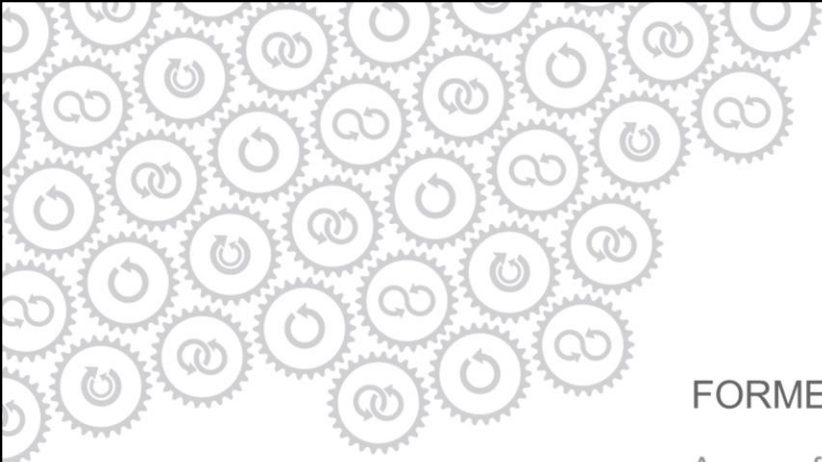


A decorative pattern of interlocking gears, each containing a circular arrow, arranged in a triangular shape on the left side of the slide.

YOUR CLINICAL
TRIALS AUTOMATED.
EVERYWHERE.

FORMEDIX ON

A powerful platform to
accelerate clinical trials

2000: Formedix founded to improve how trials are run

2003: CDISC-based study design (CRFs)

2008: CDISC-based dataset design

2014: On demand services

✓ Great for building studies, working with datasets and generating submission deliverables

✗ Separate systems – no central management

2017: ?

...



2017 brings a new 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

Manage assets across the end to end life cycle of your studies

This includes forms, datasets, terminologies, files, links and more, for example:

- Studies may contain the protocol, a set of Forms, a visit schedule, an EDC test plan, Terminologies, SDTM/ADaM dataset definitions and mappings, statistical analysis plan, and reviewers guides
- Standards may contain a number of variations on a Form, related SDTM/ADaM datasets and mappings, Terminologies, and instructions on how to use the Standard

Now let's take a look...

formedium

by formedium

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?](#)

