

YOUR CLINICAL
TRIALS AUTOMATED.
EVERYWHERE.

FORMEDIX ON

Advanced Metadata Management,
Now With Data!

2000: Formedix founded to improve how trials are run

2003: CDISC-based study design (CRFs)

2008: CDISC-based dataset design

2014: On demand services

2017: Centralized metadata governance platform

- ✓ Great for building studies, managing standards, and generating submission deliverables

- ✓ Impact analysis and governance

- ✗ Dataset conversions are manual

2019: Data integrations and automated SDTM conversions

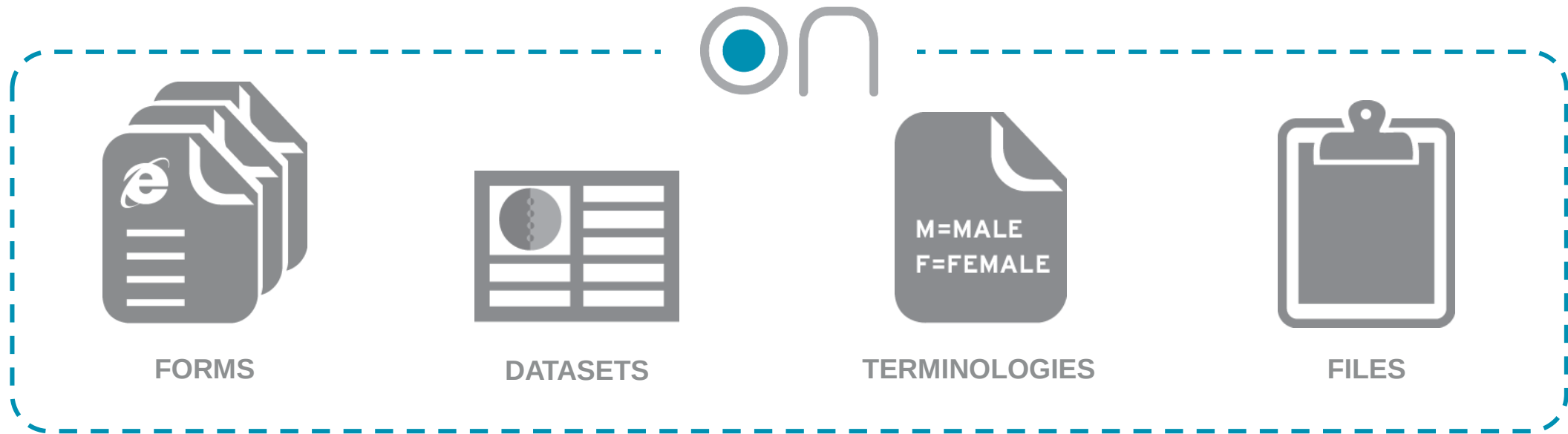


An advanced, fully integrated online platform to facilitate clinical trials. This includes:

- A central repository for storing and managing all your metadata, across the end-to-end life cycle of your studies
- Management of organizational standards, helping you increase data quality and decrease downstream costs



Your whole team can now **access all your studies and organizational standards in one place**, on the web



All your metadata is managed in one place

This greatly simplifies the management of studies and standards

Welcome Back

TRY OUR FREE VALIDATE SERVICES

Maintain your studies against standards.

Discover more

Sign in

Username / email address

kburgess

Password

.....

[Forgot password?](#)

[Don't have an account?](#)

Sign in

By signing in you are agreeing to our [terms of service](#) and [privacy and cookies policy](#).



Chat With Us

 Training

 Designers

 Help

 Support

 About

Welcome to Formedix On
Who would you like to work with today?



My Org



Generico



Formedix

 Repository

 Services

 Training

 Shop

 Designers

 Admin

 Help

 Support

 About

Welcome to Formedix On
What would you like to do?



