementation of the information in the IG</p> | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Veronica Martin | GSK | NV | Section 3.1/Point 6 |  | Incorrect use of NVELINVT for 'over last night's sleep' | This is quite a stretch. It literally means between midnight and 8 a.m., which I think is different from "over the last night's sleep" | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Veronica Martin | GSK | NV | Section 3.1/Point 6 |  | Provide further clarification/guidance for example 'f' | <p>This is very confusing. Are you suggesting we should substitute "RFXSTDTC" with the value of RFXSTDTC (e.g. 2012-01-01)? Or are you suggesting putting it into "RFXSDTC"? The latter is useless and not compliant with ISO8601. Also -TPT and -TPTREF aren't supposed to be cryptic or ISO8601 – see SDTM IG 4.1.4.10.</p> | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Veronica Martin | GSK | NV | Section 3.1/Point 6 |  | Provide further clarification/guidance for example 'g' | <p>The intended result isn't at all clear, and -TPTRF is defined inappropriately. -TPTRF for "time since last medication" would be -TPTRF="Previous Medication", --RFTDTC={ISO8601 representation of that date}</p> | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS<br/>QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTRF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Veronica Martin | GSK | NV | Section 3.1/Point 6 |  | Provide further clarification/guidance for example 'h' | Why doesn't the VISIT text include the word "unscheduled"? Why is controlled terminology for VISIT and TPT being put into this document? | <p>6/4/12 SRC agreement:<br/> Updated the explanation of QSEVLINT and the use of s new SUPPQS<br/> QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/> a. "over last 24 hours" – NVEVLINT = -PT24H<br/> b. "over last hour" – NVEVLINT = -PT1H<br/> c. "over last week" – NVEVLINT = -P1W<br/> d. "right now" – the NVDTC value will indicate 'right now'<br/> CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 2 |  |  | <p>"Numerical rating scales" and "Verbal rating scales" are listed as though they are different things. I'm not sure what non-numerical scales would be. Numerical scales could be administered verbally or in writing. "Verbal" or "Written" might be considered methods.</p>   | <p>The Pain STANDARDS Working Group differentiated these as different methods to capture the pain intensity data as a common practice in Pain studies. When using a numerical rating scale, the subject is presented with the numerical range of numbers. In a verbal rating scale, the subject is asked to provide the "text" value of the rating without knowledge of the number assigned to the "text" value.</p>   | 5/7/2012 |
| Diane Wold | GSK | NV | Section 3.2, bullet 5 |  |  | <p>I don't understand the point of statement, "When a study is performed for a specific type of pain, the Medical History MHTERM for the MHCAT=PRIMARY DIAGNOSIS will indicate the type of pain (.ex Fibromyalgia, Diabetic Neuropathy, etc.)". Is the expectation that when a MHTERM with MHCAT=PRIMARY DIAGNOSIS is present, then LOC for pain scales should not be populated?</p> | <p>6/4/12 SRC agreement: Updated the location description to explain the difference between specific pain location in the anatomical terminology and the indication of the study separately.</p> <p>Correct interpretation. Pain studies are done in a variety of ways and for some the Primary Diagnosis is the reason for the study and in the conditions presented, such as "Fibromyalgia", this was not a location. In other types of studies, the location of the pain is specified as part of the data capture. If multiple pain locations are specified separately at the same time point, separate records will be created for each anatomical location in order to enable analysis for each location.</p> | 6/4/2012 |

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| Diane Wold | GSK | NV | Section 3.2, bullet 6d |  | Change to, "right now - this time is expressed using DTC and whichever of VISIT, TPTREF, and TPT are applicable. As this is an assessment at a point in time, rather than over an interval, -- EVLINT is not populated." | For an assessment made at a point in time, the evaluation interval should be null. The time at which the assessment was made will be described in absolute terms by the DTC variable and in study plan terms by VISIT, TPTREF (if applicable) and TPT (if applicable). | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of a new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now' CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 6e |  | Propose new variables to convey evaluation interval, since it is not expressed in terms of an 8601 duration. For example, --EVLIST, Start of Evaluation interval, to be populated with a description of the activity at which the evaluation interval starts, and --EVLIN, End of Evaluation interval, to be populated with a description of the activity at which the evaluation interval ends. If the end of the evaluation interval is the assessment which is the topic of this observation, then --EVLIN = 'Topic assessment' | The intended content of EVLINT is an amount of time expressed in the kind of ISO8601 expression that starts with a P. This is used in combination with DTC to form an ISO8601 description of a period of time of the kind that consists of an end time (the DTC) and an amount of time (the EVLINT). The proposed expression, T00:00/T8:00, is not a valid ISO8601 representation of an interval of time, since it omits the date components, presumably on the assumption that these are supplied by the DTC. Even if this bending of the rules were accepted, "over the last night's sleep" cannot be assumed to correspond to "from midnight to eight o'clock on the day the question was asked." | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of a new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 6f |  | Propose new variables to convey evaluation interval, since it is not expressed in terms of an 8601 duration. | The proposed methods for representing the evaluation are inconsistent with the intended uses of the TPT and TPTREF variables. | <p>6/4/12 SRC agreement:<br/> Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/> a. "over last 24 hours" – NVEVLINT = -PT24H<br/> b. "over last hour" – NVEVLINT = -PT1H<br/> c. "over last week" – NVEVLINT = -P1W<br/> d. "right now" – the NVDTC value will indicate 'right now'<br/> CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2,<br>bullet 6g |  | Propose new variables to convey evaluation interval, since it is not expressed in terms of an 8601 duration. | The proposed methods for representing the evaluation are inconsistent with the intended uses of the TPT and TPTREF variables. | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now' CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 6h |  | <p>Change to, "At use of rescue medication – the time when rescue medication is administered is the planned time of a point-in-time pain assessment, even though this time point cannot be described relative to a reference time point such as dosing. The value of --TPT = 'Rescue medication'. Since there is no reference time point, --TPTREF and --ELTM will be null."</p> | <p>If the protocol instructs that pain be measured at the time of rescued medication, then that is a planned time point, even if it is not expected that all subjects will experience the time point.</p> | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTRF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now' CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 7 |  |  | <p>I don't understand just what information is being captured. It sounds like this is not a response to "How frequently did you have to take measures to relieve pain" but something about describing the schedule of pain assessments. I'm guessing that the protocol describes a pain event (e.g., molar extraction, migraine onset) and then describes the schedule of pain assessments relative to that event in terms such as "hourly for 8 hours." Such a description would be translated into REFTPT (molar extraction, migraine onset, etc.) and a series of time points (e.g., TPT names with ELTM values of P1H, P2H, ... P8H). If so, then this is not something that needs to wait for further development of trial design. There is no "Trial Time points" dataset, but time points are defined implicitly by the values of TPTREF, TPT, TPTNUM, and ELTM that appear in a domain. The fact that a</p> | <p>6/4/12 SRC agreement: Updated the explanation of QSEVLINT and the use of a new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPTREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/> a. "over last 24 hours" – NVEVLINT = -PT24H<br/> b. "over last hour" – NVEVLINT = -PT1H<br/> c. "over last week" – NVEVLINT = -P1W<br/> d. "right now" – the NVDTC value will indicate 'right now'<br/> CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
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| Diane Wold | GSK | NV | Section 3.2, bullet 8   |  |  | Might consider suggesting the addition of CDASH "COND" variable to SDTM.                              | 6/4/12 SRC agreement to use SUPPQUAL.<br><br>The use of a new variable can be considered. Reviewed this concept with a number of SDS team members, but will revise upon consensus with the SDS team. Until a potential new variable will be reviewed to be added to the FINDINGS Class, the current agreement is to use SUPPNV for this variable. | 6/4/2012 |
| Diane Wold | GSK | NV | Section 4   |  |  | Above comments mean that many of these mappings would no longer be valid.                             | 6/4/2-12 SRC agreements to revise mappings to QS domain   | 6/4/2012 |
| Diane Wold | GSK | NV | Time to event measures, such as "Time to Perceptible Pain Relief" |  |  | Is this collected data? Usually time-to-event data is derived. If derived, it may not belong in SDTM. | Time to perceptible pain relief and time to meaningful pain relief is measured with a clock in minutes per the CRF examples provided for this data element. It is not planned, so can not be used in any time reference fields.   | 5/7/2012 |

