



ARE YOU READY FOR SEND?

Presented by Roman Radelicki

Clinical Data Programmer Coordinator

SGS Life Science Services

WHEN YOU NEED TO BE SURE



- Assigned to drive the process of evaluating
 - what is needed to implement SEND
 - how best to implement this within our organization.
- Followed the CDISC SEND training as a starting point and based on this I have put together an implementation plan for our organization.



FDA BINDING GUIDANCE

Providing Regulatory Submissions in
Electronic Format — Submissions Under
Section 745A(a) of the Federal Food,
Drug, and Cosmetic Act

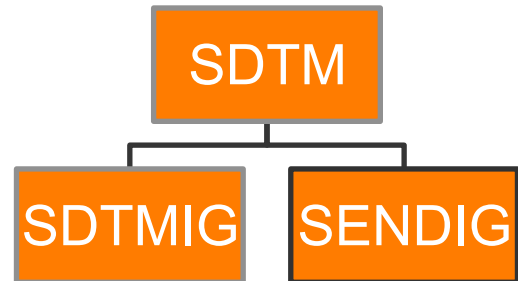
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014
Electronic Submissions

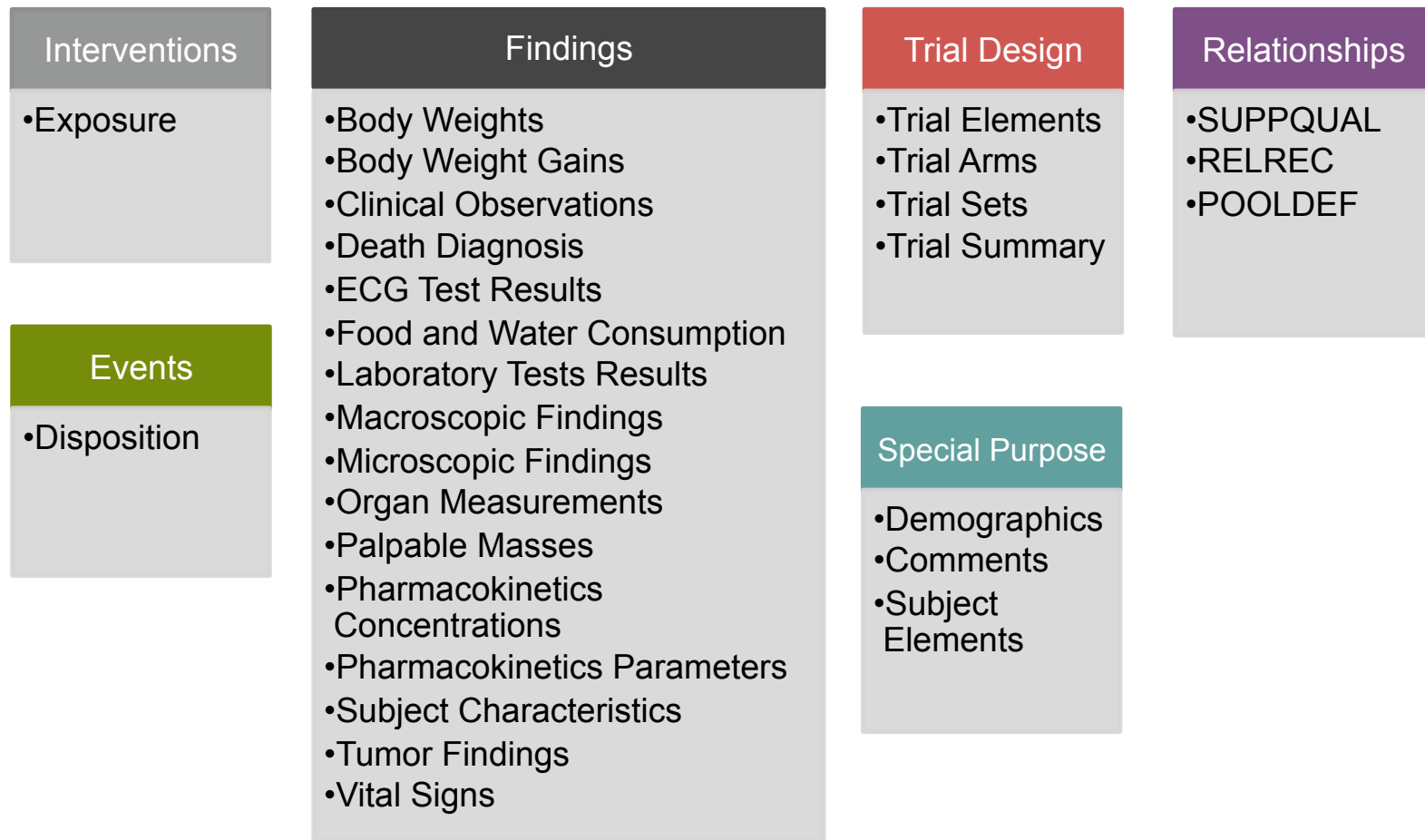
- From December 2016 nonclinical data will have to be submitted in SEND format
- Start to think about how SEND will be implemented
- What does it take for an organization with SDTM knowledge to be able to deliver SEND datasets