Browse your standards



Browse your studies



On demand services



Administer your account

- Repository
- Standards
- Studies**
- Find an asset
- Change requests
- Services
- Training
- Shop
- Designers
- Admin
- Help
- Support
- About

Browse studies

Add filter

Create study

Protocol ID: KB

KB Study 1

Published Aug 31, 2017 Status Draft Version 1 Therapeutic area Dermatology Protocol ID KB001

KB Study 2

Published Aug 31, 2017 Status Draft Version 1 Therapeutic area Dermatology Protocol ID KB002

Repository

Standards

Studies

Find an asset

Change requests

Services

Training

Shop

Designers

Admin

Help

Support

About

Find an asset

Asset type: Form

Asset therapeutic area: Opiates



Opiate Assessment Forms

Part of the **Opiate Assessment [QSOP]** standard - Version 3 - Draft



Standard



Form



Opiate Assessment Forms

Part of the **KB Study 2** study - Version 2 - Draft



Study



Form



Opiate Assessment Forms

Part of the **Opiate Assessment [QSOP]** standard - Version 2 - Approved



Standard



Form

on

My Org

kburges

KB Study 1

KB Study 1 (Version 2 - Draft)

Properties

Name

KB Study 1

Version

2

Owner

kburges

Description

None

Updated

Sep 1, 2017 3:15:22 PM

Status

Draft

Protocol ID

KB001

Protocol name

First study for KB

Protocol title

A randomized, double blind,

Assets

Datasets

Files

Forms

Terminologies

Visit schedules

Asset groups

Forms

SDTM



My Org



kburgess ▾



Assets



Studies

KB Study 1 (Version 2 - Draft)

Assets



Vital Signs



Container version

2 ▾

Asset type

Form

Questions

Locale: default

Filter form



Name	Text	Data type	Length	Mandatory	Terminology	Units	Range check
Vital Signs Date	Date of collection	date		Yes			
Weight	Weight	float	8	Yes		Details	
Height	Height	float	8	Yes		Details	
Vital Signs Position	Vital Signs Position	integer	8	Yes	Vital Signs Position		
Blood Pressure Systolic	Systolic Blood Pressure	integer	3	Yes		mmHg	Details
Blood Pressure Diastolic	Diastolic Blood Pressure	integer	3	Yes		mmHg	
Pulse Rate	Pulse Rate	integer	3	Yes		Beats per minute	

Vital Signs asset comparison



Comparison of:



Vital Signs

Version: 2



Vital Signs

Version:

1

[Show changes only](#)

Question: I.VS.WEIGHT

Name:

Weight

Text:

Weight

Data type:

float

Length:

8

Mandatory:

Yes

Terminology:

Units:

Kilograms [MU.KG]
Symbol:
kg
Pounds [MU.LBS]
Symbol:
lbs

Range check:

Question does not exist

Assets ?

Studies

KB Study 1 (Version 2 - Draft)

Assets



VS



Container version 2 ▾

Asset type Dataset

Variables

Locale: default



Name	Description	Data type	Length	Key sequence	SAS field name	Terminology
STUDYID	Study Identifier	text	200	1	STUDYID	
DOMAIN	Domain Abbreviation	text	2	2	DOMAIN	Domain Abbreviation - VS
USUBJID	Unique Subject Identifier	text	200	3	USUBJID	
VSSEQ	Sequence Number	float	200	4	VSSEQ	
VSTESTCD	Vital Signs Test Short Name	text	8		VSTESTCD	Vital Signs Test Code
VSTEST	Vital Signs Test Name	text	40		VSTEST	Vital Signs Test Name
VSCAT	Category for Vital Signs	text	200		VSCAT	
VSPOS	Vital Signs Position of Subject	text	200		VSPOS	Position

- Define and maintain organizational standards that can be used to **build studies, increase data quality** and **reduce design time**
 - These can be managed by your standards team and made available to your study teams for building studies
- Standardizing variations of assets for specific therapeutic areas further increases the efficiency of your study design process



- Your organizational standards can contain **assets from any part of the clinical lifecycle**
 - This allows standards to be managed end-to-end
E.g. an "AE" standard may contain AE-related CRFs, any related datasets and mappings, and instructions on how to use the standard
- Ensuring all **assets in your standard are consistent** with each other, makes **building studies a breeze**
 - e.g. Your datasets match your CRF and are mapped to it





