MEDDEVICETRACKER
CITELINE COMMERCIAL

Meddevicetracker FAQs

Contents

What can I ask Meddevicetracker's analysts and how do I contact them?

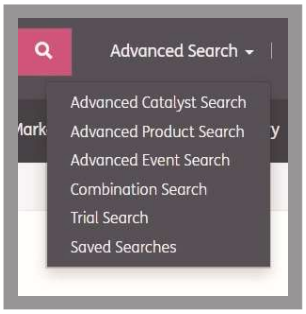
Meddevicetracker's analysts are available to answer a variety of questions - from financial to scientific. Some past questions the analysts have provided a solution for include:

1. How do I figure out when the new AbbVie Humira injection device may come to market?
2. I need information on clinical trials for balloon catheters used to treat peripheral artery disease or limb ischemia. I need to find out what trials are occurring and what trials are planned over the next year or two.
3. How do I find a list of all of the bead and sphere devices that treat liver cancer?
4. How can I find a list of all of the companion diagnostics for lung cancer?
5. What are the trends in the autoinjectable/PEN market in the treatment of diseases like Obesity and PCSK9 therapy?
6. Do you have any data on Medtronic and competitors developing heart valve replacements?

To contact our Ask the Analyst service, email us at mdtaskanalyst@sagientresearch.com. Or click on the Ask the Analyst button in the top right corner of Meddevicetracker.

How do I use the Advanced Product Search?

Once logged in, click on the Advanced Search drop-down menu on the top rightside of the home screen. Navigate to the Advanced Product Search on the drop-down menu.



You can then track upcoming milestones for products of interest and stay up-to-date on product events related to trials, regulatory filings/ approvals, reimbursement, partnering, and product launches. Simply type the product/ brand name into the filter box. You can choose to refine your search by company, product, phase, product type, indication and keyword.

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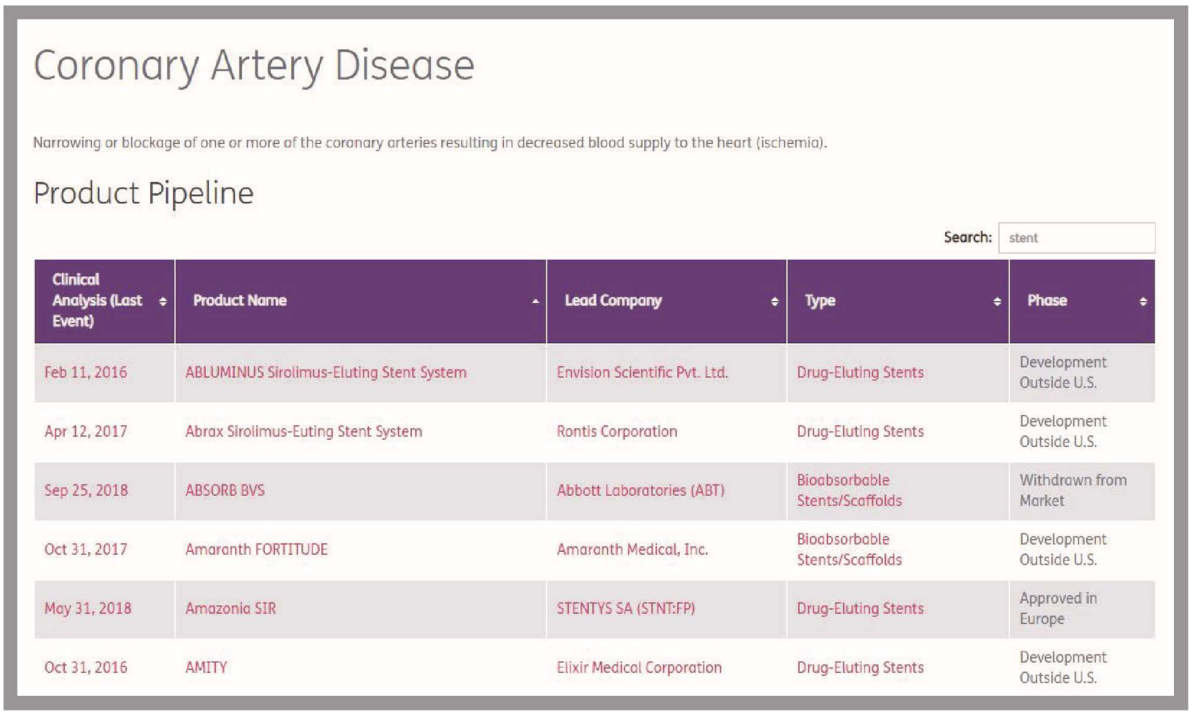
How can I search by product type and indication?

You can search across the entire database for products by both product type and indication. From the indication report, use Search box to type the product type.



Coronary Artery Disease

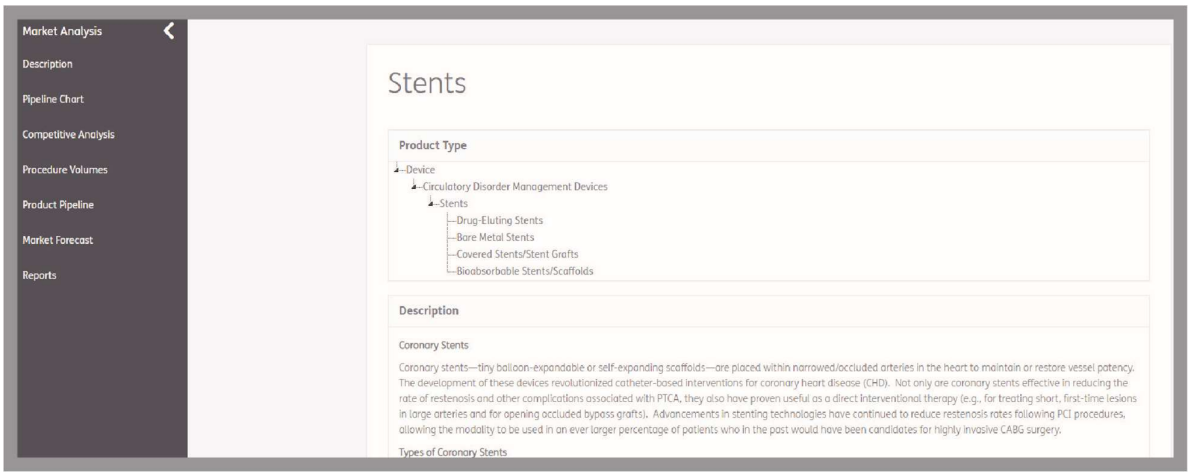
Narrowing or blockage of one or more of the coronary arteries resulting in decreased blood supply to the heart (ischemia).