- SEND finds its foundations in the SDTM standard
- Knowledge gained and software tools built for SDTM can be used to a great extent
- Relatively small updates are needed to adapt current processes
- Create a new library for SEND like you would create a new library for
 - new/upgraded SDTM versions
 - Sponsor specific SDTM versions



- Annotation
- Conversion process
 - Map, merge and convert source data (EDC, third party data, raw data files)
 - Scheduling/follow-up complete conversion process
- Transfer of datasets (draft, interim, final)
- Format of transferred datasets (SAS, XPT, Dataset-XML, CSV)
- Creation of define metadata
- Validation checks
- Trial design tables

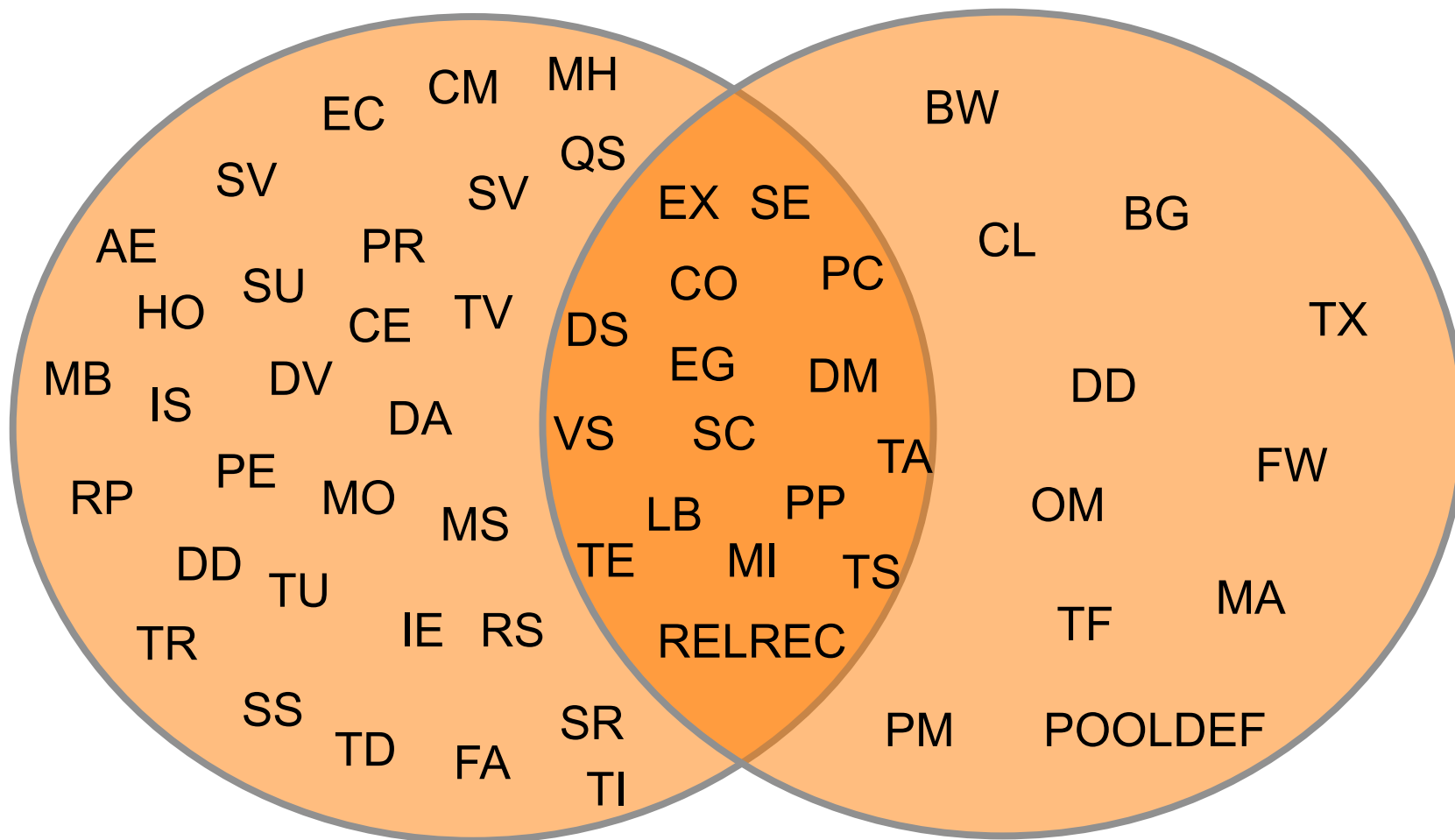
SENDIG V3.0 DOMAIN MODEL



SDTM

SEND

Trial on humans



Study on animals

DIFFERENCES BETWEEN SEND & SDTM

- Trial design
 - No TV, TI, TD
 - TX: trial sets
- Subject Pooling
 - POOLDEF: POOLID vs. USUBJID
- Tumor.xpt
- DM differences
 - No SUPPDM
- No SV / VISIT / VISITNUM, only VISITDY used

DIFFERENCES BETWEEN SEND & SDTM

Trial Design

- No TV, TD or TI
- TX: Trial Sets

SEND - Trial Design

- Trial Elements
- Trial Arms
- Trial Sets
- Trial Summary

SDTM - Trial Design

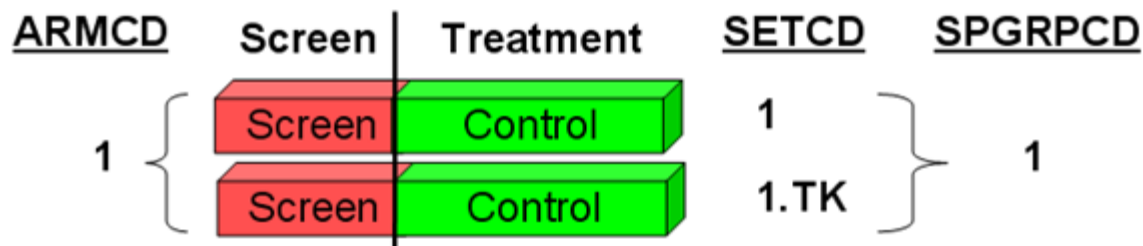
- Trial Elements
- Trial Arms
- Trial Inclusion/Exclusion Criteria
- Trial Disease Assessment
- Trial Visits
- Trial Summary

