

PRACTICAL BENEFITS OF EC: BUILDING A COMPREHENSIVE EXPOSURE STORY

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WHEN YOU NEED TO BE SURE



OVERVIEW

WHEN YOU NEED TO BE SURE





- Introduction
- Case Studies
 - Unblinding in an orderly fashion
 - Capturing relevant exposure info
 - Factual data entry
 - Per dose traceability
 - Multiple dose medications
 - Complex dosing schemes
- Conclusion
- Q&A

INTRODUCTION

WHEN YOU NEED TO BE SURE



How can we document the exposure?

In such a way that it is

Easily analysable

Factually correct

EX

EX documents the actual exposure
and is used for analysis.

As it should be **easily analysable**, EX can
miss information or become too
cluttered,
so we don't want it to be
the sole exposure capturing panel.

EC

Factual recording: the exposure how it happens on site.

Flexibility in the actual dose recording
(concentration vs formulation, single line or multiple lines,...)

EC enables us to document an **accurate, traceable and clearly structured** exposure story in situations where the exposure data and its origin might otherwise be unclear or ambiguous.

EC

Exposure as Collected

Factual data entry

EX

Exposure

Derived from EC using the
data in EC, protocol
data, unblinding data,
medication logs,...

ECTRTR	ECDOSE	ECDOSU
TRT OR PLACEBO	1	TABLET
ECPSTRG	ECPSTRGU	
250	mg/tablet	

EXTRT	EXDOSE	EXDOSU
TRT	250	mg

EC and EX are connected

linking via RELREC

derivation documented

RELATIONSHIP BETWEEN EC AND EX

RELREC – EC Setup

USUBJID	ECLNKID	ECTRT	ECDOSE	ECDOSU	ECPSTRG	ECPSTRGU	VISIT
101	1.007-2017-07-20T08:30-2017-07-20T08:30	TRT	2	CAPSULE	300	mg/CAPSULE	P1_D7
101	1.008-2017-07-21T08:30-2017-07-21T08:30	TRT	2	CAPSULE	300	mg/CAPSULE	P1_D8

RELATIONSHIP BETWEEN EC AND EX

RELREC – EX Setup

USUBJID	ECLNKID	ECTRT	ECDOSE	ECDOSU	VISIT
101	1.007-2017-07-20T08:30-2017-07-20T08:30	TRT	600	mg	P1_D7
101	1.008-2017-07-21T08:30-2017-07-21T08:30	TRT	600	mg	P1_D8

RELATIONSHIP BETWEEN EC AND EX

RELREC

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
STUDY NAME	EC		ECLNKID		ONE	1
STUDY NAME	EX		EXLNKID		ONE	1

RELATIONSHIP BETWEEN EC AND EX

RELREC

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
STUDY NAME	EC		ECLNKID		MANY	1
STUDY NAME	EX		EXLNKID		ONE	1

The derivation is documented in the metadata (and optionally described in the SDRG).

E	C	STUDYID	DOMAIN	USUBJID	ECSEQ	ECGRPID	ECREFID	ECSPID	ECLNKID	ECLNKR	ECTRT	ECMOD	ECCAT
E	X	STUDYID	DOMAIN	USUBJID	EXSEQ	EXGRPID	EXREFID	EXSPID	EXLNKID	EXLNKR	EXTRT		EXCAT

E	C	ECSCAT	ECPRESP	ECOCCUR	ECDOSE	ECDOSTXT	ECDOSU	ECDOSEFRM	ECDOSEFRQ	ECDOSETOT	ECDOSEGRM	ECROUTE	ECLOT
E	X	EXSCAT			EXDOSE	EXDOSTXT	EXDOSU	EXDOSEFRM	EXDOSEFRQ		EXDOSEGRM	EXROUTE	EXLOT

E	C	ECLOC	ECLAT	ECDIR	ECPORTOT	ECFAST	ECPSTRG	ECPSTRGU	ECADJ	VISITNUM	VISIT	VISITDY	EPOCH
E	X	EXLOC	EXLAT	EXDIR		EXFAST			EXADJ	VISITNUM	VISIT	VISITDY	EPOCH