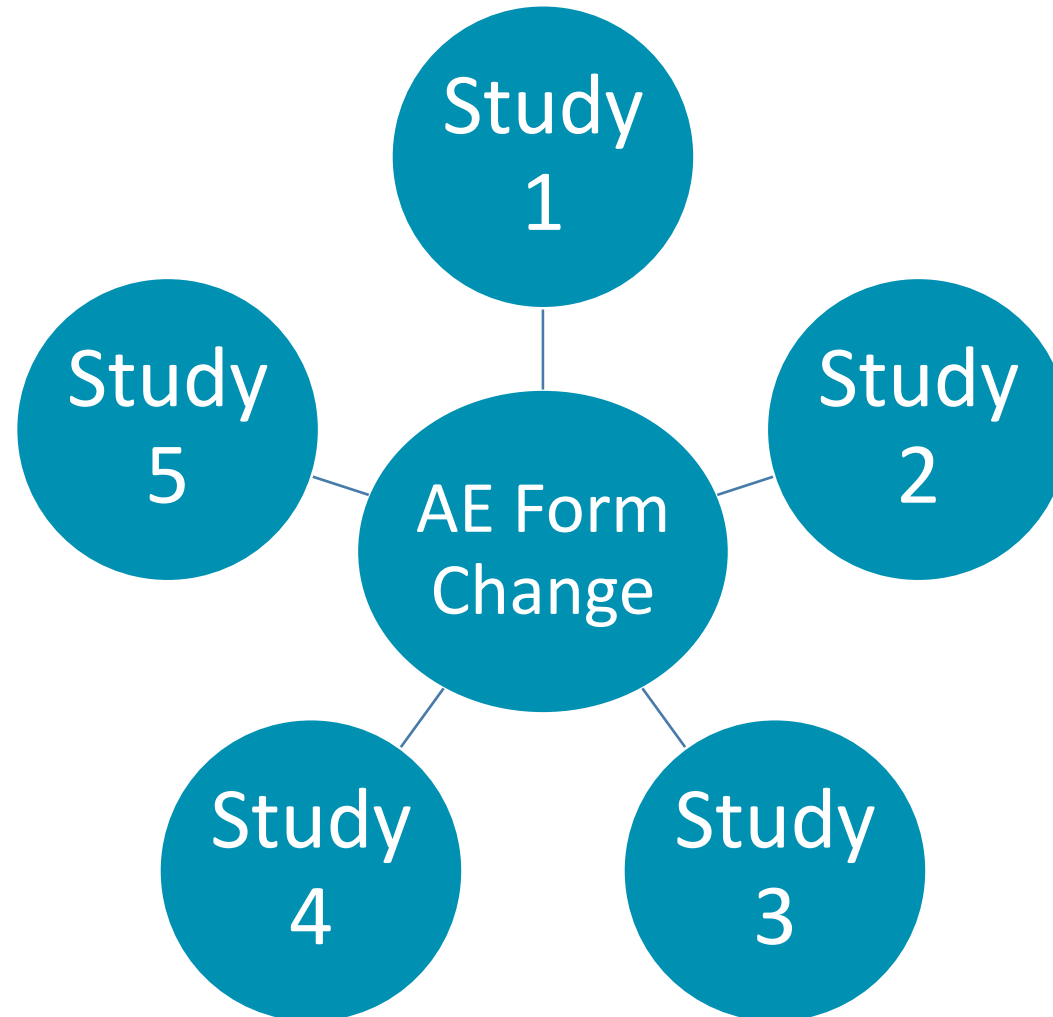
Compare a study to your standards, or other studies, or previous versions

	A	B	C	D	E	F	G	H	I
9	CSNTSIG	Consent Signed	Informed Consent given?	text	4	Yes	CL YN	1	
10	CSNTDAT	Consent Date	Date Of Informed Consent	date	5	No			
11	BRTHTDC	Birth Date	Date of Birth	date	6	Yes			
12	SEX	Sex	Sex	text	7	Yes	CL SEX	1	
13	AGE	Age	Age	integer	7	Yes		3	
14	RACE	Race	Race	text	8	Yes	CL C74457 RACE	1	
15	RACESP	Race Other Specify	If Race is 'Other' please specify	text	9	No		200	
16									
17	Summary of question changes								
18	Added	0							
19	Removed	1							
20	Changed	3							
21									
22	Section/Question	Property	Current value	Comparison value					
23	SEX [IG_DEMOGRAPHICS]	Order Number	7	8					
24	RACE [IG_DEMOGRAPHICS]	Order Number	8	9					
25	RACESP [IG_DEMOGRAPHICS]	Order Number	9	10					
26									
27									

