

Sure-Real user manual

Introduction

Sure-Real is modelling tool for multi-scenario trial development. It has been developed as part of the IMI GetReal project. The tool represents an environment for interactive study design incorporating a number of models. The different elements relating to the tool and models is shown here (Figure 1).

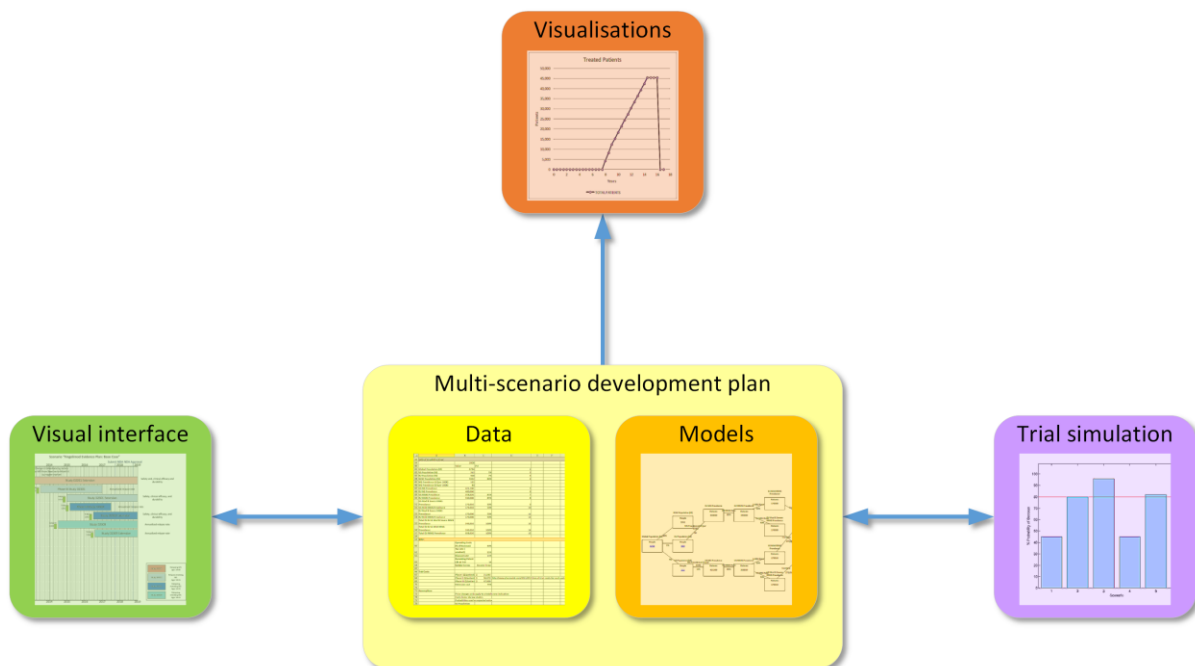


Figure 1 Structure showing the different elements of modelling tool

The modelling tool is designed for multi-scenario development plans, containing a data repository and appropriate models, including optional interaction with trial simulation software (such as Kerus software from Exploristics [<https://www.exploristics.com>]). Interactive user interaction is realised through a user friendly customised visual interface. Additional outputs include reporting and visualisations.

The core of the tool is realised as a Microsoft Excel Add-In, with data repositories and models, incorporated in Excel spreadsheet(s). It requires Microsoft Excel and Microsoft Visio.

Requirements

In order to use Sure-Real, prerequisite is the following software:

- Windows operating system
- Microsoft Excel 2010 or higher
- Microsoft Visio 2010 or higher

Installation

Select the Sure-Real installer executable, which will show an installation wizard dialog to guide de installation process. Successful installation of Sure-Real can be verified by opening Excel which should show the Sure-Real menu ribbon, as shown in the next section. The example model will be installed in the location:

My Documents \ Sure-Real \ SureReal example.xlsx

Using Sure-Real

The main user interface of Sure-Real is the Visio interface, with addition of a custom menu ribbon both in Excel (Figure 2) and Visio (Figure 3). Three types of interfaces have been designed, each of which allows direct interaction with the scenario data through the Shape Data interface.