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| Diane Wold | GSK | NV |        |  | Remove pain rating scale data from this domain.  | Rating scales for pain, including VAS and numerical and verbal scales, are questionnaires and this data should be placed in QS.  | <p>5/21/12 SRC Decision: these type of scales are now populated in the QSMETHOD field and the QS domain is now used for Pain Intensity, Pain Relief and General Clinical Global Impressions&gt;</p> <p>This topic was reviewed with CDISC SDS technical team members, who determined that these data items were groups of questions mainly used for efficacy analysis and did not fit the QS concept, being a standard fixed set of numbered questions. The general pain concepts are asked in a varied number of ways with a number of optional fields to be included. Draft v1.0 for public review revised the capture of these general pain concepts for Pain Intensity, Pain Relief and General Clinical Global Impressions from the FA domain to be part of a Physiology Nervous System Findings domain after a F2F review with the SDS team. This NV domain will be reviewed again with the SDS QS Team for</p> | 5/21/2012 |
| Diane Wold | GSK | NV | RESCAT |  | Represent kind of summary of pain over the evaluation interval in TEST or propose a new variable for this information. | RESCAT is intended to categorize results. What kind of summary of pain over the evaluation interval is being measured (average, min, max, etc.) is part of the question, not a categorization of response. | <p><b>5/8/2012 RESOLUTION:</b><br/>Reviewed with Gary C. and agreed to revising to separate QSTESTCD/QSTEST values for Average Pain Intensity, Minimal Pain Intensity, Maximum Pain Intensity, Worst Pain Intensity and Least Pain Intensity</p>  | 5/10/2012 |

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| Diane Wold | GSK      | NV        |             | LOC | Expand description of use.  | LOC can describe either the question (e.g., how severe is the pain at LOC?) or be part of the result (e.g., how bad is your pain and where is it?). Only in the latter case can there be multiple values of LOC for an observation. If multiple questions about pain | 6/4/12 SRC agreement:<br>Updated the location description to explain the difference between specific pain location in the anatomical terminology and the indication of the study separately.   | 6/4/2012 |
| E.Lombardi | Syneract | NV-SDTMUG | page 11.5.e | n/a | Over last night sleep should be done through FATPT = "OVER LAST NIGHT'S SLEEP" and FATPTREF = "BEDTIME" or similar or if time of sleep is recorded then used date/time. | Possible that T00:00/T8:00 would be used for something else and doesn't make too much sense to assume sleeping times   | 6/4/12 SRC agreement:<br>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.<br><br>The examples on page 5 item 6. are referring to the NVTPTRF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.<br><br>Current CDISC SRC agreement is listed below:<br>a. "over last 24 hours" – NVEVLINT = -PT24H<br>b. "over last hour" – NVEVLINT = -PT1H<br>c. "over last week" – NVEVLINT = -P1W<br>d. "right now" – the NVDTC value will indicate 'right now'<br>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with | 6/4/2012 |

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| E.Lombardi | Synteract | NV-SDTMUG | page 11.5.h | n/a | do not like the idea of CT on VISIT on -- TPT seems fine  | <p>VISIT should be defined by sponsor and not limited by CT. should allow sponsor to assign all VISIT and VISITNUM as these can be pre-defined. Adding CT for VISIT would be a big deal for programming. Often these records would not even have a VISIT mapped as they could occur at home and not during a "VISIT".</p> | <p>6/4/12 SRC agreement:<br/>Updated the explanation of QSEVLINT and the use of s new SUPPQS QNAM=Q=EVLINTTX for use as explained in the assumptions section.</p> <p>The examples on page 5 item 6. are referring to the NVTPREF as the DM reference start and stop dates. Including these in Quotes implies the actual date values are to be populated.</p> <p>Current CDISC SRC agreement is listed below:<br/>a. "over last 24 hours" – NVEVLINT = -PT24H<br/>b. "over last hour" – NVEVLINT = -PT1H<br/>c. "over last week" – NVEVLINT = -P1W<br/>d. "right now" – the NVDTC value will indicate 'right now'<br/>CDISC is investigating potential new fields to define descriptions of reference time points. Until that is determined, the use of SUPPNV will be used to store these type of descriptions with</p> | 6/4/2012 |
| E.Lombardi | Synteract | NV-SDTMUG | page 11.6   | n/a | I think by mentioning the Frequency Ct you don't need to give examples. Perhaps reference the code used in SDTM.IG (FREQ). I need an example of this in use to comment properly. I don't understand | <p>The frequency assumption was updated based on input form B. Dworkin the STANDARDS co-chair and SUPPQS is not being used.</p>   | 6/4/2012  |          |

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| E.Lombardi   | Syneract | NV-SDTMUG | page 12+   | n/a     | confused as to why examples reference SDTM.QS. Are those meant to be FA? |   | In the Colloquia review, the general pain concepts were included in the FA domain and the copyrighted/public domain questionnaires were aligned to the QS domain. Prior to the public review, the FA domain was converted to use the draft Physiology Nervous System domain. 5/21/12 SRC decision was to use QS domain. | 5/21/2012 |
| Anthony Chow | Allergan | QS        | "SDTM QS-C-SSRS BASELINE v1 Approved 2012-03-03.doc", Section 3.2, pages 4 - 6 | QSSCAT  | Consider the use of QSSCAT   | QSSCAT can be used to delineate the different sections within the questionnaire.<br><br>Also, when a section is not done, implementers can use QSSCAT = <<section>>, QSTESTCD = "QSALL", and QSSTAT = "NOT  | After reviewing this form with the QS Team, it was determined that QSSCAT is not required for data analysis   | 5/10/2012 |
| Anthony Chow | Allergan | QS        | * General  | QSCAT   | Add/clarify expectation on version indicator                             | The annotated questionnaire only shows QSCAT without numeric suffixes, while individual supplemental documents show. For example, "QSCAT = COMM" as annotation vs. "COMM01" in QSCAT column in "SDTM QS-COMM v1 Approved"<br><br>Wouldn't version information should go to the define.xml anyway? | QSCAT doesn't need a version number since QSTESTCD has version numbers. CDISC Terminology team defined the QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms  | 4/25/2012 |
| Anthony Chow | Allergan | QS        | * General  | QSORRES | Add/clarify expectation on text case sensitivity                         | It appears from the individual supplemental documents, text in QSORRES needs to match what's on   | QSORRES matches the case sensitivity per the CRF.   | 4/25/2012 |