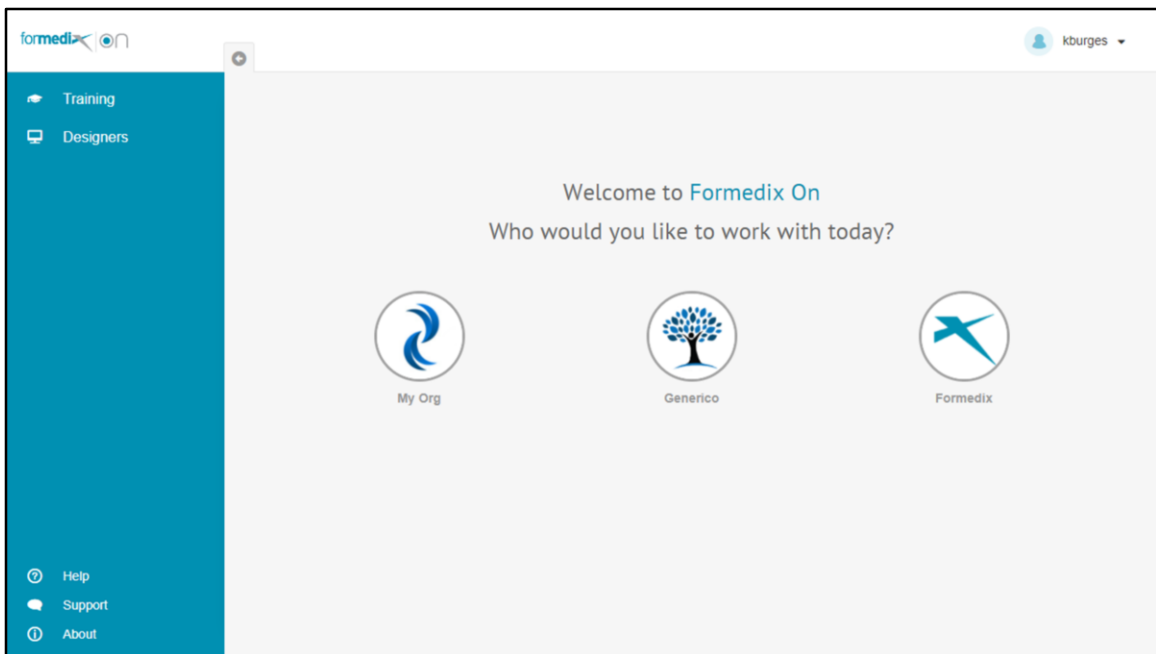
Sign in

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

f RSS t in

Chat With Us

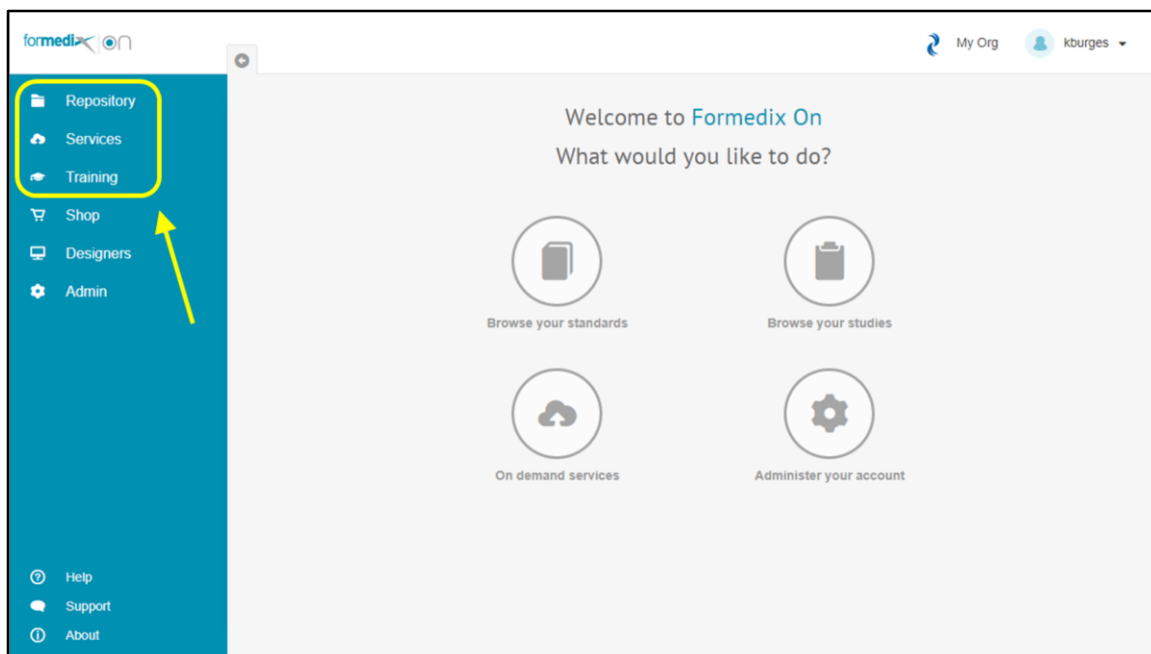
First step is to sign in using my username and password. Alternatively it can integrate with my Single Sign On



My user account can be associated with multiple companies. For example:

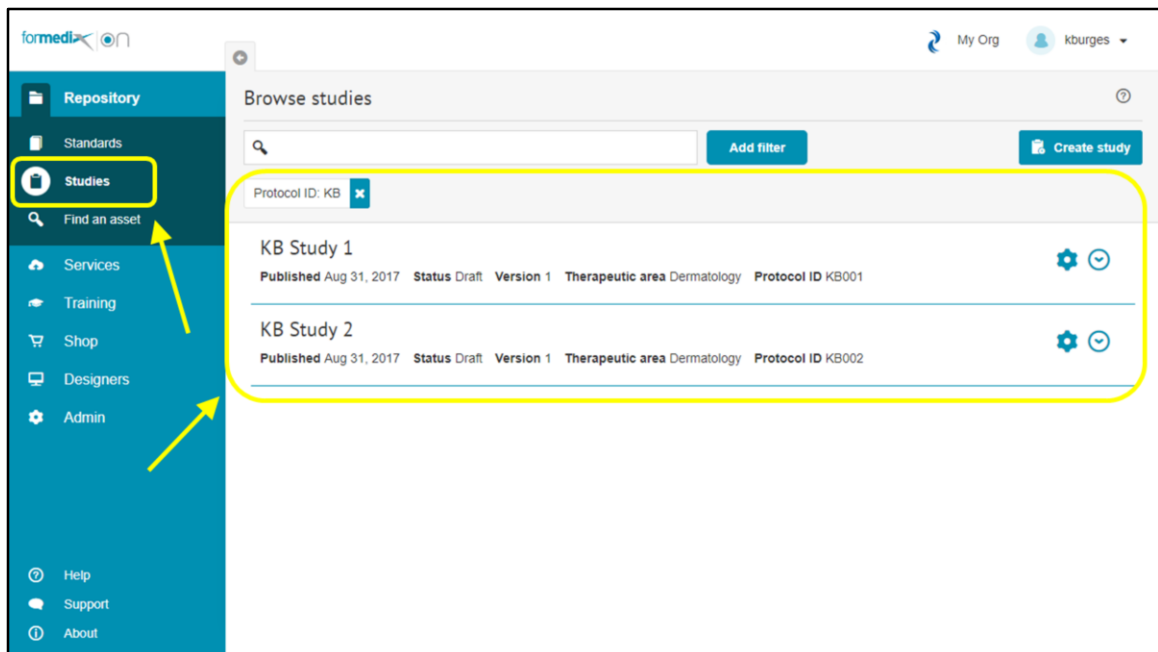
- CROs or independent contractors may work with a number of Sponsors
- Sponsors may work with a number of CROs

When I sign in, I chose who I'd like to work with, keeping a clear separation between different partners



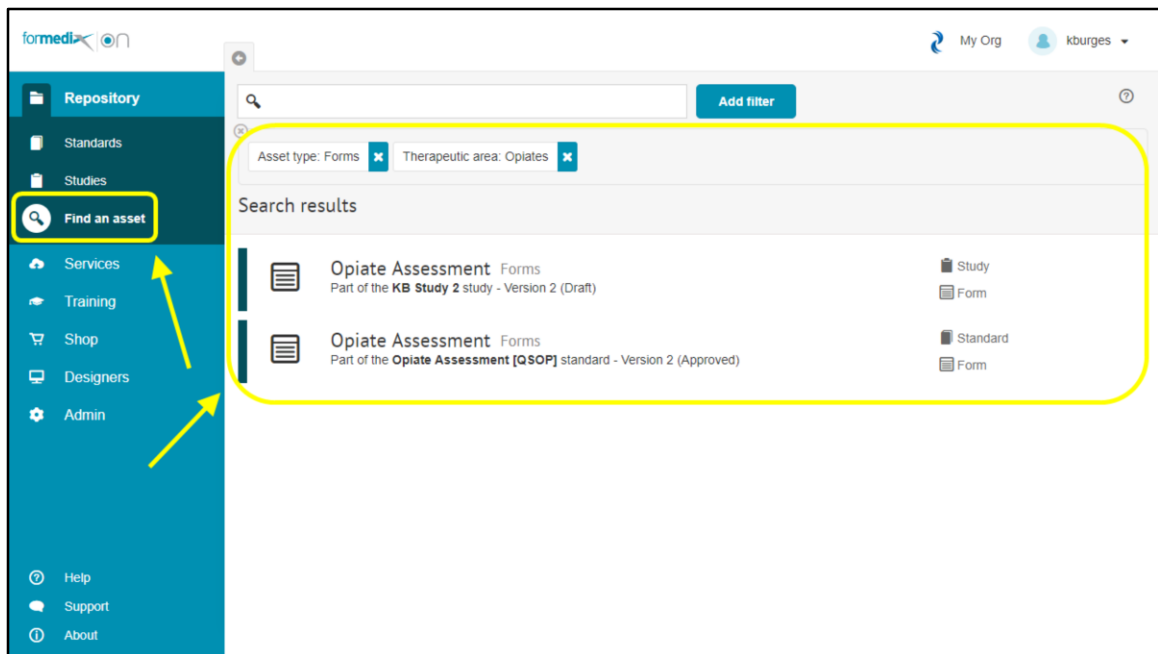
Once I'm signed in I can see the main areas of the system:

