

November 29, 2012

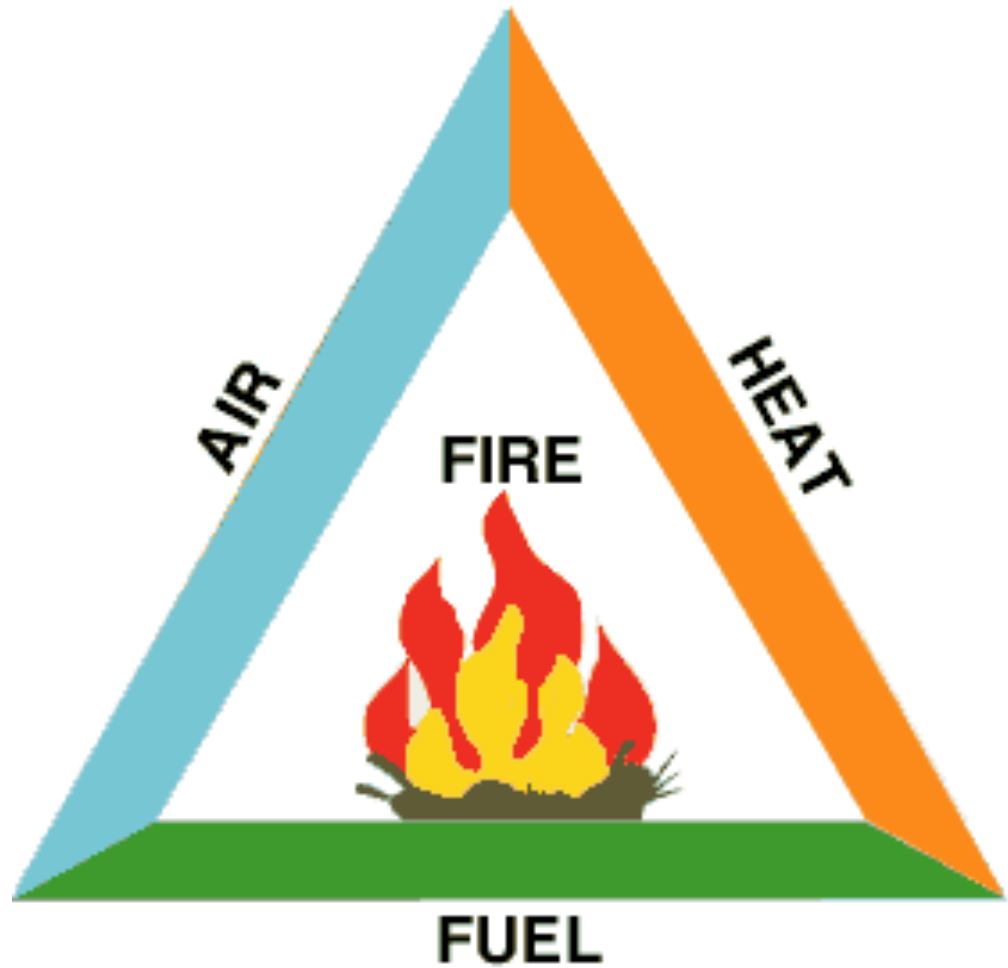
Implementing metadata standards at the protocol level