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| Anthony Chow | Allergan                   | QS | * General               | QSSTRELO, QSSTREHI, QSSTNRC | Add/clarify expectation on usage of these variables  | Some examples show the use of QSSTRELO, QSSTREHI, and/or QSSTNRC, while some don't even when these SDTM variable could be applicable. For example, they are not used in the Current Opioid Misuse Measure (COMM)® questionnaire's supplemental document. | 6/4/12 SRC agreement: QSSTNRC, QSSTRNLO & QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br>QNAM=RNGTXTLO<br>QNAM=RNGTXTHI<br>QNAM=RNGVALLO<br>QNAM=RNGVALHI<br>By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br>*****<br>*****<br>*****<br>In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous | 6/4/2012  |
| Anthony Chow | Allergan                   | QS | * General               | QSTEST                      | Remove the questionnaire short name from QSTEST  | QSCAT already has the necessary questionnaire descriptor, having it repeat in the QSTEST, which is limited to be 40 characters, is redundant. QSTESTCD appears to have already served the purpose too.<br><br>For example, "CSS01-Non-Specific           | CDISC Terminology team defined the QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms   | 4/25/2012 |
| Denis Michel | Janssen, Johnson & Johnson | QS | 4/SDTM Mapping Strategy | QSSTNRC                     | QSSTNRC is incorrectly entered in some scale tables as "QSSTRNC". Please globally change all references to QSSTNRC. Scales with incorrect references: FPSR Questionnaire | Correct reference to standard variable name QSSTNRC  | Corrected.   | 4/25/2012 |

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| Susan Timinski | Teva    | QS | ALL                            | xxTEST            | Remove value of scale from QSTEST. It is duplicate information and does not need to be repeated.  | This could lead to issue with other scales and length issue with QSTEST being only 40 characters | CDISC Terminology team defined the QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms  | 4/25/2012 |
| Susan Timinski | Teva    | QS | ALL                            |                   | Change use of describe/specify results in QSORRES to supplemental. In the event the answer to a previous question is No, there is no real value for ORRES. This would fail SDTM rule needing xxSTAT or xxORRES populated for a finding. The sponsor is faced with deleting the missing records for submission or explaining to in reviewer notes. | Issues with SDTM compliance  | This was a QS and CDISC Terminology Team's decision to create separate field for the specify text values in the questionnaire. Will update the data example with "text" values and specify this is being done to indicate a value will be used in the real life situation and thus will not be left NULL and then in conflict with the QSSTAT logic. If the initial question is answered as NO, there would be not TEXT records created, based on the presence of data concept. | 5/10/2012 |
| Denis Michel   | Janssen | QS | BPI / Appendix 2 / Page 10     | QSORRES, QSORRESU | If QSORRES will be a text description, then incorporate 'hours' into the description and leave QSORRESU empty.  |  | 5/8/2012: QSORRES=Four Hours<br>Agreed with Gary C. that QSORRES should contain the actual text on the CRF and not separate out UNITS.  | 5/11/2012 |
| Denis Michel   | Janssen | QS | BPI / Appendix 2 / Page 10     | QSSTRESU          | Add QSSTRESU or indicate that it is the same as QSORRESU. Same applies to BPI Short Form.   |  | Added QSSTRESU to the data table to BPI and Short Form BPI  | 5/11/2012 |
| Denis Michel   | Janssen | QS | BPI / Section 6.3.5.2 / Page 4 | QSTEST            | Should QSTEST for BPI107 read "Pain Due to One of Your Symptoms"?   |  | No. 'Pain Due to One of Your Symptoms' is for BP108   | 4/25/2012 |
| Susan Timinski | Teva    | QS | BPI and ALL                    | QSCAT             | Use full validated scale name. Brief Pain Inventory(BPI)  | BPI, SOAPP-R is not obvious to everyone  | CDISC Terminology team defined the QSCAT/QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms  | 4/25/2012 |

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| Steve Gingras | Janssen                    | QS | BPI Long Form, Appendix 2              | QSTESTCD=BPI107...BPI108, BPI112...BPI115, BPI121...BPI122O, BPI123A...BPI123G, BPI126...BPI128, BPI129...BPI131G | List each QSTESTCD and QSTEST separately   | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values. It the values of QSORRES, QSSTRESC, QSSTRESN and QSSTNRC are the same for a set of questions, the values of QSTESTCD | All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.   | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Long Form, Appendix 2              | QSTESTCD, QSTEST  | QSTESTCD and QSTEST for all text fields (e.g, BPI102A, BPI109A, BPI116, etc) are missing                             | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values.  | These tests have only free TEXT Values and need no mapping strategy.<br><br>All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system. | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Long Form, Appendix 2, page 10     | QSTESTCD=BPI119   | add column for QSSTRNC in table  | make consistent with similar question in BPI Short From   | Corrected.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Long Form, Appendix 2, page 9      | QSTEST  | change "Symptoms" to "Symptoms" for QSTESTCD=BPI108  | misspelling   | Corrected.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Long Form, section 6.3.5.1, page 3 |   | change from "...foreign-language translations; and the BPI..." to "...foreign-language translations, and the BPI..." | grammar   | Corrected.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Short Form, Appendix 2             | QSTESTCD, QSTEST  | QSTESTCD and QSTEST for QSTESTCD=BPI102A is missing  | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values.  | These tests have only free TEXT Values and need no mapping strategy.<br><br>All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system. | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Short Form, Appendix 2, page 8     | QSTESTCD=BPI208   | remove comment "add QSORRESU & QSSTRNC" in table header  | Does not belong. Columns already added.   | Was corrected   | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | BPI Short Form, Appendix 2, page 8     | QSTRNC for QSTESTCD=BPI208  | remove the semicolon in the word "Complete" (Complete) for each row in the table                                     | typo  | Corrected.  | 4/25/2012 |
| Steve Gingras | Janssen, Johnson & Johnson | QS | BPI Short Form, section 4, page 7      | QSTESTCD=BPI208   | remove comment "add QSORRESU & QSSTRNC" in table header  | Does not belong. Columns already added.   | Was corrected   | 4/25/2012 |

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|----------------|---------|----|--|---------|--|--|---|-----------|
| Steve Gingras  | Janssen | QS | BPI Short Form, section 6.3.5.1, page 3              |         | change from "...foreign-language translations; and the BPI..." to "...foreign-language translations, and the BPI..."   | grammar  | Corrected.  | 4/25/2012 |
| Denis Michel   | Janssen | QS | BPI SHORT FORM/ Appendix 2: Mapping/ Page 8          | QSSTRNC | missing for QSTRN=0 but the description include 0% as no relief  |  | Corrected.  | 4/25/2012 |
| Denis Michel   | Janssen | QS | BPI SHORT FORM/ section 6.3.5.2 Examples/ Pages 7-10 | QSSTNRC | Correct column header and other references to QSSTNRC from "QSSTRNC"   | The standard variable is --STNRC. Some references incorrectly typed --STRNC.   | Corrected.  | 4/25/2012 |
| Sherry Meeh    | Janssen | QS | BPI v1, Example 1, page 4                            | All     | in the sample, it states that "Row 3 and 66 are for illustrative purposes, actual missing record would not be created in the QS domain". Will it be clear to keep those records with blank (or "N/A") values in QS domain as they are not missing record, they are records with blank (or "N/A") values. | By keeping the record with blank values, it shows clearly that the value is not available; and it is not missing because it was not collected. In other words, blank value does provide information. For example, in row 3, the question is "Professional Degree" and the value is blank, it means that the subject probably does not have professional degree, so CRF query can be sent out for clarification; or maybe "N/A" / "None" can be added into a codelist or a analysis variable for analysis needs. By keeping the | Updated the data example with QSORRES="text" values and described this is being done to indicate a value will be used in the real-life situation and this will not be left NULL and then in conflict with the QSSTAT logic. | 4/25/2012 |
| Denis Michel   | Janssen | QS | BPI/Appendix 2: Mapping/Page 10                      | QSSTNRC | In Short form, it contains description but in BPI, it doesn't. It should be consistent   |  | Corrected.  | 4/25/2012 |
| Susan Timinski | Teva    | QS | COMM   | QSCAT   | Why use 01 in name?  | If the author does not have a version 01, suggest to not use in naming. Some validated scales use effective  | Corrected.  | 4/25/2012 |
| Susan Timinski | Teva    | QS | COMM   | QSCAT   | Why use 01 in name?  | If the author does not have a version 01, suggest to not use in naming. Some validated scales use effective  | Corrected.  | 4/25/2012 |