- Repository is where all my studies and standards are managed
- Services is where I run on demand services such as converting SAS XPT files to Define-XML metadata
- Training is an online learning platform, where my users can learn about Formedix products or CDISC standards



In the Repository section I can browse Standards, Studies, or search for a specific asset like a Form

I can filter based on any property. In this case I'm looking at all Studies with KB in the Protocol ID



And here I'm looking for any asset that is in the Opiate Therapeutic Area

I can also do things like search for Forms that have a Question that contains the text "feel pain", or search for Datasets that use a particular Terminology

The screenshot displays the 'KB Study 1' interface. At the top, the breadcrumb 'Studies > KB Study 1' is visible. Below this, the 'Study' header includes a dropdown menu set to 'Forms: Medidata Rave eCRF Preview' and a 'View' button. To the right of the header, the text 'Published: Aug 31, 2017 Status: Draft Version: 1' is shown, along with links to 'Edit this study' and 'Approve this study'. The main content area is divided into two panels: 'Properties' and 'Assets'. The 'Properties' panel lists various study details, and the 'Assets' panel lists different asset types with expandable arrows.

Properties	
Name	KB Study 1
Owner	kburges
Description	
Protocol ID	KB001
Protocol name	First study for KB
Protocol title	A randomized, double blind,
Client	My Big Client
Program	Wonder Drug

Assets	
Datasets	>
Files	>
Forms	>
Terminologies	>
Visit schedules	>

When I open up a particular Study I can see various properties of the study, and links to all the different asset types

KB Study 1

Studies > KB Study 1 (Draft) > KB Study 1 assets

Vital Signs

Oracle InForm eCRF Preview [View](#)

Asset type: Form

Questions

Name	Text	Data type	Length	Mandatory	Terminology	Units
Vital Signs Date	Date of collection	date		Yes		
Vital Signs Position	Vital Signs Position	integer	8	Yes	Vital Signs Position link	
Blood Pressure Systolic	BP Systolic	integer	3	Yes		mmHg link
Blood Pressure Diastolic	BP Diastolic	integer	3	Yes		mmHg link
Pulse Rate	Pulse Rate	integer	3	Yes		Beats per minute link

I can look at the definition of a Form, which shows all the questions, and gives a feel for the content of the form

I can select which columns are shown, so I can tailor the view to my own needs

The screenshot shows a web interface for 'KB Study 1'. The breadcrumb trail is 'Studies > KB Study 1 (Draft) > KB Study 1 assets'. The asset type is 'VS' and the dataset is 'Dataset'. Below this is a 'Variables' section with a 'Filter dataset' input and a table of variables.

