FORMEDIX ON

YOUR CLINICAL TRIALS AUTOMATED. EVERYWHERE.

A powerful platform to accelerate clinical trials
<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Formedix founded to improve how trials are run</td>
</tr>
<tr>
<td>2003</td>
<td>CDISC-based study design (CRFs)</td>
</tr>
<tr>
<td>2008</td>
<td>CDISC-based dataset design</td>
</tr>
<tr>
<td>2014</td>
<td>On demand services</td>
</tr>
</tbody>
</table>

- ✅ 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.
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...
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
When I open up a particular Study I can see various properties of the study, and links to all the different asset types
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.
I can see a similar view of the matching dataset
I can click to see the details of any value lists
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.
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.
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.
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
And here’s what the same Form will look like in Rave

As you would expect the layout is different, but it’s gathering the same data.
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
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.
Here I can see the eCRF with OID annotations so I can trace each object on the form back to my study design
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
I can see what the datasets exported from my EDC are going to look like, which allows me to define my mappings to SDTM.
I can see what my Define-XML will look like when viewed with the CDISC stylesheet
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.
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.
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.
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.
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.
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.
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.
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
I can see my previously run services, view any issues with them, and download the output
ACCESS CONTROL

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

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.