E	C	ECSTDTC	ECENDTC	ECSTDY	ECENDY	ECDUR	ECTPT	ECTPTNUM	ECELT	ECTPTREF	ECRFTDTC
E	X	EXSTDTC	EXENDTC	EXSTDY	EXENDY	EXDUR	EXTPT	EXTPTNUM	EXELT	EXTPTREF	EXRFTDTC

CASE STUDIES

WHEN YOU NEED TO BE SURE



■ Case Studies

- Unblinding in an orderly fashion
- Capturing relevant exposure info
- Factual data entry
- Per dose traceability
- Multiple dose medications
- Complex dosing schemes

UNBLINDING IN AN ORDERLY FASHION

ECTRT is a general placeholder term and EC contains the exposure data as it is captured

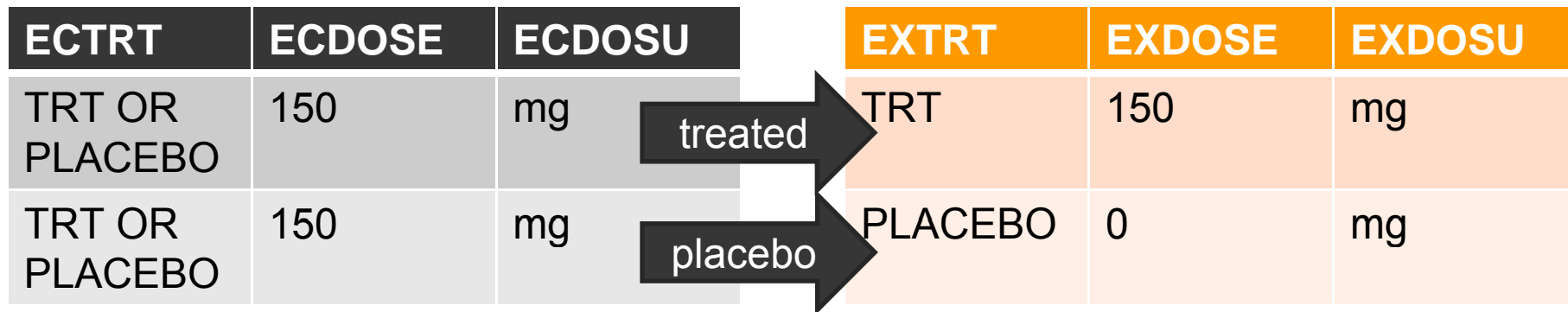
EXTRT describes the actual medication and EX contains the exposure data for analysis

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UNBLINDING IN AN ORDERLY FASHION

Placebo-controlled trials



UNBLINDING IN AN ORDERLY FASHION

Double dummy trials

ECTRT	ECDOSE	ECDOSU	EXTRT	EXDOSE	EXDOSU
TRT A OR TRTB OR PLACEBO	1	TABLET	TRT A	150	mg
TRT A OR TRTB OR PLACEBO	1	TABLET	PLACEBO	0	mg
TRT A OR TRTB OR PLACEBO	1	TABLET	TRT B	250	mg

Dose strength:

TRT A = 150 mg/tablet - TRT B = 250 mg/tablet

CAPTURING RELEVANT EXPOSURE INFO

Capturing relevant exposure information without cluttering
EX/SUPPEX

Even for open label trials

EC documents the reason why a concentration in EX is not as
expected.

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CAPTURING RELEVANT EXPOSURE INFO

USUBJID	EXTRT	EXDOSE	EXDOSU
1001	TRT	150	mg
1002	TRT	147	mg

USUBJID	ECTRT	ECDOSE	ECDOSU	ECPSTRG	ECPSTRGU
1001	TRT OR PLACEBO	100	mL	1.50	mg/mL
1002	TRT OR PLACEBO	98	mL	1.50	mg/mL

CAPTURING RELEVANT EXPOSURE INFO

USUBJID	EXTRT	EXDOSE	EXDOSU
1001	TRT	15.8800	mg
1002	TRT	15.0400	mg
1003	TRT	15.1632	mg

USUBJID	ECTRTRT	ECDOSE	ECDOSU
1001	TRT OR PLACEBO	0.2	mg/kg
1002	TRT OR PLACEBO	0.2	mg/kg
1003	TRT OR PLACEBO	0.2016	mg/kg

