



7 COMMON CRF ISSUES & HOW TO OVERCOME THEM

7 COMMON CRF ISSUES WE HEAR ABOUT

There are many difficulties with CRFs. These are the ones we hear about most:

1. Creating CRFs from scratch for every study takes lots of time. It also increases the risk of admin errors, and makes consistency difficult to achieve.
2. Creating annotations from new every time is a fiddly and time consuming job.
3. Not having CRFs stored together in one place makes it difficult to find what you need. It also makes reviewing and sharing documents more tricky.
4. You can't see what CRFs and annotations look like **until you've built your EDC system**. Plus, different stakeholders need different views of the data according to their roles.

7 COMMON CRF ISSUES WE HEAR ABOUT

5. You need to go back and forth between teams making changes and rebuilding your EDC until everyone is happy. This creates extra work and causes delays getting studies built and approved.
6. There's no easy way to manage changes to CRFs. It's difficult to see if you're using the correct version of a CRF, and to see a history of changes and approvals.
7. It's not easy to see the *impact* of any changes. It's difficult to make decisions when you can't see what else is affected – and what else may need changing as a result.

SO WHAT CAN YOU DO?

Implementing these changes will make a big difference:

- **Standardization**

Establish approved CRF designs and annotations. Standardizing CRFs will save lots of time, because you'll have pre-approved content that can be reused across many standards and studies. It'll also help you improve consistency and data quality as a result.

- **CRF library**

Set up a central storage place for your standardized CRFs and study assets. An online clinical metadata repository (MDR) keeps everything together in one place. It makes it easy for people to find what they're looking for. And your standardized metadata is then available for all stakeholders to reuse.

SOME BEST PRACTICES BEFORE YOU START

Using best practise from CRF design through to EDC build will save time, money and effort. Plus you'll have good quality, consistent CRFs too.

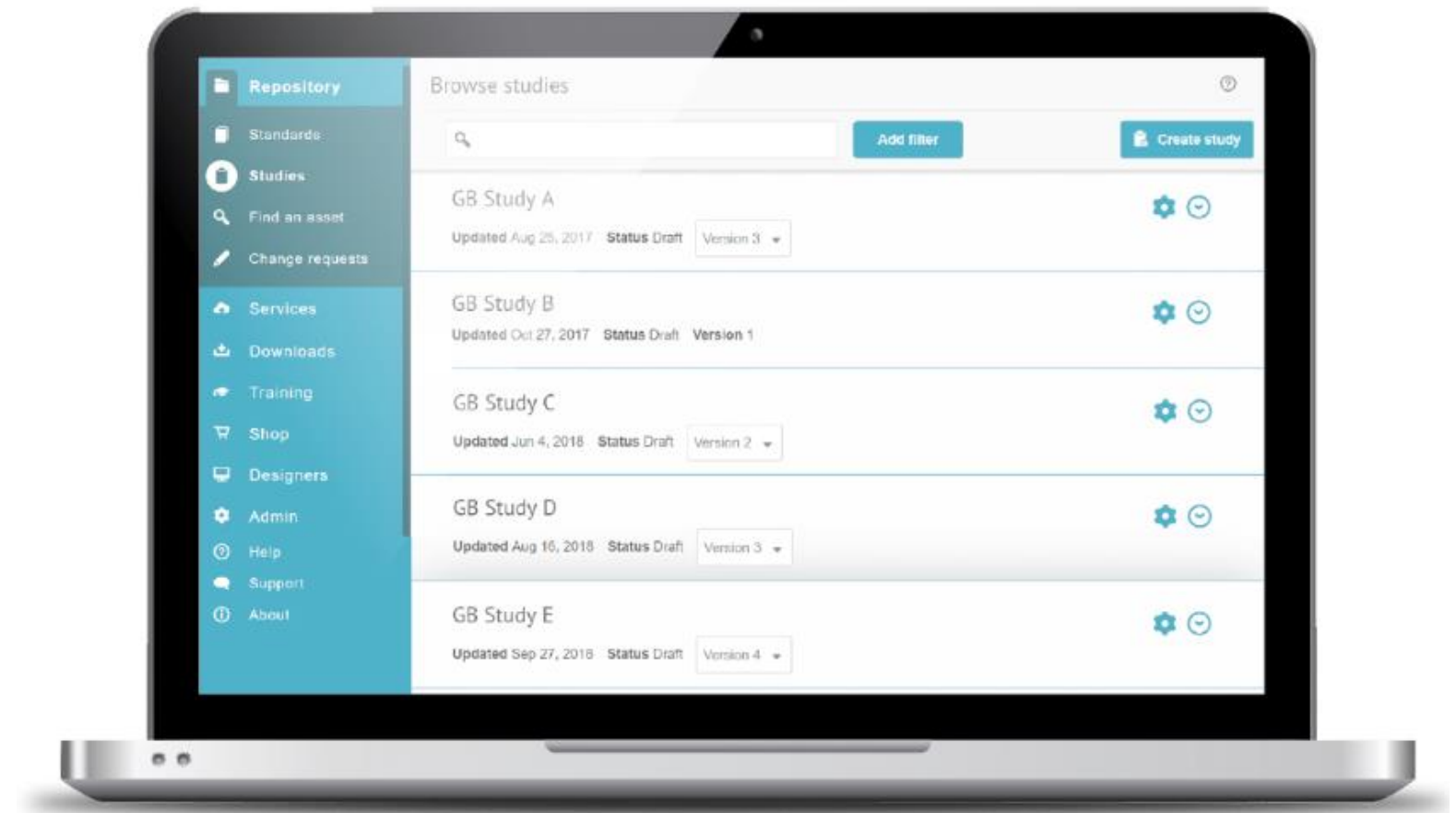
- Get key stakeholders involved from the start, and clearly define objectives at the outset.
- Set up consistent, user friendly CRFs to reduce data entry errors.
- Use simple designs and avoid calculated or derived fields to ensure that data collection is cost-effective.
- Incorporate user feedback and provide CRF guidelines to help with data capture and data quality.