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|---------------|----------------------------|----|----------------------------------|----------------------------|--|---|--|-----------|
| Denis Michel  | Janssen, Johnson & Johnson | QS | COMM Supplement/section 4/page 6 | QSSTRESN                   | COMM QSSTRESN values of "> or = 9" and "< 9" are character values not appropriate for QSSTRESN. A numeric coded value is appropriate. Consider revising QSORRES, QSSTRESC, QSSTRESN. Page 6 mapping is inconsistent with page 5 display. | QSSTRESN should contain numeric values. Consistency with page 5 display.  | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |
| Steve Gingras | Janssen                    | QS | COMM, 6.3.5.2, page 4            | QSTEST                     | For QSTESTCD=COMM104, change QSTEST from "COMM1-Taken Meds Other Than Prescribed" to "COMM1-Taken Meds Not How Prescribed"   | The way it is currently worded, it sound like the subject is indicating that he/she took meds other than those prescribed. That is not the  | CDISC Terminology team defined the QSCAT/QSTESTCD/QSTEST terminology process.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | COMM, Appendix 2                 | QSTESTCD=COMM101...COMM117 | List each QSTESTCD and QSTEST separately   | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values. If the values of QSORRES, QSSTRESC, QSSTRESN and QSSTNRC are the same for a set of questions, the values of QSTESTCD   | All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS | COMM, Appendix 2                 | QSTESTCD=COMM18            | should be QSTESTCD=COMM118   | typo  | Corrected.   | 4/25/2012 |
| Sherry Meeh   | Janssen                    | QS | COMM, Example 1, page 4          | QSDRVLFL                   | In the sample, for rows 18, it states that 'QSDRVLFL is set to "Y"', should variable QSDRVLFL (should it be QSDRVFL ?) not be populated?   | If question COMM118 is collected from CRF as indicated in the CRF instructions, i.e, entered by a investigator site coordinator, per CDISC SDTM IG 3.1.2, the derived flag is not populated if the data is received from a vendor (or collected from CRF). Here is the sample provided in SDTM IG 3.1.2 page 47: "For example in ECG data, if QTc | Corrected. Add QSDRVFL to the dataset.   | 4/25/2012 |

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| Denis Michel   | Janssen | QS | COMM/ Appendix 2: Mapping/ Pages 5-6 | QSSTRESN                                     | COMM QSSTRESN values of "> or = 9" and "< 9" are character values not appropriate for QSSTRESN. A numeric coded value is appropriate. Consider revising QSORRES, QSTRESC, QSSTRESN | QSSTRESN should contain numeric values.   | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |
| Denis Michel   | Janssen | QS | COMM/ Appendix 2: Mapping/ Pages 5-6 | QTESTCD                                      | For the final score QTESTCD is COMM118, not COMM18. QTESTRN should be numeric score.   |   | Corrected.   | 4/25/2012 |
| Susan Timinski | Teva    | QS | C-SSRS                               | QSSCAT                                       | Use SCAT for distinguishing the separate questions which are grouped like SUICIDAL IDEATION vs INTENSITY OF IDEATION   | If a subject never had an ideation, they would not go to additional questions. In this event, the questions would not exist, rather than be   | After reviewing this with the QS Team, it was determined that QSSCAT is not required for data analysis   | 5/10/2012 |
| Steve Gingras  | Janssen | QS | C-SSRS BASELINE, 6.3.5.1, page 3     |  | change from "...ideation rating scale, it rates..." to "...ideation rating scale. It rates..."   | grammar   | Corrected.   | 4/25/2012 |
| Steve Gingras  | Janssen | QS | C-SSRS BASELINE, Appendix 2          | QTESTCD=CSS0101...CSS0105, CSS0112...CSS0120 | List each QTESTCD and QTEST separately   | Appendix 2 should supply the full set of values for QTESTCD and QTEST. One should not need to refer to the example to obtain the values. It the values of QSORRES, QSTRESC, QSSTRESN and QSSTNRC are the same for a set of questions, the values of QTESTCD and QTEST could be stacked on top of the table, but complete values of each QTESTCD and QTEST | All QTEST/QTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |

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| Steve Gingras | Janssen  | QS | C-SSRS BASELINE, Appendix 2                             | QSTESTCD, QSTEST | QSTESTCD and QSTEST for all text/date fields (e.g, CSS0101A, CSS0121A, etc) are missing   | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values.   | No mapping strategy is needed for these TEXT fields.<br><br>All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.   | 4/25/2012 |
| Sherry Meeh   | Janssen  | QS | C-SSRS BASELINE, Example 1, page 4                      | All              | in the sample, it states that "Row 8, 10, and 27 are for illustrative purposes, actual missing record would not be created in the QS domain". Will it be clear to keep those records with blank (or "N/A") values in QS domain as they are not missing record, they are records with blank (or "N/A") values. | By keeping the record with blank values, it shows clearly that the value is not available; and it is not missing because it was not collected. In other words, blank value does provide information. For example, in row 8, the question is "Ideation With Intent No Plan Descr" and the value is blank, it means that the subject probably does not have "ideation intent" so there is no descr (it seems to be confirmed by row 7), so CRF query can be sent out for clarification; or maybe "N/A" / "None" can be added into a codelist or a analysis variable for analysis needs. By | Updated the data example with QSORRES="text" values and described this is being done to indicate a value will be used in the real-life situation and this will not be left NULL and then in conflict with the QSSTAT logic. | 4/25/2012 |
| Denis Michel  | Janssen  | QS | C-SSRS/ Appendix 2/ Pages 6                             | QSORRES          | For 'Most Severe Ideation', are there no descriptions associated with the numeric scores? If there are then QSORRES should include those descriptions   |  | Since the expected input for this field is number (1-5), the QSORRES is set to 1-5. There is instruction on the form explain the meaning of 1-5: 1-5 from above, with 1 being the least severe and 5 being the most severe  | 4/25/2012 |
| Anthony Chow  | Allergan | QS | Example, "SDTM QS-MNSI v1 Public Domain 2012-03-03.doc" | QSEVAL           | Consider the use of QSEVAL  | First section is by the subject himself, whereas second section is by the site   | Added QSEVAL=SUBJECT on page 1 and QSEVAL=INVESTIGATOR on page 2  | 5/11/2012 |