Name	Description	Data type	Length	Key sequence	Terminology	Value list
STUDYID	Study Identifier	text	200	1		
DOMAIN	Domain Abbreviation	text	2	2	Domain Abbreviation - VS link	
USUBJID	Unique Subject Identifier	text	200	3		
VSSEQ	Sequence Number	float	200	4		
VSTESTCD	Vital Signs Test Short Name	text	8		Vital Signs Test Code link	
VSTEST	Vital Signs Test Name	text	40		Vital Signs Test Name link	
VSCAT	Category for Vital Signs	text	200			
VSPOS	Vital Signs Position of Subject	text	200		Position link	
VSORRES	Result or Finding in Original Units	text	200			Details link

I can see a similar view of the matching dataset
 I can click to see the details of any value lists

eCRF
PREVIEWSEDIT CHECK
SPECIFICATIONSSDTM MAPPING
SPECIFICATIONSANNOTATED
CRFs

Your teams can access advanced visualizations of your assets

Available anytime, anywhere, on the web

As well as viewing your content in the ways already shown, there are many role-specific visualizations available to your teams. For example:

- **eCRF previews, edit check specifications, SDTM mapping specifications and annotated CRFs**

Custom visualizations can also be defined to match your own desired formats. These can help integrate the system with your existing tools and processes

Subject: Subject Name
Page: Vital Signs

Date of collection: [Date Picker]

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

Apply to Record

Vital Signs - Form-level

Vital Signs - Position-level

*Vital Signs Position

*BP Systolic

*BP Diastolic

*Pulse Rate

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

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

See exactly how your forms will look in your chosen EDC

No need to build the EDC system first

You can design studies specifically for your chosen EDC system, and see how your forms will look as you're designing them

Reviewers can see exactly how forms will look before approving the study design

No need to build the EDC system first

This slide shows an example of the same form rendered for three different EDC systems

- 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

...

This means you're in control.

There's no need to hope someone can interpret your spec correctly only to find out weeks later there was a misunderstanding.

You can see exactly how your forms will look at any time.

The most important thing is that your study designs are not just specifications – with the click of a button you have your EDC system

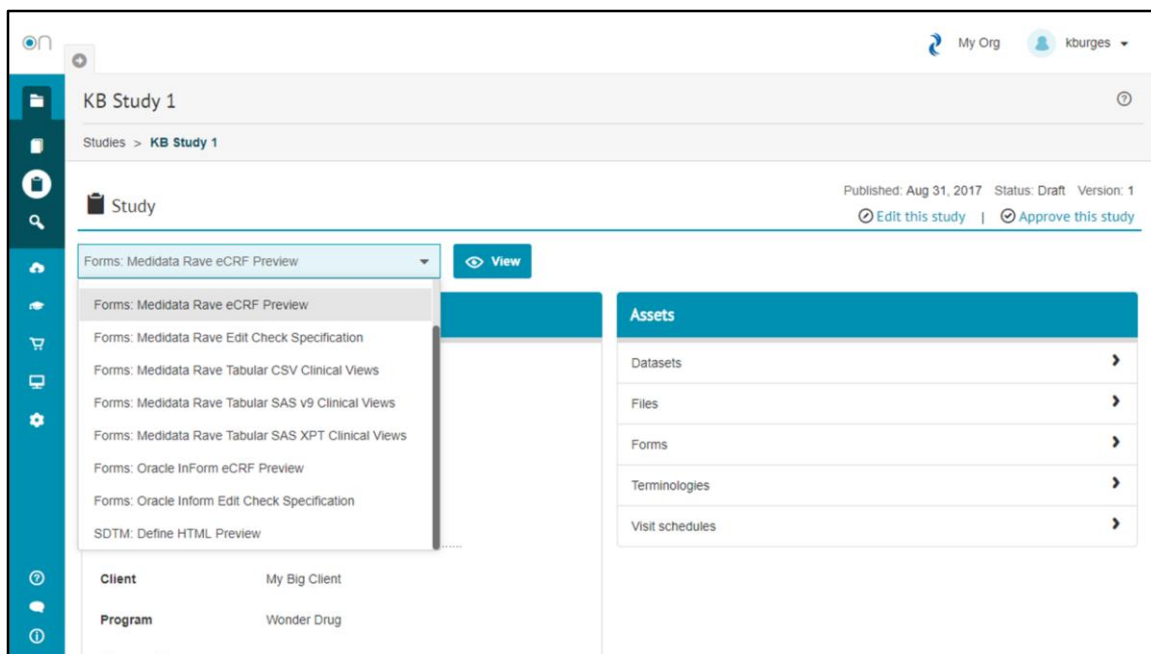
The screenshot displays the Oracle InForm interface for 'KB Study 1'. The top navigation bar shows 'Studies > KB Study 1 (Draft) > KB Study 1 assets'. The main content area is titled 'Vital Signs' and features a dropdown menu for 'Oracle InForm eCRF Preview' with options for 'Form Preview', 'Medidata Rave eCRF Preview', and 'Oracle InForm eCRF Preview'. A 'View' button is visible next to the dropdown. Below the dropdown is a table with the following data:

