Handling of Multiple IC Forms in SDTM

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Agenda

- Handling IC Forms in accordance to the SDTMIG
- Having multiple IC Forms in the CRF – how to map that
- How to deal with partial withdrawals
- Special Scenarios

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Handling IC forms in accordance to the SDTMIG

- IC Forms belong to the DS domain:

d. When DSCAT="PROTOCOL MILESTONE", DSTERM and DSDECOD will contain the same value drawn from the sponsor's controlled terminology. Examples of controlled terms include "INFORMED CONSENT OBTAINED" and "RANDOMIZED." EPOCH should not be populated when DSCAT = "PROTOCOL MILESTONE".

DOMAIN(DOMAIN=*DS*)

{Study Number} **STUDYID**

Informed Consent

DSCAT(DSCAT=*PROTOCOL MILESTONE*)

Main Informed consent obtained

Date of Informed consent dd MMM yyyy **DSSTDTC**

DSDECOD = INFORMED CONSENT OBTAINED

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Mapping example for the IC Form in SDTMIG

- Only a simple example is provided, for one IC Form obtained during a study

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
1	ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-21	2003-09-21
2	ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2003-09-29	2003-09-29
3	ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2003-09-30	2003-09-30
4	ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2003-10-31	2003-10-31
5	ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2003-11-15	2003-11-15
6	ABC123	DS	123102	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-11-21	2003-11-21
7	ABC123	DS	123102	2	SUBJECT DENIED MRI PROCEDURE	PROTOCOL VIOLATION	DISPOSITION EVENT	SCREENING	2003-11-22	2003-11-20
8	ABC123	DS	123103	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2003-09-15	2003-09-15

- …but the real life looks different
- Few studies without a protocol amendment
  - For most protocol amendments there is a new IC Form to be signed by each subject

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Where to store such data (1)

- There are two options to store these data:

- 1) in DS domain

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2013-09-29	2013-09-29
ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2013-09-29	2013-09-29
ABC123	DS	123101	4	Protocol Amendment 2.0 signed	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2014-04-03	2014-04-03
ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2014-10-31	2014-10-31
ABC123	DS	123101	6	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2014-11-15	2014-11-15

- Pro: all data are in chronological data, all data are visible
- Contra: could create duplicates, when only the --DECOD and --CAT is reviewed (e.g. by the OpenCDISC validator), there could be more than one such entry – makes it difficulty to filter the important data

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Where to store such data (2)

- 2) in SUPPDS, linked to the first ICF line

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2013-09-29	2013-09-29
ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2013-09-29	2013-09-29
ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2014-10-31	2014-10-31
ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2014-11-15	2014-11-15

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC123	DS	123101	DSSEQ	1	PROTVERS	Protocol Amendment Number	2.0	CRF	
ABC123	DS	123101	DSSEQ	1	AM2ICDTC	Date of Amendment 2.0 IC Signed	2014-04-03	CRF	

- Pro: slim DS domain
- Contra: need to check the SUPPDS for additional information, there could be more than one line in the DS that belongs together

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IC forms for Special Assessments

- More IC Forms could be needed for special assessments

Informed Consent Type	DSDECOD
	o Informed consent for amendment o Informed consent/assent for amendment o Pharmacogenetic research informed consent o Informed consent for Extension Phase o Informed consent after Recovery of consciousness o Informed consent for continued follow-up with study related intervention o Informed consent for continued follow-up with no study related intervention o Informed consent for Pre-screening o Informed consent for sub-study participation o Informed consent for protocol defined procedure o Informed consent for Biomarker sub-study o Informed consent for pharmacokinetic sub-study o Informed consent for Study updates o …

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Best Practice To Map Multiple IC Forms

- Questions:
  - Do we have to list all IC agreements?
  - Is it enough to ask once with a N/Y question for all special IC Forms in the CRF?
  - What is the best way to store these information – option 1 or 2
  - …or is there an option 3?