Product Pipeline

Search: stent

Clinical Analysis (Last Event)	Product Name	Lead Company	Type	Phase
Feb 11, 2016	ABLUMINUS Sirolimus-Eluting Stent System	Envision Scientific Pvt. Ltd.	Drug-Eluting Stents	Development Outside U.S.
Apr 12, 2017	Abrax Sirolimus-Euting Stent System	Rontis Corporation	Drug-Eluting Stents	Development Outside U.S.
Sep 25, 2018	ABSORB BVS	Abbott Laboratories (ABT)	Bioabsorbable Stents/Scaffolds	Withdrawn from Market
Oct 31, 2017	Amaranth FORTITUDE	Amaranth Medical, Inc.	Bioabsorbable Stents/Scaffolds	Development Outside U.S.
May 31, 2018	Amazonia SIR	STENTYS SA (STNT:FP)	Drug-Eluting Stents	Approved in Europe
Oct 31, 2016	AMITY	Elixir Medical Corporation	Drug-Eluting Stents	Development Outside U.S.

Once you click into the Product Type you are interested in, you will be able to view all products that fall into that product type classification. In addition, you will be able to navigate to sections of interest using the left side navigation.



You can also use the Advanced Product Search to search across both product type and indication. From the Advanced Product Search, use the Product Type and Disease Group/Indication trees to select your area(s) of interest.

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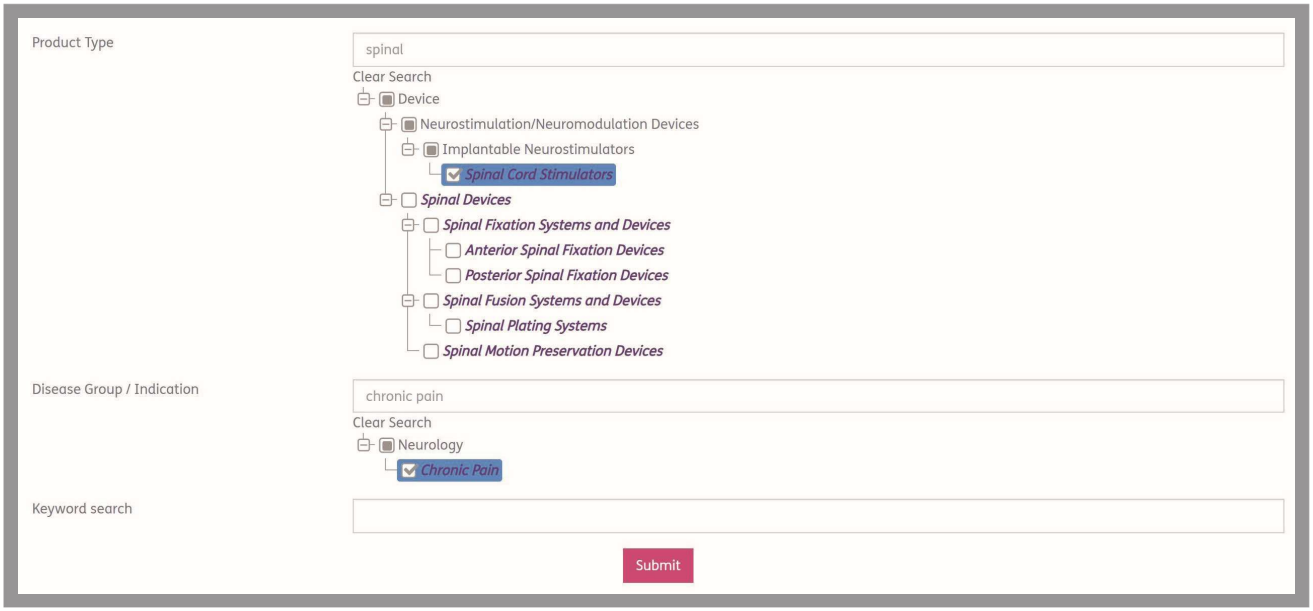
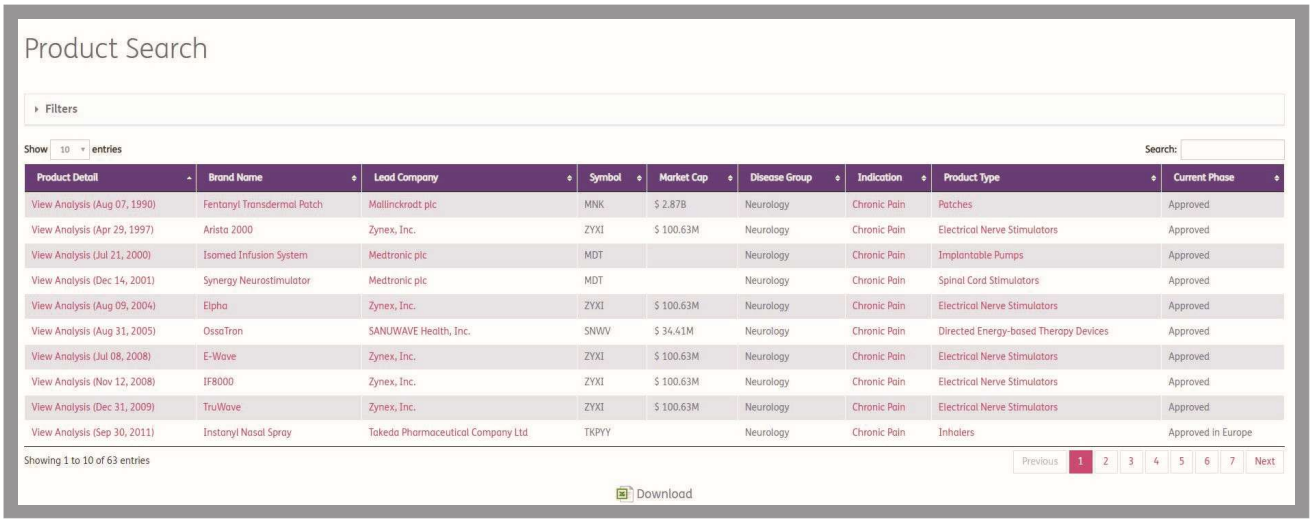


How do I download a company pipeline or indication pipeline into Excel?

Once logged in, navigate to the Advanced Product Search via the Advanced Searches drop-down menu.



Select your chosen company(ies) or indication(s) and click ‘Submit’. On the results page, an Excel icon will appear below the list of products, click this to download as an Excel Spreadsheet.

