AdisInsight - Frequently Asked Questions

updated June 4, 2015

1. **What is AdisInsight?**
   AdisInsight is an integrated and easy-to-use database providing scientifically-based content compiled from multiple sources to provide access to relevant, unbiased records with clear referencing and links to original source across publishers. AdisInsight brings together the most relevant data on the development of drugs, clinical trials, adverse drug reaction case reports, and the latest mergers, acquisitions, and licensing opportunities.

2. **How do I log into AdisInsight?**
   Visit: AdisInsight.Springer.com
   If you have a login for another Springer product, you can use that information to access AdisInsight.Simply visit the URL, enter yourUserID (your email address) and password. If your organization is IP authenticated, you will be able to begin using the site immediately.

3. **How do I create a passcode?**
   From the home page, select 'Sign up/Log in' link in upper right corner. Follow instructions under 'Don't have an account?' heading.

4. **I just created an account, why can't I access the database?**
   After you create an account, the AdisInsight Administrator for your organization will need to 'associate users' in order for your account to be recognized as valid. Once your Administrator enters your email address in the Admin panel, and sends invite, you will receive an email with a link which you should click on to complete the process.

5. **What sources are monitored?**
   Our scientific editors monitor thousands of sources daily including: medical journals, press releases, conference proceedings, company websites and pipelines, trial registries, and regulatory agency websites.

6. **What ontology does AdisInsight follow?**
The indications and adverse events used in AdisInsight are primarily aligned with MeSH terms. In recent years, we have also used MedDRA as an alternate source. We don't have different options to choose a dictionary to search by disease terms; we only have our list of Adis terms.

Adis drug names are primarily aligned with INNs but also may include company drug codes and vaccine names which are not INNs.

The WHO Drug Dictionary is also primarily aligned with WHO.However, when searching by drug name/classes, you can choose our Adis terms to search by, but you can also search by EPhMRA, WHO or CAS codes. This provides four dictionary options for drug names/drug classes.

7. **How can I search for PDUFA Dates in AdisInsight?**
If you want to see which PDUFA dates are current (i.e. still pending) then use free text = PDUFA AND Update date is for change to Pre-registration for example, 1 year ago (or you can make it longer). PDUFA dates are given usually around the time a regulatory submission is made; hence the reason for this search structure. Usually a submission is reviewed (in the US) within about 10-12 months; longer in the EU (<= 15 months). You can then review each profile to understand whether the PDUFA dates are still current or whether the submission has already been approved for that indication, in which case the PDUFA date is obviously irrelevant.

8. **Clinical Trial Registries covered – National registries highlighted in yellow**

ClinicalTrials.gov (US)
ISRCTN: Current Controlled Trials

M.D. Anderson Cancer Center
Barbara Ann Karmanos
National Cancer Institute of Canada
UMIN (Japan)
Mayo Clinic
Memorial Sloan-Kettering Cancer Center
University of Southern California/Norris
Robert H. Lurie
Vanderbilt Clinical Trials and Vanderbilt-Cancer Trials
EuropeanClinical Trials Database (EudraCT)
Oregon Health and Science University
UK Clinical Trials Register
Australia & New Zealand Clinical Trials Register
Netherlands Clinical Trials Register
China Clinical Trials Register
India Clinical Trials Register
Brazilian Clinical Trials Register
Clinical Research Information Service (CriS)-Republic of Korea
Cuban Clinical Trial Registry
German Clinical Trial Register
Iranian Registry of Clinical Trials
Pan-African Clinical Trial Register
Sri Lanka Clinical Trials Registry

9. Patents

We do capture patent information when it is available. However, this info is not included within every profile. If it is captured, it appears below the key development milestone section. To locate compounds with patent information, you can always build your search query and then append with the term 'patent' in the full text search to see if this content is available. The patent information included within our database is sourced from media releases and Credit Suisse data.

10. What does "Research" mean when noted in the Phase field?

By our definition, research is the earliest stage of development that RDI covers. It is the very early stage of the program where bench analysis is taking place. This includes in vitro work, target exploration, receptor binding studies, etc. Research is considered active development. It is the stage prior to preclinical work which is the next stage of development where molecules are tested in animals.

Conversely, inactive development includes suspended, discontinued or no development reported. Although, with 'no development reported' there may be development going on however, no progress has been reported for a substantial period.

11. What Journals are covered in AdisInsight?

We currently monitor 936 journals for trials and an additional 5,960 journals for safety.

12. How many therapeutic areas does AdisInsight include?

AdisInsight covers 54 therapeutic areas.

