

BizInt Smart Charts

Patents | Drug Pipelines | Clinical Trials | Sequences

“You Don’t Know What You’re Missing”

*Evaluating Competitor Clinical Trials with the
BizInt Smart Charts Product Family*

November 2013

Diane Webb, President

Barbara Gilmore, Application Consultant

New additions to the BizInt team

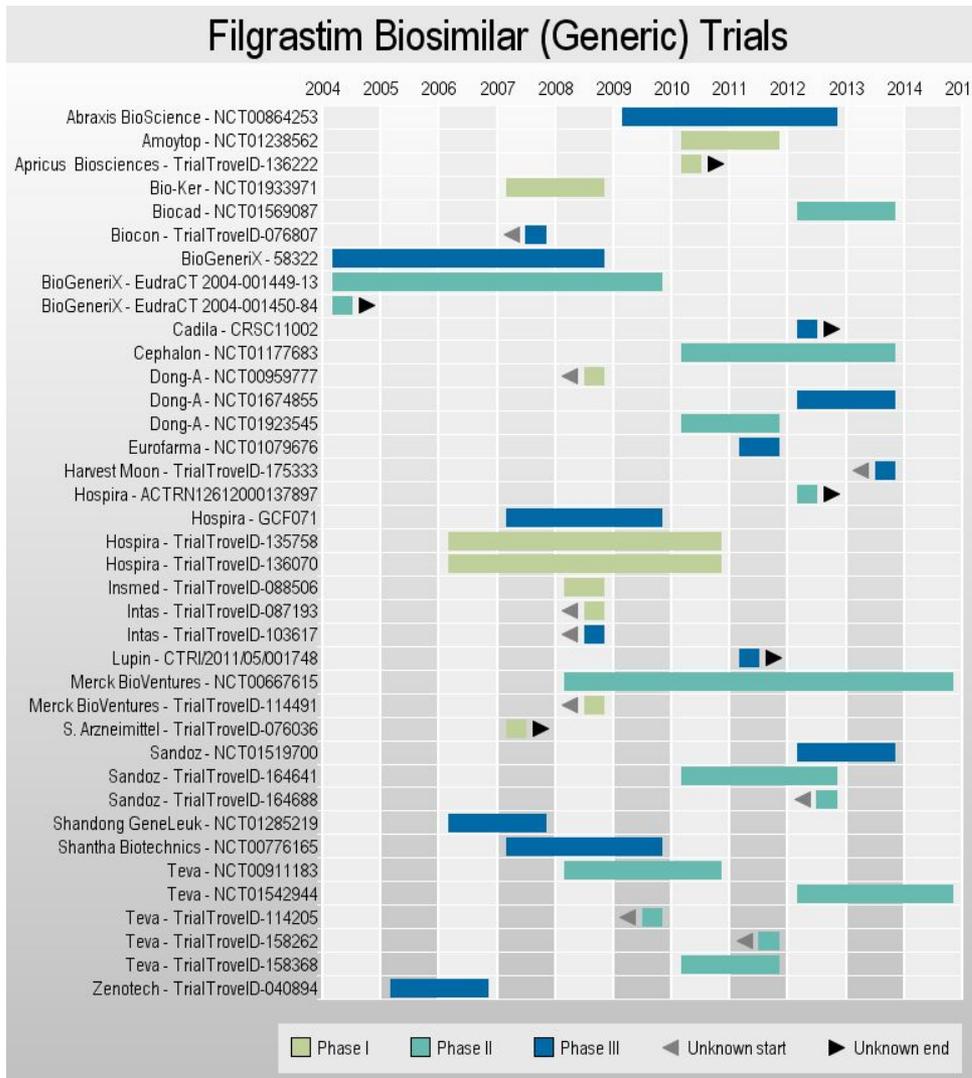


Matt Eberle
Product Specialist
*Formely at Wyeth,
Pfizer, Sunovion*



Barbara Gilmore
Application Consultant
Formerly Genentech, Kai

Creating a trial timeline...



...to identify competitor companies working on generic filgrastim biosimilars to benchmark potential product launch timing.

bizcharts.com/slides

Task 1: Search the trial databases

- Searched two clinical trials databases:
 - Citeline TrialTrove (TT)
 - ClinicalTrials.gov (CT.gov)
- Searched: Drug = Filgrastim

The screenshot displays the Citeline website interface. At the top, the Citeline logo is on the left, and navigation tabs for TrialTrove, Trialpredict, Sitetrove, and Pipeline are in the center. The text 'an informa business' is on the right. Below the navigation, there are tabs for Home, Search, Search History, and Watched Searches & Trials. The main content area is divided into two columns. The left column contains a 'Did You Know?' section with links for training, search results, updates, and analyst assistance, and a 'Support' section with a link for client services. The right column features a 'Clinical Trials By Therapeutic Category' section with links for Autoimmune Inflammation, Cardiovascular, Allergic Rhinitis, Asthma, Chronic Obstructive Pulmonary Disease, Lupus, Osteoarthritis, and Other Inflammatory Arthritis. A box in the bottom right corner highlights the ClinicalTrials.gov logo and its affiliation with the U.S. National Institutes of Health and the National Library of Medicine.