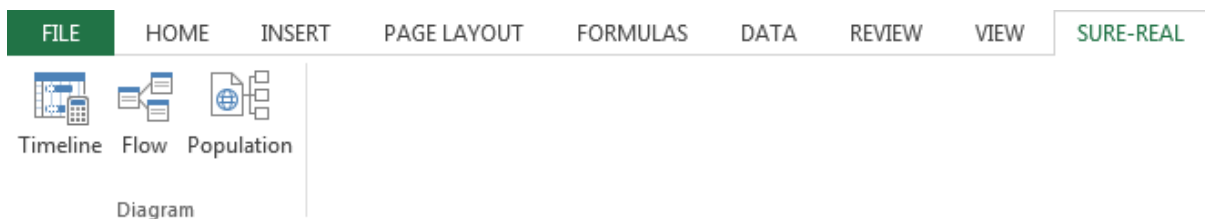


Figure 2 Sure-Real Excel menu ribbon

The Sure-Real Excel menu exposes the following functionality:

- Generating interactive visualisations of the currently active worksheet
 - Timeline Designer: interact with all scenario time lines
 - Patient Experience Manager: interact with patient flows
 - Population Manager: interact with population branching

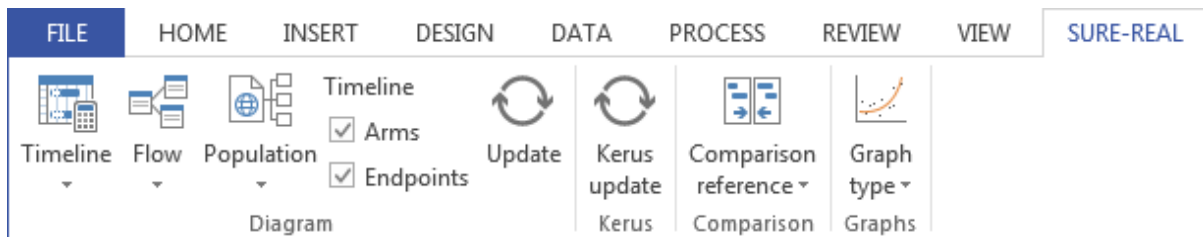


Figure 3 Sure-Real Visio menu ribbon

The Sure-Real Visio menu exposes the following functionality:

- Generating interactive visualisations of selected scenarios
 - Timeline Designer: interact with all scenario time lines
 - Patient Experience Manager: interact with patient flows
 - Population Manager: interact with population branching
- Interaction with trial simulation software
- Comparing two scenarios
- Generating graphs of modelled data

When generating a scenario visualisation diagram (Timeline, Patient Experience or Population), a Visio file will be generated and automatically saved to the same location where the Sure-Real Excel file is located. The file name will be generated using the Sure-Real Excel file (e.g. 'SureReal example'), the scenario worksheet label (e.g. 'Test Case') and the Visio template name (e.g. 'time_line') and automatically concatenated (e.g.: 'SureReal example Test Case time_line').

The main Sure-Real user interface can be accessed in two ways:

- Open a Sure-Real Excel model file, and in the Sure-Real menu select one of the options in the Diagram menu
- Open an existing Sure-Real Visio diagram file, which will automatically attempt to open the corresponding Sure-Real Excel model file

Timeline Designer

The Timeline Designer interface (Figure 4) visualises the Time Lines as horizontal bars with time represented as linear scale on the horizontal axis. These then contain coloured bars representing time line intervals, and on their right showing Endpoints. Endpoints can be used for study outcomes and can contain numeric values. Arms can be included directly below timeline intervals. Additionally, Events can be added and shown as vertical lines across the timeline. Finally, Legends can be included on the bottom right.

