

Public Review 2 Webinar - Type 1 Diabetes (T1D) Exercise & Nutrition Targeted Review

Presented by

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21st January 2021



Type 1 Diabetes (T1D) – Exercise and Nutrition

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Type 1 Diabetes

Pediatrics and Devices

- Diabetes History
- On-study DKA
- Devices in Diabetes
- CGM
- Insulin Management
- Pediatric Growth & Growth Percentiles
- Pubertal Status in Diabetes
- QRS

Exercise and Nutrition

Screening, Staging and Monitoring Pre-Clinical T1D

- Islet Autoantibodies
- Polygenic Risk Score
- Staging Module
- Viral Infections/Microbiome
- QRS

Pediatrics & Devices

Diabetes Hx

Devices in T1D

Puberty in T1D

Exercise & Nutrition

Screening, Staging and Monitoring Pre-Clinical T1D

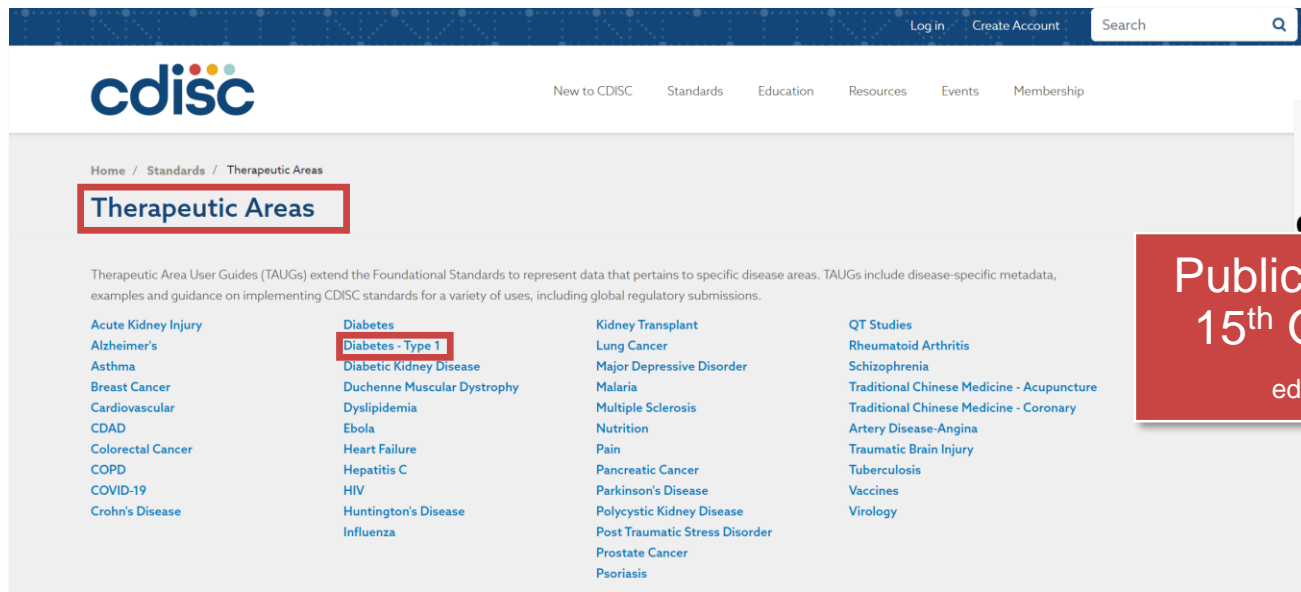
Screen

Stage

Monitor

T1D Pediatrics and Devices

- Publication week of 21st September 2020



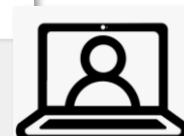
The screenshot shows the CDISC website's 'Therapeutic Areas' page. The navigation bar includes 'Log in', 'Create Account', and a search box. The main content area features a grid of therapeutic areas. 'Diabetes - Type 1' is highlighted with a red box. A red callout box on the right side of the page contains the text: 'Publication Webinar 15th October 2020 education/webinars'.

Home / Standards / Therapeutic Areas

Therapeutic Areas

Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertains to specific disease areas. TAUGs include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submissions.