Task 2: Import and combine search results

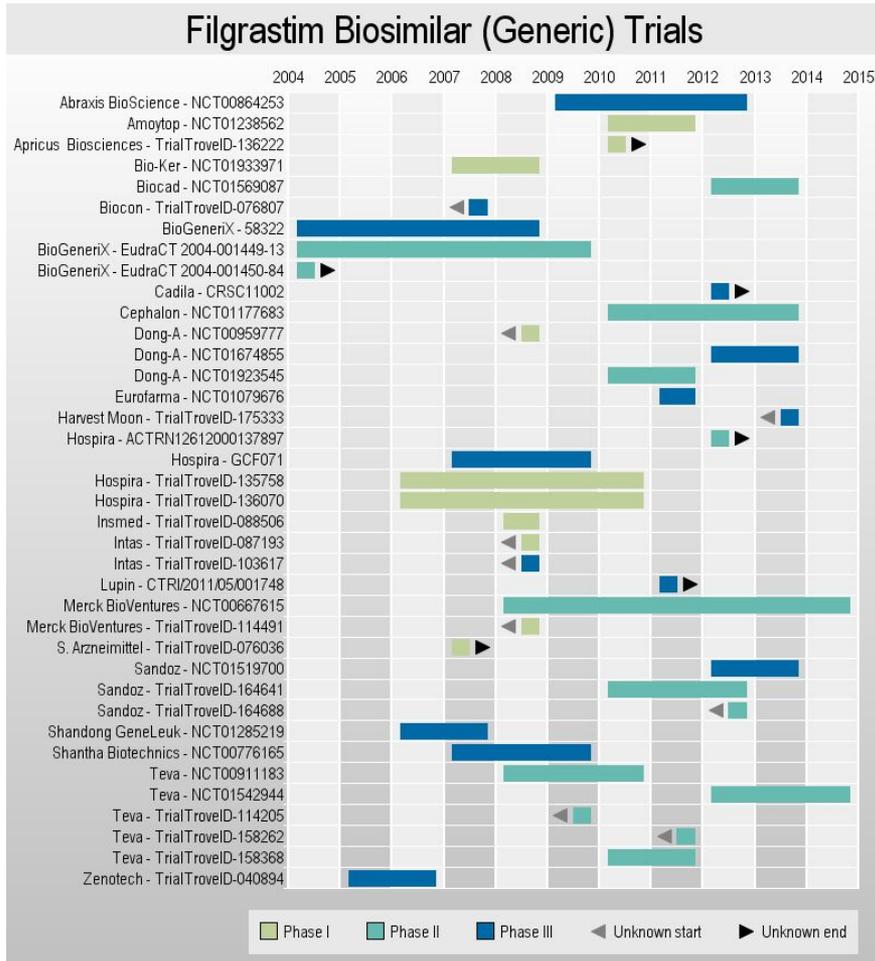
BizInt Smart Charts

for Drug Pipelines

3.6

- **Import** search results from TrialTrove and CT.gov
- **Combine** results into single report.
- Use **Identify Common Trial ID tool** to identify related trials across databases.
- Select the **columns** to display in the trial timeline (title, phase, sponsor, completion date, start date)

Task 3: Select the trial start and end dates



Need a trial **start and end date** for the timeline.

Cannot always find this information in the data. And sometimes the trial is ongoing.

TrialTrove: Available Date Information

Citeline TrialTrove: Filgrastim

	Trial Title
1	Phase I bioequivalence study of IN: in healthy volunteers.
2	Comparison of the Pharmacodynam Biosimilar Filgrastim and Amgen Fil from a Randomized, Phase I Trial.
3	Pharmacokinetic Profiles of a Bios And Amgen Filgrastim: Results Fro Phase I Trial
	A Phase I-II Study of Pentostatin, C Bituximab, and Mitoxantrone in Dr

Display Columns

Available Columns

- Internal Comments
- Investigators / Contacts
- Last Full Review
- Last Modified
- Notes
- Other Drugs
- Other Endpoints
- Patient Population
- Patient Segment
- Primary Endpoints
- Prior/Concurrent Therapy
- Record Number
- Record URL
- Reported Sites
- Study Design
- Study Keywords
- Supporting URLs

Selected Columns

- Trial Title
- Trial Identifier
- Primary Drugs
- Sponsorship
- Trial Phase
- Start Date
- Primary Endpoints Reported

Date Ranges

Search Fields

Start Date (mm/dd/yyyy) To (mm/dd/yyyy)

End Date (mm/dd/yyyy) To (mm/dd/yyyy)

TrialTrove “date” information includes trial “Start Date” and “Primary Endpoints Reported” date.