	A	B	C	D	E	F	G	H	
1	Section								
2	OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition	IsF
3	IG.VSFRM	Vital Signs - Form-level	No		1	Yes			
4	Questions								
5	OID	Name	Text	DataType	Order No.	Mandatory	Terminology	Length	Sig
6	I.VS.DT	Vital Signs Date	Date of collection	date	1	Yes			
7	I.VS.WEIGHT	Weight	Weight	float	2	Yes		8	1
8	I.VS.HEIGHT	Height	Height	float	3	Yes		8	1
9									
10	Section								
11	OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition	IsF
12	IG.VSPOS	Vital Signs - Position-level	Yes		2	Yes			
13	Questions								
14	OID	Name	Text	DataType	Order No.	Mandatory	Terminology	Length	Sig
15	I.VS.POS	Vital Signs Position	Vital Signs Position	integer	1	Yes	CL.VSPOS	8	
16	I.VS.SYSBP	Blood Pressure Systolic	Systolic Blood Pressure	integer	2	Yes		3	
17	I.VS.DIABP	Blood Pressure Diastolic	Diastolic Blood Pressure	integer	3	Yes		3	
18	I.VS.PULSE	Pulse Rate	Pulse Rate	integer	4	Yes		3	
19									
20	Summary of question changes								
21	Added	2							
22	Removed	0							
23	Changed	2							
24									
25	Section/Question	Property	Current value	Comparison value					
26	I.VS.SYSBP [IG.VSPOS]	Text	Systolic Blood Pressure	BP Systolic					
27	I.VS.DIABP [IG.VSPOS]	Text	Diastolic Blood Pressure	BP Diastolic					
28									
29									
30									



Impact analysis **helps you make informed choices**



Impact analysis

Impact analysis for Vital Signs (F_VS_002) Form within Forms

Standard: Vital Signs [VS] (Version 1 - APPROVED)

Relationships to other standards/studies

Filter table...

Relationship ▼	Type	Container name	Versions	Asset group name	Hierarchy	Used by
Used in	Study	KB Study 2	2	Forms	Vital Signs [VS] (Forms) > KB Study 2 (Forms)	Visit schedule: KB002

Define your own **governance processes and approval gates**

Use change requests to **manage updates in a controlled and consistent manner**

CR-7

Update Vital Signs Form 

Add new Test code for Respiratory Rate

Owner:  stevenb

Assignee:  stevenbenham

Properties

Containers

Vital Signs (VS)

State

Review

Template

Update Form

Created

Feb 14, 2019

Due date

Feb 15, 2019 

Team

Data Management

Files

 Vital Signs Test Codes.docx

Workflow

Select state...

Transition

 stevenbenham

(QA)

Comments

 stevenb

Created on: Feb 14, 2019

Analysis Complete

 stevenb

Created on: Feb 14, 2019

Added new Test Code

Watchers

 stevenb

Define your own metadata lifecycle

E.g. Studies may have the following states:

Draft, In review, Production, Rejected, Not in use

Standards may have:

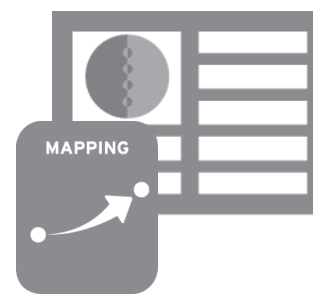
Draft, In review, Production, Rejected, Not in use, Superseded



eCRF
PREVIEWS



EDIT CHECK
SPECIFICATIONS



SDTM MAPPING
SPECIFICATIONS



ANNOTATED
CRFs

Your teams can access advanced visualizations of your assets

Available anytime, anywhere, on the web

Subject: **Subject Name**
Page: **Vital Signs**

Date of collection / /

Currently viewing line 1 of 2.
Click here to return to "Complete View"

Apply to Record ☐

Vital Signs Position

BP Systolic mmHg

BP Diastolic mmHg

Pulse Rate bpm

Save Cancel

Complete View

#	Vital Signs Position	BP Systolic	BP Diastolic	Pulse Rate	
1	SUPINE (after 10 minutes)	-	-	-	☐ ☐ ☐ ☐ ☐
2	STANDING (after 2 minutes)	-	-	-	☐ ☐ ☐ ☐ ☐

