

PRACTICAL BENEFITS OF EC: BUILDING A COMPREHENSIVE EXPOSURE STORY

Presented by Donald Benoot, SGS Life Sciences

Zegher Vereecke, SGS Life Sciences

WHEN YOU NEED TO BE SURE



OVERVIEW

- Introduction

- Case Studies

- Conclusion

- Q&A



WHEN YOU NEED TO BE SURE

SGS

INTRODUCTION

WHEN YOU NEED TO BE SURE



HOW DO WE WANT TO DOCUMENT THE EXPOSURE?

- Easily analysable
- Factually correct

HOW CAN WE DOCUMENT THE EXPOSURE?

EX

(Exposure)

- Actual exposure
- Easily analysable
- Miss information
- Too cluttered

HOW CAN WE DOCUMENT THE EXPOSURE?

EX

(Exposure)

- Actual exposure
- Easily analysable

EC

(Exposure as collected)

- Factual recording
- Flexibility in actual dose recording
- Accurate
- Traceable
- Clearly structured

WHEN YOU NEED TO BE SURE



HOW CAN WE DOCUMENT THE EXPOSURE?

EX

(Exposure)

- Actual exposure
- Easily analysable
- Derived from EC using the data in EC, protocol data, unblinding data, medication logs,...

EC

(Exposure as collected)

- Factual recording
- Flexibility in actual dose recording
- Accurate
- Traceable
- Clearly structured

WHEN YOU NEED TO BE SURE

SGS

EXAMPLE

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

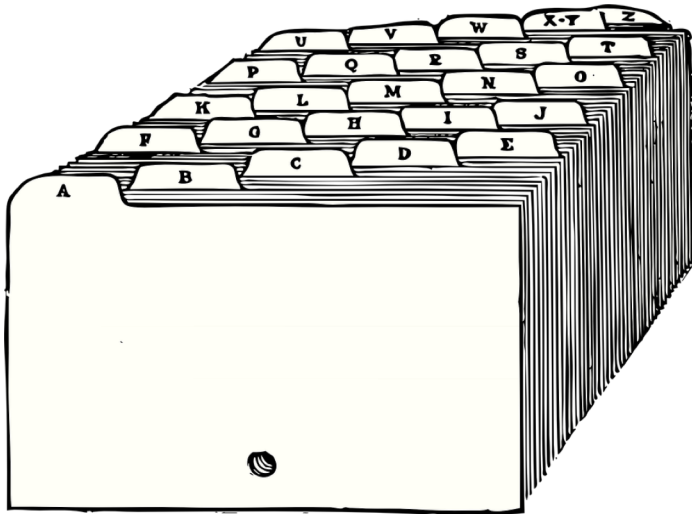
EXTRT	EXDOSE	EXDOSU
TRT	250	mg

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
- Using ECMOOD to document scheduled and performed exposures