Acute Kidney Injury	Diabetes	Kidney Transplant	QT Studies
Alzheimer's	Diabetes - Type 1	Lung Cancer	Rheumatoid Arthritis
Asthma	Diabetic Kidney Disease	Major Depressive Disorder	Schizophrenia
Breast Cancer	Duchenne Muscular Dystrophy	Malaria	Traditional Chinese Medicine - Acupuncture
Cardiovascular	Dyslipidemia	Multiple Sclerosis	Traditional Chinese Medicine - Coronary
CDAD	Ebola	Nutrition	Artery Disease-Angina
Colorectal Cancer	Heart Failure	Pain	Traumatic Brain Injury
COPD	Hepatitis C	Pancreatic Cancer	Tuberculosis
COVID-19	HIV	Parkinson's Disease	Vaccines
Crohn's Disease	Huntington's Disease	Polycystic Kidney Disease	Virology
	Influenza	Post Traumatic Stress Disorder	
		Prostate Cancer	
		Psoriasis	



Publication Webinar
15th October 2020

education/webinars

T1D Exercise and Nutrition

cdisc

New to CDISC Standards Education Resources Events Membership

Home / Public Reviews

Public Reviews

Standard/Therapeutic Area	Comments Due
Study Data Tabulation Model Metadata Submission Guidelines v2.0	20 November 2020
SENDIG v3.1.1 and SEND Conformance Rules v2.0	2 November 2020
Therapeutic Area User Guide for Crohn's Disease: Work Package 1	28 October 2020
Therapeutic Area User Guide - Type 1 Diabetes - Exercise and Nutrition	26 October 2020
Controlled Terminology Package 44 Public Review	18 October 2020

On-Line demo to access documents and commenting

Instructions for Reviewers

Created by John Owen, last modified on Jan 30, 2020

Reviewers are requested to provide comments via JIRA, wiki and JIRA use the same credentials, so if you can see this page, then you can use JIRA.

The project associated with the TAUG-Crohn's Disease - Work Package 1 Modules is **Crohn's Disease (CROHNS)**, located at: <https://jira.cdisc.org/projects/CROHNS/>

- If you have no edits or comments to a page
- To add comments to JIRA from within the Wiki
- To add comments from within JIRA

If you have no edits or comments to a page

1. Click 'Like' at the bottom of the page. This will help us determine who has read each page.

To add comments to JIRA from within the Wiki

1. Select the text (ideally, a short, unique phrase) to which you wish to attach the comment. After a moment, two icons should appear.
2. Click on the 3 arrow JIRA icon. This will trigger a Create Issue form.
3. Choose the project associated with this document from the **Project** drop-down menu ("Crohn's Disease").
4. Choose "Review Comments" from the **Issue Type** drop-down menu.
5. Fill out the form.
 - a. The **Summary** field will be pre-populated with the text that you selected. You can change this or leave it as it is.
 - b. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
 - c. In the **Components** field, choose the module to which the comment applies.
 - d. In case of technical difficulties, please make sure to include a brief description of the context of your comment.
6. Click the "Create" button in the bottom left corner of the form to submit your comment as an issue.

Instructions for creating an issue from within the Wiki can be found [here](#).

To add comments from within JIRA

1. Go to the JIRA project associated with this document (https://jira.cdisc.org/projects/CROHNS/).
 - Keeping JIRA open in a separate window to capture screenshots.
2. Click on the "Create" button in the top menu to bring up the "Create Issue" form.
3. Choose the project associated with this document from the **Project** drop-down menu.
4. From the **Issue Type** drop-down menu, set the issue type to "Review Comments".
5. Fill out the form.
 - a. In the **Summary** field, describe the content to which you wish to attach the comment.
 - b. In the **Components** field, choose the module to which the comment applies.
 - c. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
6. Click the "Create" button in the bottom right corner of the form to submit your comment as an issue.

Instructions for creating an issue can be found here: <https://cdisc.org/wiki/creating-an-issue>

◆ For Public Review 2, please only provide comments on Example 3

Handgrip Strength 📄 **TADIAB-894** 📄 **UNDER TEAM REVIEW**

The handgrip strength test is a common method of measuring muscular strength: it is an isometric grip strength test generally performed using a handgrip dynamometer to measure the force exerted as the subject squeezes the device. It is important to establish whether the results of the handgrip strength test are affected by any injury or disability because results affected by injury or disability are less useful as an indicator of subjects' overall strength and fitness.

