



IMPACT ANALYSIS

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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:

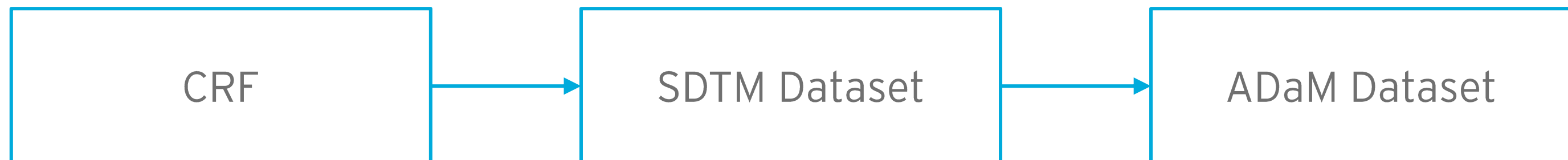
- SDTM datasets that are mapped to the form
- ADaM datasets that are mapped to SDTM datasets that are mapped to the form
- Asset groups in other standards that use the same form
- Asset groups in studies that use the same form

FEATURES

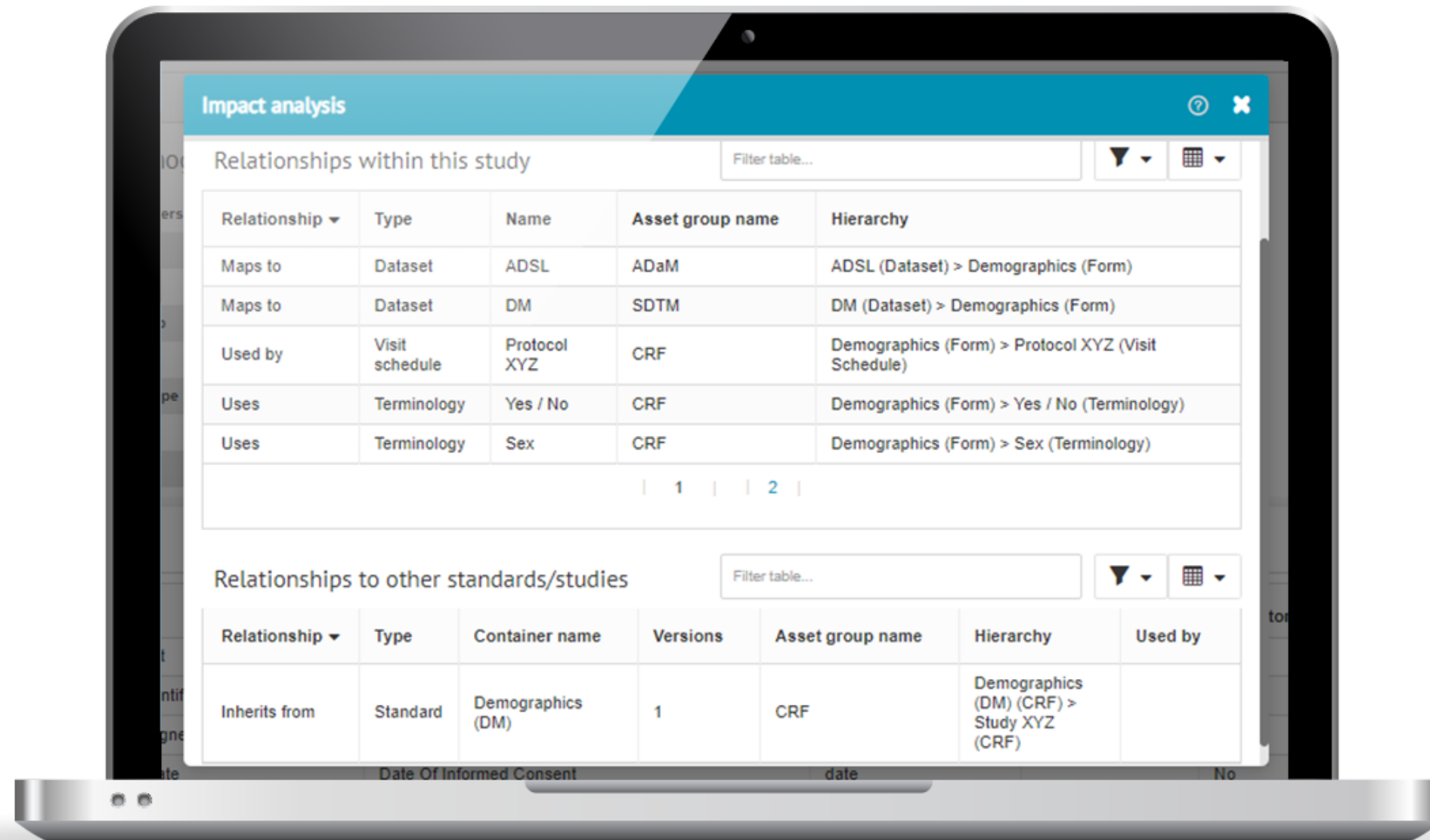
Impact analysis shows "deep relationships". That is the knock-on effects of a change to an asset.

"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 application. It contains two main sections, each with a table and a 'Filter table...' input field.

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) |

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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) | |

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