INSTANTLY FIND, SHARE & REVIEW CRFS

The Formedix MDR provides a central place to store clinical metadata - a 'single source of truth.'

Search the entire library and quickly find CRFs - plus all your other assets. Then review, reuse and share designs across teams.

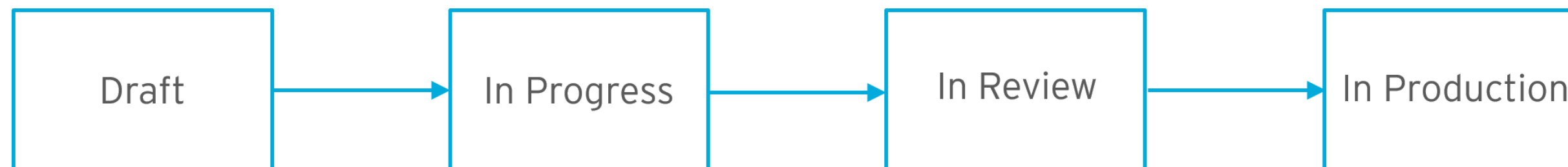
All your content is connected - everything from eCRFs to submission deliverables.



EASILY CREATE STANDARDIZED CRFS

Use built in approval processes in the Formedix platform to create standardized CRFs. Or decide your own lifecycle states for standards and studies.

Once CRFs are approved, they're there in your MDR ready to use - again and again! That goes for CRFs, annotations, edit checks and more. So that's less time creating new content, and a head start on study build.



SEE WHAT CRFS LOOK LIKE - *BEFORE* BUILDING YOUR EDC

Forget not knowing how CRFs look. Or not having the right format and visual for each stakeholder. With Formedix visualization tools, you get all the views and formats you need. No delays, and no back and forth with EDC builds:

- See what CRFs look like in your EDC - as you design forms in Formedix. Use Rave, InForm or 5 other EDCs, and validate CRFs against the rules of your specific EDC.
- See your metadata specifications.
- See your visit structure.
- Download and view your edit check specifications.
- See your mapping specifications.
- See the annotations on your CRFs.
- Get SAS XPT and SAS v9 clinical views.

