Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013-09-24</td>
<td>1.0</td>
<td>Modified Medical Research Council (MMRC) Dyspnea Scale DRAFT</td>
</tr>
<tr>
<td>2013-10-09</td>
<td>1.0</td>
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1 Introduction
This document describes the CDISC implementation of the Modified Medical Research Council (MMRC) Dyspnea Scale, a standard scale that is typically used in clinical trials to provide an assessment of a patient’s level of dyspnea.

The MMRC Dyspnea Scale preceded the CDISC CDASH CRF standards and based on its public domain status cannot be modified to CDASH standards.

The representation of data collected for this scale is based on the Study Data Tabulation Model Implementation Guide (SDTMIG) Questionnaires (QS) domain model, which can be found on the CDISC website at: (http://www.cdisc.org/sdtm).

The specific implementation details for this scale/questionnaire are meant to be used in conjunction with the SDTMIG. All scale/questionnaire documentation can be found on the CDISC website at: (http://www.cdisc.org/content2909).

The CDISC Intellectual Property Policy can be found on the CDISC website at: (http://www.cdisc.org/bylaws-and-policies).

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers
This document is a supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials and is covered under Appendix F of that document, which describes representations, warranties, limitations of liability, and disclaimers. Please see Appendix F of the SDTMIG for a complete version of this material.

2 Copyright Status
This instrument is in the public domain. CDISC has included the Modified Medical Research Council (MMRC) Dyspnea Scale as part of CDISC Data Standards. Hence, CDISC developed QSTESTCD and QSTEST for the scale. There may be other versions of this questionnaire in the public domain. CDISC has chosen to use this version as the data standard.

The CDISC documentation of this instrument consists of: (1) controlled terminology, (2) standard database structure with examples, and (3) case report form annotated with the CDISC SDTMIG submission values.

Note: CDISC controlled terminology is maintained by NCI EVS. The most recent version should be accessed through the CDISC website at: (http://www.cdisc.org/terminology).

CDISC has developed this documentation at no cost to the instrument author or any additional cost to users of the instrument.

The reference for this scale is:
3 The QS Domain Model

3.1 Assumptions for Questionnaire Domain Model

All assumptions and business rules described in the SDTMIG QS domain are applicable to this supplement. Additional assumptions specific to the Modified Medical Research Council Dyspnea Scale are listed below.

Modified Medical Research Council (MMRC) Dyspnea Scale: MMRC Dyspnea Scale is a 1-item instrument that uses a 5-point ordinal scale response format.

1. The questionnaire evaluator should be stored in QSEVAL.

2. Terminology:
   a. QSCAT, QSTESTCD and QTEST are approved CDISC controlled terminology.
   b. A full list of value sets for test and result fields is provided in Section 4: SDTM Mapping Strategy.
### 3.2 Example for Modified Medical Research Council Dyspnea Scale (MMRC) QS Domain Model

The MMRC Dyspnea Scale example below shows the terminology used to implement the scale in the QS domain. This example shows the data for three subjects collected at one visit each. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT.

**Rows 1-3:** Represent the MMRC Dyspnea Scale results for three subjects. All original results are represented with preferred terminology in QSORRES. QSSTRESC and QSSTRESN contain the standard results, which are the scale numeric ratings. In this example, the three observations represent baseline values and are flagged accordingly with QSBLFL.

#### QS.XPT

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>QSSEQ</th>
<th>QSTESTCD</th>
<th>QSTEST</th>
<th>QSCAT</th>
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<tr>
<td>1</td>
<td>STUDYX</td>
<td>QS</td>
<td>P101</td>
<td>1</td>
<td>MMRC0101</td>
<td>MMRC01-Description of Breathlessness</td>
<td>MMRC</td>
</tr>
<tr>
<td>2</td>
<td>STUDYX</td>
<td>QS</td>
<td>P102</td>
<td>1</td>
<td>MMRC0101</td>
<td>MMRC01-Description of Breathlessness</td>
<td>MMRC</td>
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<tr>
<td>3</td>
<td>STUDYX</td>
<td>QS</td>
<td>P103</td>
<td>1</td>
<td>MMRC0101</td>
<td>MMRC01-Description of Breathlessness</td>
<td>MMRC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Row</th>
<th>QSORRES</th>
<th>QSSTRESC</th>
<th>QSSTRESN</th>
<th>QSBLFL</th>
<th>QSEVAL</th>
<th>VISITNUM</th>
<th>QSDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (cont)</td>
<td>Stops for breath after walking about 100 yards or after a few minutes on the level</td>
<td>3</td>
<td>3</td>
<td>Y</td>
<td>STUDY SUBJECT</td>
<td>1</td>
<td>2012-12-05</td>
</tr>
<tr>
<td>2 (cont)</td>
<td>Not troubled with breathlessness except with strenuous exercise</td>
<td>0</td>
<td>0</td>
<td>Y</td>
<td>STUDY SUBJECT</td>
<td>1</td>
<td>2012-12-28</td>
</tr>
<tr>
<td>3 (cont)</td>
<td>Troubled by shortness of breath when hurrying on the level or walking up a slight hill</td>
<td>1</td>
<td>1</td>
<td>Y</td>
<td>STUDY SUBJECT</td>
<td>1</td>
<td>2013-01-04</td>
</tr>
</tbody>
</table>
4 SDTM Mapping Strategy

MMRC Dyspnea Scale specific mapping strategy: This section is used for reference with the annotated CRF for further details on the CRF data capture and to understand the alignment of the questionnaire to the SDTM QS domain. It also provides guidance on how the results variables (QSORRES, QSSTRESC, and QSSTRESN) should be populated for the scale.

QTESTCD=MMRC0101  QTEST= MMRC01-Description of Breathlessness

<table>
<thead>
<tr>
<th>QSORRES</th>
<th>QSSTRESC</th>
<th>QSSTRESN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not troubled with breathlessness except with strenuous exercise</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Troubled by shortness of breath when hurrying on the level or walking up a slight hill</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Stops for breath after walking about 100 yards or after a few minutes on the level</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Too breathless to leave the house or breathless when dressing or undressing</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

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