|              |                            |    |  |                    |   |   |   |           |
|--------------|----------------------------|----|--|--------------------|---|---|---|-----------|
| Anthony Chow | Allergan                   | QS | Example, "SDTM QS-MNSI v1 Public Domain 2012-03-03.doc"        | QSSCAT             | Consider the use of QSSCAT  | QSSCAT can be used to delineate the different sections within the questionnaire.<br><br>Also, when a section is not done, implementers can use QSSCAT = <<section>>, QSTESTCD = "QSALL", and QSSTAT = "NOT DONE". | After further review with the QS Team, it was decided that this would be added as QSSCAT=HISTORY or PHYSICAL ASSESSMENT will be added. There would be not need to add the QSEVAL in this dataset, based on this decision. Also, the QSLAT field will be removed from the CRF annotation for the Physical Assessments page, since each question indicated the LEFT/RIGHT foot. | 5/11/2012 |
| Anthony Chow | Allergan                   | QS | Example, "SDTM QS-MNSI v1 Public Domain 2012-03-03.doc"        | QSTESTCD           | Correct QSTESTCD values to match those on the annotated questionnaire   | Annotated questionnaire has a 4-digit numeric suffix, whereas example is 3-digit  | Corrected.  | 4/25/2012 |
| Anthony Chow | Allergan                   | QS | Example, "SDTM QS-RDQ v1 Public Domain 2012-03-03.doc"         | QSDRVFL            | Consider adding the QSDRVFL column in the example's table   | This suggestion is to make the example explicit and to compliment row 25's text instruction.  | Corrected. Add QSDRVFL to the dataset.  | 4/25/2012 |
| Anthony Chow | Allergan                   | QS | Example, page 4, "SDTM QS-RDQ v1 Public Domain 2012-03-03.doc" | QSDRVFL            | Correct "QSDRVFL" to read "QSDRVFL"   | Typographical error   | Corrected.  | 4/25/2012 |
| Denis Michel | Janssen, Johnson & Johnson | QS | MNSI Supplement/pages 5-9                                      | QSSTRESC,QSSTR ESN | Change to consistent coding: For QSORRES="Yes", QSSTRESC="1", QSSTRESN=1. For QSORRES="No", QSSTRESC="0", QSSTRESN=0. For QSORRES="Checked", QSSTRESC="1", QSSTRESN=1. For QSORRES="Unchecked", | Inconsistent coding of Yes/ no and checked/unchecked and Present/absent responses.  | On Part B of the MNSI form, 'Yes/No' and 'present/absent' are defined using different coding for different questions. Correct Checked/Unchecked to be consistent.   | 4/26/2012 |
| Denis Michel | Janssen                    | QS | MNSI/ Appendix 2: Mapping/ Pages 8-9                           | QSSTRESC,QSSTR ESN | Change to consistent coding: For QSORRES="Yes", QSSTRESC="1", QSSTRESN=1. For QSORRES="No", QSSTRESC="0", QSSTRESN=0. For QSORRES="Checked", QSSTRESC="1", QSSTRESN=1. For                      | Inconsistent coding of Yes/ no and checked/unchecked responses.   | On Part B of the MNSI form, 'Yes=0;No=1' is defined on the form. That's why Yes/No has different coding. Fix Checked/unchecked to be consistent.  | 4/25/2012 |

|                |                            |    |                                      |                             |   |  |  |           |
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| Denis Michel   | Janssen                    | QS | MNSI/ Appendix 2: Mapping/ Pages 8-9 | QSSTRESN                    | Should QSSTRESC and QSSTRESN exist for QSTESTCD=MNSI124-127 as in MNSI118-121? Or combine these as in other questions   |  | Left and right feet were considered separate tests.<br><br>All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.   | 5/11/2012 |
| Denis Michel   | Janssen                    | QS | MNSI/ Appendix 2: Mapping/ Pages 8-9 | QSORRES, QSSTRESC, QSSTRESN | Please consistently code 0=No; 1=Yes; 0=Unchecked, 1=Checked  | Consistent controlled terminology  | On Part B of the MNSI form, 'Yes=0;No=1' is defined on the form. That's why Yes/No has different coding. Fix Checked/unchecked to be consistent.   | 4/26/2012 |
| Denis Michel   | Janssen                    | QS | MNSI/ Appendix 2: Mapping/ Pages 9   | QSSTRESC, QSSTR ESN         | For MNSI124 to MNSI127 (left foot deformities), QSSTRESC and QSSTRESN should be the same as for   |  | Corrected.   | 4/25/2012 |
| Denis Michel   | Janssen                    | QS | MNSI/ Section 6.3.5.2/ Pages 5-6     | QSTEST                      | Change QSTEST for 'MNSI1 -Total' to 'MNSI1 -Total Patient Score' and  | Should clarify in QSTEST which part the questionnaire is the source of the | Corrected.   | 4/25/2012 |
| Susan Timinski | Teva                       | QS | SF36                                 |                             | Provide guidance on use of recall like 2 or 4 weeks. Should QSTEST be changed or QSSCAT, QSTPT used.  | We have a method in use and I am sure companies implement different.       | SF36 is a non-approved copyright questionnaire and thus CDISC can not provide more mapping strategy other than the QESTCD/QSTEST generic terminology. If this is every approved, the use of QSTPT and VISITNUM will be evaluated instead if QSSCAT   | 4/26/2012 |
| Denis Michel   | Janssen, Johnson & Johnson | QS | SOAPP-R Supplement/section 4/page 6  | QSSTRESN                    | SOAPP-R QSSTRESN values of "> or = 18" and "< 18" are character values not appropriate for QSSTRESN. A numeric coded value is appropriate. Consider revising QSORRES, QSSTRESC, QSSTRESN. Page 6 mapping is inconsistent with page 5 display. | QSSTRESN should contain numeric values. Consistency with page 5 display.   | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |

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| Steve Gingras | Janssen | QS | SOAPP-R, 6.3.5.2, page 4             | QSTEST                        | For QSTESTCD=SOAPR112, change QSTEST from "SOAPR1-Expressed Concern Over Med Use" to "SOAPR1- Others Concerned Over Med Use"  | The way it is currently worded, it does not specify that it is others who are concerned about the subjects med use  | All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |
| Steve Gingras | Janssen | QS | SOAPP-R, 6.3.5.2, page 4             | QSTEST                        | For QSTESTCD=SOAPR113, change QSTEST from "SOAPR1-How Often Friends Had Problem" to "SOAPR1-Friends Have Alcohol or Drug Prob"  | The way it is currently worded, there is no way to know that the question specifically deals with a drug/alcohol problem  | All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |
| Steve Gingras | Janssen | QS | SOAPP-R, Appendix 2                  | QSTESTCD=SOAP R101...SOAPR124 | List each QSTESTCD and QSTEST separately  | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values. It the values of QSORRES, QSSTRESC, QSSTRESN and QSSTNRC are the same for a set of questions, the values of QSTESTCD | All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |
| Steve Gingras | Janssen | QS | SOAPP-R, Appendix 2                  | QSTESTCD, QSTEST              | QSTESTCD and QSTEST for text field QSTESTCD=SOAPR125 missing  | Appendix 2 should supply the full set of values for QSTESTCD and QSTEST. One should not need to refer to the example to obtain the values.  | These tests have only free TEXT Values and need no mapping strategy.<br><br>All QSTEST/QSTESTCD are defined by CDISC Terminology Team, which can be referenced from NCI EVS system.  | 4/25/2012 |
| Denis Michel  | Janssen | QS | SOAPP-R/ Appendix 2: Mapping/ Page 6 | QSSTRESN                      | SOAPR126 QSSTRESN values of ">" or "= 18" and "< 18" are character values not appropriate for QSSTRESN. A numeric coded value is appropriate. Consider revising QSORRES, QSSTRESC, QSSTRESN | QSSTRESN should contain numeric values.   | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |

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| Susan Timinski | Teva    | QS | WPAI-SHP                               |         | Version is not captured in this example under any variable. What if the author sends new version? How will the standard change with this? | We should set things up knowing versions will be added. Using version in QSCAT some other variable will enable the data to be distinguished. | QSCAT doesn't need a version number since QSTESTCD has version numbers. CDISC Terminology team defined the QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms | 4/25/2012 |
| Denis Michel   | Janssen | QS | WPAI-SHP/Appendix 2:Mapping/ Pages 6-7 | QSSTRNC | Correct column header and other references to QSSTRNC from "QSSTRNC"  | The standard variable is --STRNC. Some references incorrectly typed --STRNC.   | Corrected.   | 4/25/2012 |