TX: Trial Sets

- Subdivide Arms
- Group multiple arms

DIFFERENCES BETWEEN SEND & SDTM

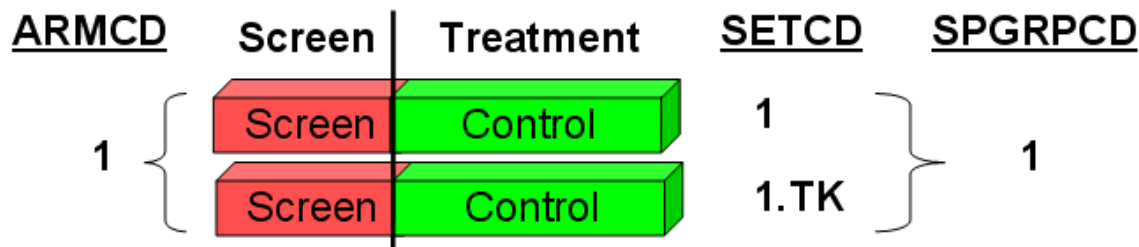
TX: Trial Sets



Excerpted from CDISC SEND Implementation Guide Version 3.0

DIFFERENCES BETWEEN SEND & SDTM

TX: Trial Sets

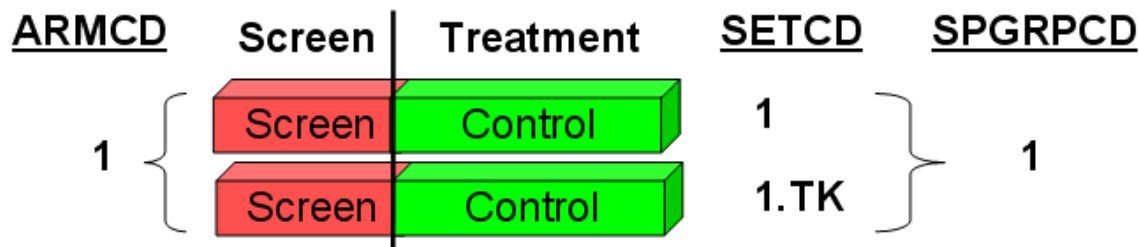


Row	STUDYID	DOMAIN	SETCD	SET	TXSEQ	TXPARMCD	TXPARAM	TXVAL
1	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	1	ARMCD	Arm Code	1
2	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	2	SPGRPCD	Sponsor-Defined Group Code	1
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5	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	5	TRTDOS	Dose Level	0
6	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	6	TRTDOSU	Dose Units	mg/kg/day
7	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	7	TCNTRL	Control Type	Vehicle Control
8	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	8	TKDESC	Toxicokinetic Description	NON-TK
9	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	9	PLANMSUB	Planned Number of Male Subjects	7
10	TDM2	TX	1	Control Group, Vehicle Control once daily, Non-TK	10	PLANFSUB	Planned Number of Female Subjects	7
11	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	11	ARMCD	Arm Code	1
12	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	12	SPGRPCD	Sponsor-Defined Group Code	1
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14	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	14	SETLBL	Set Label	Group 1, Control - TK