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

This screen shows some examples of visualizations available for individual Forms, such as:

- eCRF previews showing how the form looks in various EDC systems

Here's what my Vital Signs Form will look like in InForm



This screen shows examples of visualizations available for the whole Study, such as:

- eCRF previews of the whole Study
- Views of the EDC export datasets
- A spec of all the edit checks
- An HTML version of my SDTM Define-XML

formedium RAVE

Subject: Subject Name
Page: Concomitant Therapy

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

Concomitant Therapy

- Index
- Informed Consent & Demographics
- Medical History
- Vital Signs
- Inclusion / Exclusion Criteria
- Adverse Event
- Study Completion
- Comments

Apply to Record

Indication

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									

When I look at the eCRF previews for a whole Study I can easily navigate between all the different Forms

I can also chose to turn on annotations, which can be OIDs, SDTM or anything else

The screenshot displays the Formedix eCRF interface for a 'Concomitant Therapy' form. The form is titled 'Concomitant Therapy' and includes a 'Hide Annotations' button. The form fields are as follows:

- Subject: Subject Name
- Age: 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
- Dos: I.CM.DOSE (highlighted with a yellow box and a yellow arrow pointing to it from the left)
- Unit: I.CM.DOSU
- Unit dropdown: CL.CMUNIT (highlighted with a yellow box and a yellow arrow pointing to it from the right)
- Freq: I.CM.DOSFRQ
- Route: I.CM.ROUTE
- Start Date / Time: I.CM.STDTC
- Ongoing: I.CM.ONGO
- End Date / Time: I.CM.ENDTC

The interface also shows a 'MEDIDATA RAVE' header and a 'Hide Annotations' button. The form is currently displaying line 1 of 1.

Here I can see the eCRF with OID annotations so I can trace each object on the form back to my study design

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[FAE]					Adverse Event
Study Completion[F.COMPLETION]					Study Completion
Comments[F.COMMENT]					Comments
All	Subject Name	Screening Visit	Visit 2	Common	All

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Here I can see the visit schedule for my EDC

Each of the Forms link to the visualization of that Form so that I can easily see what they look like

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

I can see what the datasets exported from my EDC are going to look like, which allows me to define my mappings to SDTM

SDTM-IG 3.2

▼ Annotated CRF
Tabulation Datasets
Comments (CO)
Demographics (DM)
Concomitant Medications
Adverse Events (AE)
Disposition (DS)
Medical History (MH)
Inclusion/Exclusion Criteria
Vital Signs (VS)
► Value Level Metadata
► Controlled Terminology

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

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

I can see what my Define-XML will look like when viewed with the CDISC stylesheet