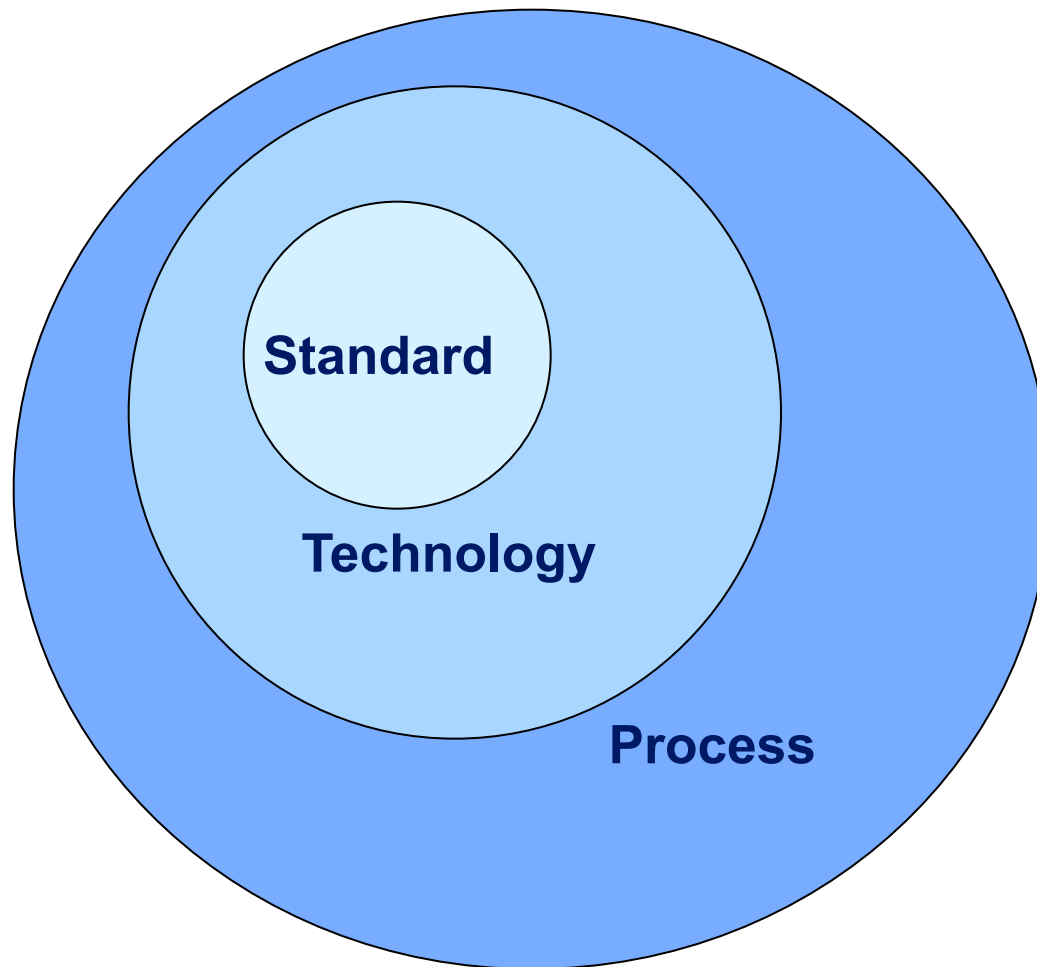
Phuse Berlin

October 2010

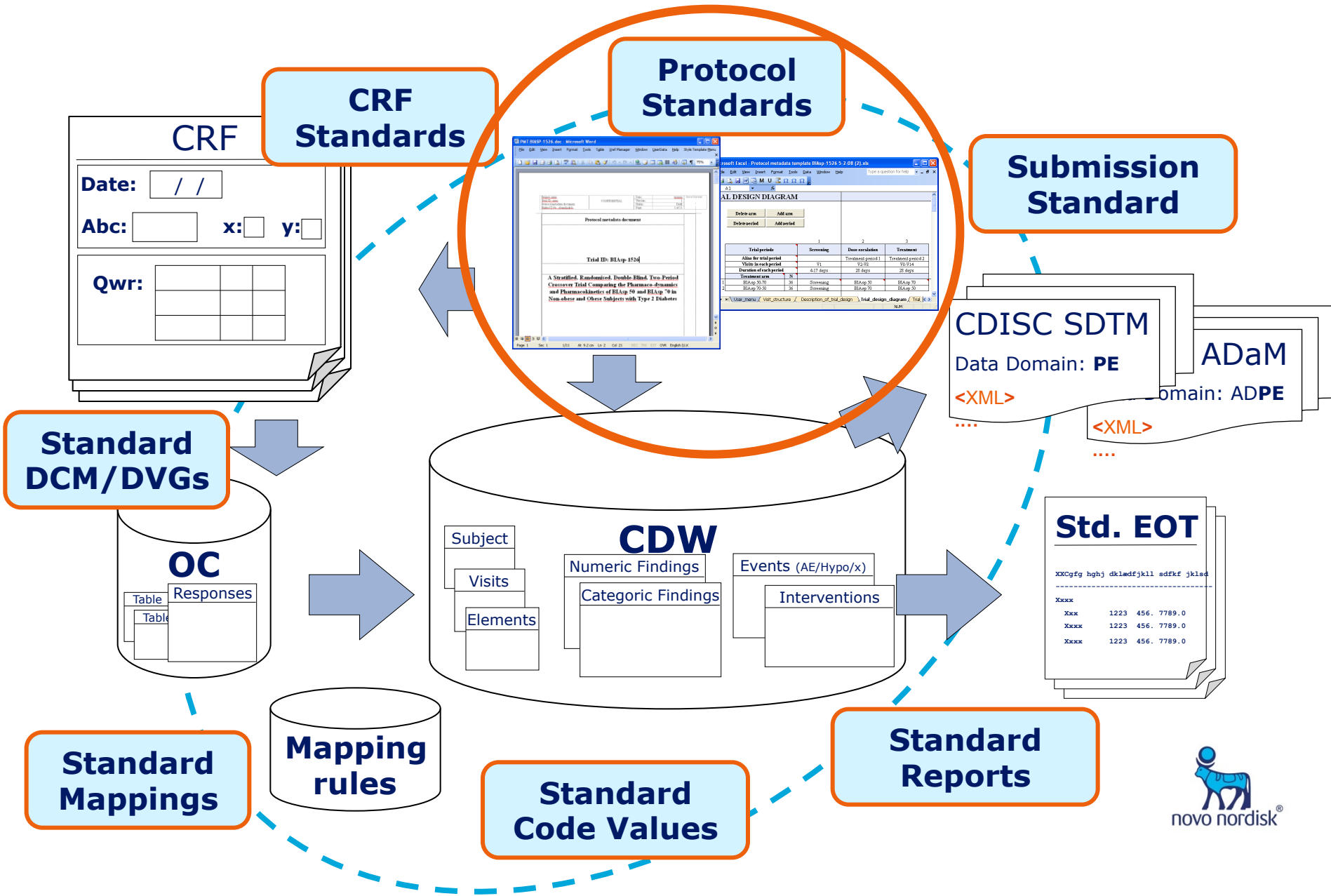
Annabel Acs

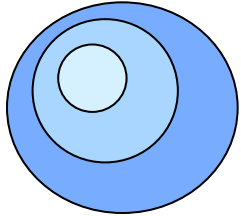
aacs@novonordisk.com



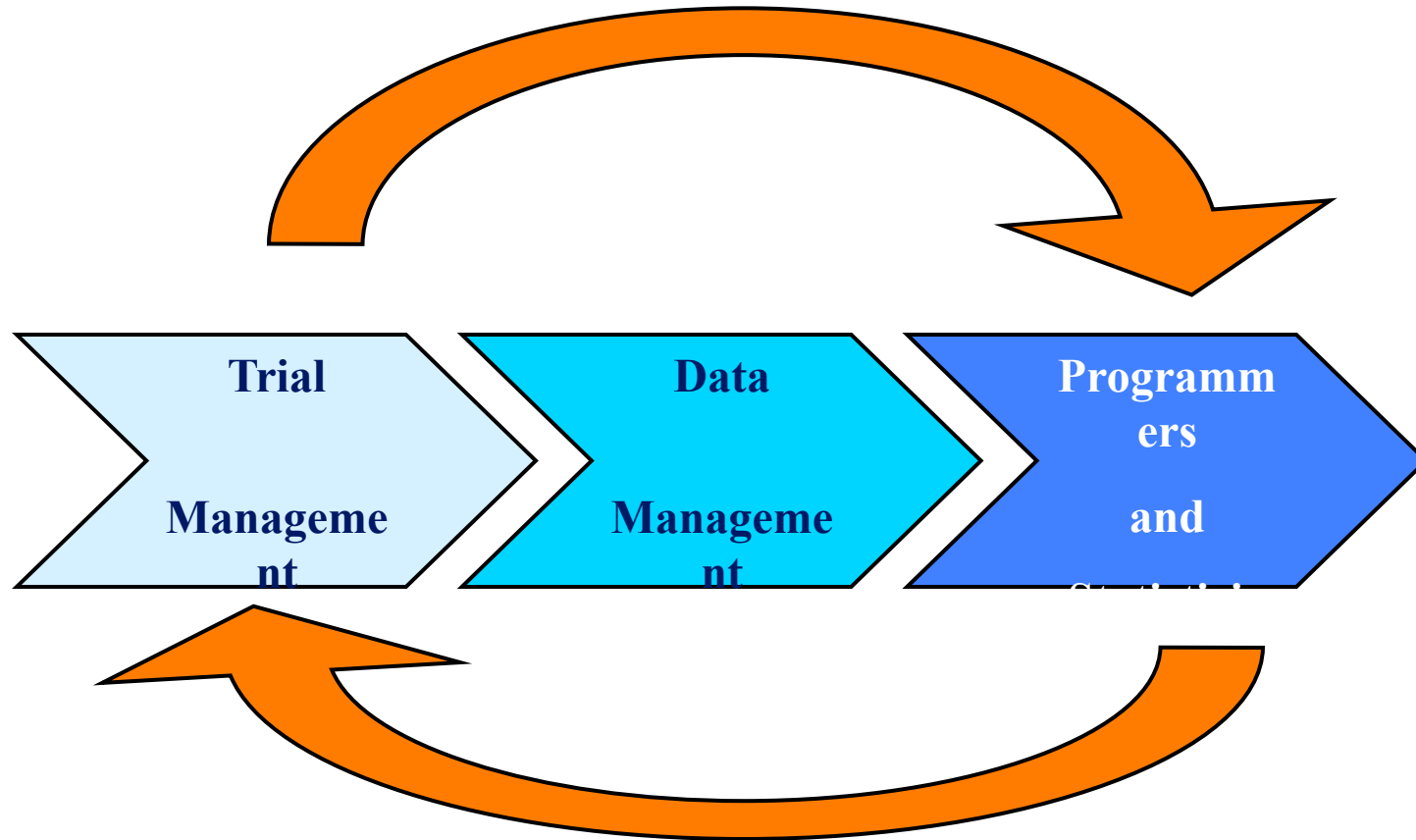


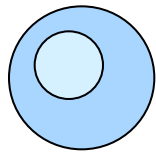
The standards and technology at NN





The *process* supporting standards and technology at NN





PMT
technology

- Protocol Metadata Template (Excel)
 - Inexpensive
 - Easy to use
 - Easy to modify
 - Familiar to everyone

Microsoft Excel - Protocol metadata template.xls [Read-Only]

File Edit View Insert Format Tools Data Window Help

Type a question for help

Latest code update: 16-Jun-2010

USER MENU

Version	4.0	Download codes from GlobeShare	
Latest code update: 16-Jun-2010			
Trial ID		Update sub headers in trial flow chart	Show toolbar
Name			
Initials			
Date			

Template	Select	Unhide selected templates
VISIT STRUCTURE	☒	
DESCRIPTION OF TRIAL DESIGN	☒	
TRIAL DESIGN DIAGRAM	☒	
TRIAL PRODUCT	☒	
DOSAGE	☒	
TRIAL FLOW CHART	☒	
SELF MEASURED PLASMA GLUCOSE	☒	
SAMPLING PROFILE 1	☒	
SAMPLING PROFILE 2	☒	
SAMPLING PROFILE 3	☒	