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16	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	16	TRTDOSU	Dose Units	mg/kg/day
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18	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	18	TKDESC	Toxicokinetic Description	TK
19	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	19	PLANMSUB	Planned Number of Male Subjects	3
20	TDM2	TX	1.TK	Control Group, Vehicle Control once daily, TK	20	PLANFSUB	Planned Number of Female Subjects	3

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DIFFERENCES BETWEEN SEND & SDTM

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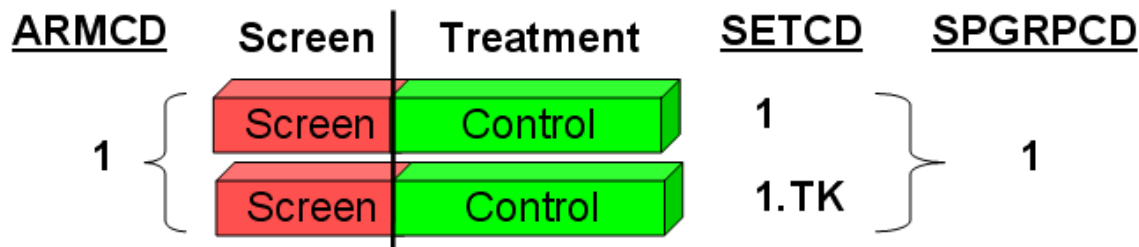


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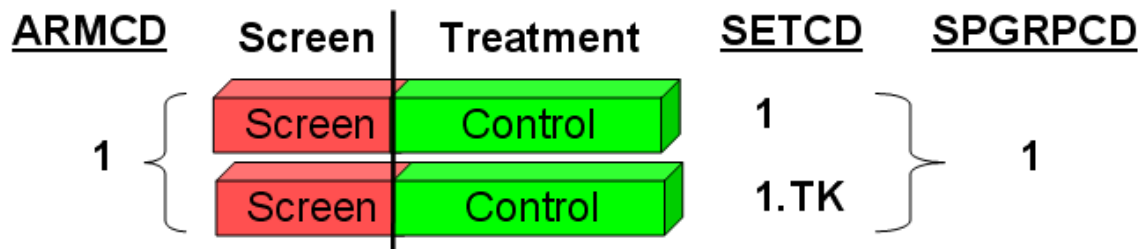


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DIFFERENCES BETWEEN SEND & SDTM

Subject Pooling

- POOLDEF
- POOLID vs. USUBJID

SEND - Relationships

- SUPPQUAL
- RELREC
- POOLDEF

SDTM - Relationships

- SUPPQUAL
- RELREC

Pools of subjects are defined in POOLDEF domain

POOLID and USUBJID are mutually exclusive. Therefore either USUBJID or POOLID should be populated.

Row	STUDYID	POOLID	USUBJID
1	ABC1	CAGE1 P1	ABC1-1001
2	ABC1	CAGE1 P1	ABC1-1002
3	ABC1	CAGE1 P1	ABC1-1003
4	ABC1	CAGE1 P2	ABC1-1001
5	ABC1	CAGE1 P2	ABC1-1003

Excerpted from CDISC SEND Implementation Guide Version 3.0

POOLID values are unique for a given set of subjects

Tumor.xpt

- According to regulatory guidelines for the submission of carcinogenicity data.