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| Sarah Latimer | Program Management Support<br>FDA ITSS | QS - General |  |          | <p>1. The questionnaires cover a range of neurological and psychiatric conditions (including depression and suicidality), or even general health assessment (such as "global improvement). Why are all of them covered under "pain standard"? Perhaps, it's easier administratively to pass a bunch of questionnaires (QS domain) in one fell swoop, but I wonder if this approach could make it harder to integrate with other neurological and psychiatric domains, which would likely require the same attributes.</p> <p>On many occasions, response values appear to be complex attributes, including some that are likely captured elsewhere in SDTM, such as Clinical Events (CE), Adverse Events (AE), and Findings About (FA) domains. E.g., consider an attribute from HAMD 17 below: Symptoms like backaches, headaches, and loss of energy are all possible "signs and symptoms" that could appear in the above domains (and should ideally belong to CDISC SDTM Controlled Terminology, or any other one referenced by the standard). Not having individual elements linked across domains would apparently limit our range of analyses.</p> <p>QSORRES</p> |   | <p>1. The STANDARDS Working Group decided on the instruments to include in the Pain Data Standards. The Pain User Guide explains the process followed. L. Burke, FDA, was a member of the working group and provided input from FDA perspective. Also, this is v1.0 of the Pain Standard and the working group has intentions of adding additional pain related rating scales in future versions.</p> <p>The CDISC Safety data based domains that are mentioned were not considered as part of this project, since they are already designed for implementation in any TA in the current SDTMIG v3.1.2. All of the pain instruments in v1.0 are either copyrighted or public domain scales which can not be modified and are considered either a Questionnaire or as part of the Physiology Nervous System Findings domain. All of these data elements are considered as Efficacy and not Safety data for the Pain Data Standard</p> | 5/5/2012 |
| Anthony Chow  | Allergan                               | QS-CGI       | "SDTM QS-CGI v1 Public Domain 2012-03-03.doc", Section 4, page 5 | QSORRES  | Consider using QSRESCAT  | Is it possible to use QSRESCAT for "Marked" when QSSTRESN is between 1 and 4, "Moderate" when QSSTRESN is between 5 and 8, and so on? | There are 16 different unique values with specific text values. They can not just be grouped into 4 NVRESCAT values of Unchanged, Minimal, Moderate and Marked. The QS team agreed with the response.  | 5/6/2012 |
| Anthony Chow  | Allergan                               | QS-CGI       | "SDTM QS-CGI v1 Public Domain 2012-03-03.doc", Section 4, page 5 | QSSTRESN | Remove leading zeros in the "QSTESTCD= CGI0103" table  | QSSTRESN is a numeric variable and can't have leading zeros   | Corrected  | 5/6/2012 |

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| Denis Michel  | Janssen, Johnson & Johnson | QS-CGI | CGI Supplement/section 4/page 5 | QSORRES                     | Change "Not accessed" to Not <b>assessed</b> . Also, note that missing values are not appropriate as results as per SDTMIG 3.1.2 section 4.1.2.5. QSSTAT and QSREASND can be used to represent not assessed observations. | Correct word; CDISC SDTM IG 3.1.2 section 4.1.2.5 Convention for missing values | Assessed corrected; Since this is a value within each of the questions as part of a public domain questionnaire, it was determined that QSSTAT would not be used. This will be confirmed with the QS team.                                     | 4/25/2012 |
| Steve Gingras | Janssen                    | QS-CGI | CGI, Appendix 2, page 6         | QSSTRESN                    | remove the leading zero's from 01 through 9 in the table  | numeric field; also, to make consistent with data in the example                | Corrected.   | 4/25/2012 |
| Steve Gingras | Janssen                    | QS-CGI | CGI, section 6.3.5.1, page 3    |                             | change from "...tools in psychiatry, the CGI..." to "...tools in psychiatry. The CGI..."  | grammar   | Wording came directly from the CGI standard CRF definition. Made change to be as requested for clarity.  | 4/25/2012 |
| Steve Gingras | Janssen                    | QS-CGI | CGI, section 6.3.5.1, page 3    |                             | change from "...provide that..." to "...provided that..."   | grammar   | Corrected.   | 4/25/2012 |
| Denis Michel  |                            | QS-CGI | CGI/6.3.5.1/Page 3              |                             | Change "provide that" to "provided that"  | Grammar   | Corrected.   | 4/25/2012 |
| Denis Michel  | Janssen                    | QS-CGI | CGI/Appendix 2/page 5           |                             | This version of the CGI seems to be specific for psychiatric illness. Is it appropriate for pain studies?   |   | This CGI form is in the public domain and is used for a variety of indications. The severity and improvement questions were added separately to the General Clinical Global Impressions questionnaire for evaluation by both the INVESTIGATOR. | 5/21/2012 |
| Denis Michel  | Janssen                    | QS-CGI | CGI/Appendix 2/page 5           | QSORRES, QSSTRESC, QSSTRESN | QSORRES=Not assessed should not be stored in these variables according to SDTM IG 3.1.2 convention for missing values. QSSTAT and QSREASND can be used to represent not assessed observations.                            | CDISC SDTM IG 3.1.2 section 4.1.2.5 Convention for missing values               | Assessed corrected; Since this is a value within each of the questions as part of a public domain questionnaire, it was determined that QSSTAT would not be used. This was confirmed with the QS team.   | 4/25/2012 |
| Denis Michel  | Janssen                    | QS-CGI | CGI/Appendix 2/page 6           | QSORRES, QSSTRESC, QSSTRESN | QSORRES=Not "accessed" should not be stored in these variables according to SDTM IG 3.1.2 convention for missing values. QSSTAT and QSREASND can be used to represent not assessed observations.                          | CDISC SDTM IG 3.1.2 section 4.1.2.5 Convention for missing values               | Assessed corrected; Since this is a value within each of the questions as part of a public domain questionnaire, it was determined that QSSTAT would not be used. This was confirmed with the QS team.   | 4/25/2012 |

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| Anthony Chow   | Allergan | QS-COMM   | "SDTM QS-COMM v1 Approved 2012-03-03.doc", Example 1, pages 4 - 5              | QSDRVFL | Consider adding the QSDRVFL column in the example's table   | This suggestion is to make the example explicit and to compliment row 18's text instruction  | Corrected. Add QSDRVFL to the dataset.   | 4/25/2012 |
| Anthony Chow   | Allergan | QS-COMM   | "SDTM QS-COMM v1 Approved 2012-03-03.doc", Example 1, pages 4 - 5              | QSDRVFL | Consider adding the QSDRVFL column in the example's table   | This suggestion is to make the example explicit and to compliment row 18's text instruction  | Corrected. Add QSDRVFL to the dataset.   | 4/25/2012 |
| Anthony Chow   | Allergan | QS-CSSR   | "SDTM QS-C-SSRS BASELINE v1 Approved 2012-03-03.doc", Section 3.2, pages 4 - 6 | QSSCAT  | Consider the use of QSSCAT  | QSSCAT can be used to delineate the different sections within the questionnaire.<br><br>Also, when a section is not done, implementers can use QSSCAT = <<section>>, QSTESTCD = "QSALL", and QSSTAT = "NOT   | After reviewing this with the QS Team, it was determined that QSSCAT is not required for data analysis       | 4/25/2012 |
| Anthony Chow   | Allergan | QS-HAMD17 | "SDTM QS-HAMD 17 v1 Public Domain 2012-03-03.doc", Example 1, page 4           | QSDRVFL | Add QSDRVFL to row 19 (both text and example record)  | Total score is added from the 17 questions, i.e., derived.<br><br>QSDRVFL is used in Current Opioid Misuse Measure (COMM)@.  | Corrected. Add QSDRVFL to the dataset.   | 4/25/2012 |
| Anthony Chow   | Allergan | QS-MNSI   | "SDTM QS-MNSI v1 Public Domain 2012-03-03.doc", Example 1, page 6              | QSDRVFL | Add QSDRVFL to rows 16, 37 (both text and example record)   | Total score is added, i.e., derived.<br><br>QSDRVFL is used in Current Opioid Misuse Measure (COMM)@.  | Corrected. Add QSDRVFL to the dataset.   | 4/25/2012 |
| Randall Austin | GSK      | RDQ       | 3.1  |         | replace "following assumptions apply " with "following assumption applies "   | only one item is listed so "assumption" should be singular   | Corrected.   | 4/25/2012 |
| Randall Austin | GSK      | RDQ       | 3.2  |         | reword or remove the statement "Values for QSORRES are for prospective data collection. Sponsors mapping legacy data should retain legacy values for QSORRES. " | the phrase "prospective data collection" is very confusing. I think you mean, "going forward, use these terms but don't retrospectively change what you've already done." That doesn't need to be said because Original Result is by definition the collected result. Mapping legacy data is a controversial topic in its own right and this document doesn't need | Values for QSORRES are for prospective data collection. The prospective approach is the CDISC agreed method. | 4/24/2012 |