Add a new log line Inactivate

Vital Signs

Vital Signs - Form-level

1.* Date of collection / /

Vital Signs - Position-level

*Vital Signs Position	*BP Systolic	*BP Diastolic	*Pulse Rate
2.a SUPINE (after 10 minutes)	mmHg	mmHg	bpm
2.b STANDING (after 2 minutes)	mmHg	mmHg	bpm

Trial Number: Patient Initials:
Patient Number: Visit Name:

Vital Signs

Vital Signs - Form-level

1. Date of collection YYYY/MM/DD

Vital Signs - Position-level

2. Vital Signs Position

3. BP Systolic

4. BP Systolic - Units

5. BP Diastolic

6. BP Diastolic - Units

7. Pulse Rate

8. Pulse Rate - Units

Add More

See exactly how your forms will look in your chosen EDC

No need to build the EDC system first

- Unique integrations with the top EDC systems



- Pick your EDC system with the click of a button
- Design your entire study in Formedix On
- Automatically build the EDC database

KB Study 1 (Version

Asset type

Questions

Name	Text	Units	Range check
Vital Signs Date	Date		
Weight	Weight	float 8 Yes	Details
Height	Height	float 8 Yes	Details
Vital Signs Position	Vital Signs Position	integer 8 Yes	Vital Signs Position
Blood Pressure Systolic	Systolic Blood Pressure	integer 3 Yes	mmHg Details
Blood Pressure Diastolic	Diastolic Blood Pressure	integer 3 Yes	mmHg
Pulse Rate	Pulse Rate	integer 3 Yes	Beats per minute

✕

 Search visualizations



General

Medidata Rave eCRF Preview

Oracle InForm eCRF Preview

Form Preview

Vital Signs

Vital Signs - Form-level

1.* Date of collection

/ / 

Vital Signs - Position-level

	*Vital Signs Position	*BP Systolic	*BP Diastolic	*Pulse Rate	
2.a	SUPINE (after 10 minutes)	mmHg	mmHg	bpm	
2.b	STANDING (after 2 minutes)	mmHg	mmHg	bpm	

Subject: Subject Name
Page: Vital Signs





Date of collection

...





Currently viewing line 1 of 2.
Click here to return to "Complete View"

Apply to Record

☐

☐

☐

☐

Vital Signs Position

SUPINE (after 10 minutes)