CT.gov: Available Date Information

The screenshot shows the ClinicalTrials.gov website interface. On the left, a table displays trial information:

	Trial Title
1	A Study Comparing Pegylated Filgrastim and Filgrastim in Support for Chemotherapy

Overlaid on the right is a 'Display Columns' dialog box. It contains two lists:

- Available Columns:** # Arms, Acronym, Arms, Countries, Detailed Description, Eligibility Criteria, Full Text Link, Gender, Healthy Volunteers?, Interventions, Maximum Age, Minimum Age, Num. Locations, Num. Recruiting, Original Title, Overall Official, Oversight, ...
- Selected Columns:** Trial Title, Drugs, Sponsor(s), Brief Summary, Overall Status, Primary Outcome, Secondary Outcome, Enrollment, Condition, **Start Date**, **Completion Date**, **Last Changed Date**

The 'Start Date', 'Completion Date', and 'Last Changed Date' items in the 'Selected Columns' list are circled in green.

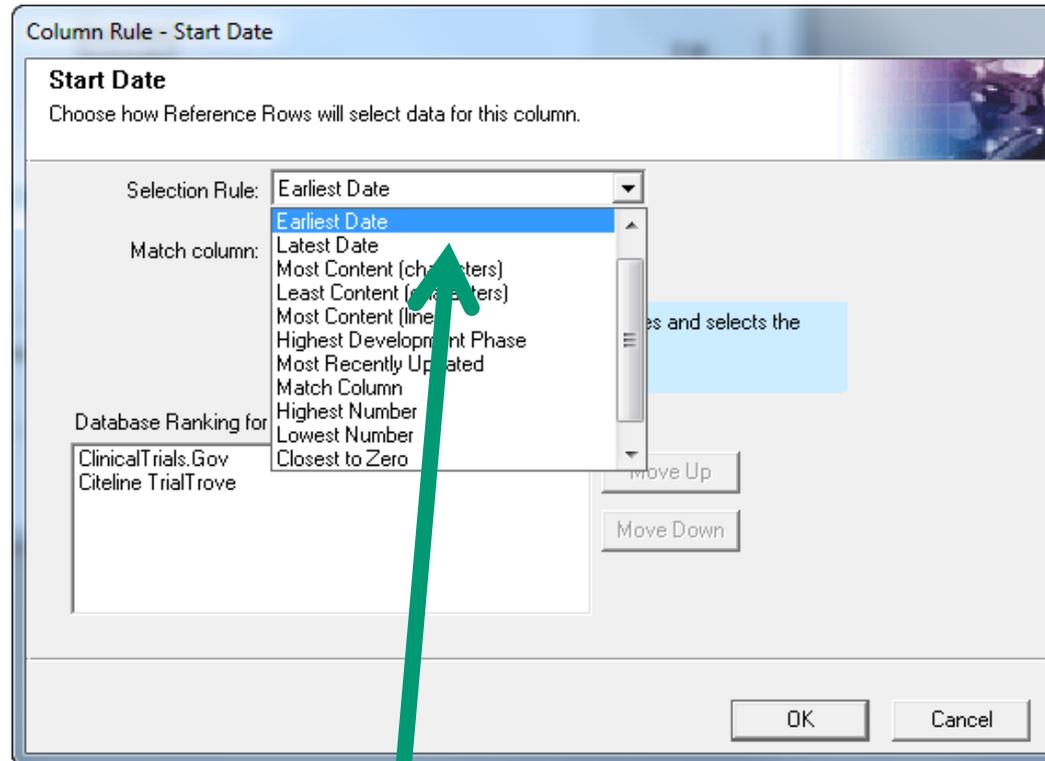
CT.gov date fields include "Start Date," "Completion Date" and the "last change date" for the record.

Task 3: Select the trial start and end dates

BizInt Smart Charts

Reference Rows™

- Merge data from different records for the same trial
- Use the Start Date from one record and the End Date from another.



Use the "Earliest Date" rule to select the Start Date.

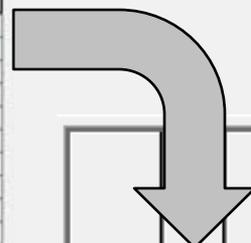
Task 4: Data necessary for the timeline



- **Start and end years** for each trial timeline bar
(2012-04-01, April 2008, 2013, 31 May 2006)
- **Trial phase** to color-code each trial
(I, II, Phase 1, Phase 2, Phase 1/Phase 2)
- **Company name and trial ID** to label each trial.
(e.g. Teva NCT00911183)

