Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Brief Pain Inventory-BPI CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

• QS – Questionnaires (v3.3)

Brief Pain Inventory-BPI CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire 1 Have Pain Other Than Everyday Kind of Pain Indicator (Question 1-9(A-G)) 7092575 BPI201	A person's stated observation of whether or not pain, other than everyday kinds of pain such as minor headaches, sprains, and toothaches, is being experienced today, using a yes or no response. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI201, QSEVINTX (6659632) = TODAY and QSCAT (6648971) = BPI SHORT FORM; General Question #1 of 9	CHARACTER. Use choice list
Brief Pain Inventory Short Form Questionnaire 2A Feel Pain Diagram Area Shading Text (Question 1-9(A-G)) 7092582 BPI202A	A person's stated observation of where pain is felt, using a diagram. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI202A and QSCAT (6648971) = BPI SHORT FORM; General Question #2A of 9	ALPHANUMERIC

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire Area that Hurts Most Diagram Text (Question 1-9(A-G))	A person's stated observation of where pain is felt, using a diagram.	ALPHANUMERIC
7263040	CDASH: No Match;	
BPI202B	SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI202B and QSCAT (6648971) = BPI SHORT FORM; General Question #2B of 9	
Brief Pain Inventory Short Form Questionnaire 3 Last 24 Hours Pain at its Worst Score 11 Point Likert Scale (Question 1-9(A-G))	A person's stated observation rating pain at its worst in the last 24 hours, using a 11 point Likert scale.	NUMBER. Use choice list.
7092597 BPI203	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI203, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #3 of 9	
Brief Pain Inventory Short Form Questionnaire 4 Last 24 Hours Pain at its Least Score 11 Point Likert Scale	A person's stated observation rating pain at its least in the last 24 hours, using a 11 point Likert scale.	NUMBER. Use choice list.
(Question 1-9(A-G))		
7092617 BPI204	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI204, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #4 of 9	
Brief Pain Inventory Short Form Questionnaire 5 Last 24 Hours Pain on the Average Score 11 Point Likert Scale (Question 1-9(A-G))	A person's stated observation rating average pain in the last 24 hours, using a 11 point Likert scale	NUMBER. Use choice list.
7092629 BPI205	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI205 and QSCAT = BIP SHORT FORM; General Question #5 of 9	

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire 6 Have Pain Right Now Score 11 Point Likert Scale	A person's stated observation rating current pain, using a 11 point Likert scale	NUMBER. Use choice list.
(Question 1-9(A-G)) 7092625 BPI206	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI206 and QSCAT = BIP SHORT FORM; General Question #6 of 9	
Brief Pain Inventory Short Form Questionnaire 7 Treatment or Medication Receiving for Pain Descriptive Text	A person's stated observation that describes treatment or medication name currently being received for pain	ALPHANUMERIC
(Question 1-9(A-G)) 7092559 BPI207	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI207 and QSCAT = BIP SHORT FORM; General Question #7 of 9	
Brief Pain Inventory Short Form Questionnaire 8 Last 24 Hours How Much Relief Received from Treatment or Medication Score 11 Point Percent Likert Scale (Question 1-9(A-G))	Brief Pain Inventory Short Form Questionnaire 8 Last 24 Hours How Much Relief Received from Treatment or Medication Score 11 Point Percent Likert Scale	NUMBER. Use choice list.
7092605 BPI208	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI208, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #8 of 9	

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire 9A Last 24 Hours Pain Interfered with General Activity Score 11 Point Likert Scale (Question 1-9(A-G)) 7074649 BPI209A	interfered with general activity in the last 24 hours, using a 11 point Likert scale CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI209A, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9A of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered	NUMBER. Use choice list
Brief Pain Inventory Short Form Questionnaire 9B Pain Interfered with Mood Score 11 Point Likert Scale (Question 1-9(A-G)) 7092609 BPI209B	with your: A person's stated observation of how much pain has interfered with mood in the last 24 hours, using a 11 point Likert scale CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI209B, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9B of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	NUMBER. Use choice list
Brief Pain Inventory Short Form Questionnaire 9C Last 24 Hours Pain Interfered with Walking Ability Score 11 Point Likert Scale (Question 1-9(A-G)) 7092613 BPI209C	A person's stated observation of how much pain has interfered with walking ability in the last 24 hours, using a 11 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI209C, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9C of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	NUMBER. Use choice list