Ready NUM

Microsoft Excel - Protocol metadata template.xls [Read-Only]

File Edit View Insert Format Tools Data Window Help

Type a question for help



Latest code update: 16-Jun-2010

USER MENU

Version

4.0

Latest code update: 16-Jun-2010

Trial ID

Name

Initials

Date

Download codes from GlobeShare



Update sub headers in trial flow chart

Show toolbar

Template

Select

Unhide selected templates

VISIT STRUCTURE

☒

DESCRIPTION OF TRIAL DESIGN

☒

TRIAL DESIGN DIAGRAM

☒

TRIAL PRODUCT

☒

DOSAGE

☒

TRIAL FLOW CHART

☒

SELF MEASURED PLASMA GLUCOSE

☒

SAMPLING PROFILE 1

☒

SAMPLING PROFILE 2

☒

SAMPLING PROFILE 3

☒

◀ ▶ 🔍

User_menu / Visit_structure / Description_of_trial_design / Trial_design_diagram / Trial_product / 🔍

Ready

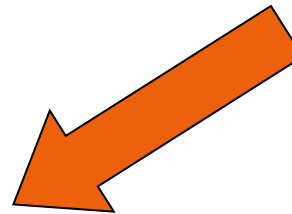
NUM

Protocol Metadata Template *standards*

Leucocytes

WBC

White
Blood
Cells



CODES USED IN THE MODEL

Admin unprotect

Admin update codes

Haematology

Erythrocytes	ERCS, Red Blood Cells, RBC
ESR	SR, Erythrocyte Sedimentation Rate, Sed-Rate
Haptoglobin	HAPT, Haptoglob, Hp, Hpt
