



# IMPACT ANALYSIS IN THE FORMEDIX CLINICAL MDR

## IMPACT ANALYSIS... AN OVERVIEW

Impact analysis lets you see the impact of making a change to a standard or study. *Before you make it.*

This helps you make informed change control decisions. It lets you determine the scope of updates that may be needed, as a result of a proposed change.

Impact analysis information also lets you see how assets and asset groups relate to each other, throughout the repository.

## IMPACT ANALYSIS AT ASSET LEVEL

Impact analysis shows studies, standards or assets that are related to an asset and would be impacted by any changes to it. For example, adding a question to a form in a standard.

Impact analysis shows other assets and asset groups that may need updated in response to that change. Such as:

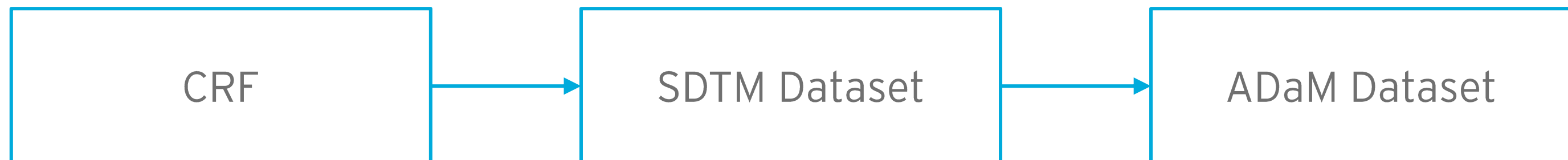
- SDTM datasets that are mapped to the form
- ADaM datasets that are mapped to SDTM datasets that are mapped to the form
- Asset groups in other standards that use the same form
- Asset groups in studies that use the same form

## FEATURES

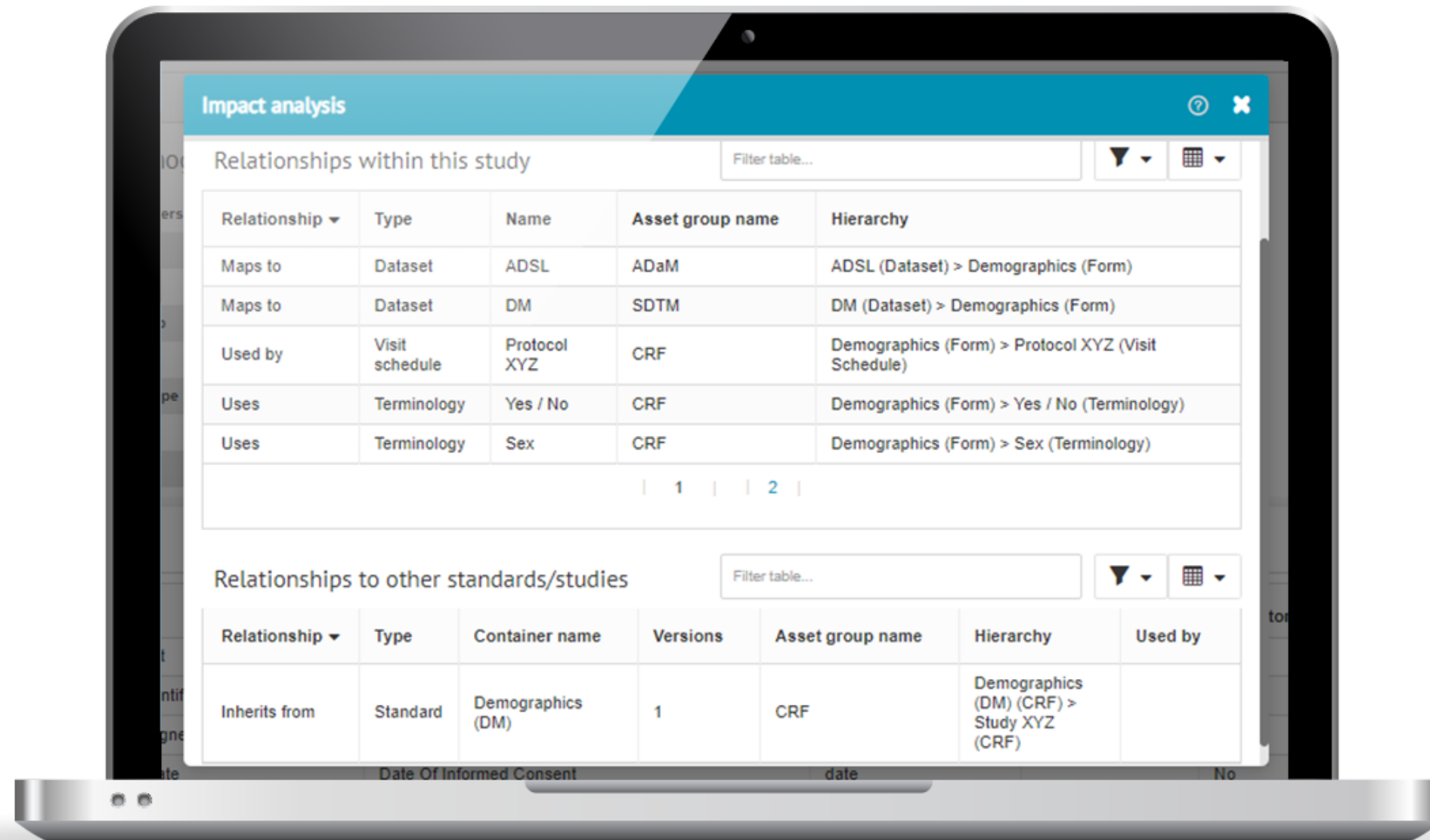
Impact analysis shows "deep relationships". That is the knock-on effects of a change to an asset.

"Deep relationships" show parent, child and sibling relationships, all the way back to the source.

For example, assets that may be indirectly impacted such as a form that maps to an SDTM dataset that maps to an ADaM dataset.



# IMPACT ANALYSIS EXAMPLE IN FORMEDIX...



The screenshot displays the 'Impact analysis' window in the Formedix software. It contains two main sections, each with a table of relationships. The first section, 'Relationships within this study', shows internal data mappings. The second section, 'Relationships to other standards/studies', shows how the current data maps to external standards.

Impact analysis				
Relationships within this study				
Relationship ▼	Type	Name	Asset group name	Hierarchy
Maps to	Dataset	ADSL	ADaM	ADSL (Dataset) > Demographics (Form)
Maps to	Dataset	DM	SDTM	DM (Dataset) > Demographics (Form)
Used by	Visit schedule	Protocol XYZ	CRF	Demographics (Form) > Protocol XYZ (Visit Schedule)
Uses	Terminology	Yes / No	CRF	Demographics (Form) > Yes / No (Terminology)
Uses	Terminology	Sex	CRF	Demographics (Form) > Sex (Terminology)

Relationships to other standards/studies						
Relationship ▼	Type	Container name	Versions	Asset group name	Hierarchy	Used by
Inherits from	Standard	Demographics (DM)	1	CRF	Demographics (DM) (CRF) > Study XYZ (CRF)	

## WANT TO KNOW MORE?

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