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Best Practice To Map Multiple IC Forms

- Option 1 could look like that:

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	2	Pharmacogenetic Research ICF Signed	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	3	IC for Sub-Study Participation Signed	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2013-09-29	2003-09-29
ABC123	DS	123101	5	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2013-09-29	2013-09-29
ABC123	DS	123101	6	Protocol Amendment 2.0 signed	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2014-04-03	2014-04-03
ABC123	DS	123101	7	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2014-10-31	2014-10-31
ABC123	DS	123101	8	IC for FUP with Study Rel. Int. signed	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2014-10-31	2014-10-31
ABC123	DS	123101	9	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2014-11-15	2014-11-15

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Best Practice To Map Multiple IC Forms

- Option 2 could look like that:

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	2	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2013-09-29	2003-09-29
ABC123	DS	123101	3	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2013-09-29	2013-09-29
ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2014-10-31	2014-10-31
ABC123	DS	123101	5	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2014-11-15	2014-11-15

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC123	DS	123101	DSSEQ	1	PGICF_YN	Pharmacogenetic Research ICF Signed	Y	CRF	
ABC123	DS	123101	DSSEQ	1	SSICF_YN	IC for Sub-Study Participation Signed	N	CRF	
ABC123	DS	123101	DSSEQ	1	AMDICFYN	Informed Consent for Amendment Signed	Y	CRF	
ABC123	DS	123101	DSSEQ	1	PROTVERS	Protocol Amendment Number	2.0	CRF	
ABC123	DS	123101	DSSEQ	1	AM2ICDTC	Date of Amendment 2.0 IC Signed	2014-10-03	CRF	
ABC123	DS	123101	DSSEQ	4	FUPICFYN	IC for FUP with Study Rel. Int. signed	Y	CRF	

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How to deal with partial withdrawals

- Same problem for partial withdrawals:

DOMAIN(DOMAIN=*DS*)

{Study Number} **STUDYID**

Withdrawal of Informed Consent

DSCAT(DSCAT=*PROTOCOL MILESTONE*)

Type of IC withdrawn	**DSDECOD(NCOMPLT)**
	o Informed consent for amendment o Informed consent/assent for amendment o Pharmacogenetic research informed consent o Informed consent for Extension Phase o Informed consent after Recovery of consciousness o Informed consent for continued follow-up with study related intervention o Informed consent for continued follow-up with no study related intervention o Informed consent for Pre-screening o Informed consent for sub-study participation o Informed consent for protocol defined procedure o Informed consent for Biomarker sub-study o Informed consent for pharmacokinetic sub-study o Informed consent for Study updates o …

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Best Practice To Map Multiple IC Forms (2)

- More Questions:
  - Do we have to list all IC withdrawals (beside the primary ICF)?
  - How to store these information – option 1 or 2
  - …or is there an option 3?

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Special Scenarios: Early Phase

- Early Phase works with cohorts
- Often more subjects are screened than needed
  - Subjects not included are “on hold”
- When such subject joins the next cohort, most times an additional IC Form is signed
  - Which IC Form date should be taken?
  - Should both be listed? Or are we allowed to “ignore” one of both?
  - What happens to other data taken at first visit (LB, VS, IE)?

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Special Scenarios: Pediatric Studies

- Subjects younger than 18 years need the signature from an adult person
  - When more than one signature exists – how should we document that?
  - Do we need a re-signature when the subject gets 18?
  - Does it make sense to use the AP approach here?

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Special Scenarios: Screen Failures

- All IC Forms should be documented

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
ABC123	DS	123101	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-08-21	2013-08-21
ABC123	DS	123101	2	EXC_14 missed	SCREEN FAILURE	DISPOSITION EVENT	SCREENING	2013-09-01	2013-09-01
ABC123	DS	123101	3	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE		2013-09-21	2013-09-21
ABC123	DS	123101	4	COMPLETED	COMPLETED	DISPOSITION EVENT	SCREENING	2013-09-29	2003-09-29
ABC123	DS	123101	5	RANDOMIZED	RANDOMIZED	PROTOCOL MILESTONE		2013-09-29	2013-09-29
ABC123	DS	123101	6	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2014-10-31	2014-10-31
ABC123	DS	123101	7	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2014-11-15	2014-11-15

- More guidance should be provided with SDTMIG 3.3

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Thank you

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