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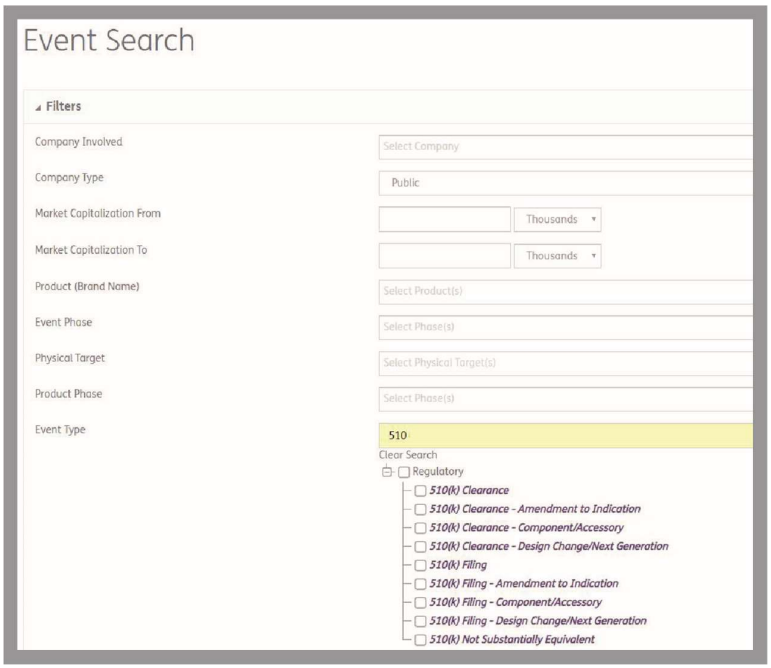
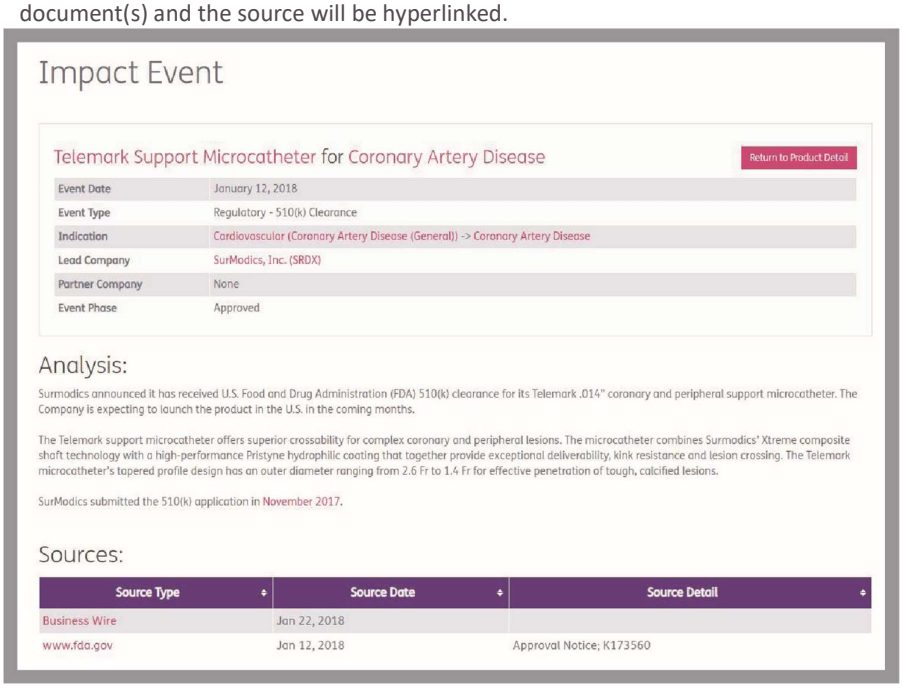
How do I find approval documents relating to a device or diagnostic

In order to locate approval documents relating to a device or diagnostic, run an Advanced Event Search for the type(s) of approvals you are looking for. Select the event types of interest.



Once the search results load on the page, click into the approval event. The source for the approval event will be the approval document(s) and the source will be hyperlinked.



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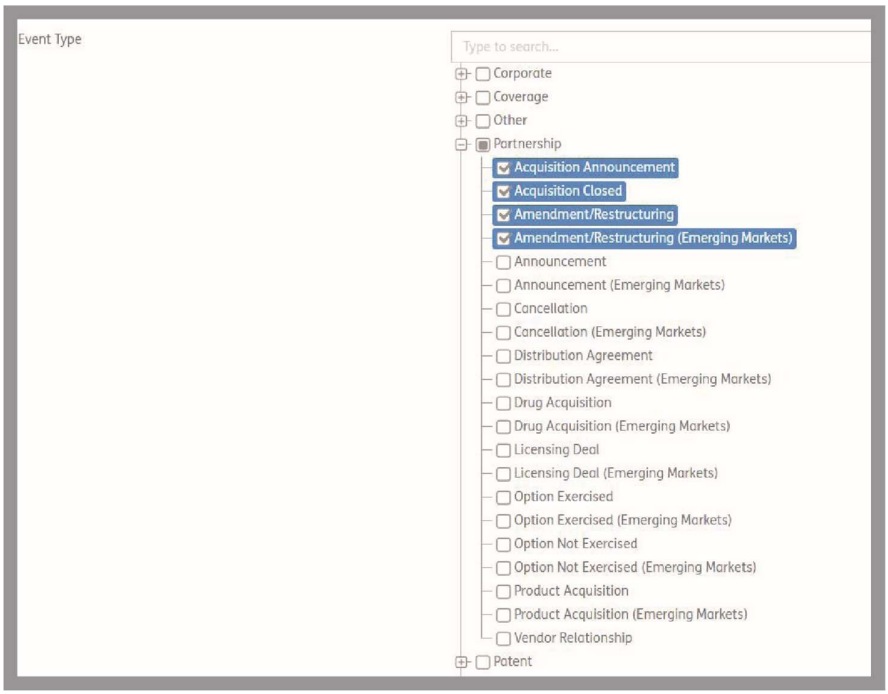
How can I find M&A and licensing deal information

Meddevicetracker does have M&A and licensing data on the platform. To find this information, first go to the Advanced Event Search. Next, find the Event Types parameters and select the Partnership events.



For licensing deals, use the Partnership-Licensing Deals event type. For M&A activity, use the PartnershipAcquisition or Partnership-Product Acquisition event types.

Should you need any assistance with this search, please use our Ask the Analyst service at mdtaskanalyst@sagientresearch.com.

What kind of sources does Meddevicetracker use?

Daily updates are accumulated through news releases, earnings calls, SEC filings, company websites, regulatory sites, journals and publications.

New approvals, would be captured on a company website if they issue a press release or through the FDA's Medical Devices website.

Advisory panel meetings are also tracked and the analyst team will add impact events based on the FDA briefing documents when they become available. Descriptions and indications of approved products are often based on regulatory documents. We directly source individual approval letters for 510(k), PMA, De Novo, HDE, and CLIA, if available.

If you have any questions about sources, please use our Ask the Analyst service at mdtaskanalyst@sagientresearch.com.

How are pivotal trials defined in Meddevicetracker

Trials marked as pivotal are the trials companies will use as the basis for approval for their products. These often will have significant data released that the companies will use in their filings.