13. How long between drug updates before we consider a drug no longer active or discontinued?

When a certain period of time elapses and we have heard nothing to suggest that any new developments have taken place, we will report that no recent development has been reported. This period ranges from 3-4 years for a research programme and approximately 2 years for a programme in clinical development for a particular indication. We always check to see whether the clinical trial that was ongoing is an extended trial in which case we may just leave the programme active even though no new development have been reported for that line of investigation. The NDR status is an indication for the user that we have heard nothing new about development in that area and we can't confirm that the company has stopped development altogether (discontinued). If we can confirm that development has stopped either for the drug programme as a whole or for a particular disease area then we will update the status to discontinued. When a company reports activity as "Suspended development" we update our records accordingly.

14. What is AdisInsight's definition of a small molecule?

We define drugs as small molecules if their molecular weight is less than 800 Daltons. We don't follow Lipinski's rule of 5 strictly because we find that many companies these days consider their drugs to fall

into the small molecule category when they have mol weights above that of 500 Daltons which is a criteria of Lipinski's rule of 5.

15. If a drug is discontinued in all areas of its development, how long does it stay in AdisInsight?
Once a drug is added to our database, it remains in our database indefinitely.

16. What is the inclusion criteria for adding Drugs to AdisInsight?
AdisInsight: Drugs includes all new and novel prescription drugs in development, across all therapeutic areas, where a corporate entity is involved.

17. What is the inclusion criteria for adding Trials to AdisInsight?
AdisInsight: Trials covers all clinical trials for drugs profiled within AdisInsight: Drugs.

18. What is the inclusion criteria for adding Safety data to AdisInsight?
AdisInsight: Safety summarizes the published adverse drug reaction case reports and the world's adverse drug reaction news for all drugs.

19. What is the inclusion criteria for adding Deal information to AdisInsight?
AdisInsight: Deals includes summaries of the agreements between organizations for pharmaceutical products in R&D.

20. Why is the CSV file I exported unreadable?
In order to view CSV files, the separating value in your file should be set as "comma." Typically, in the US and UK this is the default. However, if you are outside of these regions, you can check your settings by following these steps:
1. Select Windows Start Menu
2. Click Control Panel
3. Open the Region and Language dialog box
4. Select Additional settings
5. Type a new separator in the List Separator box
6. Click 'Apply'
It may be necessary to reboot your system to see these changes.

21. I exported data to a CSV file and all content appears in one column. How can I display in multiple columns?
Open the csv file:
Highlight column A
1. Select Data tab
2. Text to Columns
3. Delimited, 'NEXT'
4. Check 'Comma,' and NEXT
5. select Finish

You will need to insert a row with the headers.

22. Why can't I save my searches or set up an alert?
In order to save searches and set up email alerts, users need a personal account

(Username/password) set up and linked to the institution in order to save searches and create alerts. You can create a personal account from the home page.

> Select 'Sign up/Log in' link in upper right corner.
> Follow instructions under 'Don't have an account?' heading
> Then your account administrator will associate your account with your organization in the AdisInsight/Springer Admin panel.

23. What are the system requirements?

There are no specific OS requirements as all major browser types are supported. However, it is preferred that IE users are using version 9 or later.

24. I created an Advanced Search query with an update date.Why are the approximate results different than what appears on the results page?

The search results estimates that appear on the Advanced Search query page are not accurate when searching by update date. In some cases they are drastically different because the estimates are calculated using indexes and not the search itself. To calculate the estimate for update date we count all the profiles where any update date meets the search criteria and any update date events are significant. In the search we include the profile only if the update date that meets the search criteria is also a significant event. We do it this way because it is much faster to estimate using indexes than the actual search.

When you execute the search by clicking the 'Show Results' button, you will see the correct profile results on the results page.

25. I have additional questions, who can I contact?

Our global team is available to answer any additional AdisInsight questions you may have. Contact our experts via this email.

26. Steps for creating a BizInt Charting report

1. BizInt Web Charts for AdisInsight will open. Click 'OK' to import the selected records and create a new chart.
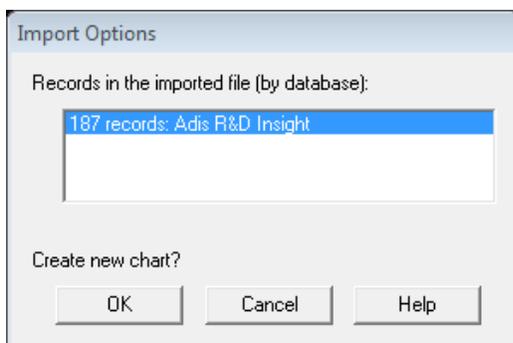
2. Adis has designed several templates to aid in analysis of clinical trial information.