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire 9D Last 24 Hours Pain Interfered with Work Score 11 Point Likert Scale (Question 1-9(A-G)) 7092601 BPI209D	A person's stated observation of how much pain has interfered with normal work (including both work outside the home and housework) in the last 24 hours, using a 11 point Likert scale	NUMBER. Use choice list
BEIZUAD	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI209D, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9D of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	
Brief Pain Inventory Short Form Questionnaire 9E Last 24 Hours Pain Interfered with Relations with Other People Score 11 Point Likert Scale (Question 1-9(A-G)) 7092593	A person's stated observation of how much pain has interfered with relations with other people in the last 24 hours, using a 11 point Likert scale	NUMBER. Use choice list
BPI209E	CDASH: No Match; CDASH: QSORRES (6659268) where QSTESTCD = BPI209E, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9E of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Brief Pain Inventory Short Form Questionnaire 9F Last 24 Hours Pain Interfered with Sleep Score 11 Point Likert Scale (Question 1-9(A-G)) 7092621	A person's stated observation of how much pain has interfered with sleep in the last 24 hours, using a 11 point Likert scale CDASH: No Match;	NUMBER. Use choice list
BPI209F	SDTM: QSORRES (6659628) where QSTESTCD = BPI209F, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9F of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	
Brief Pain Inventory Short Form Questionnaire 9G Last 24 Hours Pain Interfered with Enjoyment of Life Score 11 Point Likert Scale (Question 1-9(A-G))	A person's stated observation of how much pain has interfered with enjoyment of life in the last 24 hours, using a 11 point Likert scale	NUMBER. Use choice list
7092571 BPI209G	CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD = BPI209G, QSEVLINT= -P24H and QSCAT = BIP SHORT FORM; General Question #9G of 9; Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	

Annotated CRF: Brief Pain Inventory-BPI CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Brief Pain Inventory-BPI CDISC Aligned NCI Standard Template

Question 1-9(A-G) Questions

CRF Question		Value Domain
Throughout our lives, pain from time to time headaches, sprains anyou had pain other thakinds of pain today? (CDE Short Name: BPI	e (such as minor nd toothaches). Have an these everyday 7092575)	CHARACTER – Maximum Length = 3 No – No Yes – Yes
CDASH: No Match	1	
QSTESTCD (6659	632) = TODAY and	
On the diagram, shad you feel pain. (709258 CDE Short Name: BPI	2)	ALPHANUMERIC – Maximum Length = 200
CDASH: No Match	1	
SDTM: QSORRES QSTESTCD (6659 and QSCAT (6648 FORM		

CRF Question	Value Domain
Put an X on the area that hurts the most. (7263040)	ALPHANUMERIC – Maximum Length = 200
CDE Short Name: BPI202B	
CDASH: No Match	
SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI202B and QSCAT (6648971) = BPI SHORT FORM	
Please rate your pain by circling the one number that best describes your pain at its WORST in the last 24 hours. (7092597)	NUMBER – Maximum Length = 2
CDE Short Name: BPI203	□ 0 – Pain Rating Score 0□ 1 – Pain Rating Score 1
CDASH: No Match	□ 2 – Pain Rating Score 2□ 3 – Pain Rating Score 3
SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI203, QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT FORM	 4 - Pain Rating Score 4 5 - Pain Rating Score 5 6 - Pain Rating Score 6 7 - Pain Rating Score 7 8 - Pain Rating Score 8 9 - Pain Rating Score 9 10 - Pain Rating Score 10
Please rate your pain by circling the one number that best describes your pain at its LEAST in the last 24 hours. (7092617)	NUMBER – Maximum Length = 2
CDE Short Name: BPI204	□ 0 – Pain Rating Score 0□ 1 – Pain Rating Score 1
CDASH: No Match	2 – Pain Rating Score 23 – Pain Rating Score 3
SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI204, QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT FORM	 4 - Pain Rating Score 4 5 - Pain Rating Score 5 6 - Pain Rating Score 6 7 - Pain Rating Score 7 8 - Pain Rating Score 8 9 - Pain Rating Score 9 10 - Pain Rating Score 10