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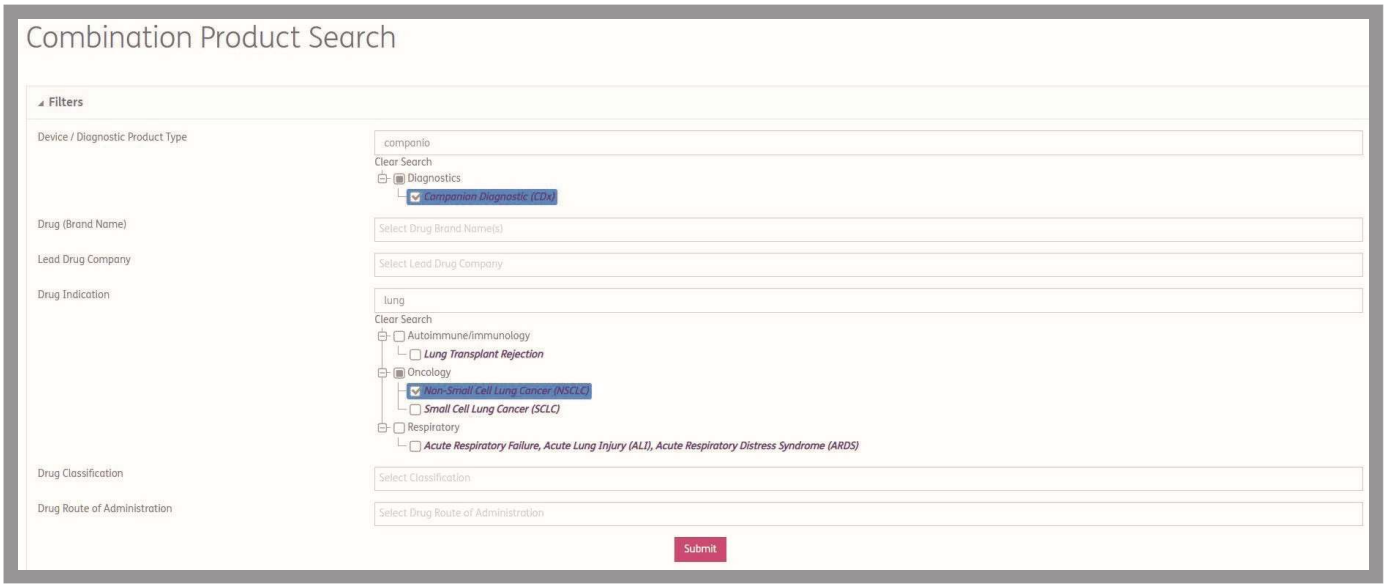
How do I search for all companion diagnostics for non-small cell lung cancer?

To search for companion diagnostics for non-small cell lung cancer, use the Combination Product Search, and select the Device Type companion diagnostics and Drug Indication non-small cell lung cancer (NSCLC).



How do I find digital health products for the diabetes market

Meddevicetracker's digital health coverage encompasses medical devices that can communicate with other devices or systems.

Inclusions

- Artificial intelligence algorithms used within medical devices, such as continuous glucose monitors (i.e. artificial pancreases), CGM's that do not require finger sticks, and wearable ECG/heart monitor devices (i.e. Apple Watch)
- Connected devices (i.e. devices that transmit data - usually using Bluetooth to a mobile app, website portal, etc.)
- Mobile applications that treat a condition or is indicated for a disease
- Wearable devices
- Wireless medical devices
- Software based treatment platforms (i.e. software as a medical device - usually FDA approved or undergoing approval process)

Exclusions

- Artificial intelligence imaging or diagnostic based software/systems
- Health information technology
- Medical device data systems
- Mobile applications used for general wellness (i.e. calorie counting/weight loss, meditation, general mental health, activity monitors)
- Telehealth and telemedicine

To find digital health products for diabetes, use the Advanced Product Search. Within the Product Filters section, select Disease Group/Indication Diabetes and Digital Health Product "Yes".

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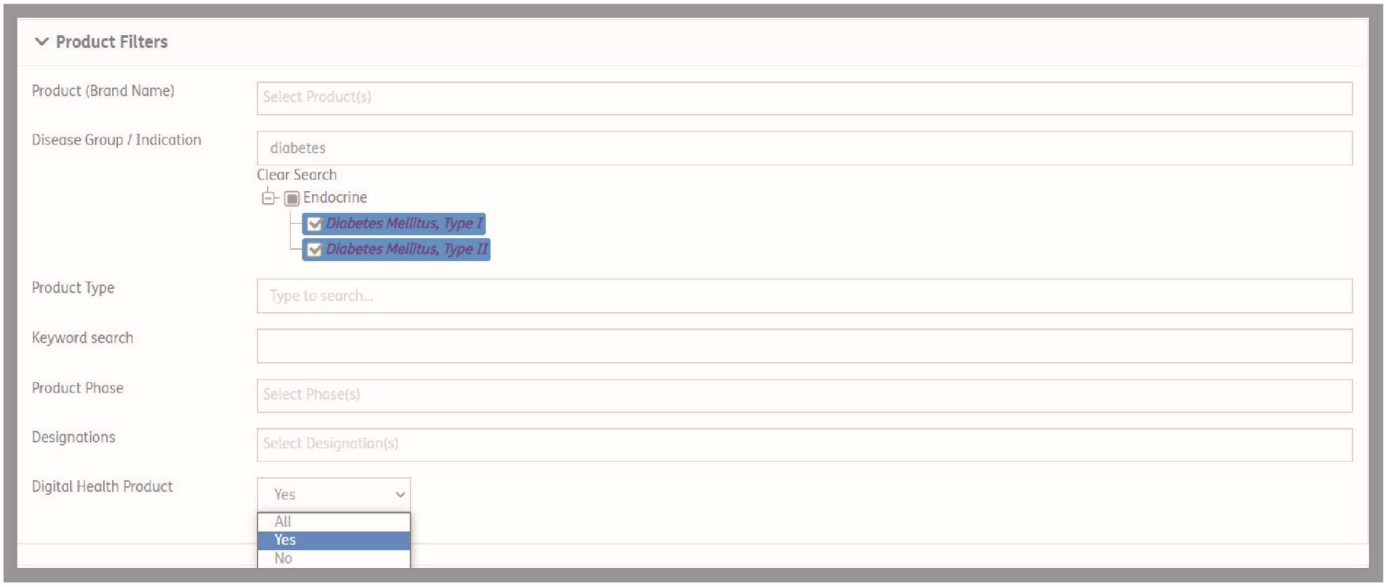


How do I find a list of all hip implants that are approved in Europe

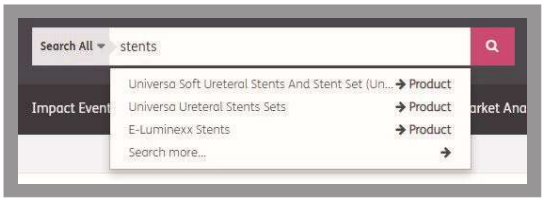
To find a list of all CE Marked hip implants, use the Advanced Product Search. Select CE Marking "Yes" from the drop-down selection in the Approvals Section.