	A	B	C	D	E
1	Domain	Name	Description	Data Type	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 , "-", SUBJECTI)
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	VSORRES	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	VSTRESC	Character Result/Finding in Std Format	text	Convert to standard unit(ValueList: Value Data Value, ValueList: Value Original Unit)
11	VS	VSTRESN	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	VSTRESU	Standard Units	text	Do Not Uppercase (Get standard unit(ValueList: Value Data Value, 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					

And I can see how my SDTM datasets are mapped from my collected EDC datasets

This shows a row for each variable in my Vital Signs dataset, with a human readable description of the mapping in the right hand column

The highlighted mapping shows that VSBLFL will be set to "Y" for any records coming from the Screening event in my EDC

- 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



One of the big ticket features is the ability to manage your organizational standards. This allows you to increase data quality and reduce study design time. Your standards team can define standards for individual TAs, to further speed up study design and increase consistency.

- 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



Standards can contain assets from any part of the clinical life cycle, allowing you to standardize end-to-end content. For example:

- An Adverse Event standard might include a **CRF, completion instructions, edit checks, AE dataset** and **mappings**

Managing your standards end-to-end like this makes building studies really simple, as you know all your content already works



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

A key use of the system is to see how Studies compare to your Standards, to other Studies, or to a previous version of the same Study

	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	BRTHDTC	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	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									

I can view the differences between my Study and my organization's Standards. This allows me to see for example:

- Any changes made to my standard Forms
- Any datasets that have not come from my Standards

This makes it simple for someone to say whether these deviations from the standards are acceptable or not.

This example shows that I've removed the Age question from my standard Demographics form.

A	B	C	D	E	F	G	H	
1	Section							
2	OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition
3	IG.VSFRM	Vital Signs - Form-level	No		1	Yes		
4	Questions							
5	OID	Name	Text	DataType	Order No.	Mandatory	Terminology	Length
6	I.VS.DT	Vital Signs Date	Date of collection	date	1	Yes		
7	I.VS.WEIGHT	Weight	Weight	float	2	Yes		8
8	I.VS.HEIGHT	Height	Height	float	3	Yes		8
9								
10	Section							
11	OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition
12	IG.VSPOS	Vital Signs - Position-level	Yes		2	Yes		
13	Questions							
14	OID	Name	Text	DataType	Order No.	Mandatory	Terminology	Length
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								

I can view the differences between a version of my Study or Standard and the previous version, or see how it compares to another similar study. This example shows in green that I've added "Weight" and "Height" questions, and in blue that I've changed the question text for Systolic and Diastolic Blood Pressure.

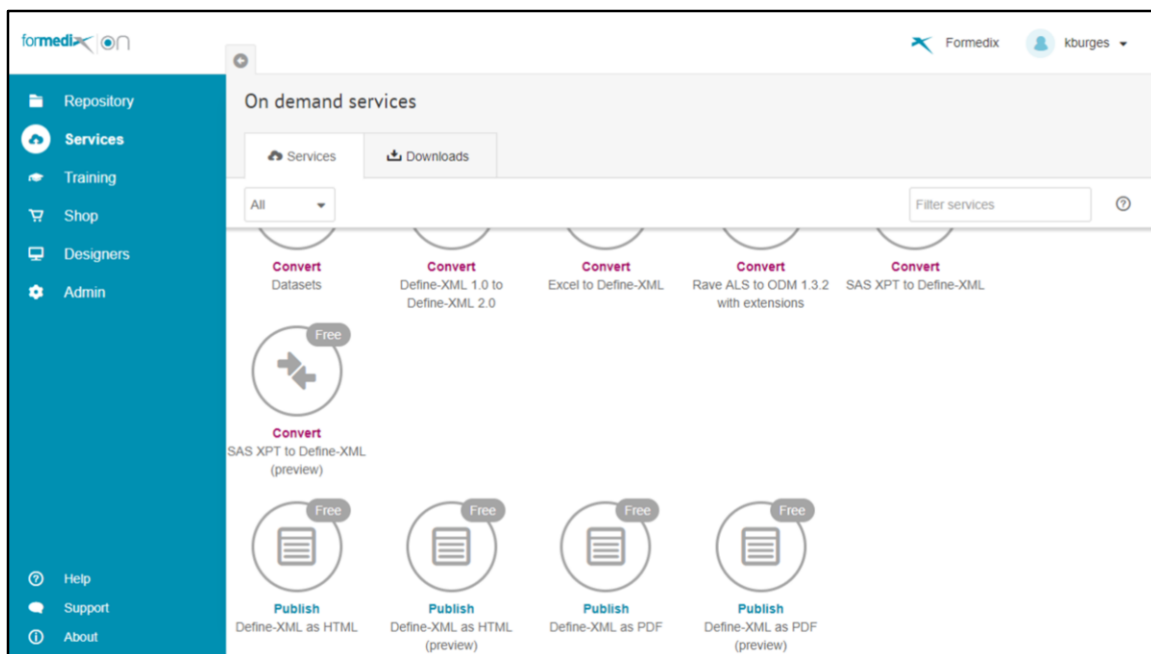
I can also use this report to see differences between datasets I have defined in my study specification and datasets that have been delivered to me by a partner. I commonly call this comparing "as specified" datasets to "as built" datasets