Example 3

In this example, the sponsor collected the handgrip strength test results only at a baseline visit. If the assessment were repeated throughout a study, the question relating to the subject's dominant hand would only be asked on the first occasion.

> aCRF Handgrip Strength Test

📄 **TADIAB-963** 📄 **UNDER TEAM REVIEW** 📄 **TADIAB-977** 📄 **UNDER TEAM REVIEW**

The results of the handgrip strength test are demonstrated 📄 **TADIAB-950** 📄 **UNDER TEAM REVIEW** below. MKSPID demonstrates the order of the test; MKREPNUM shows that the manner of testing alternated between left hand and right hand order. The MKLOC variable qualifies the test to indicate that the grip strength assessment location was the hand and the MKLAT variable indicates which hand was assessed. The value of the SPDEVID variable identifies the model of device that was used for each handgrip strength test that was performed. The sponsor recorded the type, manufacturer and model number of each model of device in the DI domain (see [example DI dataset](#)).

> mlc.xpt

The SC domain was used to represent the dominant hand for each subject in the study. Dominance may play a role in the results of the handgrip strength test. SCAT was used to indicate the data was collected as part of the handgrip strength assessment.

> sc.xpt

Two types of device were used in the handgrip tests in this example; a grip dynamometer and a force gauge. The sponsor assigned the value for the SPDEVID variable based on the collected information for each unique

📄 **TADIAB-951** 📄 **UNDER TEAM REVIEW** model of device (as identified by the device type, manufacturer and model number). For more information, see the SDTMIG for Medical Devices v1.1, Section 2.5 (available at <https://www.cdisc.org/standards/foundational/>).

> di.xpt

```
graph TD; A[Exercise & Nutrition] --> B[Fitness & Strength]; A --> C[Nutrition]; A --> D[Exercise Types & Activity Devices]; A --> E[QRS];
```

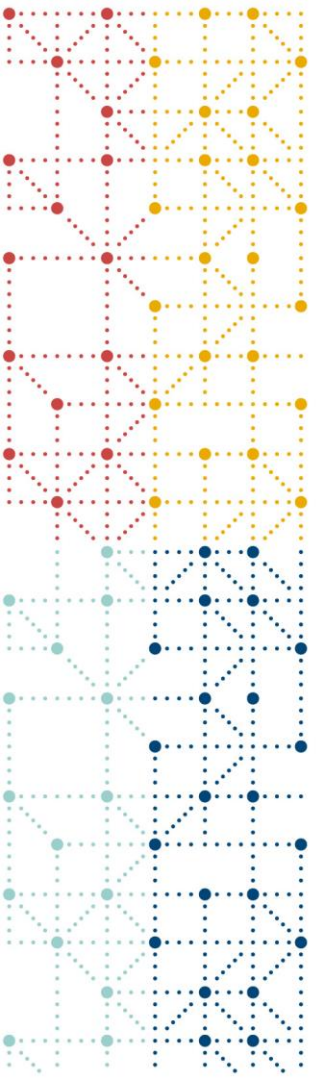
Exercise & Nutrition

Fitness &
Strength

Nutrition

Exercise Types &
Activity Devices

QRS



Handgrip Strength Test

Rebecca Baker

Richard Marshall

Changes

Entire change was from collecting details of specific injuries or disabilities to collecting the impact of any injury/disability in general of any injury

- Removal of MH dataset to record injury or disability
- Was testing prevented by injury or disability OR were any results affected by injury or disability?
 - Preventing
 - Ask the “Reason Not Done” for the entire test and the right and left hand individually
 - Ask specifically about Injury/Disability or Other, specify
 - Affecting
 - Use of NSV to record whether HG test results are affected by injury or disability
- Two minor updates
 - CT updates for Test Codes
 - SCTESTCD “HANDDOM” for SCTEST “Dominant Hand”
 - Device Identifier dataset additions
 - Two unique devices shown

Handgrip Strength Test – CRF part 1

Repeating form designed to collect all injuries/disabilities

Title: Handgrip Strength Test

Medical History Hand or Arm Disabilities Section

CRF Completion Instructions

Complete this form for each hand and each arm injury or disability, including any that may affect the handgrip test. Repeat until all hand and arm injuries are collected.