Extract the Year from each start/end date

	# Records	# Instances	End Date
1	2	2	2010-03-09
2	2	2	2011-11-07
3	2	2	2012-04-01
4	1	1	01 Dec 2013 (planned)
5	1	1	01 Oct 2010 (planned)
6	1	1	19 Oct 2011 (planned)
7	1	1	2006-01-01
8	1	1	2007-03-01
9	1	1	2008-04-28
10	1	1	2008-07-10
11	1	1	2009-03-01
12	1	1	2009-06-01
13	1	1	2009-09-20
14	1	1	2011-11-01
15	1	1	2012-10-19
16	1	1	2013-02-01
17	1	1	2013-04-06
18	1	1	2013-06-01
19	1	1	2014-05-01
20	1	1	31 May 2006 (actual)
21	1	1	April 2008 (Actual)
22	1	1	August 2011 (Anticipated)



	# Records	# Instances	End Date: Dates/Extract Years
1	7	7	2013
2	6	6	2011
3	4	4	2012
4	4	4	2009
5	3	3	2010
6	3	3	2008
7	2	2	2006
8	1	1	2024
9	1	1	2015
10	1	1	2014
11	1	1	2007

vantage
point
BizInt Smart Charts
Edition

Clean-up the Trial Phase terminology

The screenshot shows the VantagePoint SCE interface. On the left, a sidebar displays 'Common Trial ID' with '0 Titles, 0 Selected'. The main area contains two tables. A large grey arrow points from the top table to the bottom table, indicating a transition or update.

Table 1 (Top):

	# Records	# Instances	Study Phase
1	16	16	III
2	11	11	II
3	8	8	I
4	3	3	N/A
5	2	2	Phase 1
6	2	2	Phase 2
7	2	2	Phase 3
8	1	1	VII
9			
10			

Table 2 (Bottom):

	# Records	# Instances	Study Phase	Phase I	Phase I/II	Phase II	Phase III	Phase II/III	Phase IV
1	16	16	III						
2	11	11	II						
3	8	8	I						
4	3	3	N/A						
5	2	2	Phase 1						
6	2	2	Phase 2						
7	2	2	Phase 3						
8	1	1	VII						
9	1	1	Phase 2/Phase 3						
10	1	1	Phase 4						

vantage
point
BizInt Smart Charts
Edition

Append the Company to the Trial ID field

VantagePoint SCE - [VantagePoint1]

File Edit View Sheets Fields Groups Tools Scripts Window Help

Modify Script Menu...

AdunaClusterMap.vpm
BubbleChart.vpm
CompanyActivityGantt.vpm
CopySheets.vpm
ExportGroups2Excel.vpm
ExportGroups2Text.vpm
ExportList2Text.vpm
ExportTitleList.vpm
MakeBarFromListSelecti...
MakeDonutFromListSele...
MakeHorizontalBarFrom...
MakeLineFromListSelect...
MakePieFromListSelecti...
MarkUnique.vpm
MoveGroups.vpm
PlotList.vpm
PlotMatrix.vpm
TimelineGantt.vpm
WorldMap.vpm
WorldMapNonPatent...
CatenateFields.vpm

Common Trial ID

0 Titles, 0 Selected

1
2
3
4
5
6
7
8
9
10

VantagePoint

Choose an appropriate field for each category:

First Field Company

Second Field Common Trial ID

Restore Defaults OK Cancel

VantagePoint

Enter a name for your new field:

OK

Cancel

Company - Common Trial

vantage
point

BizInt Smart Charts

Edition

Task 5: Generate the trial timeline



- Scripts Window Help
- Modify Script Menu...
- AdunaClusterMap.vpm
- BubbleChart.vpm
- CompanyActivityGantt.vpm
- CopySheets.vpm
- ExportGroups2Excel.vpm
- ExportGroups2Text.vpm
- ExportList2Text.vpm
- ExportTitleList.vpm
- MakeBarFromListSelection.vpm
- MakeDonutFromListSelection.vpm
- MakeHorizontalBarFromListSelection.vpm
- MakeLineFromListSelection.vpm
- MakePieFromListSelection.vpm
- MarkUnique.vpm
- MoveGroups.vpm
- PlotList.vpm
- PlotMatrix.vpm
- TimelineGantt.vpm**
- WorldMap.vpm
- WorldMapNonPatent.vpm
- CatenateFields.vpm

VantagePoint SCE Browser

Timeline Gantt

Select the field to chart:

Company - Common Trial

Select a group All items in field

Select Start Year: Start Date: Dates/Extract Years

Select Completion Year: End Date: Dates/Extract Years

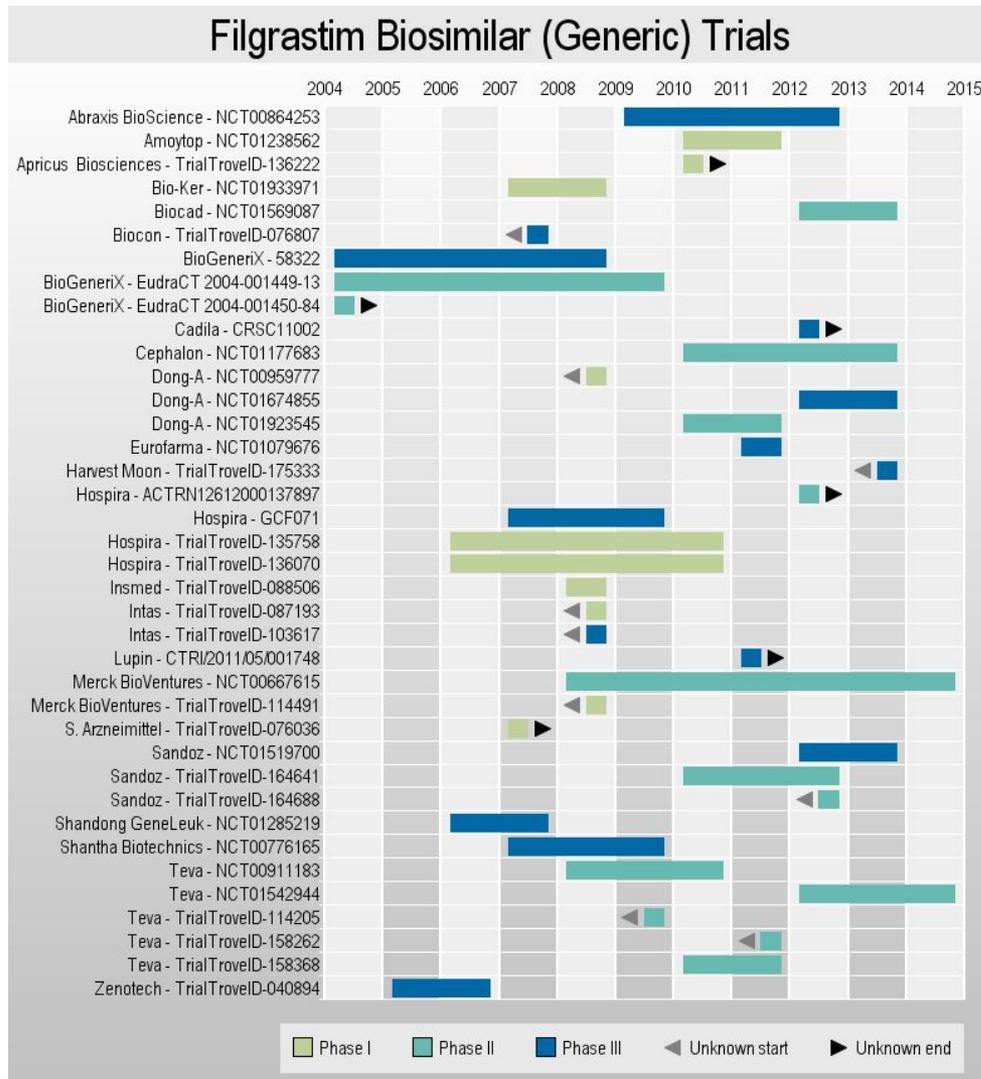
Select Phase Field: Study Phase

Name this timeline: Filgrastim Biosimilar (Generic) Timeline

The Gantt chart displays trial phases for various Filgrastim Biosimilar (Generic) trials from 2004 to 2015. The trials listed on the y-axis include: Abraxis BioScience - NCT00864253, Almotriptan - NCT01236562, Apricus Biosciences - TrialTroveID-138222, Bio-Kar - NCT01933871, Biocad - NCT01569087, Biocor - TrialTroveID-078607, BioGenex - 58322, BioGenex - Eudract 2004.004489.13, BioGenex - Eudract 2004.001451.84, Cadila - CDR011002, Cephalon - NCT01177683, Dong-A - NCT00959777, Dong-A - NCT01674855, Dong-A - NCT01922545, Eurafarma - NCT01073676, Hovord Moon - TrialTroveID-175333, Hospira - ACTRN12912000137897, Hospira - GCFO71, Hospira - TrialTroveID-135758, Hospira - TrialTroveID-136707, Inmed - TrialTroveID-088508, Intra - TrialTroveID-087183, Intra - TrialTroveID-102617, Lupin - CTR020110500748, Merck BioVentures - NCT00667615, Merck BioVentures - TrialTroveID-14491, S. Kocemil - TrialTroveID-070208, Sandoz - NCT01519700, Sandoz - TrialTroveID-104641, Sandoz - TrialTroveID-164698, Shandong Genet. suk. - NCT01282119, Shantha Biotechnics - NCT00778165, Teva - NCT00911183, Teva - NCT01542944, Teva - TrialTroveID-114205, Teva - TrialTroveID-156262, Teva - TrialTroveID-163038, and Zentech - TrialTroveID-040894. The chart shows phases I, II, and III for each trial, with some trials having unknown start or end dates.