CRI	F Question	Value Domain
nun	ase rate your pain by circling the one nber that best describes your pain on the ERAGE. (7092629)	NUMBER – Maximum Length = 2
CDI	E Short Name: BPI205	□ 0 – Pain Rating Score 0
		☐ 1 – Pain Rating Score 1
	CDASH: No Match	☐ 2 – Pain Rating Score 2
		☐ 3 – Pain Rating Score 3
	SDTM: OSODDES (6650629) whore	☐ 4 – Pain Rating Score 4
	SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI205 and	☐ 5 – Pain Rating Score 5
	QSCAT (6648971) = BPI SHORT	☐ 6 – Pain Rating Score 6
	FORM	☐ 7 – Pain Rating Score 7
		□ 8 – Pain Rating Score 8
		☐ 9 – Pain Rating Score 9
		☐ 10 – Pain Rating Score 10
nun	ase rate your pain by circling the one nber that best describes how much pain have RIGHT NOW. (7092625)	NUMBER – Maximum Length = 2
-	E Short Name: BPI206	□ 0 – Pain Rating Score 0
		☐ 1 – Pain Rating Score 1
	CDASH: No Match	☐ 2 – Pain Rating Score 2
		☐ 3 – Pain Rating Score 3
	ODTM 000DDE0 (0050000)	☐ 4 – Pain Rating Score 4
	SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI206 and	☐ 5 – Pain Rating Score 5
	QSCAT (6648971) = BPI SHORT	☐ 6 – Pain Rating Score 6
	FORM	☐ 7 – Pain Rating Score 7
		☐ 8 – Pain Rating Score 8
		☐ 9 – Pain Rating Score 9
		☐ 10 – Pain Rating Score 10
rec	at treatments or medications are you eiving for your pain? (7092559) E Short Name: BPI207	ALPHANUMERIC – Maximum Length = 200
	CDASH: No Match	
	SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI207 and QSCAT (6648971) = BPI SHORT FORM	

CRF Question	Value Domain	
In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows how much RELIEF you have received.	NUMBER – Maximum Length = 2 0 – Percentage Relief From Pain	
(7092605) CDE Short Name: BPI208 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI208, QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT FORM	Treatment or Medication Score 0 10 – Percentage Relief From Pain Treatment or Medication Score 10 20 – Percentage Relief From Pain Treatment or Medication Score 20 30 – Percentage Relief From Pain Treatment or Medication Score 30 40 – Percentage Relief From Pain Treatment or Medication Score 40 50 – Percentage Relief From Pain Treatment or Medication Score 50	
	 □ 60 – Percentage Relief From Pain Treatment or Medication Score 60 □ 70 – Percentage Relief From Pain Treatment or Medication Score 70 □ 80 – Percentage Relief From Pain Treatment or Medication Score 80 □ 90 – Percentage Relief From Pain Treatment or Medication Score 90 □ 100 – Percentage Relief From Pain Treatment or Medication Score 100 	
General Activity (7074649) CDE Short Name: BPI209A	NUMBER – Maximum Length = 2 □ 0 – Pain Interference Score 0	
CDASH: No Match	 1 – Pain Interference Score 1 2 – Pain Interference Score 2 	
SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI209A, QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT FORM	 3 - Pain Interference Score 3 4 - Pain Interference Score 4 5 - Pain Interference Score 5 6 - Pain Interference Score 6 7 - Pain Interference Score 7 8 - Pain Interference Score 8 9 - Pain Interference Score 9 	
	□ 10 – Pain Interference Score 10	