Record whether the subject has any disability or injury that may affect the handgrip test.

If No, skip the rest of this section.

If Yes, complete this form for each hand and each arm injury or disability, then repeat until all hand and arm injuries are collected.

Answer questions for each injury/disability location, one at a time.

If yes, please enter the injury/disability in the Medical History CRF. Complete an entry for each hand and each arm injury or disability, including any that may affect performance of the handgrip test, then repeat until all hand and arm injuries are collected.

Answer questions for each injury/disability location, one at a time.

If both hand and arm have injuries, complete separate data collection entry for each. For example, if the right hand and arm are broken, complete an entry for right broken arm and a form for right broken hand.

Medical History Category	MHCAT	Hidden/pre-populated	HANDGRIP STRENGTH ASSESSMENT
Does the participant have an injury or disability in either hand/arm? MHOCCUR MHOCCUR where MHTERM = "INJURY OR DISABILITY IN HAND OR ARM"			<input type="radio"/> Yes <input type="radio"/> No
Injury	MHPRESP	Hidden/pre-populated	Y
Injury/Disability	INJDIS_MHTERM	MHTERM Hidden/pre-populated	INJURY OR DISABILITY
What is the injury/disability? MHTERM			
Indicate whether the hand or arm has the injury/disability. MHCLOC MHCLOC = "ARM" or "HAND" AND MHLAT = "RIGHT" or "LEFT"			<input type="radio"/> Right Hand <input type="radio"/> Right Arm <input type="radio"/> Left Hand <input type="radio"/> Left Arm

BEFORE

Handgrip Strength Test – CRF part 2

BEFORE

Was the handgrip test performed? MKPERF If MKPERF="N", MKSTAT is "NOT DONE" where MKTESTCD = "GRIPSTR". If MKPERF = "Y", MKSTAT is null.	<input type="radio"/> Yes <input type="radio"/> No
Which hand is dominant? SCORRES SCORRES where SCTESTCD = "DOMHAND"	<input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> An
Was the handgrip test performed for the right hand? GRIPSTR_RIGHT_MKPERF If "No" then MKSTAT = "NOT DONE" where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" AND MKLAT = "RIGHT" If "Yes", then NOT SUBMITTED	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>
Was the handgrip test performed for the left hand? GRIPSTR_LEFT_MKPERF If "NO" then MKSTAT = "NOT DONE" where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" and MKLAT = "LEFT" IF "YES", then NOT SUBMITTED	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>
Handgrip Strength Test Location MKLOC Hidden/pre-populated	HAND
What was the result of Right Handgrip Strength Test #1? GRIPSTR_RIGHT_MKORRES1 MKORRES where MKTESTCD = "GRIPSTR" and MKLOC = "HAND" and MKLAT = "RIGHT" and MKREPNUM = "1"	<input type="text"/>
What was the result of Left Handgrip Strength Test #1? GRIPSTR_LEFT_MKORRES1 MKORRES where MKTESTCD = "GRIPSTR"	<input type="text"/>
What was the result of Right Handgrip Strength Test #2? GRIPSTR_RIGHT_MKORRES2 MKORRES where MKTESTCD = "GRIPSTR"	<input type="text"/>
What was the result of Left Handgrip Strength Test #2? GRIPSTR_LEFT_MKORRES2 MKORRES where MKTESTCD = "GRIPSTR"	<input type="text"/>
What was the result of Right Handgrip Strength Test #3? GRIPSTR_RIGHT_MKORRES3 MKORRES where MKTESTCD = "GRIPSTR"	<input type="text"/>
What was the result of Left Handgrip Strength Test #3? GRIPSTR_LEFT_MKORRES3 MKORRES where MKTESTCD = "GRIPSTR"	<input type="text"/>
Handgrip Strength Unit GRIPSTR_MKORRESU MKORRESU = "Other" then NULL	<input type="radio"/> kg <input type="radio"/> Other <From UNIT codelist>
What was the device type used for the handgrip strength test? DEVTYPE_CDIVAL If not "Other" then DIVAL where DIPARMCD = "DEVTYPE"	<input type="radio"/> Grip Dynamometer <input type="radio"/> Other
If Other, what was the device type used for the handgrip strength test? CDEVTYPEOTH_CDIVAL DIVAL where DIPARMCD = "DEVTYPE"	<input type="text"/>
Who was the manufacturer of the device? MANUF_DIVAL DIVAL where DIPARMCD = "MANUF"	<input type="text"/>
What is the model number of the device? MODEL_DIVAL DIVAL where DIPARMCD="MODEL"	<input type="text"/>

Does the participant have an injury or disability in either hand or arm? Y/N

What is the injury or disability?