These items can be added, modified, or removed in the diagram. To add an item, select it on the Shapes view on the left hand side of the window, and drag it into the main diagram. To remove an item, select it in the diagram and press the Delete key, or from the item's context menu select Cut. Key properties can be modified by moving an item across the time scale, or repositioning it relative to other Time Lines.

Other properties for Time Lines, Endpoints, Arms, Events and Legends can be accessed via Shape Data. (Shape Data can be shown by enabling Shape Data Window in the Data menu (for Visio Pro), or by selecting an item in the diagram and from the context menu selecting Data -> Shape Data.) Shape Data is shown in the view on the right hand side of the window. Properties like Label or Value can then be modified by changing the content of the corresponding Shape Data entry.

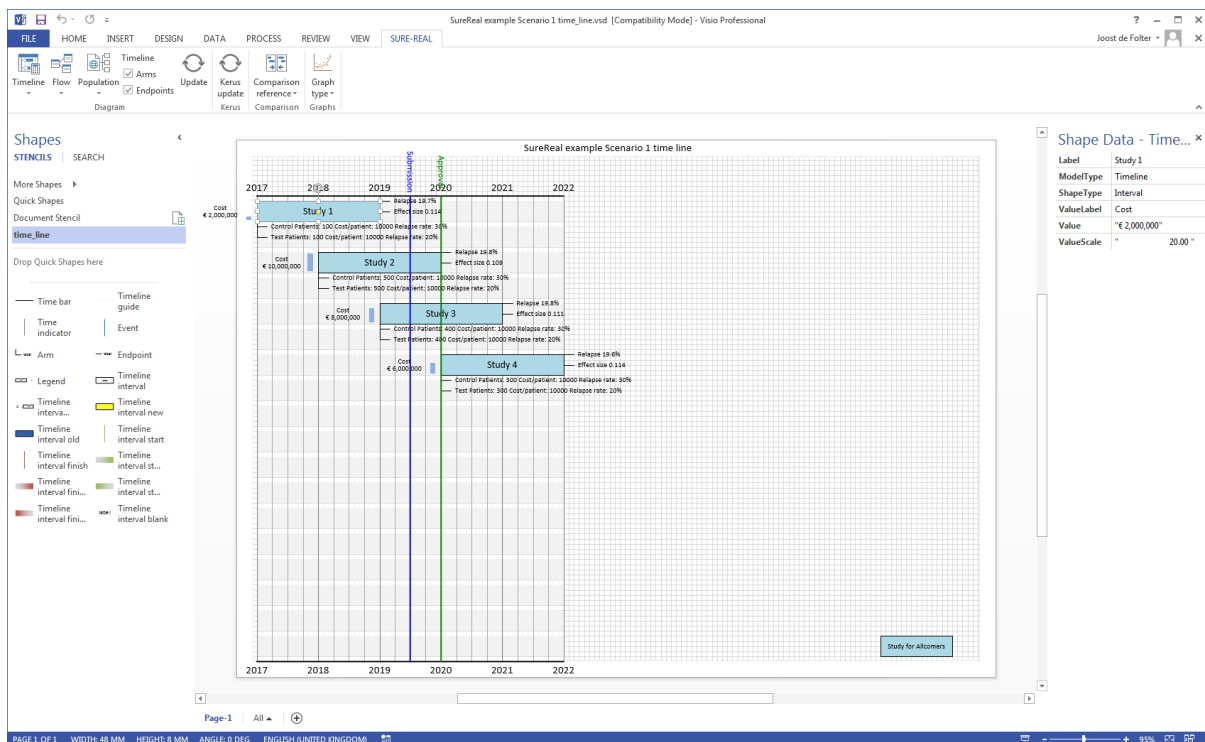


Figure 4 Sure-Real Timeline Designer

Patient Experience Manager

The Patient Experience Manager (Figure 5) visualises patient flows which shows patient numbers, costs and other parameters, and relationships between each of these. Dynamic labels and values can be shown on branches and nodes.