And then select the Product Type "Implantable Hip Repair and Replacement Devices".

This will generate a list of all the CE Mark Approved products in the Implantable Hip Repair and Replacement devices market.

How do I find a market forecast for the stent market

Market forecasts can be found either in a full market report, or in the Market Analysis modules, which are organized by product type. The best way to locate either of these, is to use the Quick Search. Select "Search more…" to generate a list of all results.



This will generate a list of all metadata in Meddevicetracker with the word/ phrase "stents".

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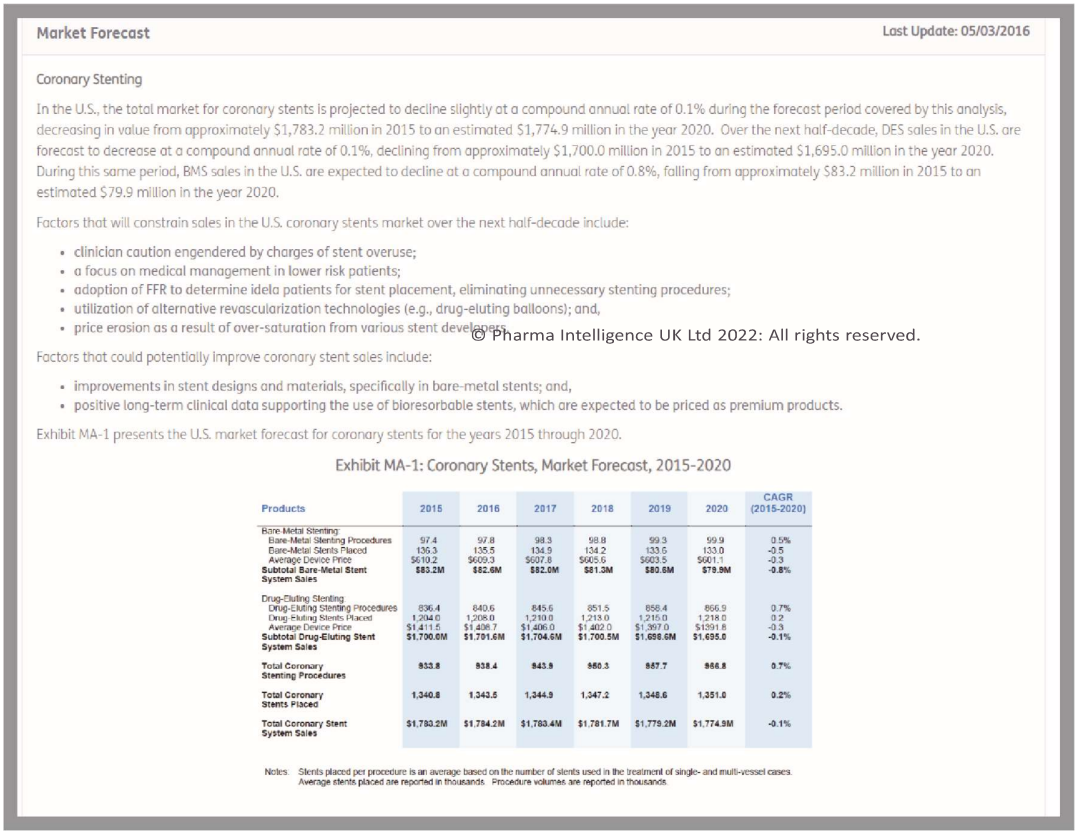
Product Types

Show 10 entries

Product Type	Number of Products	Competitive Analysis	Procedure Volumes	Market Forecast	Reports
Drug-Eluting Stents	93			05/04/2016	4
Stents	359	05/05/2016	05/03/2016	05/03/2016	5
Esophageal Stents	4				
Laryngeal and Tracheal Stents	3				
Microstents	4				
Bare Metal Stents	129				4
Biliary Stents	23				
Bioabsorbable Stents/Scaffolds	28				4
Covered Stents/Stent Grafts	75				3

You can go directly to the market forecast for stents by clicking on the Market Forecast date.
You'll be able to view the relevant 5 year market forecast for stents", as well as use the left side navigation to find other analysis of interest.



Market Forecast — Last Update: 05/03/2016

Coronary Stenting

In the U.S., the total market for coronary stents is projected to decline slightly at a compound annual rate of 0.1% during the forecast period covered by this analysis, decreasing in value from approximately $1,783.2 million in 2015 to an estimated $1,774.9 million in the year 2020. Over the next half-decade, DES sales in the U.S. are forecast to decrease at a compound annual rate of 0.1%, declining from approximately $1,700.0 million in 2015 to an estimated $1,695.0 million in the year 2020. During this same period, BMS sales in the U.S. are expected to decline at a compound annual rate of 0.8%, falling from approximately $83.2 million in 2015 to an estimated $79.9 million in the year 2020.

Factors that will constrain sales in the U.S. coronary stents market over the next half-decade include:

- clinician caution engendered by charges of stent overuse;
- a focus on medical management in lower risk patients;
- adoption of FFR to determine idela patients for stent placement, eliminating unnecessary stenting procedures;
- utilization of alternative revascularization technologies (e.g., drug-eluting balloons); and,
- price erosion as a result of over-saturation from various stent developers.

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Factors that could potentially improve coronary stent sales include:

- improvements in stent designs and materials, specifically in bare-metal stents; and,
- positive long-term clinical data supporting the use of bioresorbable stents, which are expected to be priced as premium products.

Exhibit MA-1 presents the U.S. market forecast for coronary stents for the years 2015 through 2020.