Haematocrit	HCT, Hematocrit, Packed cell volume, B-erythrocytes, vol frac, PCV
Haemoglobin	Hb, Hgb, Hemoglobin
Leucocytes	Total leucocytes count, Total LKCS count, Total White Blood Cells count, Total WBC count
Mean corpuscular haemoglobin	MCH, Erythrocyte mean corpuscular hemoglobin
Mean corpuscular haemoglobin, conc.	MCHC, Erythrocyte mean corpuscular hemoglobin concentration
Mean Corpuscular Volume	MCV, Mean cell volume
Neutrophils	
Reticulocytes	Polychromatophilic red cells
Thrombocytes	Platelets, PLT

Differential count:

TRIAL FLOW CHART

Diabetes



Add visit

Delete visit

Add row

Delete row

Non-diabetes



Add time point

Delete time point

Hide row

Unhide row

Visits



Go to footer

±

Change colour

Time points/visits



Define no of visits

Show/hide text row

New value

Trial Periods

Type of visit

Visit number

Time of visit

Weeks

Visit window

Days

SAFETY

Adverse events

Biochemistry

Albumin

ALAT

Alpha-GST

Uric Acid

Haematology

Leucocytes

ESR

-
- Erythrocytes
- ESR
- Haptoglobin
- Haematocrit
- Haemoglobin
- Leucocytes
- Mean corpuscular haemoglobin
- Mean corpuscular haemoglobin, conc.