Like the Timeline Designer, items can be added, modified, or removed in the diagram. To add an item, select it on the Shapes view on the left hand side of the window, and drag it into the main diagram. To remove an item, select it in the diagram and press the Delete key, or from the item's context menu select Cut. Item contents can be modified through the Shape Data entries.

Connections between nodes can be made using the special Connector item from the Shapes view. It can subsequently be connected to nodes by dragging each end of the connector over a node.

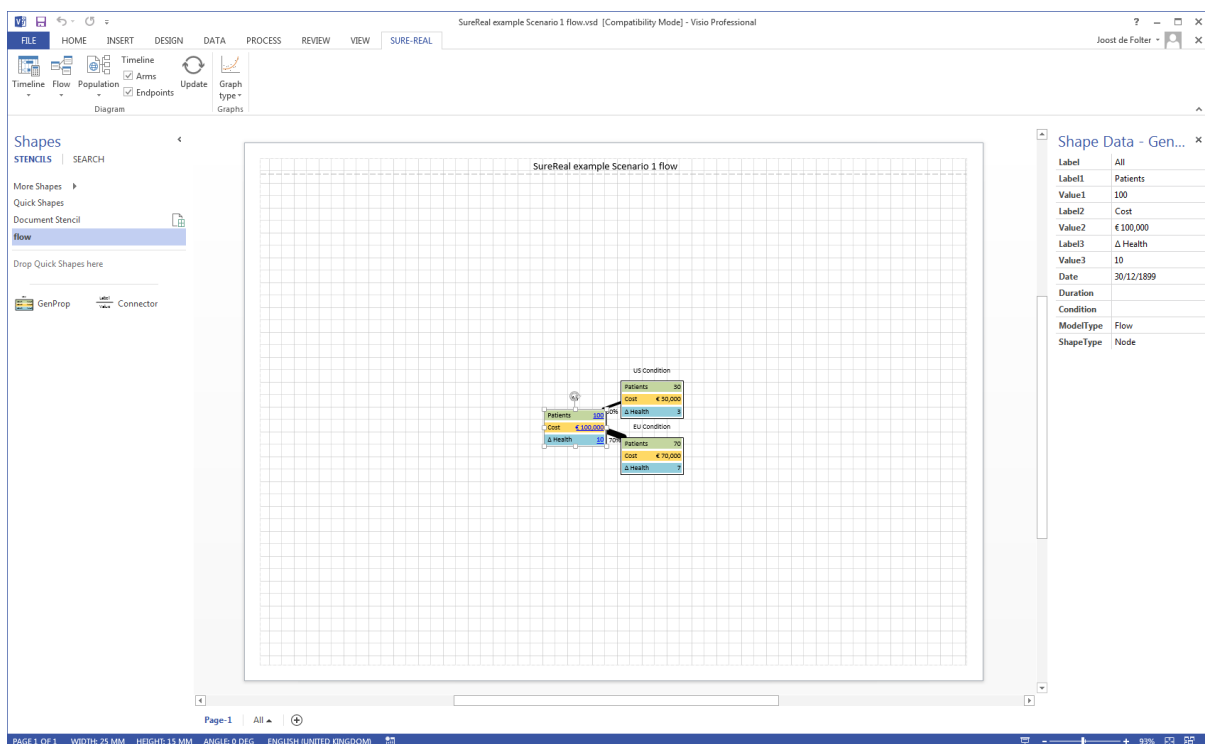


Figure 5 Sure-Real Patient Experience Manager

Population Manager

The Population Manager (Figure 6) visualises subject populations, and how these divide and recombine based on characteristics such as geographical region. Corresponding values can be shown on nodes and on branches.

Like the Timeline Designer and Patient Manager, items can be added, modified, or removed in the diagram. To add an item, select it on the Shapes view on the left hand side of the window, and drag it into the main diagram. To remove an item, select it in the diagram and press the Delete key, or from the item's context menu select Cut. Item contents can be modified through the Shape Data entries.

Connections between nodes can be made using the special Connector item, like in the Patient Manager, by dragging each end of the connector over a node.