Exhibit MA-1: Coronary Stents, Market Forecast, 2015-2020

Products	2015	2016	2017	2018	2019	2020	CAGR (2015-2020)
Bare-Metal Stenting:							
Bare-Metal Stenting Procedures	97.4	97.8	98.3	98.8	99.3	99.9	0.5%
Bare-Metal Stents Placed	136.3	135.5	134.9	134.2	133.6	133.0	-0.5
Average Device Price	$610.2	$609.3	$607.8	$605.6	$603.5	$601.1	-0.3
Subtotal Bare-Metal Stent System Sales	**$83.2M**	**$82.6M**	**$82.0M**	**$81.3M**	**$80.6M**	**$79.9M**	**-0.8%**
Drug-Eluting Stenting:							
Drug-Eluting Stenting Procedures	836.4	840.6	845.6	851.5	858.4	866.9	0.7%
Drug-Eluting Stents Placed	1,204.0	1,208.0	1,210.0	1,213.0	1,215.0	1,218.0	0.2
Average Device Price	$1,411.5	$1,408.7	$1,406.0	$1,402.0	$1,397.0	$1391.8	-0.3
Subtotal Drug-Eluting Stent System Sales	**$1,700.0M**	**$1,701.6M**	**$1,704.6M**	**$1,700.5M**	**$1,698.6M**	**$1,695.0**	**-0.1%**
Total Coronary Stenting Procedures	**933.8**	**938.4**	**943.9**	**950.3**	**957.7**	**966.8**	**0.7%**
Total Coronary Stents Placed	**1,340.8**	**1,343.5**	**1,344.9**	**1,347.2**	**1,348.6**	**1,351.0**	**0.2%**
Total Coronary Stent System Sales	**$1,783.2M**	**$1,784.2M**	**$1,786.4M**	**$1,781.7M**	**$1,779.2M**	**$1,774.9M**	**-0.1%**

Notes: Stents placed per procedure is an average based on the number of stents used in the treatment of single- and multi-vessel cases. Average stents placed are reported in thousands. Procedure volumes are reported in thousands.

You can also find the most recent report which covers Stents.

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Reports

Report Title	Date Published
Interventional Neurology: Carotid Artery Stents and Embolic Protection Systems	12/18/2018
Interventional Cardiology: Vascular Stents	01/25/2018
U.S. Markets for Interventional Cardiology Products, April 2016	04/01/2016
U.S. Markets for Stroke Management, August 2015	08/03/2015
U.S. Markets for Neurosurgical and Neurointerventional Products, September 2014	09/01/2014

Within that report, you can search via the Table of Contents Navigation to find the sections which cover market forecasts.

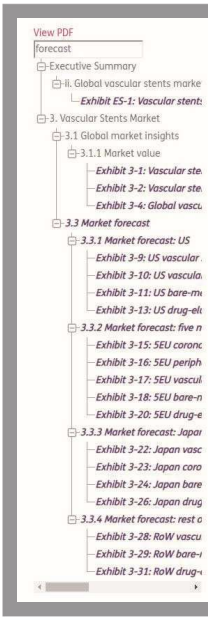
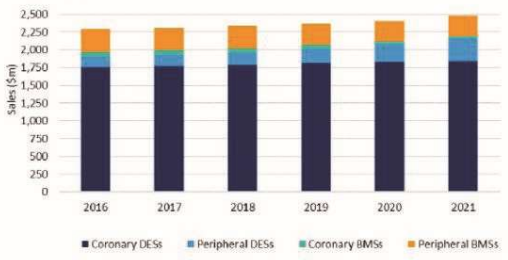


Exhibit 3-10: US vascular stent sales combined market forecast, by product segment ($m), 2016-21

Products	2016	2017	2018	2019	2020	2021	CAGR (2016-21)
Coronary DESs	1,756.1	1,773.7	1,793.2	1,811.1	1,826.5	1,841.1	0.9%
Peripheral DESs	135.3	150.2	171.2	202.0	246.5	313.0	18.3%
Total DES sales	**1,891.4**	**1,923.8**	**1,964.4**	**2013.1**	**2,073.0**	**2,154.1**	**2.6%**
Coronary BMSs	76.3	66.3	55.5	49.4	43.0	37.1	-13.4%
Peripheral BMSs	324.5	322.2	314.5	302.7	294.6	288.0	-2.4%
Total BMS sales	**400.8**	**388.5**	**370.0**	**352.1**	**337.6**	**325.1**	**-4.1%**
Total product sales	**2,292.2**	**2,312.3**	**2,334.4**	**2,365.2**	**2,410.6**	**2,479.3**	**1.6%**

Notes: Totals may not sum due to rounding. BMS = bare-metal stent; CAGR = compound annual growth rate; DES = drug-eluting stent.



Source: Meddevicetracker; company financials

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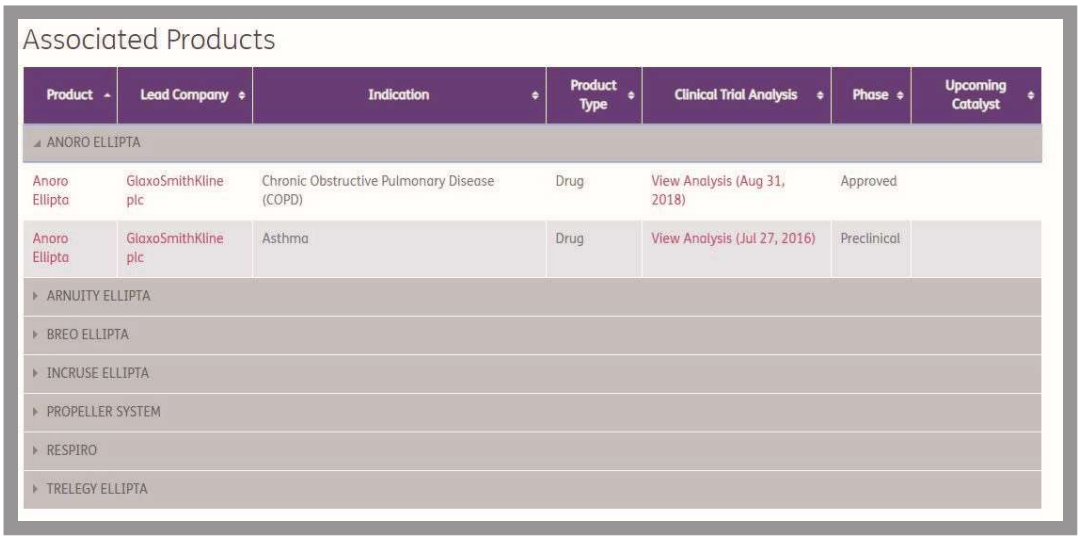
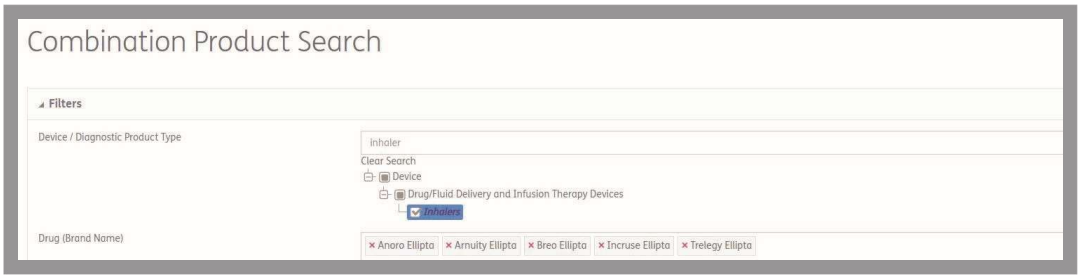
How do I find out if a device is being used with a drug

If a device or diagnostic product is being used with a drug(s) or is partnered with a drug(s), you will find the associated drug information in the Associated Products section of the Product Profile:



The Associated Products section will contain a sample of the drug information contained within our sister product, Biomedtracker. To access the full drug details, you will need a subscription to Biomedtracker.