SEE YOUR CRFS... LIKE THIS

Medical History		
Medical History		
Body System	Abnormality	Currently Active
Skin	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
Eyes	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
Heart	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
Abdomen	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
Neurological	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
Other <input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive
	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive

* Mandatory field

SEE RAVE CRFS... LIKE THIS

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MEDIDATA RAVE

Medical HistoryAdditional MetadataAnnotations

Subject: Subject Name

Page: Medical History

Currently viewing line 1 of 12.
Click here to return to "Complete View"

Apply to Record

Body System

...

Other

Abnormality

Currently Active

...

Save

Cancel


SEE ORACLE INFORM CRFS...LIKE THIS















ORACLE INFORM

Medical History

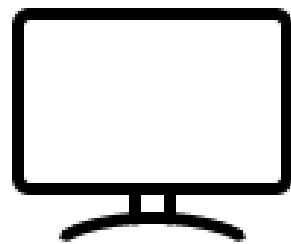
[Show Annotations](#)

Medical History


	*Body System	*Other	*Abnormality	*Currently Active	
1.a	Skin	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.b	Skin	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.c	Eyes	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.d	Eyes	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.e	Heart	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.f	Heart	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.g	Abdomen	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.h	Abdomen	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.i	Neurological	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.j	Neurological	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.k	Other	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	
1.l	Other	<input type="text"/>	<input type="text"/>	<input type="radio"/> Active <input type="radio"/> Inactive	

QUICKLY BUILD YOUR EDC

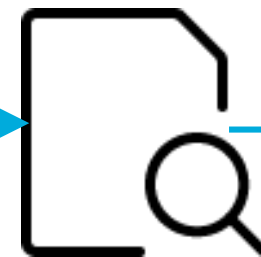
Once everyone likes what they see, it's just a quick export to build your EDC system!



Choose your
EDC



Select from your
standardized
CRFs



Preview CRFs
for your EDC



Export your
study to your
chosen EDC

EASILY KEEP TRACK OF CHANGES

You can easily control and manage changes to CRFs in the Formedix platform. By setting up author-review-approval processes, you have a clear history of all changes, by user.

Comparison reports show the difference between CRFs in different studies, for example. And version control gives you confidence that you're using the correct copy of a CRF in your study.