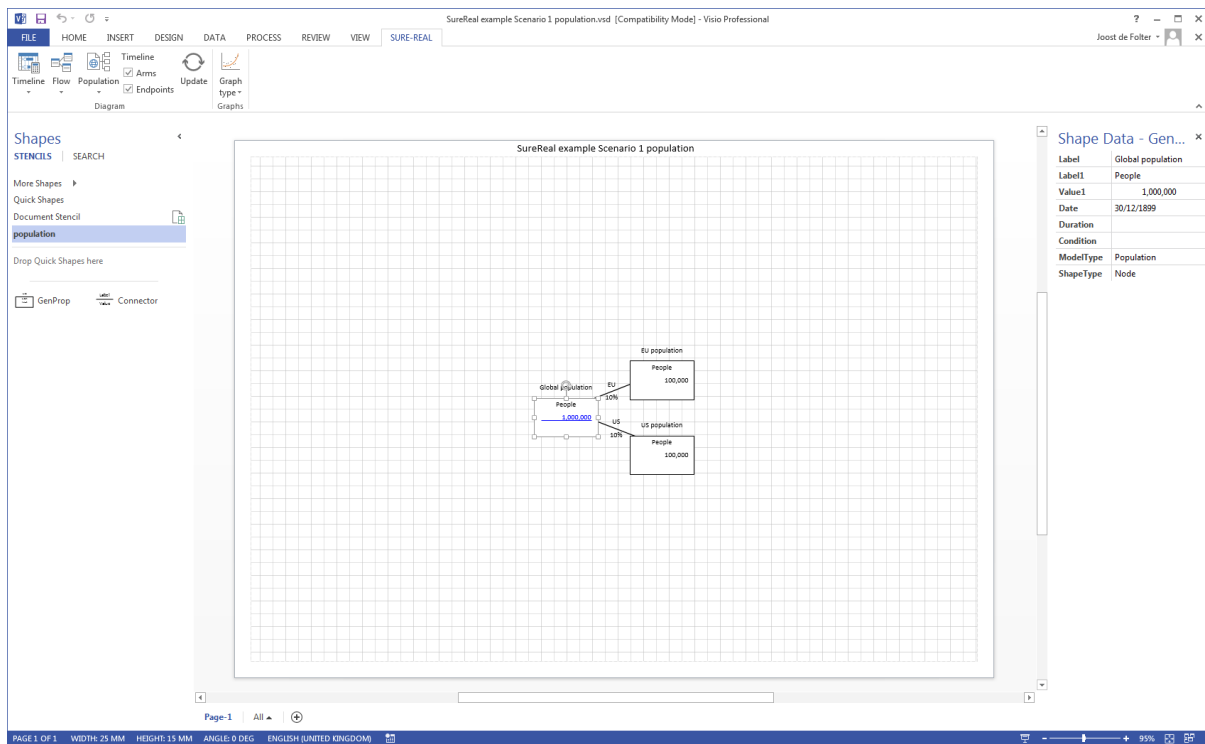


Figure 6 Sure-Real Population Manager

Scenario comparisons

Scenario comparisons are performed by selecting a Comparison reference from the Comparison section in the Visio menu ribbon (see Figure 3). This will determine the difference between the selected scenario, relative to the currently open scenario. An example of timelines is shown in Figure 7). All differences are highlighted, including timeline differences indicated by gradients, where green indicates an increase and red a decrease. Differences are also shown of any numerical values, and the same colour coding used. In contrast to the other types of diagrams, scenario comparisons are not dynamically linked to data sources and so will not automatically update when the associated data sources change, and are not automatically saved.