Select the template that best matches the analysis you need to perform. Each template can be modified and customized to best meet your needs. Select a chart and click 'ok.'
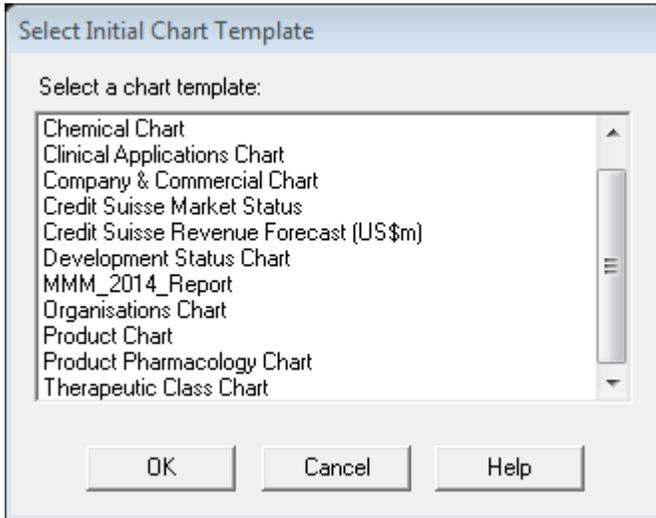
3. Select the columns image on the tool bar to modify the columns viewed within your chart.