FACTUAL DATA ENTRY

On site, exposure data is entered as performed, without making presumptions on type and concentration of the medication

Crucial when working with eSource data directly transferred to Data Management

WHEN YOU NEED TO BE SURE



FACTUAL DATA ENTRY

ECTRTR	ECDOSE	ECDOSU
TRT OR PLACEBO	1	SYRINGE
TRT OR PLACEBO	1	SYRINGE

EXTRTR	EXDOSE	EXDOSU
TRT	150	mg
PLACEBO	0	mg

PER DOSE TRACEABILITY

Dose with coded medication

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PER DOSE TRACEABILITY

USUB JID	EC TRT	EC DOSE	EC DOSU	EC PSTRG	EC PSTRGU	SUPPEC. QNAM	SUPPEC. QVAL
1001	TRT A	1	TABLET	100	mg/tablet	CODE	AABB01
1001	TRT A	1	TABLET	100	mg/tablet	CODE	AABB02
1001	TRT A	1	TABLET	100	mg/tablet	CODE	AABB03

USUBJID	EXTRT	EXDOSE	EXDOSU
1001	TRT A	300	mg

MULTIPLE DOSE MEDICATIONS

Combination of different dose

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MULTIPLE DOSE MEDICATIONS

ECTRT	ECDOSE	ECDOSU	ECPSTRG	ECPSTRGU
TRT A	1	TABLET	25	mg/tablet
TRT A	1	TABLET	50	mg/tablet
TRT A	2	TABLET	100	mg/tablet

EXTRT	EXDOSE	EXDOSU
TRT A	275	mg

COMPLEX DOSING SCHEME

Trial with 2 different inhalers

One dose = 100/10 mg

Intricate placebo-controlled design

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COMPLEX DOSING SCHEMES

ECTRTR	ECDOSE	ECDOSU	VISIT
ALT DEVICE 1	2	INHALATION	VISIT2
ALT DEVICE 2	2	INHALATION	VISIT2
ALT DEVICE 3	2	INHALATION	VISIT2
ALT DEVICE 4	2	INHALATION	VISIT2
DEVICE 1	2	INHALATION	VISIT3
DEVICE 2	6	INHALATION	VISIT3
DEVICE 1	2	INHALATION	VISIT4
DEVICE 2	6	INHALATION	VISIT4
ALT DEVICE 1	2	INHALATION	VISIT5
ALT DEVICE 2	2	INHALATION	VISIT5
ALT DEVICE 3	2	INHALATION	VISIT5
ALT DEVICE 4	2	INHALATION	VISIT5
ALT DEVICE 1	2	INHALATION	VISIT6
ALT DEVICE 2	2	INHALATION	VISIT6
ALT DEVICE 3	2	INHALATION	VISIT6
ALT DEVICE 4	2	INHALATION	VISIT6

COMPLEX DOSING SCHEMES

EXTRT	EXSCAT	EXDOSE	EXDOSTXT	EXDOSU	VISIT
PLACEBO	ALT DEVICE 1	0		mg	VISIT2
PLACEBO	ALT DEVICE 2	0		mg	VISIT2
PLACEBO	ALT DEVICE 3	0		mg	VISIT2
PLACEBO	ALT DEVICE 4	0		mg	VISIT2
TRT	DEVICE 1		200/20	mg	VISIT3
PLACEBO	DEVICE 2	0		mg	VISIT3
TRT	DEVICE 1		200/20	mg	VISIT4
TRT	DEVICE 2		600/60	mg	VISIT4
TRT	ALT DEVICE 1		200/20	mg	VISIT5
TRT	ALT DEVICE 2		200/20	mg	VISIT5
TRT	ALT DEVICE 3		200/20	mg	VISIT5
TRT	ALT DEVICE 4		200/20	mg	VISIT5
TRT	ALT DEVICE 1		200/20	mg	VISIT6
PLACEBO	ALT DEVICE 2	0		mg	VISIT6
PLACEBO	ALT DEVICE 3	0		mg	VISIT6
PLACEBO	ALT DEVICE 4	0		mg	VISIT6