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| Randall Austin  | GSK      | RDQ   | 3.1.1                       |     | replace "The patient is instructed " and "for groups of patients " with "The subject is instructed " and "for groups of subjects " | Clinical studies are not necessarily conducted on "patients". Using the word "subjects" includes patients as well as any other classes of study   | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | RDQ   | Example row 25 text & table |     | Remove example of a wholly-derived record  | A total score of this type is an analysis derivation which is an ADaM variable, not an SDTM variable. . There will be a QS IG in the not-to-distant future which will address this issue. The current               | Corrected. Add QSDRVFL to the dataset.   | 4/26/2012 |
| E.Lombardi      | Syneract | RDQ   | page 4                      | n/a | The QSDRVFL would only be used if this value is not collected on the CRF   | per SDTM.IG   | Corrected. Add QSDRVFL to the dataset.   | 4/26/2012 |
| Randall Austin  | GSK      | SF36  | 3.2                         |     | replace "CDISC not receiving Copyright permission " with "CDISC not receiving  | typo --- copyright should not be capitalized  | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | SF36  | 3.1.2                       |     | replace "the capability of integrating this data" with "the capability of integrating  | grammar --- data are plural   | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | SF36  | Example table               |     | Remove columns for QSORRES, QSSTRESC, QSSTRESN   | Users will incorrectly assume that they should put the word "Copyright" in these fields. Remove the columns entirely and put a note in the introduction that says QSORRES etc. aren't shown in the table but should | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | SF36  | section 1, 3rd paragraph    |     | "in many different therapeutic are implementations." should be "in many  | typo  | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | SF36  | section 1, 3rd paragraph    |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under About CDISC > Policies"                     | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference   | Corrected.   | 4/25/2012 |
| Randall Austin  | GSK      | SF36  | section 1, 4th paragraph    |     | replace or supplement hyperlink with a logical path, e.g. "on the CDISC website, under Standards > Questionnaires"                 | the physical address of a hyperlink is subject to change when web sites are updated, etc. If the only reference is a url hyperlink then the reference   | Corrected.   | 4/25/2012 |
| Veronica Martin | GSK      | SFMP2 | Example table               |     | Add --EVAL to the QS domain from the FINDINGS class  | To record the role of the person who provided the evaluation in this case   | Evaluator was added as QSEVAL=SUBJECT.   | 4/26/2012 |
| Veronica Martin | GSK      | SFMP2 | Example table               |     | Map LANGUAGE of scale to SUPPQUAL  | At the bottom of the scale it says that the language is US English. That should be held as information in the SDTM dataset.   | There is no reference to the Language being US English on the Annotated Short Form McGill 2 CRF. The general convention for indicating the language used on a questionnaire is to add that to the SUPPQS domain with QNAM=QSLANG and QLABEL=Questionnaire Language as appropriate. | 4/26/2012 |

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| Veronica Martin | GSK | SFMP2 | Example table |  | <p>Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels.</p> | <p>Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPQUAL with SUPQUAL variables to capture:</p> <ul style="list-style-type: none"> <li>- VAS minimum value</li> <li>- VAS minimum label</li> <li>- VAS maximum value</li> <li>- VAS maximum label</li> </ul> | <p>6/4/12 SRC agreement: QSSTNRC, QSSTRNLO &amp; QSSTRNHI will not be used for the data range values. It was agreed to use the following SUPPQS approach: Visual analog or numeric rating scales used within a questionnaire with a range of text and numeric values that are indicated in the SUPPQS domain with:<br/> QNAM=RNGTXTLO<br/> QNAM=RNGTXTHI<br/> QNAM=RNGVALLO<br/> QNAM=RNGVALHI<br/> By storing this information in SUPPQS, it is available for interpretation purposes. The SDS QS Team is researching alternative methods to handle this data, but until a new method is identified, this will be the agreed approach.<br/> *****<br/> *****<br/> *****<br/> In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous</p> | 6/4/2012  |
| Veronica Martin | GSK | SFMP2 | Example table |  | <p>For the instructions for Row 1-22 : remove reference to 'standard terminology'</p>               | <p>There is no standard terminology - the values are numeric.</p>   | <p>This is the standard terminology defined for this questionnaire. QSCAT, QSTESTCD and QSTEST were defined by the Terminology Team. The mapping strategy section defines the terminology needed for pooling data with the fields QSORRES, QSSTRESC and QSSTRESN.</p>   | 4/30/2012 |

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| Veronica Martin | GSK  | SFMP2   | Example table         |                       | For the instructions for Row 1-22 :<br>remove the last sentence 'This result is then transformed into a standard numeric score in QSSTRESN'   | There is no transformation - the value from QSORRES is copied to QSSTRESC and QSSTRESN  | Data has to be converted in some manner from numeric to character in the use of these fields. The word "transformed" can be replaced with "converted" if approved by the QS team.  | 4/30/2012 |
| Veronica Martin | GSK  | SFMP2   | Example table         |                       | Remove SFMP12 from label for QSTEST   | QSCAT tells you that it is SFMP12 scale.  | CDISC Terminology team defined the QSTESTCD/QSTEST terminology process. Confirmed that 'CDISC Submission Value' was used for all QSCAT and annotated forms   | 4/25/2012 |
| Gary Cunningham | Teva | SFMP2   | Pages 4-5             |                       | Incorrect variable names. Should be   |   | Corrected.   | 4/26/2012 |
| Gary Cunningham | Teva | SOAPP-R | Example and Section 4 | QSTESTCD = "SOAPR126" | Suggest that QSORRES be set to missing and that the categorization, e.g. "> or = 18" be placed in QSRESCAT. That is more appropriate than using QSSTRESC. Furthermore, on Page 6, the values under QSSTRESN are not even possible. QSSTRESN is numeric. |   | <b>5/8/2012 Resolution:</b><br>Mapping strategy to be updated as follows:<br><br>Add numeric score "(0-61)" and 10 for + 7 for - in QSTRESC & QSSTRSN for COMM<br>Add numeric score "(0-96)" and 21 for + 17 for - in QSTRESC & QSSTRSN for SOAPR<br>description to mapping strategy statement describing is updated | 5/11/2012 |
| Veronica Martin | GSK  | SOAPR-R | Example table         |                       | For the instructions for Row 1-24 :<br>remove reference to 'standard terminology'   | The terms used in the scale are not part of SDTM standard terminology. There is no SDTM standard terminology for the QSORRES values coming from SOAPR-R | This is the standard terminology defined for this questionnaire. QSCAT, QSTESTCD and QSTEST were defined by the Terminology Team. The mapping strategy section defines the terminology needed for pooling data with the fields QSORRES, QSSTRESC and QSSTRESN.   | 4/30/2012 |
| Veronica Martin | GSK  | SOAPR-R | Example table         |                       | Add --EVAL to the QS domain from the FINDINGS class   | To record the role of the person who provided the evaluation in this case   | QSEVAL=INVESTIGATOR was added  | 4/30/2012 |