Continuous blood pressure

measurement

CT scan

T

1

2

3

4

5

6

7

8

-1

0

1

2

3

4

±2

±2

1 week
after
vist 7



E12

fx 1

VISIT STRUCTURE

Visits

Time points/visits

Define no of visits

Delete visit

Add visit

Delete time point

Add time point

Drop-
downEnter
no.Drop-
downEnter
no.Drop-
downDrop-
down

Enter text

Drop-down

Enter text

Visit no.	Time of visit							Type of visit	Alias for type of visit
	Time unit	No.	+/-	No.	Time unit	Before/ after	Text		
1	Week	-1	±	2	days			Screening visit	
2	Week	0						Baseline/randomisa- tion visit	Start of treatment period 1
3	Week	1	±	2	days			Treatment visit	Meal test
4	Week	3	±	2	days			Treatment visit	Start of wash-out
5	Week	4	±	2	days			Treatment visit	Start of treatment period 2
6	Week	5	±	2	days			Treatment visit	Meal test
7	Week	7	±	2	days			Treatment visit	End of treatment visit
8	Week	1	±	2	days	after	V7	Follow-up visit	

TRIAL DESIGN DIAGRAM																																						
Delete arm Add arm Delete period Add period																																						
				1	2	3	4																															
				<table><tr><th colspan="2">Trial periods</th><th>Screening</th><th>Titration</th><th>Treatment</th><th>Follow-up</th></tr><tr><th colspan="2">Alias for trial period</th><td></td><td></td><td></td><td></td></tr><tr><th colspan="2">Visits in each period</th><td>Visit 1</td><td>Visit 3</td><td>Visit 4-7</td><td>Visit 8</td></tr><tr><th colspan="2">Duration of each period</th><td>2 weeks</td><td>2 weeks</td><td>14 weeks</td><td>1 week</td></tr><tr><th>Treatment arm</th><th>N</th><td></td><td></td><td></td><td></td></tr></table>	Trial periods		Screening	Titration	Treatment	Follow-up	Alias for trial period						Visits in each period		Visit 1	Visit 3	Visit 4-7	Visit 8	Duration of each period		2 weeks	2 weeks	14 weeks	1 week	Treatment arm	N								
Trial periods		Screening	Titration	Treatment	Follow-up																																	
Alias for trial period																																						
Visits in each period		Visit 1	Visit 3	Visit 4-7	Visit 8																																	
Duration of each period		2 weeks	2 weeks	14 weeks	1 week																																	
Treatment arm	N																																					
1	A	217	Screening	Liraglutide 0.6mg/1.2mg/1.8mg	Liraglutide 1.8mg	Follow-up																																
2	B	217	Screening	Exenatide 5 µg	Exenatide 10 µg	Follow-up																																

Trial Design defined in CDW-O with protocol attributes

Define Trial Design Attributes

Supply labels for Arms, Epochs, Elements, and Branches

Trial ID: 1526
Trial Def ID: PQ SDD Flow
Trial Metadata Version: 2
Trial Definition Status: Draft

			Screening Period	Treatment Period 1	Treatment Period 2	Follow-up Period
Trial Arm	Branch Arm	No of. Subjects	Screening	Treatment	Treatment	Follow-up
BIAsp 50-70 (*)	Arm 1	36	Screening	BIAsp 50	BIAsp 70	Follow-up
BIAsp 70-50 (*)	Arm 2	36	Screening	BIAsp 70	BIAsp 50	Follow-up

Define no of visits		Screening	Randomisation	Treatment	Treatment	Treatment	Treatment	Treatment	Follow-up
Show/hide text row									
Trial Periods									
Type of Visit				T		T			
Visit number		1	2	3	4	5	6	7	8
Time of visit		-1	0	1	3	4	5	7	1 w after V7
Visit window		±2		±2	±2	±2	±2	±2	±2
SUBJECT RELATED INFO/ASSESSMENTS									
Informed consent		x							
In/exclusion criteria		x							
Randomisation			x						
EFFICACY									
Meal test				x			x		
Standard meal				x			x		
Glucose metabolism			x		x	x		x	
Fasting plasma glucose			x		x	x		x	
Profiles				x			x		
Glucose				x			x		
Self measured plasma glucose			x		x	x		x	
7-point profile			x		x	x		x	
SAFETY									
Adverse events			x	x	x	x	x	x	x
PRO questionnaires			x		x	x		x	
Vital signs		x	x		x	x		x	x
Biochemistry		x	x		x	x		x	x
ALAT		x	x		x	x		x	x
Creatinine		x	x		x	x		x	x
CGM		x ¹							
Haematology		x	x		x	x		x	x
OTHER ASSESMENTS									
TRIAL MATERIAL									
REMINDERS									
Dispense Diary		x							
Dispense Glucose Meter		x							