BP Systolic

mmHg



BP Diastolic

mmHg



Pulse Rate

bpm



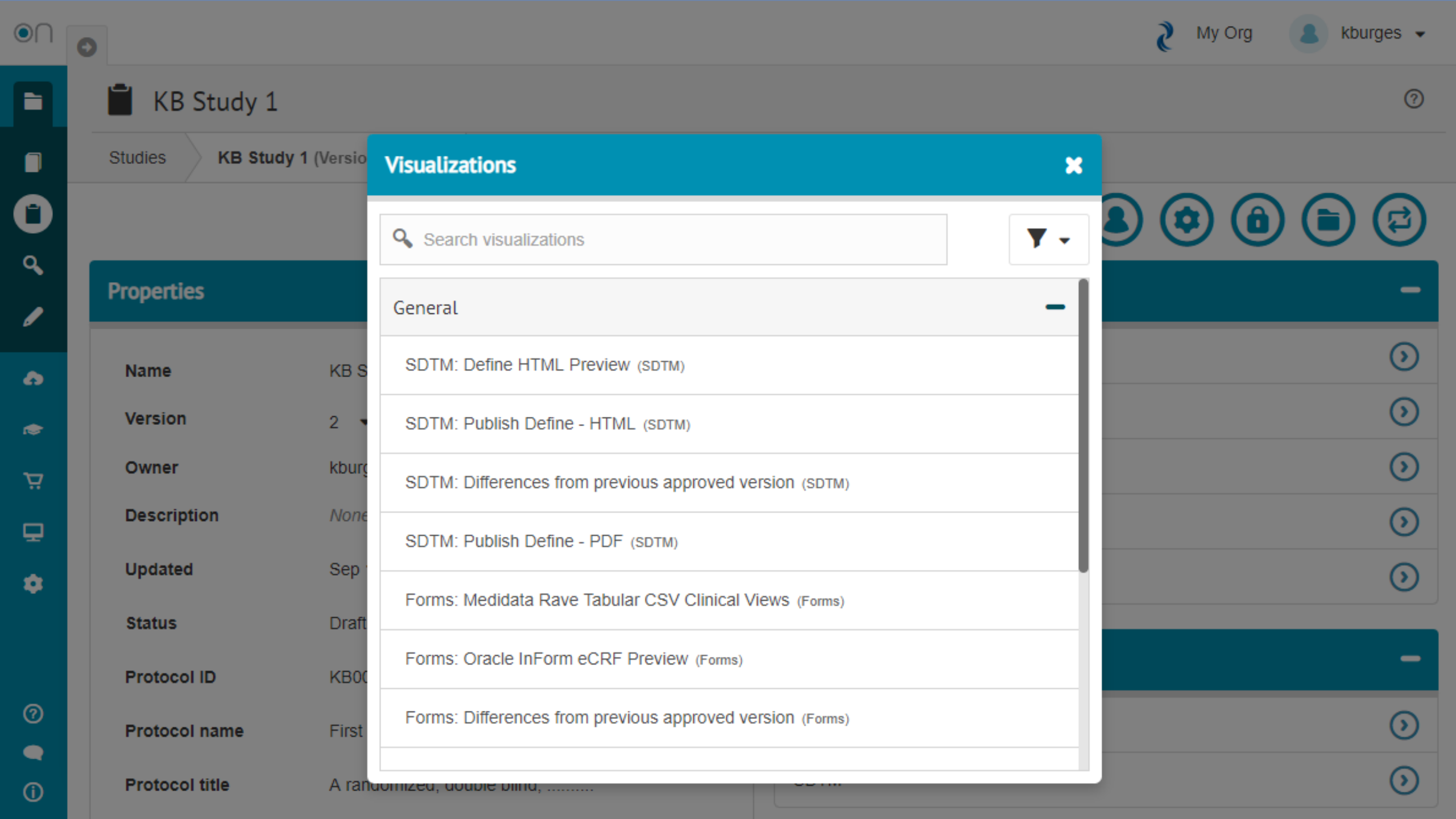
Save

Cancel

Complete View

#	Vital Signs Position	BP Systolic	BP Diastolic	Pulse Rate	
1	SUPINE (after 10 minutes)	–	–	–	     
2	STANDING (after 2 minutes)	–	–	–	     

Add a new log line Inactivate



My Org



kburgess



KB Study 1

Studies

KB Study 1 (Version 2)

Properties

Name

KB Study 1

Version

2

Owner

kburgess

Description

None

Updated

Sep 10, 2023

Status

Draft

Protocol ID

KB001

Protocol name

First

Protocol title

A randomized, double blind, placebo-controlled, parallel-group, phase 3 study of the efficacy and safety of [redacted] in the treatment of [redacted]

Visualizations



Search visualizations



General

SDTM: Define HTML Preview (SDTM)

SDTM: Publish Define - HTML (SDTM)

SDTM: Differences from previous approved version (SDTM)

SDTM: Publish Define - PDF (SDTM)

Forms: Medidata Rave Tabular CSV Clinical Views (Forms)

Forms: Oracle InForm eCRF Preview (Forms)

Forms: Differences from previous approved version (Forms)

Page: Concomitant Therapy

Currently viewing line 1 of 1
[Click here to return to "Complete View"](#)

Apply to Record 

Drug Treatment

Dose

Unit

Freq

Route

Start Date / Time

Ongoing

End Date / Time

Save

Cancel

[Complete View](#)

#	Indication	Drug Treatment	Dose	Unit	Freq	Route	Start Date / Time	Ongoing	End Date / Time	
1										



Subject: Subject Name

Page: Concomitant Therapy F.CONMED



Currently viewing line 1 of 1.
Click here to return to "Complete View"

Apply to Record

Indication I.CM.INDC

Drug Treatment I.CM.TRT

Dose I.CM.DOSE

Unit I.CM.DOSU

Freq I.CM.DOSFRQ

Route I.CM.ROUTE

Start Date / Time I.CM.STDTC

Ongoing I.CM.ONGO

End Date / Time I.CM.ENDTC

... ▼
CL.CMUNIT

☐ Once ☐ 1 / H ☐ 1 / D ☐ ad lib

CL.CMFREQ

... ▼

CL.CMROUTE

... : :