You can also use the Combination Product Search to find devices/diagnostics that are used or partnered with a drug(s). Navigate to the Combination Product Search via the Advanced Searches drop-down menu. Select the Device Type inhalers and Drug Ellipta.



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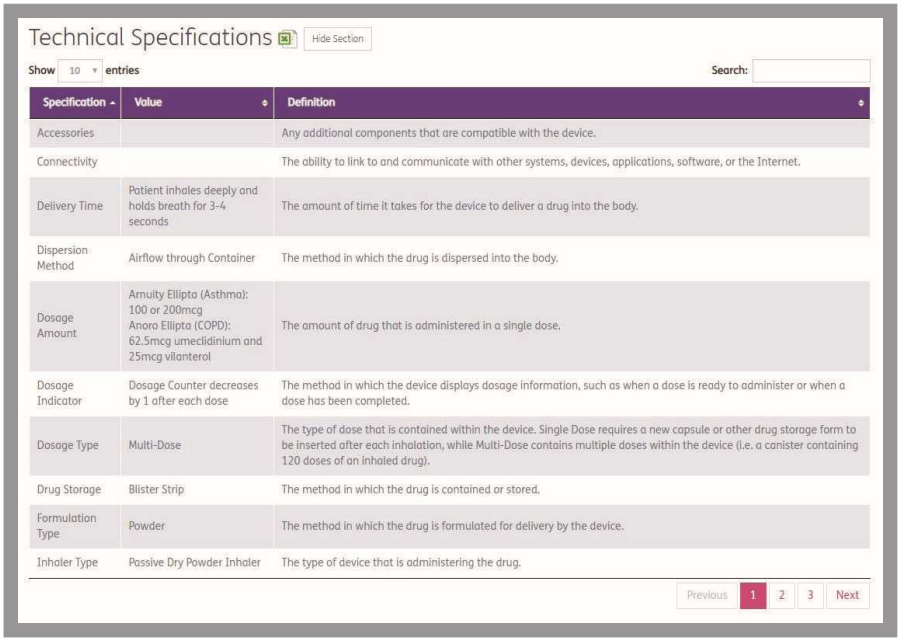
How do I find Technical Product Specifications for a product?

Use the Quick Search to look for a product name and select the product to go directly to that profile. Scroll down on the profile to the Technical Specifications section.



Technical Specifications

Hide Section

Show 10 entries

Search:

Specification	Value	Definition
Accessories		Any additional components that are compatible with the device.
Connectivity		The ability to link to and communicate with other systems, devices, applications, software, or the Internet.
Delivery Time	Patient inhales deeply and holds breath for 3-4 seconds	The amount of time it takes for the device to deliver a drug into the body.
Dispersion Method	Airflow through Container	The method in which the drug is dispersed into the body.
Dosage Amount	Arnuity Ellipta (Asthma): 100 or 200mcg Anoro Ellipta (COPD): 62.5mcg umeclidinium and 25mcg vilanterol	The amount of drug that is administered in a single dose.
Dosage Indicator	Dosage Counter decreases by 1 after each dose	The method in which the device displays dosage information, such as when a dose is ready to administer or when a dose has been completed.
Dosage Type	Multi-Dose	The type of dose that is contained within the device. Single Dose requires a new capsule or other drug storage form to be inserted after each inhalation, while Multi-Dose contains multiple doses within the device (i.e. a canister containing 120 doses of an inhaled drug).
Drug Storage	Blister Strip	The method in which the drug is contained or stored.
Formulation Type	Powder	The method in which the drug is formulated for delivery by the device.
Inhaler Type	Passive Dry Powder Inhaler	The type of device that is administering the drug.

Previous 1 2 3 Next

You may also download the full technical specifications to Excel using the Excel button.

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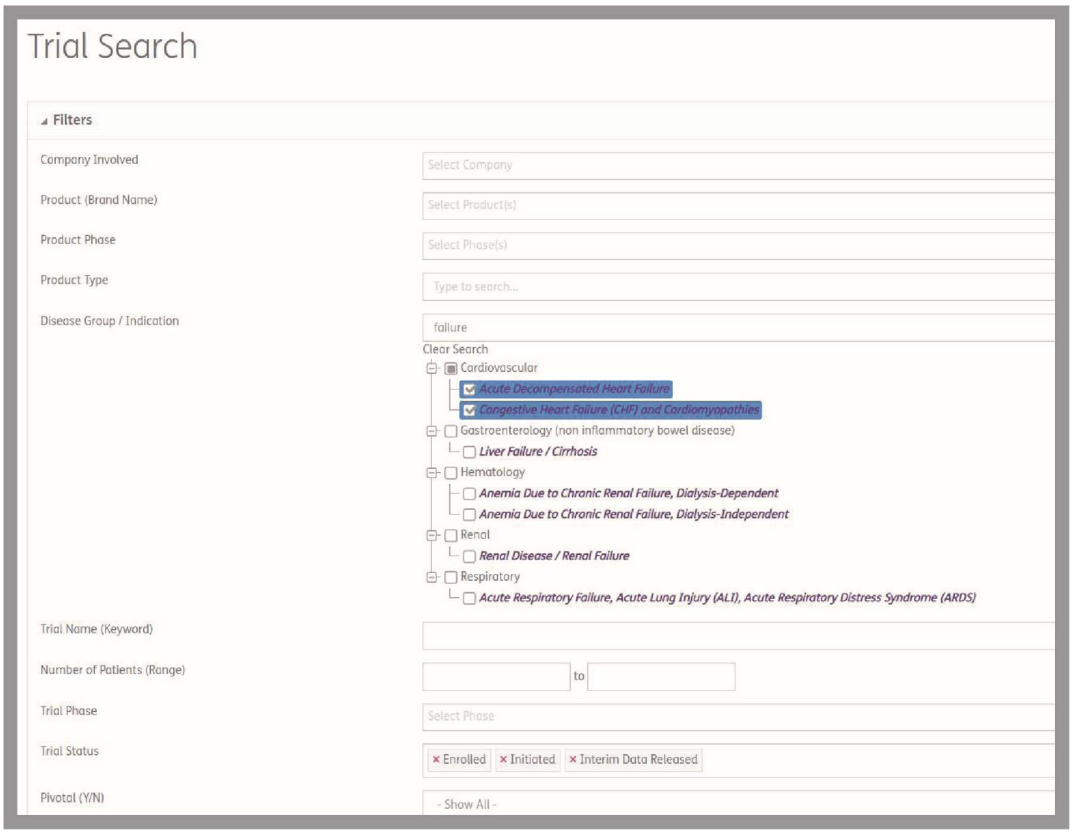
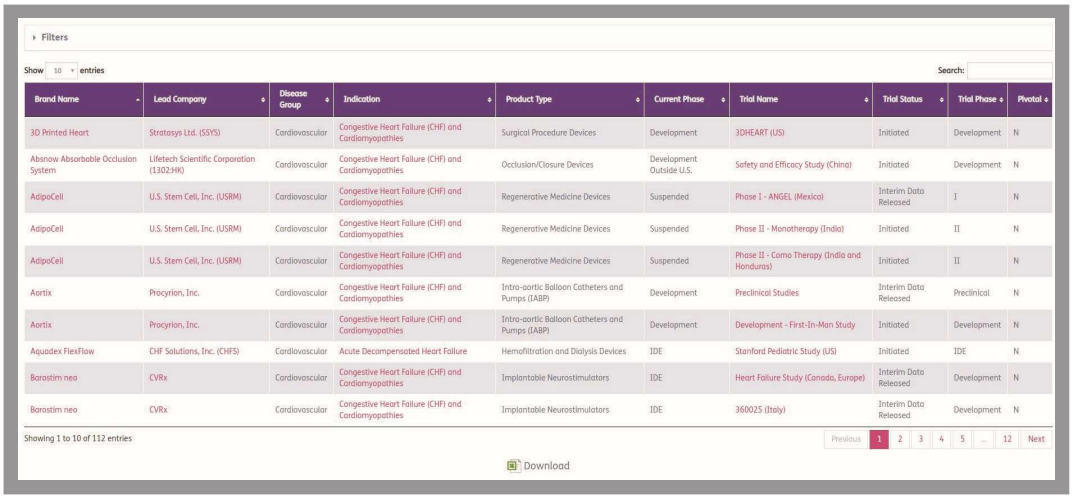
How do I generate a list of all ongoing device clinical trials for cardiac failure?