Domains required for creation tumor.xpt file:

- DM (Demographics)
- DS (Disposition)
- EX (Exposure)
- MI (Microscopic Findings)
- TF (Tumor Findings)
- TX (Trial Sets)

DIFFERENCES BETWEEN SEND & SDTM

Demographics (DM)

SEND - Demographics		SDTM - Demographics	
•STUDYID	• AGETXT	•STUDYID	
•DOMAIN	•AGEU	•DOMAIN	•AGEU
•USUBJID	•SEX	•USUBJID	•SEX
•SUBJID	• SPECIES	•SUBJID	
•RFSTDTC	• STRAIN	•RFSTDTC	
•RFENDTC	• SBSTRAIN	•RFENDTC	
		• RFXSTDTC	• RACE
		• RFXENDTC	• ETHNIC
		• RFICDTC	•ARMCD
	•ARMCD	• RFPENDTC	•ARM
	•ARM	• DTHDTC	• ACTARMCD
		• DTHFL	• ACTARM
•SITEID		•SITEID	• COUNTRY
		• INVID	• DMDTC
		• INVNAM	• DMDY
•BRTHDTC	• SETCD	•BRTHDTC	
•AGE		•AGE	

SEND - SUPPQUALS
only for General
Observation
Domains

→ No SUPPDM

DIFFERENCES BETWEEN SEND & SDTM

No Subject Visits (SV)

SEND - Special Purpose

- Demographics
- Comments
- Subject Elements

SDTM - Special Purpose

- Demographics
- Comments
- Subject Elements
- Subject Visits

In SEND only the planned study day variable is used:
VISITDY
(no VISITNUM/VISIT)

- FDA binding guidance
 - December 2016
 - Start thinking about implementation SEND
- SEND foundations SDTM
- SDTM knowledge gained and tools built can be used
- Some specific SEND - SDTM differences may cause updates

Where did you store the nonclinical data?

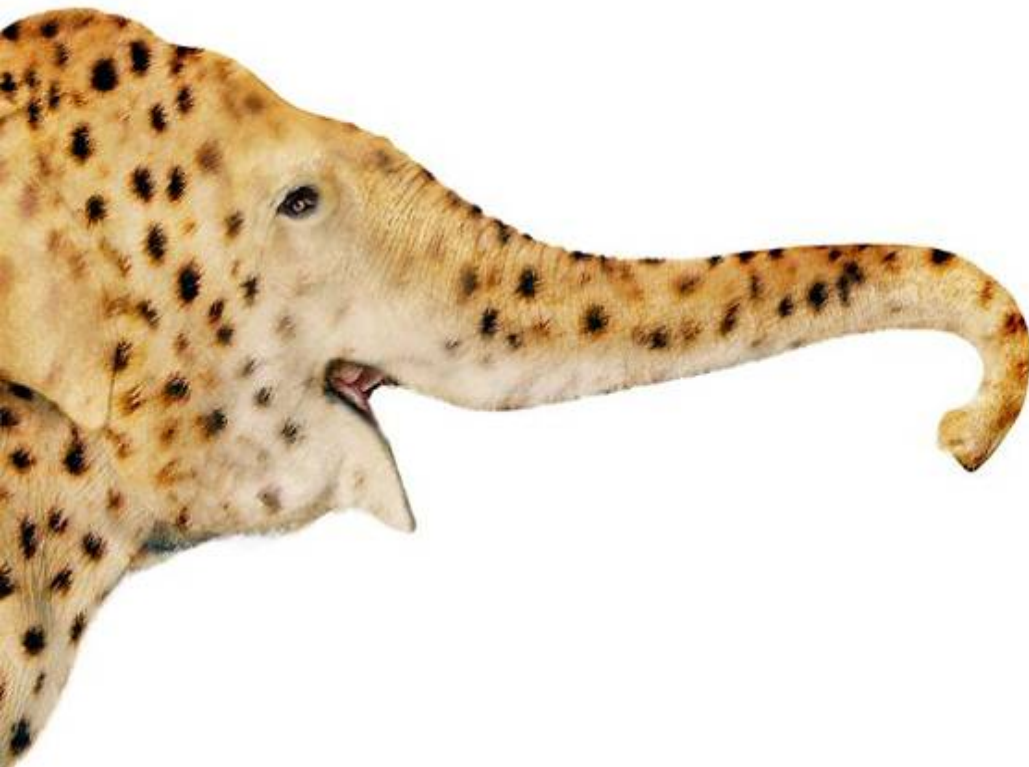


But you told me to SEND it...





THANK YOU FOR YOUR ATTENTION



WHERE MEETS EXPERIENCE SPEED

CONTACT US

CLINICAL RESEARCH

lss.info@sgs.com

EUROPE : + : +33 1 41 24 87 87

AMERICAS : +1 877 677 2667

www.sgs.com/lifescience

Roman Radelicki

Life Science Services

Clinical Data Programmer Coordinator

SGS Belgium NV

Generaal De Wittelaan 19A b5

2800 Mechelen – Belgium

Phone: +32 (0)15 29 93 45

Fax: +32 (0)15 27 32 50

E-mail : roman.radelicki@sgs.com

www.sgs.com/CRO