Goto top

Delete last footer

Add footer in bottom

Footer	Description
x ¹	Only to be performed at XX site

TRIAL FLOW CHART

Diabetes	☐	Add visit	Delete visit
Non-diabetes	☐	Add time point	Delete time point
Visits	☐		
Time points/visits	☐	Go to footer	±

Define no of visits

Show/hide text row

New value

Trial Periods

Visit number

Time point

Time of visit Days

Visit window Days

SAFETY

Adverse events

Biochemistry

Sodium

Potassium

Creatinine

Creatine kinase

Creatine kinase MB

CRP

Urea

Calcium

Chloride

Albumin

Maintain Finding Definition

Define common Finding Definition attributes

Finding Topic Code: ■

POTASSIUM_PLASMA

Short Finding Topic Code: ■

K_P

Finding Label: ■

Potassium plasma

Finding Short Label: ■

Potassium

Description:

CDISC submission value: K
CDISC synonym: potassium
CDISC: A measurement of the potassium in a biological specimen.
CDISC Preferred term: K
CDISC code: C64853

Sort Sequence: ■

116

Status: ■

Active

Language:

English (U.K.)

Standard:



External Terminology:



Finding Category:

Biochemistry

Finding Sub Category:



Finding Type: ■

Numeric Finding

Derived Variable:

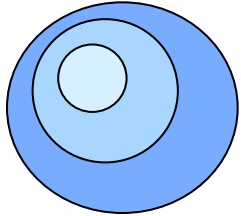


SAS Display Format:

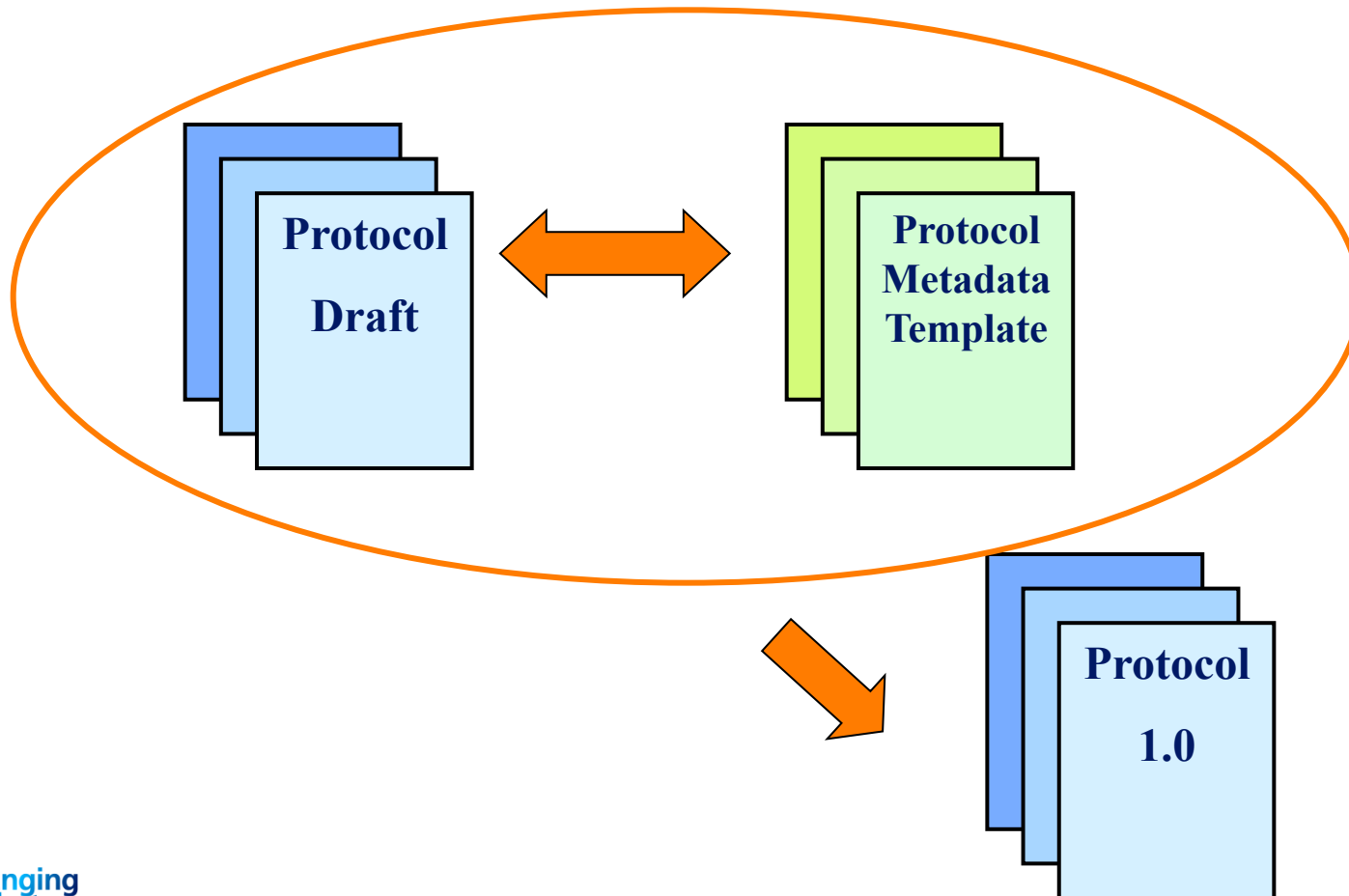
5.1

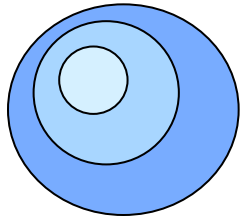
Default Flowchart Group: ■

Safety

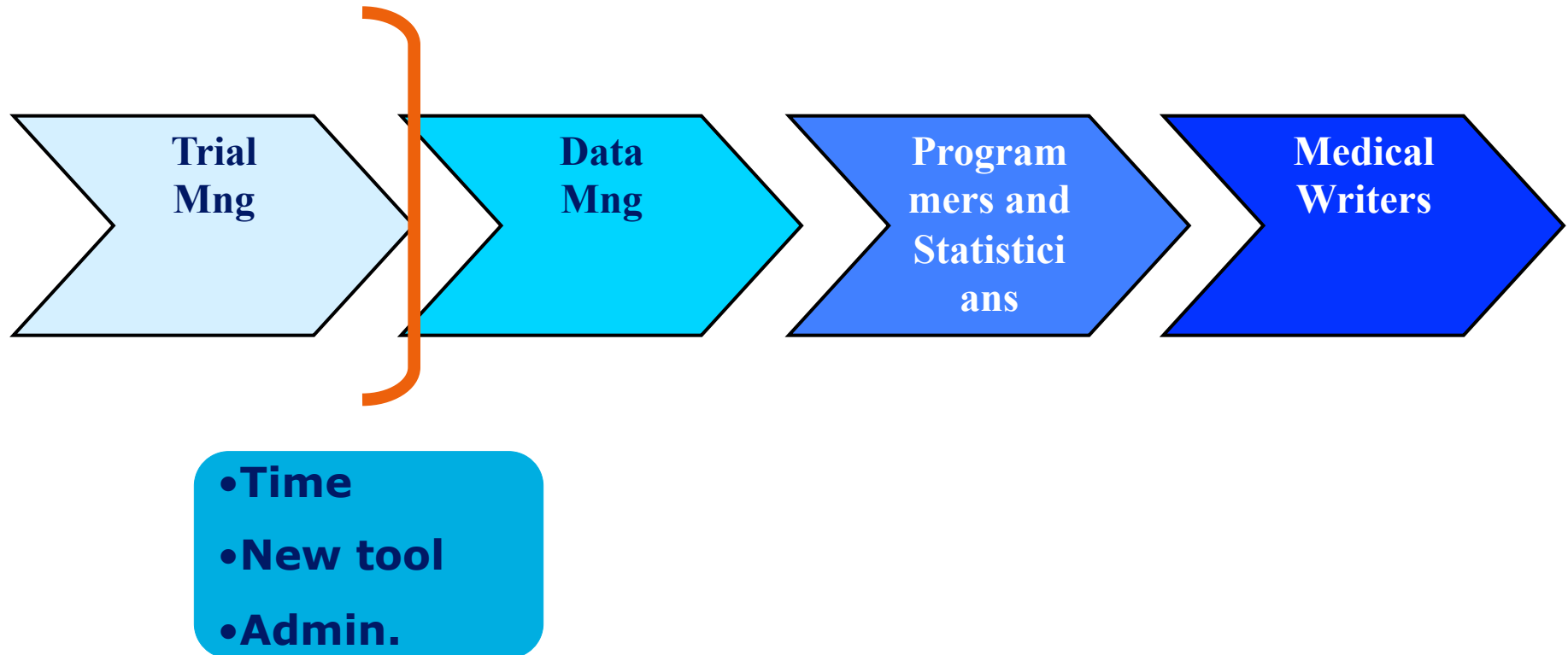