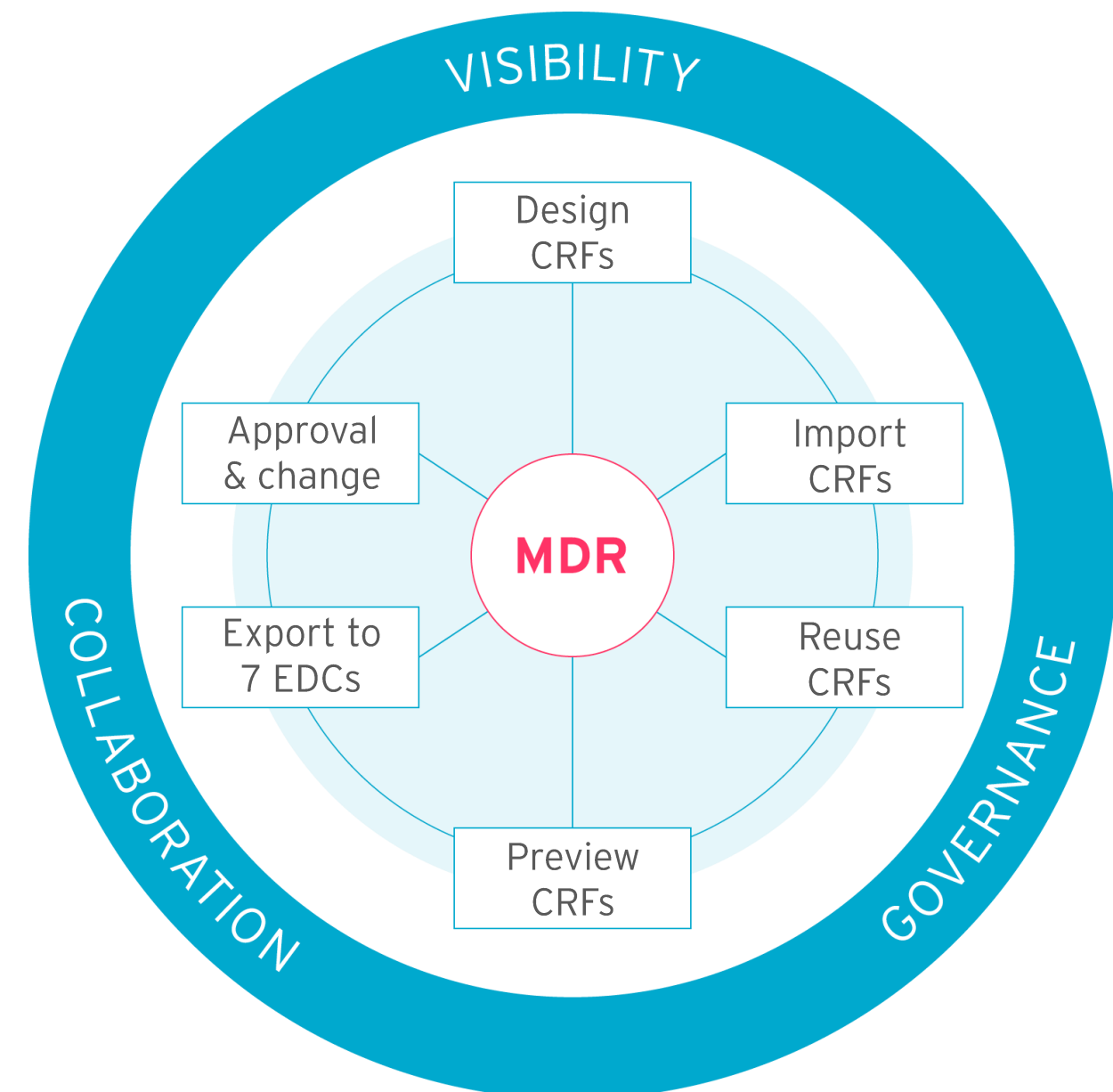
CLEARLY SEE THE IMPACT OF POTENTIAL CHANGES

The Formedix platforms shows the impact of making changes - *before you make them*. That's changes to standards, or relationships between standards. You can also see how assets relate to each other across your MDR.

Having that level of visibility helps you make informed decisions. It shows the scope of further updates that may be needed as a result of a proposed change. For example, asset groups in other standards that use the same CRF. Or SDTM datasets that are mapped to the CRF.

SO TO RECAP HOW YOU COULD BE BETTER OFF...

- Quickly find and manage CRFs in a central directory.
- Reuse standardized CRFs and annotations many times over.
- See what CRFs look like as you design.
- Collaborate and have full visibility.
- Control approvals, changes and version control with governance processes.
- Immediately see the impact of changes.



WIDER REACHING OPPORTUNITIES

- Build studies faster, with less effort.
- Run more trials - with the same resource!
- Cut trial costs and become more efficient.
- Get drugs and medical products to market sooner.
- Make greater profits.

FIND OUT MORE...

If this sounds good, as a first step you've got nothing to loose by talking to us.

We can discuss what's going on in your company. Specific hurdles you're up against. And where you'd like to get to. We'll see if our automation platform and metadata repository could help.

Click to arrange a call here - <https://www.formedix.com/call-me/>

Or if you want to see what CRFs look like, how they work and the previews you can do, request a customized demo here - <https://www.formedix.com/book-a-demo/>

We've been helping Pharmas and CROs for the past two decades. Learn more about how we could help you here: <https://www.formedix.com/>