Cancel OK

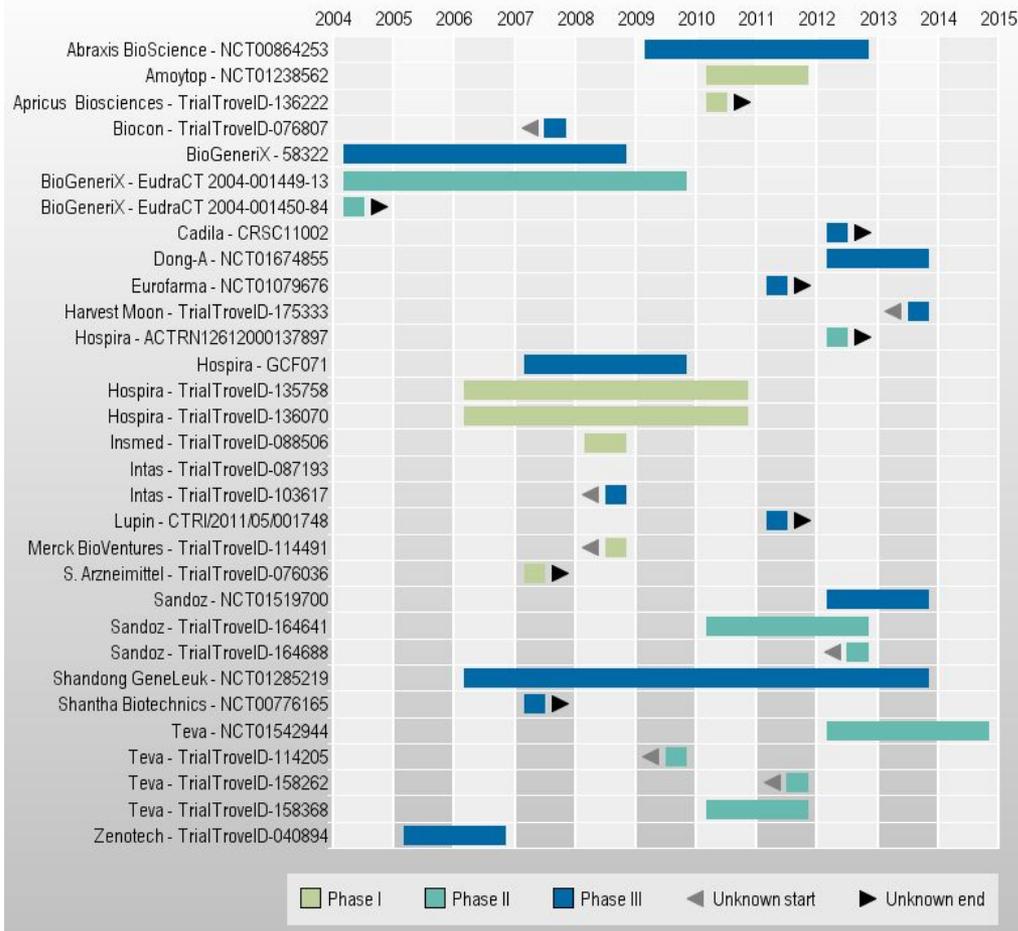
Now we can assess the trial landscape...



- + Data captures from different sources builds best picture
- + Identify trial milestones
- + Understand trial landscape before trials appear in conference papers & proceedings
- + Look for Phase 3 trial completion to focus your competitive intelligence searches for filing & launch information

