

Steve Kopko

From: Andrew Lovley <alovley@qualitymetric.com>
Sent: Tuesday, May 4, 2021 2:41 PM
To: Steve Kopko
Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Hello Steve,

I took a look at the change control and it looks good to me, thank you for directing me to the where the changes took place. I appreciate you taking care of this – I apologize for not noticing the variable’s absence previously.

Regards,
Andrew

Andrew Lovley, MA | Outcomes Research Analyst | **QualityMetric Incorporated, LLC** | +1-401-903-4610

From: Steve Kopko <skopko.external@cdisc.org>
Sent: Monday, May 3, 2021 1:37 PM
To: Andrew Lovley <alovley@qualitymetric.com>
Cc: Steve Kopko <skopko.external@cdisc.org>
Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Andrew,

Thanks for confirming this! I have created the attached SF36 V2.0 ACUTE & STANDARD CT change control for you to do a quick review before I get it approved this Thursday at the CDISC QRS CT team meeting. I inserted the new MHE Score before the Response Consistency Score based on the order of these variables provided in Mahasweta’s initial reference below on April 27 regarding “What you receive back”. The affected rows are 61, 62, 98, and 109. The RED font are the new changes, and the strikeout items are removed from the current published CT.

Once you confirm this it will get approved and added to the CDISC PKG 46 CT release in June.

Thanks,
Steve

From: Andrew Lovley <alovley@qualitymetric.com>
Sent: Friday, April 30, 2021 4:33 PM
To: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>; Steve Kopko <skopko.external@cdisc.org>; Dana Booth <dbooth@cdisc.org>
Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Hi all,

Yes the MHE should be added to the SF-36v2 Standard and Acute CDISC controlled terminology. The Scoring Guidelines that were shared by Mahasweta reflect that as part of scoring services, QM typically only returns the SF-6D_R2 and not the original SF-6D, since the SF-6D_R2 has improved algorithms to handle missing data.

Please note that the MHE score is not derived from the SF-36v1, but only version 2.

My apologies for the mix-up.

Regards,
Andrew

Andrew Lovley, MA | Outcomes Research Analyst | QualityMetric Incorporated, LLC | +1-401-903-4610

From: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>
Sent: Friday, April 30, 2021 4:09 AM
To: Steve Kopko <skopko.external@cdisc.org>; Dana Booth <dbooth@cdisc.org>; Andrew Lovley <alovley@qualitymetric.com>
Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Dear Steve and Andrew,

One of the study teams at Novartis requested for the addition of these derived variables based on the attached document from OPTUM, and I started tracking it back from there.

So, to summarize and close the loop here, below are my take-aways. Please add/correct if I am wrong.

1. Novartis will proceed adding MHE, while SDTM CT gets revised as below.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC
C176180	C101884		The Short Form 36 Health Survey Acute, US Version 2.0 Questionnaire Test Code	SF36429	SF364-Mental Component Score	The Short Form 36 Health Survey A score
C176181	C101884		The Short Form 36 Health Survey Acute, US Version 2.0 Questionnaire Test Code	SF36430	SF364-SF-6D (Utility Index) Score	The Short Form 36 Health Survey A score
C176182	C101884		The Short Form 36 Health Survey Acute, US Version 2.0 Questionnaire Test Code	SF36431	SF364-SF-6D_R2 (Util Index Rel 2) Score	The Short Form 36 Health Survey A (2) score
C176183	C101884		The Short Form 36 Health Survey Acute, US Version 2.0 Questionnaire Test Code	SF36432	SF364-Response Consistency Score	The Short Form 36 Health Survey A score

Code C176181 will be retained as is.

Code C176182 will be retired and an equivalent code for MHE will be added.

@Andrew – I see that the study team has already contacted you on a different email chain, hence I shall hop on to that for any further question.

I would like to **Thank** everyone out here for such electrifying support to get that matter rolling. Great help :)

Wish everyone a happy weekend. Stay safe!

Best Regards,
Mahasweta Bhattacharya
Principal CDS Specialist
Clinical Data Standards
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Mahasweta.Bhattacharya@novartis.com
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From: Steve Kopko <skopko.external@cdisc.org>
Sent: Friday, April 30, 2021 1:47 AM
To: Andrew Lovley <alovley@qualitymetric.com>; Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>
Cc: Dana Booth <dbooth@cdisc.org>; Steve Kopko <skopko.external@cdisc.org>
Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Andrew,

The original set of derived variables you sent on 10/7/19 provided in the attached file did not have the Mental Health Enhanced Score (MHE) Variable. So based on this message, CDISC should add it to the SF36 V1.0 ACUTE and STANDARD and SF26 V2.0 ACUTE and STANDARD controlled terminology. I will add this to the CDISC CT in a change control when you relay back to confirm this.

