The study in this example involved weekly infusions of Drug Z 10 mg/kg. If a subject experienced a dose-limiting toxicity (DLT), the intended dose could be reduced to 7.5 mg/kg.

The example CRF below was for Subject ABC123-0201, who weighed 55 kg. The CRF shows that:

- The subject's first administration of Drug Z was on 2009-02-13; the intended dose was 10 mg/kg, but the actual amount given was 99 mL at 5.5 mg/mL, so the actual dose was 9.9 mg/kg.
- The subject's second administration of Drug Z occurred on 2009-02-20; the intended dose was reduced to 7.5 mg/kg due to dose-limiting toxicity, and the infusion was stopped early due to an injection site reaction. However, the actual amount given was 35 mL at a concentration of 4.12 mg /mL, so the calculated actual dose was 2.6 mg/kg.
- The subject's third administration was intended to occur on 2009-02-27; the intended dose was 7.5 mg/kg but due to a personal reason, the administration did not occur.

Visit	**1**	**2**	**3**
Intended Dose	• **10 mg/kg** • 7.5 mg/kg	• 10 mg/kg • **7.5 mg/kg**	• 10 mg/kg • **7.5 mg/kg**
Reason for Dose Adjustment	• Dose-limiting toxicity	• **Dose-limiting toxicity**	• Dose-limiting toxicity
Dose Administered	• **Yes** • No If no, give reason: • Treatment discontinued due to disease progression • Other, specify: _____	• **Yes** • No If no, give reason: • Treatment discontinued due to disease progression • Other, specify: _____	• Yes • **No** If no, give reason: • Treatment discontinued due to disease progression • **Other, specify:** Personal reason
Date	13-FEB-2009	20-FEB-2009	27-FEB-2009
Start Time (24 hour clock)	10:00	11:00	
End Time (24 hour clock)	10:45	11:20	
Amount (mL)	99 mL	35 mL	0 mL
Concentration	5.5 mg/mL	4.12 mg/mL	4.12 mg/mL
If dose was adjusted, what was the reason:	• Injection site reaction • Adverse event • Other, specify: _____	• **Injection site reaction** • Adverse event • Other, specify: _____	• Injection site reaction • Adverse event • Other, specify: _____

The EC dataset shows both intended and actual doses of Drug Z, as collected.

Rows 1, 3, 5: Show the collected intended dose levels (mg/kg) and ECMOOD is "SCHEDULED". Scheduled dose is represented in mg/mL.
Rows 2, 4, 6: Show the collected actual administration amounts (mL) and ECMOOD is "PERFORMED". Actual doses are represented using dose in mL and concentration (pharmaceutical strength) in mg/mL.

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECLNKGRP	ECTRT	ECMOOD	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECPS
1	ABC123	EC	ABC123-0201	1		V1	DRUG Z	SCHEDULED			10	mg/kg	
2	ABC123	EC	ABC123-0201	2	20090213 T1000	V1	DRUG Z	PERFORMED	Y	Y	99	mL	5.5
3	ABC123	EC	ABC123-0201	3		V2	DRUG Z	SCHEDULED			7.5	mg/kg	
4	ABC123	EC	ABC123-0201	4	20090220 T1100	V2	DRUG Z	PERFORMED	Y	Y	35	mL	4.12
5	ABC123	EC	ABC123-0201	5		V3	DRUG Z	SCHEDULED			7.5	mg/kg	
6	ABC123	EC	ABC123-0201	6	20090227	V3	DRUG Z	PERFORMED	Y	N		mL	4.12

The reason that ECOCCUR was "N" was represented in a supplemental qualifier.

suppec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL

1	ABC	EC	ABC123-0201	ECSEQ	6	ECREASOC	Reason for Occur Value	PERSONAL REASON	CRF	

The EX dataset shows the administrations in protocol-specified unit (mg/kg). There is no record for the intended third dose that was not given. Intended doses in EC (records with EXMOOD = "SCHEDULED") can be compared with actual doses in EX.

Row 1: Shows the subject's first dose.
Row 2: Shows the subject's second dose. The collected explanation for the adjusted dose amount administered at Visit 2 is in EXADJ.

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXLNKGRP	EXTRT	EXDOSE	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EX
1	ABC123	EX	ABC123-0201	1	20090213T1000	V1	DRUG Z	9.9	mg/kg	SOLUTION	CONTINUOUS	INTRAVENOUS	
2	ABC123	EX	ABC123-0201	2	20090220T1100	V2	DRUG Z	2.6	mg/kg	SOLUTION	CONTINUOUS	INTRAVENOUS	Injec site

The sponsor wished to represent the doses in mg, as well as in mg/kg. Since a dose includes both a numeric value and a unit, the data could not be represented in a supplemental qualifier, so was represented in an FA dataset. See Section 6.4.1, When to Use Findings About Events or Interventions.

fa.xpt

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FASTRESC	FASTRESN	F
1	ABC123	FA	ABC123-0201	1	20090213T1000	DOSEALT	Dose in Alternative Unit	DRUG Z	522.5	mg	522.5	522.5	mg
2	ABC123	FA	ABC123-0201	2	20090220T1100	DOSEALT	Dose in Alternative Unit	DRUG Z	144.2	mg	144.2	144.2	mg

The RELREC dataset represents relationships between EC, EX, and FA.

Rows 1-2: Represent the one-to-one relationship between "PERFORMED" records in EC and records in EX, using --LNKID.
Rows 3-4: Represent the many-to-one relationship between records (both "SCHEDULED" and "PERFORMED") in EC and records in EX, using --LNGRP.
Rows 5-6: Represent the one-to-one relationship between records in EX and records in FA, using LNKID.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	EC		ECLNKID		ONE	1
2	ABC123	EX		EXLNKID		ONE	1
3	ABC123	EC		ECLNKGRP		MANY	2
4	ABC123	EX		EXLNKGRP		ONE	2
5	ABC123	EX		EXLNKID		ONE	3
6	ABC123	FA		FALNKID		ONE	3