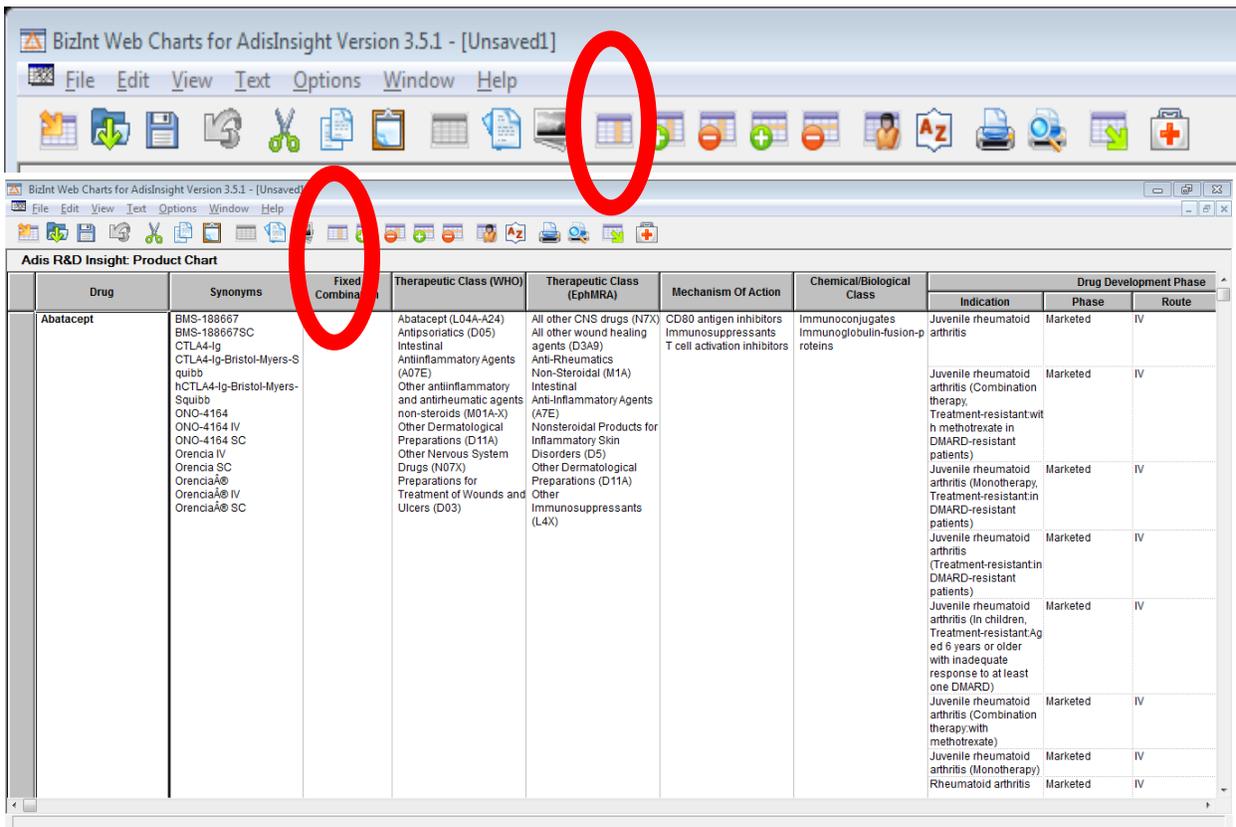
4. Add the columns you would like to view, to the right Selected Columns
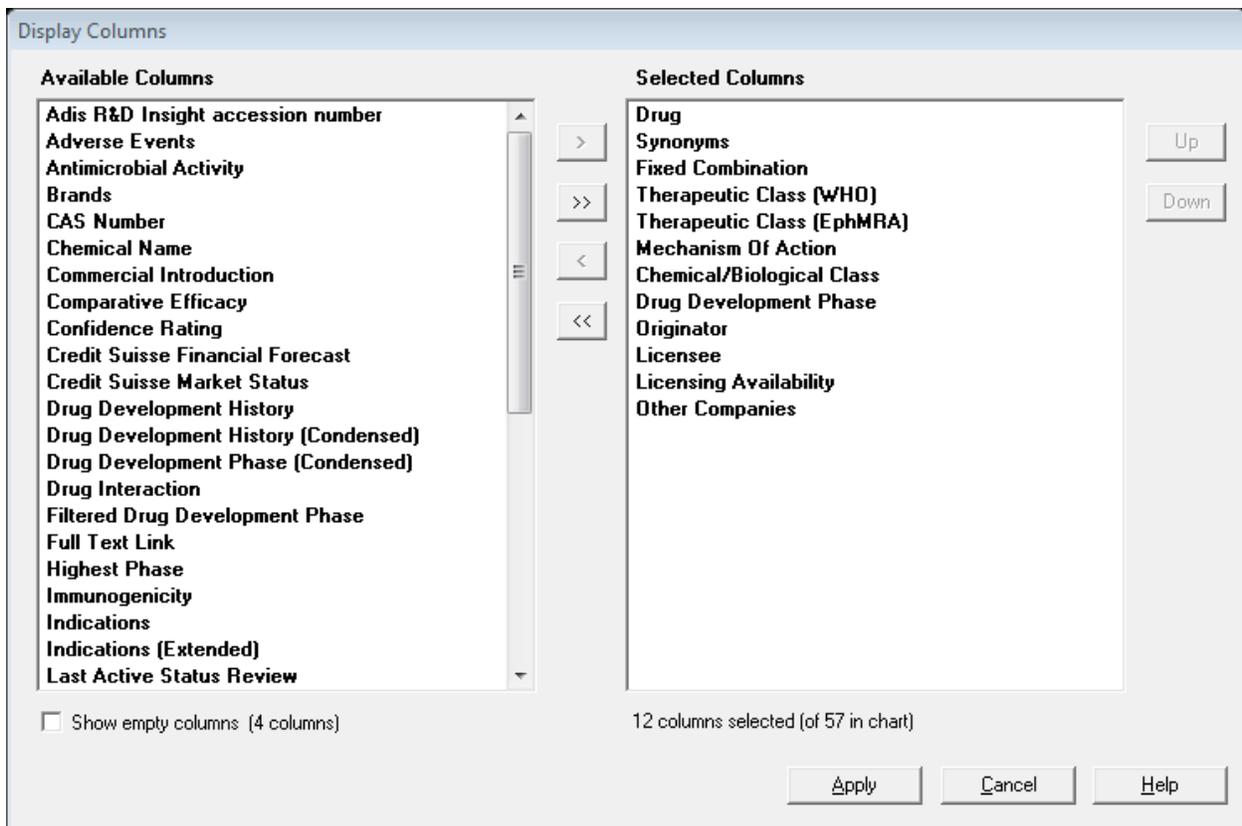
5. When finished creating your chart, select the export option on the toolbar.
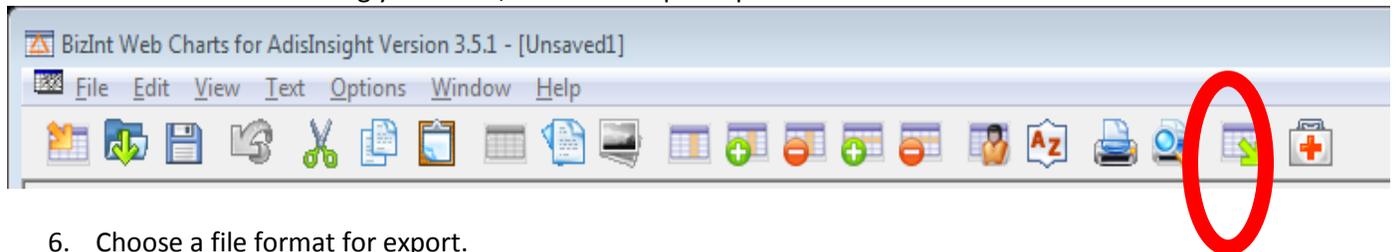
6. Choose a file format for export.