CRI	F Question	Val	ue Domain
Мо	od (7092609)	NU	MBER – Maximum Length = 2
CD	E Short Name: BPI209B		
			0 – Pain Interference Score 0
	CDASH: No Match		1 – Pain Interference Score 1
			2 – Pain Interference Score 2
	SDTM: QSORRES (6659628) where		3 – Pain Interference Score 3
	QSTESTCD (6659631) = BPI209B,		4 – Pain Interference Score 4
	QSEVLINT (6659632) = -P24H and		5 – Pain Interference Score 5
	QSCAT (6648971) = BPI SHORT FORM		6 – Pain Interference Score 6
			7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 – Pain Interference Score 9
			10 – Pain Interference Score 10
Wal	lking Ability (7092613)	NILI	MBER – Maximum Length = 2
	E Short Name: BPI209C		Widelite Waximum Longin – 2
			0 – Pain Interference Score 0
	CDASH: No Match		1 – Pain Interference Score 1
	SS/ (G. II / (G Mater)		2 – Pain Interference Score 2
			3 – Pain Interference Score 3
	SDTM: QSORRES (6659628) where QSTESTCD (6659631) = BPI209C,		4 – Pain Interference Score 4
	QSEVLINT (6659632) = -P24H and		5 – Pain Interference Score 5
	QSCAT (6648971) = BPI SHORT FORM		6 – Pain Interference Score 6
	FORIVI		7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 – Pain Interference Score 9
			10 – Pain Interference Score 10
Nisa		NII I	
hor	mal work (includes both work outside the ne and housework) (7092601)	NU	MBER – Maximum Length = 2
CDI	E Short Name: BPI209D		0 – Pain Interference Score 0
			1 – Pain Interference Score 1
	CDASH: No Match		2 – Pain Interference Score 2
ı			3 – Pain Interference Score 3
	SDTM: QSORRES (6659628) where		4 – Pain Interference Score 4
	QSTESTCD (6659631) = BPI209D, QSEVLINT (6659632) = -P24H and		5 – Pain Interference Score 5
	QSCAT (6648971) = BPI SHORT		6 – Pain Interference Score 6
	FORM		7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 – Pain Interference Score 9
			10 - Pain Interference Score 10

CRI	F Question	Val	ue Domain
Rel	ations with other people (7092593)	NU	MBER – Maximum Length = 2
CD	E Short Name: BPI209E		
			0 – Pain Interference Score 0
	CDASH: No Match		1 – Pain Interference Score 1
			2 – Pain Interference Score 2
	SDTM: QSORRES (6659268) where		3 – Pain Interference Score 3
	QSTESTCD (6659631) = BPI209E,		4 – Pain Interference Score 4
	QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT		5 – Pain Interference Score 5
	FORM		6 – Pain Interference Score 6
			7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 – Pain Interference Score 9
			10 - Pain Interference Score 10
Sle	ep (7092621)	NU	MBER – Maximum Length = 2
CD	E Short Name: BPI209F		
			0 - Pain Interference Score 0
	CDASH: No Match		1 – Pain Interference Score 1
			2 – Pain Interference Score 2
	SDTM: QSORRES (6659628) where		3 – Pain Interference Score 3
	QSTESTCD (6659631) = BPI209F,		4 – Pain Interference Score 4
	QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT		5 – Pain Interference Score 5
	FORM		6 - Pain Interference Score 6
			7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 – Pain Interference Score 9
			10 – Pain Interference Score 10
Enj	oyment of Life (7092571)	NU	MBER – Maximum Length = 2
CD	E Short Name: BPI209G		
			0 – Pain Interference Score 0
	CDASH: No Match		1 – Pain Interference Score 1
			2 – Pain Interference Score 2
	SDTM: QSORRES (6659628) where		3 – Pain Interference Score 3
	QSTESTCD (6659631) = BPI209G,		4 – Pain Interference Score 4
	QSEVLINT (6659632) = -P24H and QSCAT (6648971) = BPI SHORT		5 – Pain Interference Score 5
	FORM		6 – Pain Interference Score 6
ļ .			7 – Pain Interference Score 7
			8 – Pain Interference Score 8
			9 - Pain Interference Score 9
			10 - Pain Interference Score 10