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

Using Formedix On you can define mappings from your source data to your SDTM, and standardize those mappings for use in future studies
Study creation becomes much simpler using your Standards as your content comes already mapped
You can generate your SDTM datasets at any point once you start collecting data.

**Compare****Convert****Publish****Validate**

Formedix On comes with a set of on demand digital services to help speed up various tasks such as Comparing, Converting, Publishing and Validating files



Services include:

Convert Datasets - for turning your EDC data into SDTM

Convert Rave ALS to ODM - for importing study designs from Rave

Convert SAS XPT to Define-XML - for extracting Define metadata from SAS Transport files

Publish Define-XML as PDF or HTML - for generating a bookmarked Define.pdf for your datasets that you can submit along with your Define-XML

Compare Define-XML - for verifying that datasets generated by a partner match my specification

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 ✕

Help Support About

I can see my previously run services, view any issues with them, and download the output

- **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

...

For example:

- Sponsors can define organizational standards, and either build studies from those or allow a CRO to build studies from them
- CROs can build studies for multiple EDC systems all within the one system, and see at specification time how the forms will look. They can make those designs available to Sponsors for review
- Independent contractors can additionally use our On Demand Services to enhance their service offering, e.g. by generating Define PDF



Support for the core CDISC models

ODM	Define-XML	Dataset-XML
SDTM	Analysis Results Metadata	SEND
ADaM		NCI CT

...

And we keep it up to date as new standards are released

- Impact analysis
- Configurable change requests and review process
- Configurable governance process

So what's next?

Formedix On is already very feature rich, but we're working hard on enhancements that we know are important to you.

The first big one of these is **impact analysis**. This will help you understand the effect of making an update upon other assets in the system. This is great for planning, and helps ensure your standards and studies remain consistent with each other.

Next up is the introduction of a completely **configurable change request and review process**. You'll be able to mimic your existing process, or introduce a new one to help formalize your process

Lastly is a completely configurable metadata governance process. You'll be able to define the different life cycle stages your metadata should go through, and even define different processes for Standards and Studies

As you can see, **we've been hard at work!**

But we're not done yet...

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

...

We know there's been a lot of interest in MDRs over the last few years. We also know that various MDR implementations have not delivered on their promises. There are numerous reasons for this, including cost and complexity of rollout, difficulty of use, and limited integration with EDC systems.

Our aim is not to replicate everything that major MDRs do, but to deliver the key benefits of an MDR:

data quality and consistency, visibility of metadata, end-to-end time and resource savings

in a system that's simple and inexpensive to roll out, easy to use, and has advanced EDC integration to dramatically reduce study build and dataset generation time.

To find out more, please take a look at our website and try it out for yourself.