Finally, I am not sure where Mahasweta obtained her “What you will receive back” information listed below, but that also did not have the “SF364-SF-6D_R2 (Util Index Rel 2) Score” variable represented. This is what caused some of the confusion.

Steve

From: Andrew Lovley <alovley@qualitymetric.com>

Sent: Thursday, April 29, 2021 3:14 PM

To: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>; Steve Kopko <skopko.external@cdisc.org>

Cc: Dana Booth <dbooth@cdisc.org>

Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Hello all,

The Mental Health Enhanced Score (MHE) and SF-6D_2 are indeed separate scores. I think that the omission of the MHE score from the SDTM CT is a mistake due to oversight.

Regards,
Andrew

Andrew Lovley, MA | Outcomes Research Analyst | QualityMetric Incorporated, LLC | +1-401-903-4610

From: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>

Sent: Thursday, April 29, 2021 4:30 AM

To: Steve Kopko <skopko.external@cdisc.org>; Andrew Lovley <alovley@qualitymetric.com>

Cc: Dana Booth <dbooth@cdisc.org>

Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Dear Steve,

Many thanks for your quick response.

So, for the text highlighted in green from your response, does it mean that **Mental Health Enhanced Score and the “SF364-SF-6D_R2 (Util Index Rel 2) Score”** are **different** score? I however could not locate **Mental Health Enhanced Score** in SDTM CT. Please correct if I am mis-interpreting here.

I look forward for Andrew’s confirmation understand this better.

Best Regards,

Mahasweta Bhattacharya

Principal CDS Specialist

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From: Steve Kopko <skopko.external@cdisc.org>

Sent: Wednesday, April 28, 2021 8:30 PM

To: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>; Dana Booth <dbooth@cdisc.org>

Cc: Steve Kopko <skopko.external@cdisc.org>; Andrew Lovley <alovley@qualitymetric.com>

Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Dana/Mahasweta,

The CDISC published SF26 V2 ACUTE contains all the variables provided by Andre Lovely at QualityMetric. These proprietary derived results are provided via the QualityMetrics scoring software and will eventually be returned as captured data in the Quality Metric SDTM dataset provided back to approved users. I have copied Andrew on this message for clarification on Mahasweta's questions on the **SF364-SF-6D_R2 (Util Index Rel 2) Score**. It is my understanding that both the Mental Health Enhanced Score and the "SF364-SF-6D_R2 (Util Index Rel 2) Score" scores will be provided in the QualityMetric scoring software, but Andrew can confirm.

Steve

From: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>

Sent: Wednesday, April 28, 2021 3:35 AM

To: Dana Booth <dbooth@cdisc.org>; Steve Kopko <skopko.external@cdisc.org>

Subject: RE: SF36 V2 Acute Questionnaire || V.IMP

Importance: High

Dear Dana,

Thanks a ton for sharing the background in details. Very helpful information.

I was skeptical on using Derived flag - one of my teams have already raised a request to use derived flag for this same QS (Since our standard QS DTS template doesn't contain derived flag variable as of now), however now I understand that we really do not need it in this case.

I would wait for Steve's guidance on one last open question i.e. item 3 – highlighted in trail email.

@Steve – We have a deliverable nearing in May 1st week, hence it would be of great help to receive your guidance at the earliest, if feasible :).

Many thanks in advance!

Best Regards,

Mahasweta Bhattacharya

Principal CDS Specialist

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From: Dana Booth <dbooth@cdisc.org>

Sent: Tuesday, April 27, 2021 9:09 PM

To: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>; Steve Kopko <skopko.external@cdisc.org>

Subject: Re: SF36 V2 Acute Questionnaire || V.IMP

Hey Mahasweta,

Including Steve in on this since he developed terminology for the SF36 V2 acute.

Steve, we have a score in CT (below) that Mahasweta does not have.

C176182

SF36431

SF364-SF-6D_R2 (Util Index Rel 2) Score

The Short Form 36 Health Survey Acute, US Version 2.0 - 6D_R2 (util index rel 2) score.

She will be receiving a Mental Health Enhanced Score according to Optum. Is this the same? If you don't know, would you please e-mail Andrew to ask him about it?

Aside from that, Mahasweta, here's some info about copyright and the SF Health Surveys...

fyi, Optum no longer owns this as they no longer own QualityMetric, the original developers of these measures. We found out about this recently ourselves and are currently reworking our copyright agreement to be with QualityMetric. We have several copyright holders (including QualityMetric) that will distribute the supplements to sponsors that have copyright permission through them. I have managed to get most of them to allow the terminology to be published through NCI/EVS to cut down on error for companies using these instruments.

