

BIOSIMILARS TRIAL TIMELINE

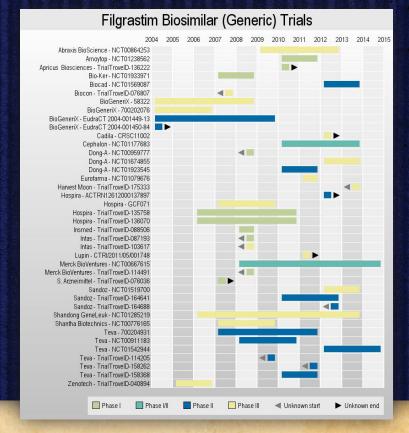
Analyze clinical trials of generic manufacturers to assess the competitive trial landscape and predict potential biosimilar launch timing.

Does your lifecycle planning process require you to anticipate your future generic competitor launches? Many generic companies compete to be the first brand replacement. It can be hard to see who the major players are and predict how soon they might launch. Clinical trial databases can reveal each company's progress via the creation of a clinical trial timeline.

BizInt Smart Charts tools help you quickly generate trial timelines incorporating data from the leading clinical trial databases, with powerful features to normalize, enhance and organize clinical trial data from your multi-database report.

This trial timeline illustrates the vast number of companies working on biosimilar (generic) trials for a blockbuster drug with key patents exclusivity that expired in the EU in August 2006 and will expire in the US in December 2013.

You can find the detailed "recipe" with complete steps for creating the trial timeline in the Cookbook of Reports and Visualizations (bizint.com/Cookbook)



Use **BizInt Smart Charts for Drug Pipelines** to combine the search results, identify related trials, and select the fields you want to display.

STEP 1: Import the search results from each trial database and use File|Combine to create a combined chart.

STEP 2: Use the Generate Common Trial ID tool to identify related trials and sort by the Common Trial ID column.

STEP 3: Scroll through the chart to review the matched trials (row shading indicates each set of trials) and edit if needed.

STEP 4: Make the columns "Phase", "Completion Date" and "Start Date" visible using View|Columns. Save and select File|Send to Reference Rows.

Use **BizInt Smart Charts Reference Rows** to select the earliest start date and latest completion date for each trial.

STEP 5: Change the rules for Start Date to "Earliest Date" and "Completion Date" to "Latest Date."

STEP 6: Use File|Export to export the chart as "Vantage Point – XML" (.vpxi file)

Use VantagePoint-BizInt Smart Charts Edition to clean up dates, phases, company names and trial IDs and create the trial timeline.

STEP 7: Extract the years from the start and completion date by selecting the List:Start Date field and applying Fields|Further Processing|Dates|Extract Years. Repeat for Completion Date.

STEP 8: To clean up the phases, select the Phase field and choose Groups|Group using Thesaurus. Select Phase field and then the DrugDevelopmentPhases thesaurus.

STEP 9: Create trial labels for your Gantt chart by combining Company names and Common Trial IDs into a new "Company - Trial" field.

STEP 10: Select Scripts|TimelineGantt.vpm. Select "Company-Trial" as the field to chart. Select the Start and Completion years, and the phase field. Enter the title for the timeline and press ok.

Sources: Adis Clinical Trials Insight, Citeline TrialTrove and ClinicalTrials.gov. We searched "Drug = Filgrastim" and "Drug Phase = Phase 1, Phase 2, Phase 3"

www.bizint.com/Cookbook