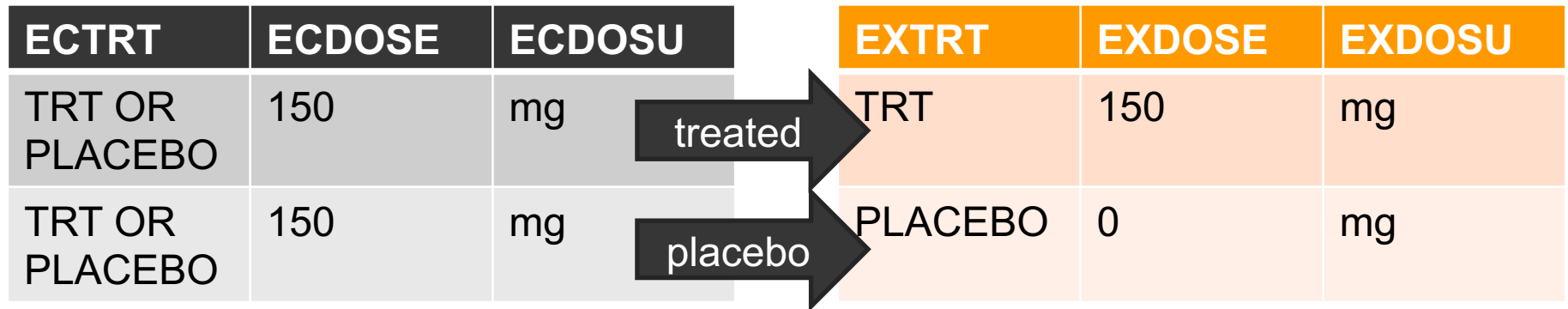
UNBLINDING IN AN ORDERLY FASHION

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

UNBLINDING IN AN ORDERLY FASHION

Placebo-controlled trials



WHEN YOU NEED TO BE SURE



UNBLINDING IN AN ORDERLY FASHION

Double dummy trials

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

Dose strength:

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

WHEN YOU NEED TO BE SURE



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.

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	ECTRT	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

WHEN YOU NEED TO BE SURE



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

FACTUAL DATA ENTRY

ECTRT	ECDOSE	ECDOSU
TRT OR PLACEBO	1	SYRINGE
TRT OR PLACEBO	1	SYRINGE



EXTRT	EXDOSE	EXDOSU
TRT	150	mg
PLACEBO	0	mg

WHEN YOU NEED TO BE SURE



PER DOSE TRACEABILITY

Dose with coded medication

WHEN YOU NEED TO BE SURE



PER DOSE TRACEABILITY

USUBJID	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

WHEN YOU NEED TO BE SURE



MULTIPLE DOSE MEDICATIONS

Combination of different dose

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

WHEN YOU NEED TO BE SURE



COMPLEX DOSING SCHEME

Trial with 2 different inhalers

One dose = 100/10 mg

Intricate placebo-controlled design

COMPLEX DOSING SCHEMES

ECTRT	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

WHEN YOU NEED TO BE SURE



COMPLEX DOSING SCHEMES

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

EXTRT	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

WHEN YOU NEED TO BE SURE



USING ECMOOD TO DOCUMENT SCHEDULED AND PERFORMED EXPOSURES

ECMOOD

ECTRT	ECMOOD	ECDOSE	ECDOSU	ECPRESP	ECOCCUR	VISIT
TRT A	SCHEDULED	50	mg			1
TRT A	PERFORMED	50	mg	Y	Y	1
TRT A	SCHEDULED	100	mg			2
TRT A	PERFORMED	100	mg	Y	Y	2
TRT A	SCHEDULED	200	mg			3
TRT A	PERFORMED			Y	N	3

EXTRT	EXDOSE	EXDOSU	VISIT
TRT A	50	mg	1
TRT A	100	mg	2

WHEN YOU NEED TO BE SURE



CONCLUSION

- Exposure documentation:
 - Accurate
 - Traceable
 - Clearly structured
- Data and origin
 - Clear
 - Unambiguous
- EX can be analysed easily.



BROAD CLINICAL RESEARCH SOLUTIONS



Agriculture, Food & Life Clinical Research

Donald Benoot

Clinical Data Manager Coordinator

SGS

Life Sciences ,
Generaal De Wittelaan 19a bus 5

2800 Mechelen
Belgium

Phone: + 32 15 283 057

Fax: +32 15 29 93 02

Mobile: +32 473 94 32 60

E-mail : donald.benoot@sgs.com

Web : www.sgs.com/CRO

Do meet us at the SGS booth 11

CONTACT US

clinicalresearch@sgs.com

EUROPE: +32 15 27 32 45

AMERICAS: + 877 677 2667

WWW.SGS.COM/CRO



JOIN THE SCIENTIFIC COMMUNITY

CONNECT ON LINKEDIN

www.sgs.com/LinkedIn-Life

COMPLEX DOSING SCHEME

Alternative derivation

COMPLEX DOSING SCHEMES

ECTRT	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

WHEN YOU NEED TO BE SURE



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

WHEN YOU NEED TO BE SURE



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

WHEN YOU NEED TO BE SURE



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

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

WHEN YOU NEED TO BE SURE



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

WHEN YOU NEED TO BE SURE