COMPLEX DOSING SCHEMES

ECTRT
ALT DEVICE 1
ALT DEVICE 2
ALT DEVICE 3
ALT DEVICE 4
DEVICE 1
DEVICE 2
DEVICE 1
DEVICE 2
ALT DEVICE 1
ALT DEVICE 2
ALT DEVICE 3
ALT DEVICE 4
ALT DEVICE 1
ALT DEVICE 2
ALT DEVICE 3
ALT DEVICE 4

EXTRT	EXSCAT
PLACEBO	ALT DEVICE 1
PLACEBO	ALT DEVICE 2
PLACEBO	ALT DEVICE 3
PLACEBO	ALT DEVICE 4
TRT	DEVICE 1
PLACEBO	DEVICE 2
TRT	DEVICE 1
TRT	DEVICE 2
TRT	ALT DEVICE 1
TRT	ALT DEVICE 2
TRT	ALT DEVICE 3
TRT	ALT DEVICE 4
TRT	ALT DEVICE 1
PLACEBO	ALT DEVICE 2
PLACEBO	ALT DEVICE 3
PLACEBO	ALT DEVICE 4

COMPLEX DOSING SCHEMES

ECDOSE	ECDOSU
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
6	INHALATION
2	INHALATION
6	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION
2	INHALATION

EXDOSE	EXDOSTXT	EXDOSU
0		mg
0		mg
0		mg
0		mg
	200/20	mg
0		mg
	200/20	mg
	600/60	mg
	200/20	mg
	200/20	mg
	200/20	mg
	200/20	mg
	200/20	mg
0		mg
0		mg
0		mg

COMPLEX DOSING SCHEMES

EXTRT	EXSCAT	EXDOSE	EXDOSTXT	EXDOSU	VISIT
PLACEBO	ALT DEVICE 1	0		mg	VISIT2
PLACEBO	ALT DEVICE 2	0		mg	VISIT2
PLACEBO	ALT DEVICE 3	0		mg	VISIT2
PLACEBO	ALT DEVICE 4	0		mg	VISIT2
TRT	DEVICE 1		200/20	mg	VISIT3
PLACEBO	DEVICE 2	0		mg	VISIT3
TRT	DEVICE 1		200/20	mg	VISIT4
TRT	DEVICE 2		600/60	mg	VISIT4
TRT	ALT DEVICE 1		200/20	mg	VISIT5
TRT	ALT DEVICE 2		200/20	mg	VISIT5
TRT	ALT DEVICE 3		200/20	mg	VISIT5
TRT	ALT DEVICE 4		200/20	mg	VISIT5
TRT	ALT DEVICE 1		200/20	mg	VISIT6
PLACEBO	ALT DEVICE 2	0		mg	VISIT6
PLACEBO	ALT DEVICE 3	0		mg	VISIT6
PLACEBO	ALT DEVICE 4	0		mg	VISIT6

COMPLEX DOSING SCHEMES

Alternative derivation

ECTRTR	ECDOSE	ECDOSU	VISIT
DEVICE 1	2	INHALATION	VISIT3
DEVICE 2	6	INHALATION	VISIT3
DEVICE 1	2	INHALATION	VISIT4
DEVICE 2	6	INHALATION	VISIT4

EXTRTR	EXSCAT	EXDOSE	EXDOSU	VISIT
COMPOUND 1	DEVICE 1	200	mg	VISIT3
COMPOUND 2	DEVICE 1	20	mg	VISIT3
PLACEBO	DEVICE 2	0	mg	VISIT3
COMPOUND 1	DEVICE 1	200	mg	VISIT4
COMPOUND 2	DEVICE 1	20	mg	VISIT4
COMPOUND 1	DEVICE 2	600	mg	VISIT4
COMPOUND 2	DEVICE 2	60	mg	VISIT4

CONCLUSION

WHEN YOU NEED TO BE SURE



Document an accurate, traceable and clearly structured exposure.

The data and its origin are clear and unambiguous.

EX can be analysed easily.

Plan ahead and learn from experience.

WHEN YOU NEED TO BE SURE



The logo consists of the letters 'SGS' in a bold, grey, sans-serif font. A thin orange vertical line is positioned to the right of the 'S', and a thin orange horizontal line is positioned below the 'S'.

Q&A

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