While we create terminology so scores can be represented in SDTM, we don't show scoring algorithms in SDTM supplements; that's part of ADQRS when possible. Scoring is indeed proprietary for QualityMetric and derived via their scoring software so even if we do ADQRS supplements for the SF Health Surveys, they won't have formulas for scoring. Scores are frequently not shown on CRFs as they're usually derived. In this case, QualityMetric doesn't show them not only because it would increase the chance of errors with people calculating them by hand, but also because their scoring algorithms are proprietary. We **do** consider them as captured data when included in SDTM data.

We have an assumption in our template that addresses this for QRS supplements and we'll be including it in the SF Health Survey supplements. So if you receive all of those totals from Optum or QualityMetric, they will go in the qs.xpt dataset with the appropriate CDISC CT and the derived flag (QSDRVFL) would still be null:

The **QRS Short_Name** instrument includes a total score (and other scores as needed. If so, change "that is" to "that are") that is considered as captured data on the CRF and is not considered as derived in the example below. These scores may be submitted in SDTM or derived in the Analysis Data Model (ADaM) per scoring instructions from *[Insert copyright holder's name or other source.]*.

- a. If operationally defined by the sponsor, it is the sponsor's responsibility to set the --DRVFL flag based on their eCRF process to derive subtotals and total scores. An investigator-derived score will be considered a captured score and not flagged. When subtotal and total scores are derived by the sponsor, the derived flag (--DRVFL) is set to "Y". However, when the subtotal and total scores are received from a central provider or vendor, the value would go into --ORRES and --DRVFL would be null (see SDTMIG Section 4.1.8.1, Origin Metadata for Variables).
- b. if scores are received by the sponsor, it is recommended that they are submitted to SDTM and verified in ADaM.

I hope this helps answer your questions!

Dana Booth | Project Manager, Foundational Standards | QRS Co-lead



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From: Bhattacharya, Mahasweta <mahasweta.bhattacharya@novartis.com>

Sent: Tuesday, April 27, 2021 6:28 AM

To: Dana Booth <dbooth@cdisc.org>

Subject: SF36 V2 Acute Questionnaire || V.IMP

Dear Dana,

Reaching to you with some questions on the SF36V2 acute questionnaire. I tried searching the annotated CRFs for same at CDISC website, however could not. Not sure if any references are stored somewhere else?

I however found the tests in SDTM CT and have certain questions:

- 1) The scoring items are not part of the SF36 V2 Acute questionnaire and I have learnt that it would be transferred through scoring vendor i.e. OPTUM. Seeing the scoring items in SDTM CT, I am assuming there must have been some agreement between the organizations (i.e. Copyrighted owners of SF36 V2 Acute QS and OPTUM), on the scoring front which is why the scoring items are not part of actual copyrighted QS and are listed separately in OPTUM scoring guidelines?
- 2) It is my assumption that all the items listed in attached guideline from OPTUM in page 4 are derived?
- 3) I could not locate below highlighted question in SDTM CT for SF 36 V2 Acute questionnaire. I am assuming 'SF364-SF-6D_R2 (Util Index Rel 2) Score' corresponds to it? If my understanding is correct, would you recommend the vendor mapping information from below highlighted variable to blue highlighted test which is from SDTM CT?

4. What you will receive back

- **Scored dataset**

The dataset you receive back from us will contain all the SF-36v2[®] scale and component score variables, with the names and labels as shown in Table 2. It will also retain any extra variables you had that weren't specifically required by us.

We will return the dataset in the same format in which it was received. For example, if you send a .csv file, we will return a .csv file.

Table 2. SF-36v2[®] derived variables that will be added to your data

Variable name	Variable label	Notes
PF	Physical functioning scale: 0-100 score	These are the raw 0-100 scores
RP	Role physical scale: 0-100 score	
BP	Bodily pain scale: 0-100 score	
GH	General health scale: 0-100 score	
VT	Vitality scale: 0-100 score	
SF	Social functioning scale: 0-100 score	
RE	Role emotional scale: 0-100 score	
MH	Mental health scale: 0-100 score	
PF_NBS	Physical functioning scale: norm-based score	
RP_NBS	Role physical scale: norm-based score	
BP_NBS	Bodily pain scale: norm-based score	
GH_NBS	General health scale: norm-based score	
VT_NBS	Vitality scale: norm-based score	
SF_NBS	Social functioning scale: norm-based score	
RE_NBS	Role emotional scale: norm-based score	
MH_NBS	Mental health scale: norm-based score	
PCS	Physical component summary	
MCS	Mental component summary	
SF6D_R2	SF-6D health utility index score	See descriptions in Section 4 "What you will receive back"
MHE	Mental Health Enhanced score	
RCI	Response Consistency Index	

Kindly share your opinion on same.

Best Regards,

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