|                 |     |         |               |  |                                   |  |  |           |
|-----------------|-----|---------|---------------|--|-----------------------------------|--|--|-----------|
| Veronica Martin | GSK | SOAPR-R | Example table |  | Map LANGUAGE of scale to SUPPQUAL | To record the language used for the scale (i.e. US vs UK english)  | There is no reference to the Language being US English on the Annotated Short Form McGill 2 CRF. The general convention for indicating the language used on a questionnaire is to add that to the SUPPQS domain with QNAM=QSLANG and QLABEL=Questionnaire Language as appropriate.   | 4/26/2012 |
| Veronica Martin | GSK | SOAPR-R | Example table |  | Remove row 25                     | No lines have been provided on the scale to capture 'additional information' - so is there anything to be captured in SDTM?  | This is CDISC Terminology Team's decision to create separate field for the specify text values in the questionnaire. Will update the data example with "text" values and specify this is being done to indicate a value will be use din the real-life situation and thus will not be left NULL and then in conflict with the QSSTAT logic. | 4/30/2012 |
| Veronica Martin | GSK | SOAPR-R | Example table |  | Remove row 26                     | There is no place to capture this information in the rating scale. SDTM should only contain captured values. Derived values should be included in the ADaM dataset | This is CDISC Terminology Team's decision to create separate field for the specify text values in the questionnaire. Will update the data example with "text" values and specify this is being done to indicate a value will be use din the real-life situation and thus will not be left NULL and then in conflict with the QSSTAT logic. | 4/30/2012 |

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|----------------------|---------|----------|--|-------------|--|--|---|-----------|
| Veronica Martin      | GSK     | SOAPR-R  | SDTM mapping strategy                  |             | Remove the table for SOAPR126  |  | Please refer the CRF instruction for how + or - are derived for QSTESTCD=SOAPR126. The CRF instructions indicates these values are the highest threshold for determining "+" = High Risk and "-" = Low Risk subjects. The actual score is populated in the QSSTRESC and QSSTRESN fields. By putting the "> 0 = 18" in quotes it is implied the values in that range would be populated in these fields. Other alternatives on expressing this logic can be evaluated. | 4/24/2012 |
| Denis Michel         | Janssen | SUPPQS   | UG section 6.4.5/paragraph 4 / page 11 |             | If the data are in FA, then the supplemental qualifiers should be in SUPPFA.                                       | Parent domain FA; but Supp domain is SUPPQS.   | Corrected in the new NV domain.   | 5/6/2012  |
| Denis Michel         | Janssen | SUPPQS   | UG section 6.4.5/paragraph 6 / page 11 |             | If the data are in FA, then the supplemental qualifiers should be in SUPPFA.                                       | Parent domain FA; but Supp domain is SUPPQS.   | Corrected in the new NV domain.   | 5/6/2012  |
| Endo Pharmaceuticals |         | SUPPQS   |  | QNAM=PIFREQ | What is the justification. Can QSTPT be used for frequency?  |  | The frequency assumption was updated based on input from B. Dworkin the STANDADS co-chair and SUPPQS is not being used.   | 6/4/2012  |
| Veronica Martin      | GSK     | WPAI-SHP | Example table                          |             | To add QSEVLINT or possibly a SUPPQUAL variable where the evaluation interval is not aligned with ISO 8601 format. | To record the evaluation interval associated with the QSTEST question which is 'during the past seven days'. | Added QSEVLINT= P7D to cover the evaluation interval of the past 7 days, based on review with the QS Team.  | 5/10/2012 |
| Veronica Martin      | GSK     | WPAI-SHP | Example table                          |             | Add --EVAL to the QS domain from the FINDINGS class  | To record the role of the person who provided the evaluation in this case                                    | QSEVAL=SUBJECT was added  | 4/30/2012 |

|                 |     |          |               |  |  |   |  |           |
|-----------------|-----|----------|---------------|--|--|---|--|-----------|
| Veronica Martin | GSK | WPAI-SHP | Example table |  | Map LANGUAGE of scale to SUPPQUAL  | At the bottom of the scale it says that the language is US English. That should be held as information in the SDTM dataset.   | There is no reference to the Language being US English on the Annotated CRF. The general convention for indicating the language used on a questionnaire is to add that to the SUPPQS domain with QNAM=QSLANG and QLABEL=Questionnaire Language as appropriate.   | 4/26/2012 |
| Veronica Martin | GSK | WPAI-SHP | Example table |  | Not to use --STRNLO, --STRNHI and --STNRC to store the VAS minimum/maximum score and labels. | Not appropriate use of --STRNLO, --STRNHI and --STNRC . This information should be mapped to SUPPQUAL with SUPPQUAL variables to capture:<br>- VAS minimum value<br>- VAS minimum label<br>- VAS maximum value<br>- VAS maximum label | In discussion with the SDS sub-group on this topic it was suggested to capture the different data range values categorical scales and anchor text values for continuous scales for on the general pain concepts of Pain Intensity, Pain Relief, General Global Impressions and any copyrighted/public domain questionnaires. Further Questionnaire team work on look-up tables may replace this in a future change control.<br><br><b>5/8/2012 QS Area Lead resolution:</b> include range of values for all scales mentioned about in QSSTNRLO & QSSTNRHI; Data anchor text values for continuous scales to be populated in SUPPQS.<br><br>Gary C. recommends in order to be compliant by using SUPPQS to store anchor text QNAM=QSANCHOR QLABEL=Data Value Anchors QVAL=NO PAIN - WORST PAIN IMAGINABLE in order to not conflict with QSSTNRC definition. This will also need | 5/11/2012 |
| Veronica Martin | GSK | WPAI-SHP | Example table |  | Add QSSTRESU   | To record the standardized units for rows 2, 3 and 4  | Revised in the updated docs.   | 4/30/2012 |

|                 |      |          |                       |  |  |   |   |           |
|-----------------|------|----------|-----------------------|--|--|---|---|-----------|
| Veronica Martin | GSK  | WPAI-SHP | Example table         |  | For row 1 - amend QSSTREC from 1 to YES .<br><br>Remove 1 from QSSTRESN. | There are no numeric values on the CRF for the YES/NO response. The standardized value should be YES unless for 'scoring' reason the data   | Corrected Yes=1 & No=0 to be QSORRESS=YES/NO and QSSTRESC=Y/N and QSSTRESN=Y/N  | 5/11/2012 |
| Veronica Martin | GSK  | WPAI-SHP | SDTM mapping strategy |  | Remove the tables  | Not required - as YES/NO should be standardized to YES/NO unless for 'scoring' reason the data needs to be held as 'number' in the standardized variables.<br><br>VAS minimum/maximum score and | Corrected; Mapping Strategy section on Yes/No values was removed.   | 5/11/2012 |
| Gary Cunningham | Teva | WPAI-SHP |                       |  | See Row 3 above.   |   | QSCAT is included in the CDISC Questionnaire Controlled Terminology and is maintained via NCI EVS. QSCAT is a single value for each individual QS instrument dataset. The NV domain example contains multiple QSCAT values and is included in Section 4: Mapping Strategy. All other QS forms have only one QSCAT value per rating scale. | 4/9/2012  |