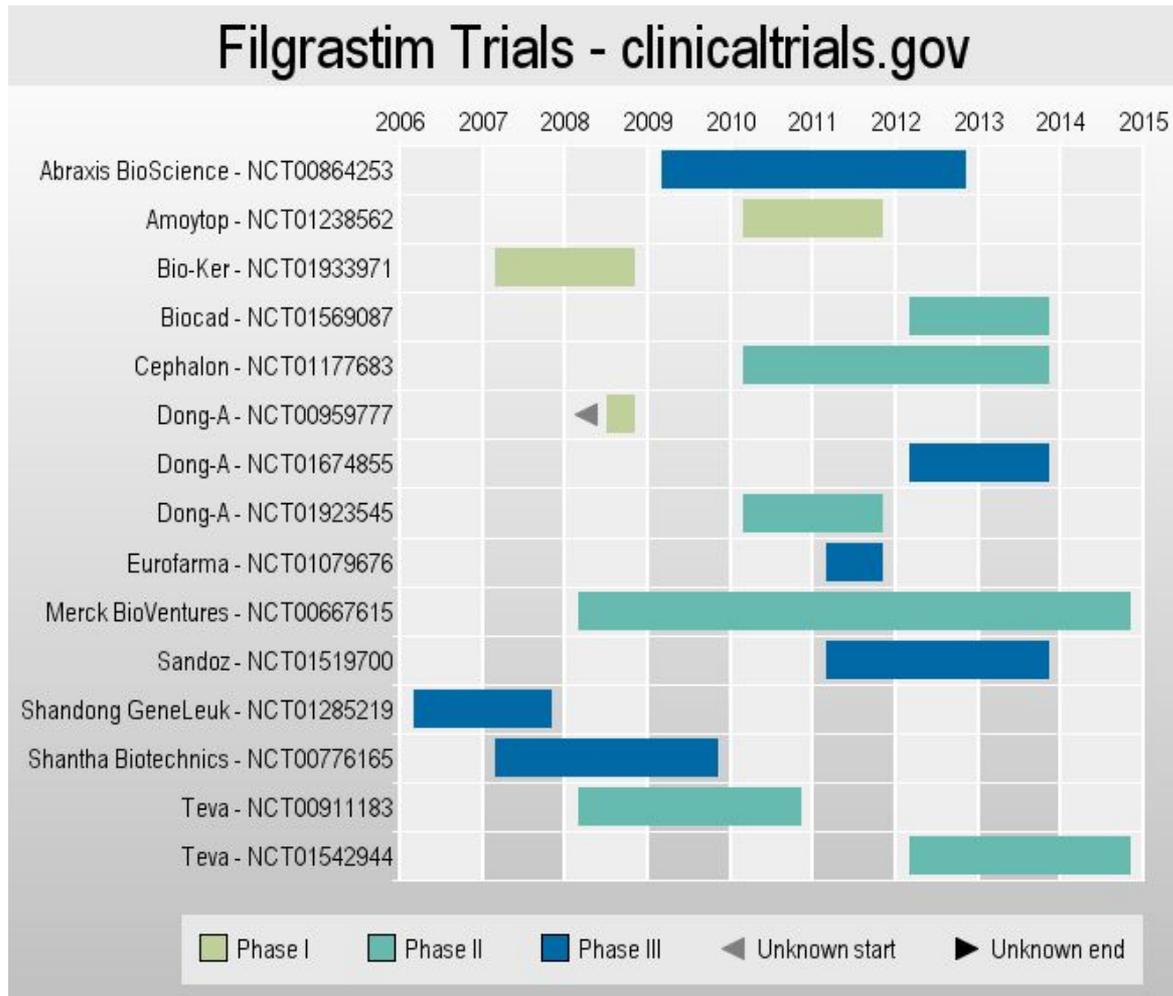
What if we searched only TrialTrove?

Filgrastim Biosimilar Trials (TrialTrove)



- * TrialTrove has broad coverage of global trial registries
- * TrialTrove does not consistently provide trial end dates.
- * Missed trials unique to other sources