MHPRESP
MHOCCUR

MHTERM

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHLNKID	MHTERM	MHCAT	MHPRESP	MHOCCUR	MHLOC	MHLAT	MHDTC	MHSTDTC	MHENDTC
1	ABC123	MH	1001	1	1	1	INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	Y			2018-07-01	2018-06-25	
2	ABC123	MH	1001	2	1	1	BROKEN WRIST	HANDGRIP STRENGTH ASSESSMENT			HAND	RIGHT	2018-07-01	2018-06-25	
3	ABC123	MH	1002	1	1		INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	N			2018-07-18		
4	ABC123	MH	1003	1	1		INJURY OR DISABILITY IN HAND OR ARM	HANDGRIP STRENGTH ASSESSMENT	Y	Y			2018-07-25	2018-07-15	
5	ABC123	MH	1003	2	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			ARM	RIGHT	2018-07-25	2018-07-15	
6	ABC123	MH	1003	3	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			ARM	LEFT	2018-07-25	2018-07-15	
7	ABC123	MH	1003	4	1		SWELLING	HANDGRIP STRENGTH ASSESSMENT			HAND	RIGHT	2018-07-25	2018-07-15	

Indicate whether the hand or arm has injury or disability?

MHLOC
MHLAT

HANDGRIP STRENGTH ASSESSMENT

MHCAT

BEFORE

Was the handgrip test performed? Y/N

UNCHANGED

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCLNKID	SCTESTCD	SCTEST	SCCAT	SCORR
1	ABC123	SC	1001	1	2	DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	LEFT
2	ABC123	SC	1002	1		DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	RIGHT
3	ABC123	SC	1003	1		DOMHAND	Dominant Hand	HANDGRIP STRENGTH ASSESSMENT	AMBIDEXTROUS

Which hand is dominant? Right hand/Left hand/Ambidextrous

SCORES where SCTESTCD = DOMHAND

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKLNKID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKORRESU	MKSTRESC	MKSTRESN	MKSTRESU	MKLOC	MKLAT	MKREPNUM	MKDTC
1	ABC123	MK	1001	ABC400	1	1	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	40.2	kg	40.2	40.2	kg	HAND	LEFT	1	2018-07-01
2	ABC123	MK	1001	ABC400	2	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.4	kg	16.4	16.4	kg	HAND	RIGHT	1	2018-07-01
3	ABC123	MK	1001	ABC400	3	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.2	kg	47.2	47.2	kg	HAND	LEFT	2	2018-07-01
4	ABC123	MK	1001	ABC400	4	4	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	14.2	kg	14.2	14.2	kg	HAND	RIGHT	2	2018-07-01
5	ABC123	MK	1001	ABC400	5	5	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.1	kg	47.1	47.1	kg	HAND	LEFT	3	2018-07-01
6	ABC123	MK	1001	ABC400	6	6	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.2	kg	16.2	16.2	kg	HAND	RIGHT	3	2018-07-01

Was the handgrip test performed for the right hand? Y/N

Was the handgrip test performed for the left hand? Y/N

What was the result of the right handgrip test #1?

What was the result of the left handgrip test #1?

MKORRES
MKLOC MKLAT
MKREPNUM

What was the device type used for the handgrip strength test?

DIVAL where DIPARMCD = "DEVTYPE"

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC123	DI	ABC400	1	DEVTYPE	Device Type	GRIP DYNAMOMETER
2	ABC123	DI	ABC400	2	MANUF	Manufacturer	Grips Inc.
3	ABC123	DI	ABC400	2	MODEL	Model	GRIPIT123

UNCHANGED

Who was the manufacturer of the device?