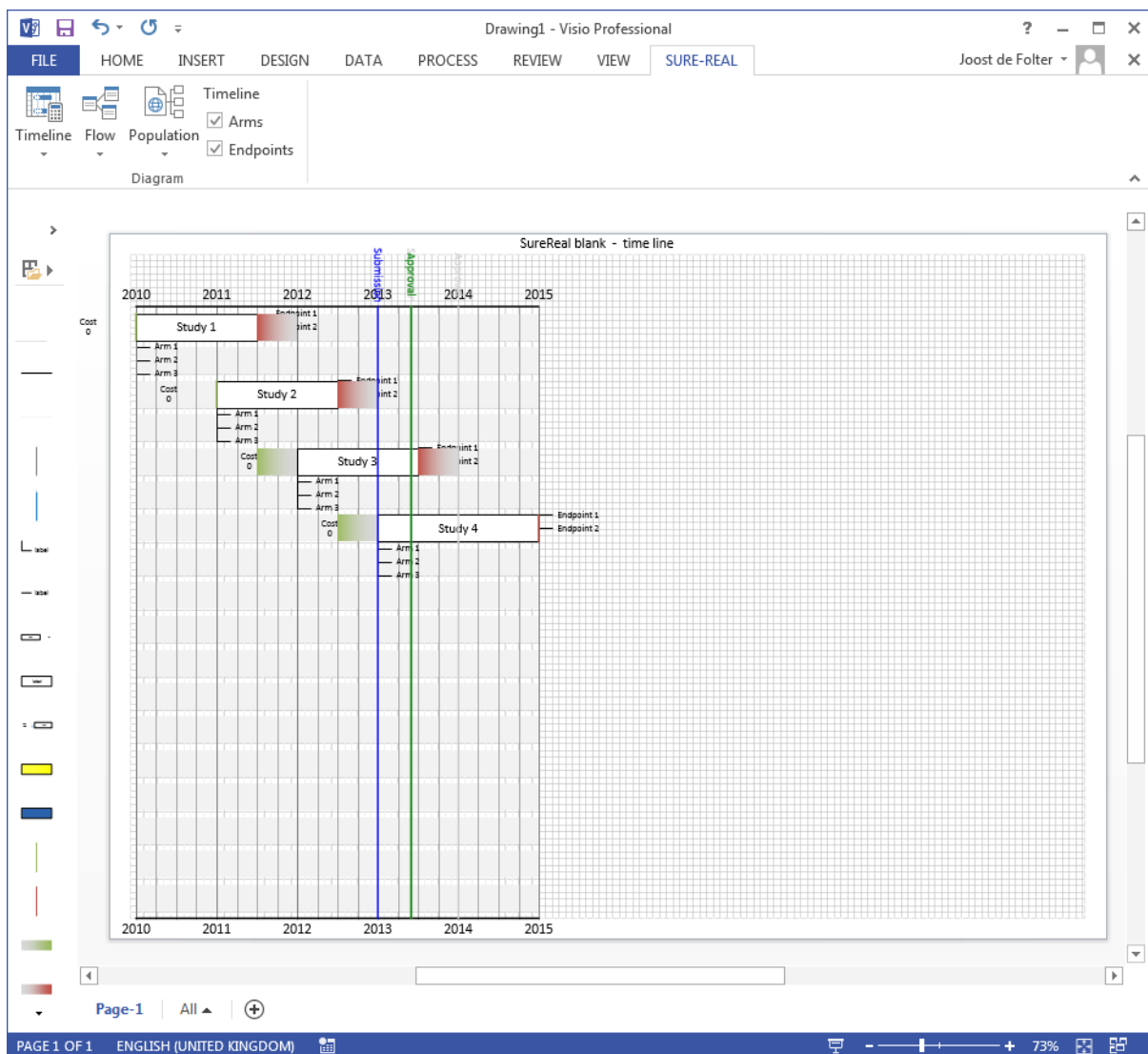


Figure 7 Comparison of scenario timelines

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Acknowledgements

32. The research leading to these results was conducted as part of the GetReal consortium (<https://www.imi-getreal.eu/>) which is a public-private partnership. The GetReal project has received support from the Innovative Medicine Initiative Joint Undertaking (www.imi.europa.eu) under Grant Agreement n° 115546, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

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