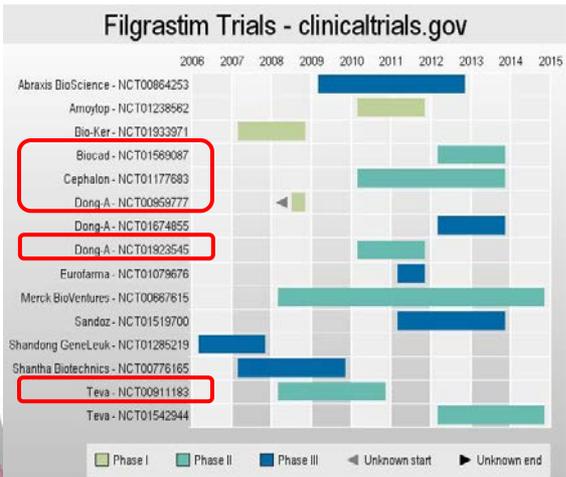
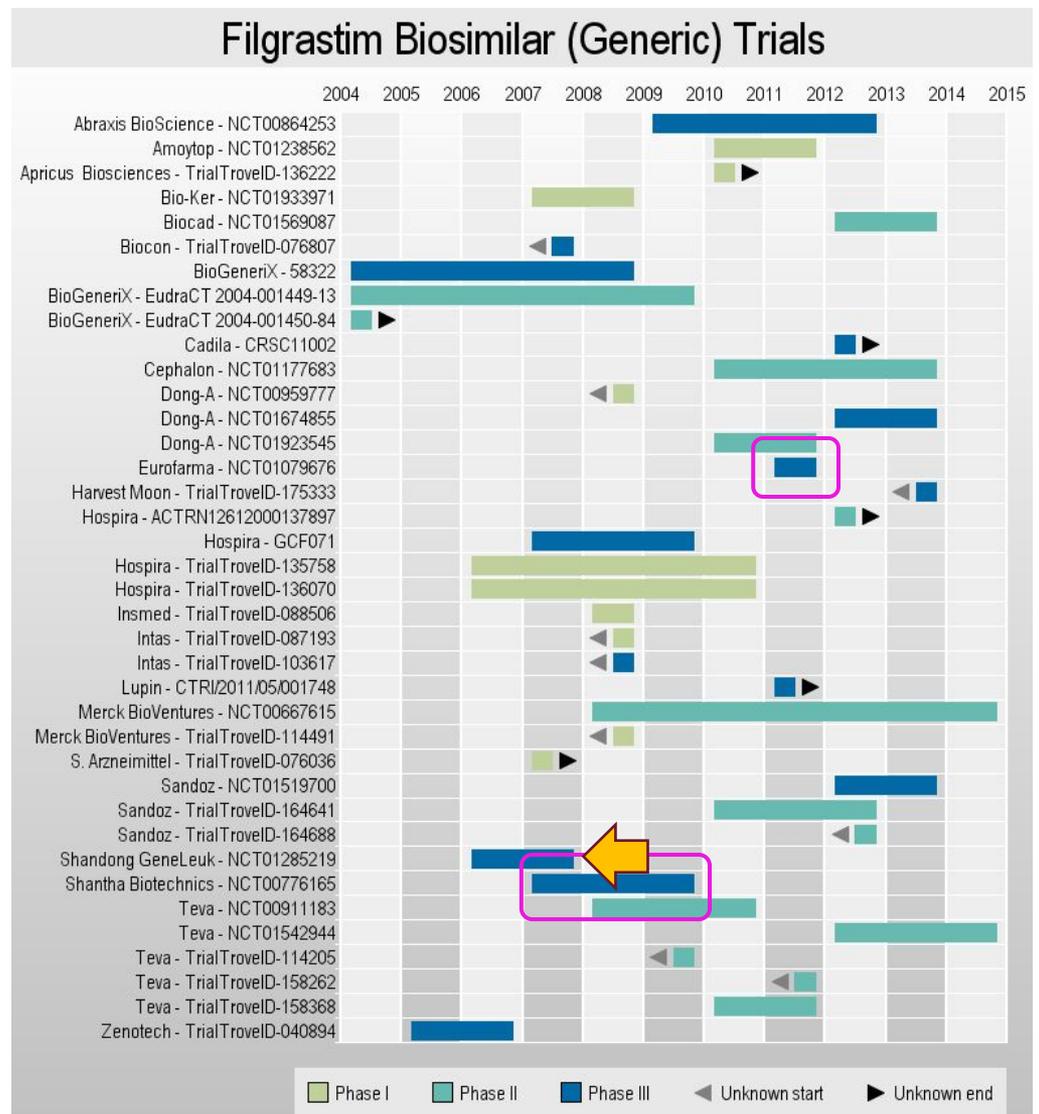
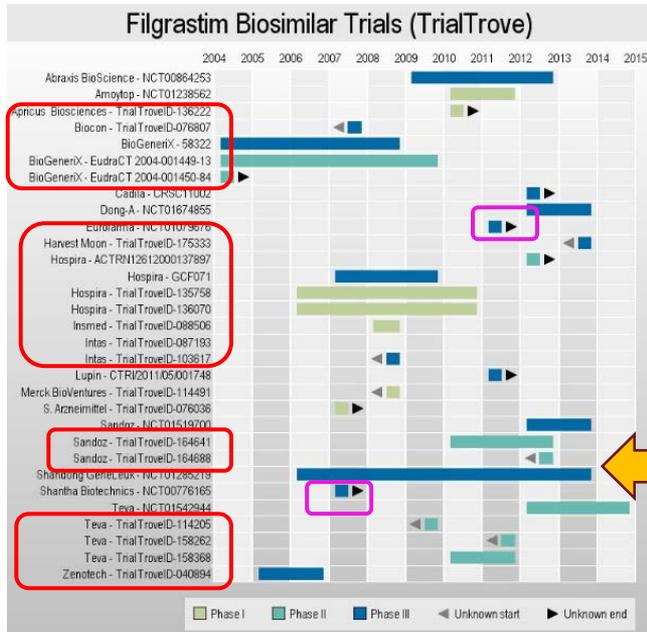
What if we searched only CT.gov?



* ClinicalTrials.gov is a US based and produced registry, with some global information.

* CT.gov filgrastim search identified 3 companies not picked up in TrialTrove.

We would miss significant trial data!



You Don't Know What You're Missing!

- No single database provides complete trial coverage.
- Even if field exists in a given database, it is not always populated.
- Database content can overlap – duplicate trial records can have different content.
- If you search multiple databases, you can capture more complete trial information.
- And you are in a better position to anticipate competitor milestones & product launches.

More sources could yield even better results

- **Adis Clinical Trials Insight**
- **Cortellis Clinical Trials Intelligence** (just announced)
- **European Clinical Trials Database** (*EudraCT*)
- And more...



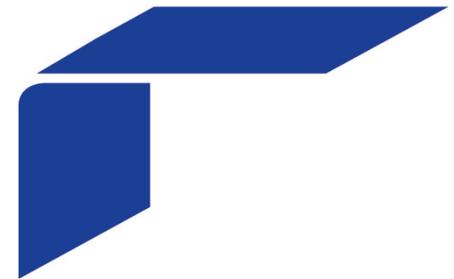


*Cookbook of
Reports and Visualizations*

CREATED WITH THE BIZINT SMART CHARTS
PRODUCT FAMILY



BizInt Smart Charts



**Come by our stand
to see the Cookbook!**

bizint.com/Cookbook