DIVAL where DIPARMCD = "MANUF"

What is the model number of the device?

DIVAL where DIPARMCD = "MODEL"

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKLNKID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKORRESU	MKSTRESC	MKSTRESN	MKSTRESU	MKLOC	MKLAT	MKREPNUM	MKDTC
1	ABC123	MK	1001	ABC400	1	1	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	40.2	kg	40.2	40.2	kg	HAND	LEFT	1	2018-07-01
2	ABC123	MK	1001	ABC400	2	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.4	kg	16.4	16.4	kg	HAND	RIGHT	1	2018-07-01
3	ABC123	MK	1001	ABC400	3	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.2	kg	47.2	47.2	kg	HAND	LEFT	2	2018-07-01
4	ABC123	MK	1001	ABC400	4	4	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	14.2	kg	14.2	14.2	kg	HAND	RIGHT	2	2018-07-01
5	ABC123	MK	1001	ABC400	5	5	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.1	kg	47.1	47.1	kg	HAND	LEFT	3	2018-07-01
6	ABC123	MK	1001	ABC400	6	6	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.2	kg	16.2	16.2	kg	HAND	RIGHT	3	2018-07-01

SPDEVID

SPDEVID = the Sponsor Device Identifier

Handgrip Strength Test – CRF

AFTER

Was handgrip test performed? Y/N

What was the reason the HG test was not performed?

Injury/Disability or Other

What was the other reason the HG test was not performed?

Free text

Were the handgrip test results for the right/left hand affected by injury/disability?

Y/N

Was the handgrip test performed? GRIPSTR_MKPERF If "No" then MKSTAT = "NOT DONE" If "Yes" then Not Submitted	<input type="radio"/> Yes <input type="radio"/> No
What was the reason that the handgrip test was not performed? GRIPSTR_MKREASND If not "Other" then MKREASND	<input type="radio"/> Injury/disability <input type="radio"/> Other
What was the other reason that the handgrip test was not performed? GRIPSTR_MKREASNDOTH If GRIPSTR_MKREASND = "Other" then MKREASND	<input type="text"/>
Which hand is dominant? SCORRES SCORRES where SCTESTCD = "HANDDOM"	<input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Ambidextrous
Was the handgrip test performed for the right hand? GRIPSTR_RIGHT_MKPERF If "No" then MKSTAT = "NOT DONE" where MKLAT = "RIGHT" If "Yes" then MKSTAT is null where MKLAT = "RIGHT"	<input type="radio"/> Yes <input type="radio"/> No
What was the reason that the handgrip test was not performed for the right hand? GRIPSTR_RIGHT_MKREASND If not "Other" then MKREASND where MKLAT = "RIGHT"	<input type="radio"/> Injury/disability <input type="radio"/> Other
What was the other reason that the handgrip test was not performed for the right hand? GRIPSTR_RIGHT_MKREASNDOTH If GRIPSTR_RIGHT_MKREASND = "Other" then MKREASND where MKLAT = "RIGHT"	<input type="text"/>
Were the handgrip test results for the right hand affected by injury or disability? GRIPSTR_RIGHT_MKAFUJDS NSMK.MKAFUJDS where MKLAT = "RIGHT"	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>
Was the handgrip test performed for the left hand? GRIPSTR_LEFT_MKPERF If "No" then MKSTAT = "NOT DONE" where MKLAT = "LEFT" If "Yes" then MKSTAT is null where MKLAT = "LEFT"	<input type="radio"/> Yes <input type="radio"/> No
What was the reason that the handgrip test was not performed for the left hand? GRIPSTR_LEFT_MKREASND If not "Other" then MKREASND where MKLAT = "LEFT"	<input type="radio"/> Injury/disability <input type="radio"/> Other
What was the other reason that the handgrip test was not performed for the left hand? GRIPSTR_LEFT_MKREASNDOTH If GRIPSTR_LEFT_MKREASND = "Other" then MKREASND where MKLAT = "LEFT"	<input type="text"/>
Were the handgrip test results for the left hand affected by injury or disability? GRIPSTR_LEFT_MKAFUJDS NSMK.MKAFUJDS where MKLAT = "LEFT"	<input type="radio"/> Yes <input type="radio"/> No <From NY codelist>