☐ Yes ☐ No

CL.YESNO

... : :

Rave Matrix Preview for "Origin Demo [S.ORIGINDEMO]"

Base

All	Subject Name	Screening Visit	Visit 2	Common	All
Informed Consent & Demographics[F.CONSENT]					Informed Consent & Demographics
Medical History[F.MEDHIST]					Medical History
Vital Signs[F.VITAL]					Vital Signs
Inclusion / Exclusion Criteria[F.INCLEXCL]					Inclusion / Exclusion Criteria
Concomitant Therapy[F.CONMED]					Concomitant Therapy
Adverse Event[F.AE]					Adverse Event
Study Completion[F.COMPLETION]					Study Completion
Comments[F.COMMENT]					Comments
All	Subject Name	Screening Visit	Visit 2	Common	All

Dataset: F_CONSENT

Variable	DataType	Length	Significant Digits	Label
projectid	integer	10		projectid
project	text	255		project
studyid	integer	10		Internal id for the study
environmentName	text	20		Environment
subjectId	integer	10		Internal id for the subject
StudySiteId	integer	10		Internal id for study site
Subject	text	50		Subject name or identifier
siteid	integer	10		Internal id for the site
Site	text	255		Site name
SiteNumber	text	50		SiteNumber
SiteGroup	text	40		SiteGroup
instanceId	integer	10		Internal id for the instance
InstanceName	text	255		Folder instance name
InstanceRepeatNumber	integer	10		InstanceRepeatNumber

SDTM-IG 3.2

Vital Signs (VS) [Location: [vs.xpt](#)]

Annotated CRF

▼ Tabulation Datasets

Comments (CO)

Demographics (DM)

Concomitant Medications

Adverse Events (AE)

Disposition (DS)

Medical History (MH)

Inclusion/Exclusion Criter

Vital Signs (VS)

► Value Level Metadata

► Controlled Terminology

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	200			
DOMAIN	Domain Abbreviation	2	text	2	["VS" = "Vital Signs"] < Domain Abbreviation - VS >		
USUBJID	Unique Subject Identifier	3	text	200			
VSSEQ	Sequence Number	4	float	200			
VSTESTCD	Vital Signs Test Short Name		text	8	Vital Signs Test Code		
VSTEST	Vital Signs Test Name		text	40	Vital Signs Test Name		
VSCAT	Category for Vital Signs		text	200			
VSPOS	Vital Signs Position of Subject		text	200	Position		
VSORRES	Result or Finding in Original Units		text	200		CRF Page 5	
VSORRESU	Original Units		text	200	Units for Vital Signs Results		
VSSTRESC	Character Result/Finding in Std Format		text	200			
VSSTRESN	Numeric Result/Finding in Standard Units		float	200			
VSSTRESU	Standard Units		text	200	Units for Vital Signs Results		
VSBLFL	Baseline Flag		text	200	["N" = "N", "NA" = "NA", "U" = "U", "Y" = "Y"] < No Yes Response >		
VISITNUM	Visit Number		float	200			
VSDTC	Date/Time of Measurements		datetime		ISO8601		