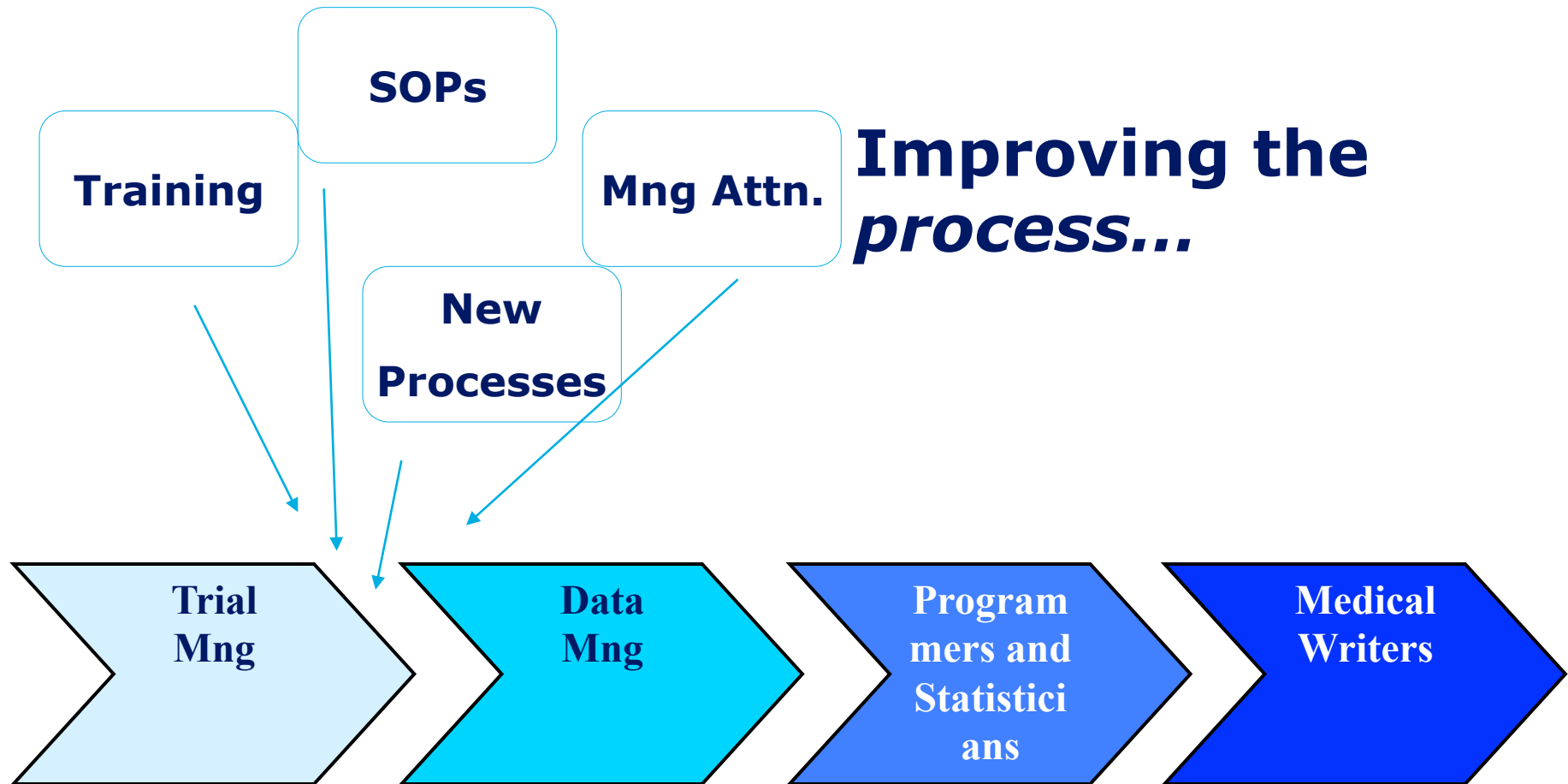
The *process* supporting the standards and technology





The *process* supporting the standards and technology





Vision for future Clinical System Architecture