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKORRESU	MKSTRESC	MKSTRESN	MKSTRESU	MKSTAT	MKREASND	MKLOC	MKLAT	MKREPNUM	MKDTC	MKAFIJD5
1	ABC123	MK	1001	ABC400	1	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	40.2	kg	40.2	40.2	kg			HAND	LEFT	1	2018-07-01	N
2	ABC123	MK	1001	ABC400	2	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.4	kg	16.4	16.4	kg			HAND	RIGHT	1	2018-07-01	Y
3	ABC123	MK	1001	ABC400	3	3	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.2	kg	47.2	47.2	kg			HAND	LEFT	2	2018-07-01	N
4	ABC123	MK	1001	ABC400	4	4	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	14.2	kg	14.2	14.2	kg			HAND	RIGHT	2	2018-07-01	Y
5	ABC123	MK	1001	ABC400	5	5	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	47.1	kg	47.1	47.1	kg			HAND	LEFT	3	2018-07-01	N
6	ABC123	MK	1001	ABC400	6	6	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	16.2	kg	16.2	16.2	kg			HAND	RIGHT	3	2018-07-01	Y
7	ABC123	MK	1002		1		GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT						NOT DONE	INJURY/DISABILITY	HAND	LEFT		2018-07-18	
8	ABC123	MK	1002	ABC500	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	87.7	LB	39.8	39.8	kg			HAND	RIGHT	1	2018-07-18	N
9	ABC123	MK	1002	ABC500	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	83.1	LB	37.7	37.7	kg			HAND	RIGHT	2	2018-07-18	N
10	ABC123	MK	1002	ABC500	4	3	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	90.4	LB	41	41	kg			HAND	RIGHT	3	2018-07-18	N
11	ABC123	MK	1003		1		GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT						NOT DONE	DYNAMOMETER NOT WORKING	HAND			2018-07-25	

MK NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MKAFIJD5	Result Affected by Injury/Disability	text	Non-standard Record Qualifier	(NY)	CRF

What was the reason the handgrip test was not performed?

MKSTAT

MKREASND

What was the reason the handgrip test was not performed? Injury/Disability/Other

MKSTAT

MKREASND

mk.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKSPID	MKTESTCD	MKTEST	MKCAT	MKORRES	MKSTAT	MKREASND	MKAFIJDS
7	ABC123	MK	1002		1		GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT		NOT DONE	INJURY/DISABILITY	
8	ABC123	MK	1002	ABC500	2	1	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	87.7			N
9	ABC123	MK	1002	ABC500	3	2	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	83.1			N
10	ABC123	MK	1002	ABC500	4	3	GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT	90.4			N
11	ABC123	MK	1003		1		GRIPSTR	Grip Strength	HANDGRIP STRENGTH ASSESSMENT		NOT DONE	DYNAMOMETER NOT WORKING	

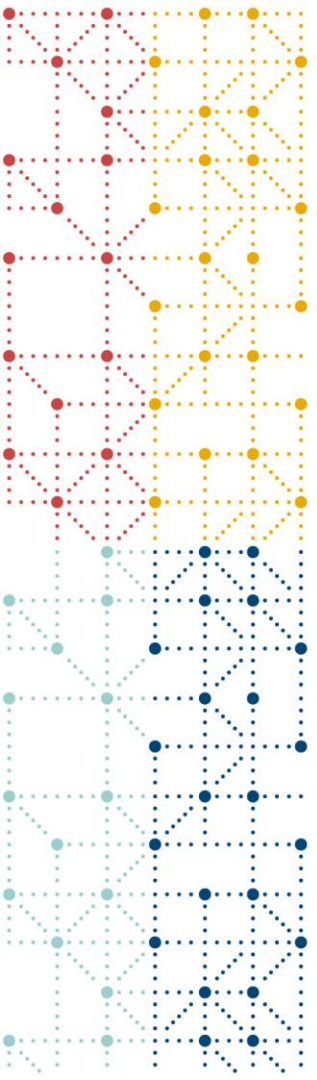
MK NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
MKAFIJDS	Result Affected by Injury/Disability	text	Non-standard Record Qualifier	(NY)	CRF

Were the handgrip test results affected by injury or disability? Y/N

NSMK.MKAFIJDS

AFTER



Thank You!