Go to the [top](#) of the define.xml

	A	B	C	D	I
1	Domain	Name	Description	DataType	Mapping
2	VS	STUDYID	Study Identifier	text	PROJECT
3	VS	DOMAIN	Domain Abbreviation	text	"VS"
4	VS	USUBJID	Unique Subject Identifier	text	Concatenate(PROJECT , "-", SITEID , "-", SUBJECTID)
5	VS	VSSEQ	Sequence Number	float	Sequence No: Sequentially Number Rows per Subject
6	VS	VSTESTCD	Vital Signs Test Short Name	text	ValueList: Value Name
7	VS	VSTEST	Vital Signs Test Name	text	ValueList: Value Label
8	VS	<u>VSORRES</u>	Result or Finding in Original Units	text	ValueList: Value Data Value
9	VS	VSORRESU	Original Units	text	Do Not Uppercase (ValueList: Value Original Unit)
10	VS	VSSTRESC	Character Result/Finding in Std Format	text	Convert to standard unit(ValueList: Value Data Value, ValueList: Value Original Unit)
11	VS	VSSTRESN	Numeric Result/Finding in Standard Units	float	If Is numeric(ValueList: Value Data Value) = "true" Then Convert to standard unit(ValueList: Value Data Value, ValueList: Value Original Unit)
12	VS	VSSTRESU	Standard Units	text	Do Not Uppercase (Get standard unit(ValueList: Value Original Unit))
13	VS	VSBLFL	Baseline Flag	text	If FOLDER = "SE_SCREEN" Then "Y"
14	VS	VISITNUM	Visit Number	float	Controlled Terminology Lookup (FOLDER , CL_VISTNUM)
15	VS	VISIT	Visit Name	text	FOLDERNA
16	VS	VISITDY	Planned Study Day of Visit	integer	Controlled Terminology Lookup (FOLDER , CL_VISTDY)
17	VS	VSDTC	Date/Time of Measurements	datetime	Substring before(Convert datetime to ISO 8601(VSDAT), "T")
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					

- Define mappings from your source data to SDTM
- Generate SDTM datasets from your EDC and other source data
- Run dataset conversions throughout your study

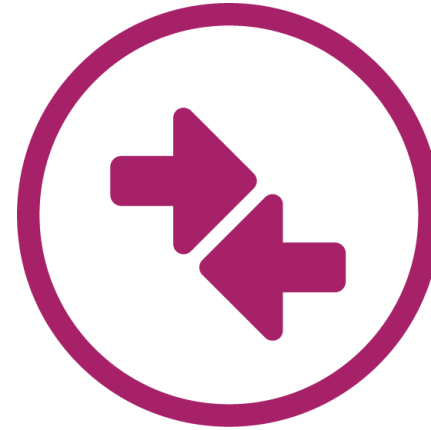
2019 brings data integration with 3rd party systems, allowing an **automated end-to-end data conversion process**

This includes:

- Linking your studies to your EDC system
- Scheduled data import into Formedix On
- Automated conversion of data to SDTM
- Automated push of SDTM data into downstream systems



Compare



Convert



Publish



Validate

Repository

Services

Training

Shop

Designers

Admin

Help

Support

About

On demand services



Services

Downloads

All ▾

Filter services

Compare

Define-XML 2.0



Free

Convert

Convert Medidata Rave
4.1 to Formedix On



Free

Convert

Convert Medidata Rave
4.2 to Formedix On



Free

Convert

Convert Oracle InForm
to Formedix On



Free

Convert

Datasets



Free

Convert

Define-XML 1.0 to
Define-XML 2.0



Free

Convert

Excel to Define-XML 2.0



Free

Convert

SAS XPT to Define-XML
1.0



Free

Convert

SAS XPT to Define-XML
1.0 (preview)

- Repository
- Services** 3
- Training
- Shop
- Designers
- Admin

- Help
- Support
- About

On demand services

Services

Downloads 3

Remaining credits: unlimited

Update

Filter downloads

	Service	Started	Status	Cost
	! Convert Rave ALS to ODM 1.3.2 with extensions	Aug 31, 2017 10:12	Completed with issues Details	Download
	✓ Convert Define-XML 1.0 to Define-XML 2.0	Aug 31, 2017 10:11	Completed	Download
	✓ Compare Define-XML 1.0	Aug 31, 2017 10:10	Completed	Download

- **Role-based access to standards and studies**

- Standards can be available to all, or locked down to specific teams
- Studies can be open to all or restricted to a smaller study team



- **Individual teams can have different access**

- Data Managers may be able to edit forms and view datasets
- Biostatisticians may be able to view forms and edit datasets and mappings



- **Single Sign On (SSO)**

- User provisioning and access rights can be controlled through your organization's identity management platform

- Sponsors
- CROs
- Independent contractors



Support for the core CDISC models

ODM

Define-XML

Dataset-XML

SDTM

Analysis Results Metadata

SEND

ADaM

NCI CT

As you can see, we've been hard at work enhancing Formedix
On to enable a **fully automated SDTM generation process**

Metadata repositories are all the rage, but they often haven't delivered
We're focused on delivering the key benefits of the MDR vision in a simple,
affordable, user friendly format with deep EDC integration

formedix.com