Navigate to the Trial Search via the Advanced Searches drop-down menu. Select the Disease Group/Indications for cardiac failure, and the Trial Statuses enrolled, initiated, and interim data released.



View the results on the screen or download extended trial details in excel.



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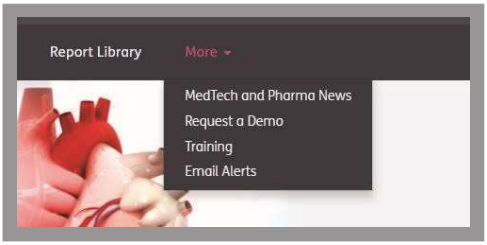
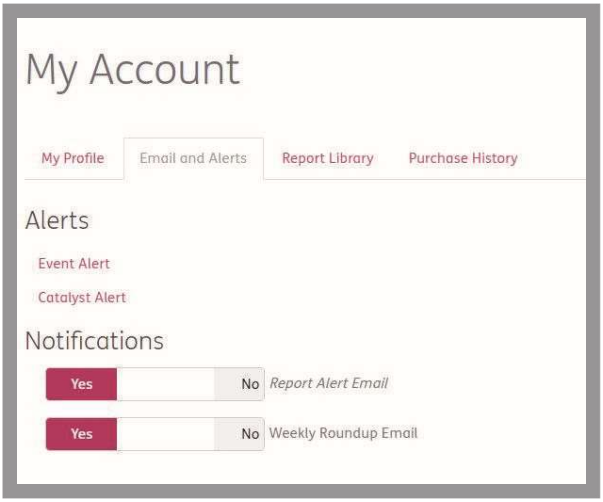
How do I get alerted about important events for my competition?

Navigate to your Email Alert settings in My Account.



Select the Alert type you would like to set.



Event Alert will send you alerts when any new event occurs that matches your criteria. Select one or many options for your event alerts, including companies, product types, indications, etc. If you do not make any criteria selections, your alerts will include all events added. If you make at least one criteria selection, your alerts will be filtered based on that selection. Be sure to select at least one option from the Alert Timing section to ensure you receive alerts either immediately, daily, and/or weekly.

Catalyst Alert will send you daily and/or weekly alerts for upcoming events that match your criteria. Select one or many options for your catalyst alerts, including companies, product types, indications, etc. If you do not make any criteria selections, your alerts will include all catalysts added or updated. If you make at least one criteria selection, your alerts will be filtered based on that selection. Be sure to select at least one option from the Alert Timing section to ensure you receive alerts either daily and/or weekly.

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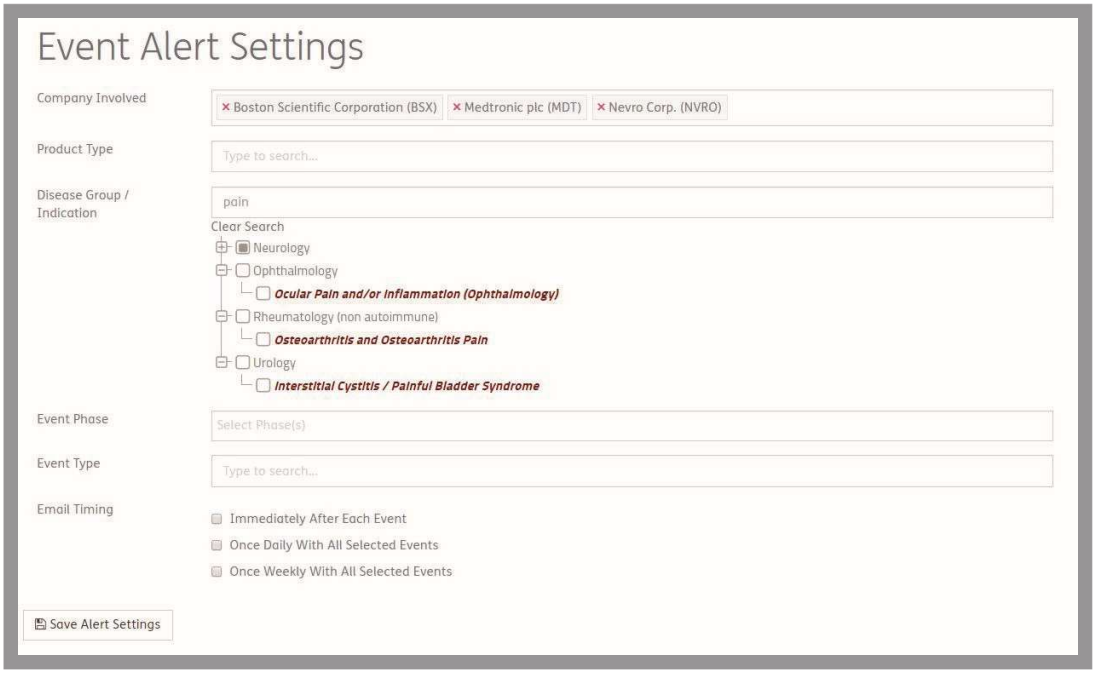
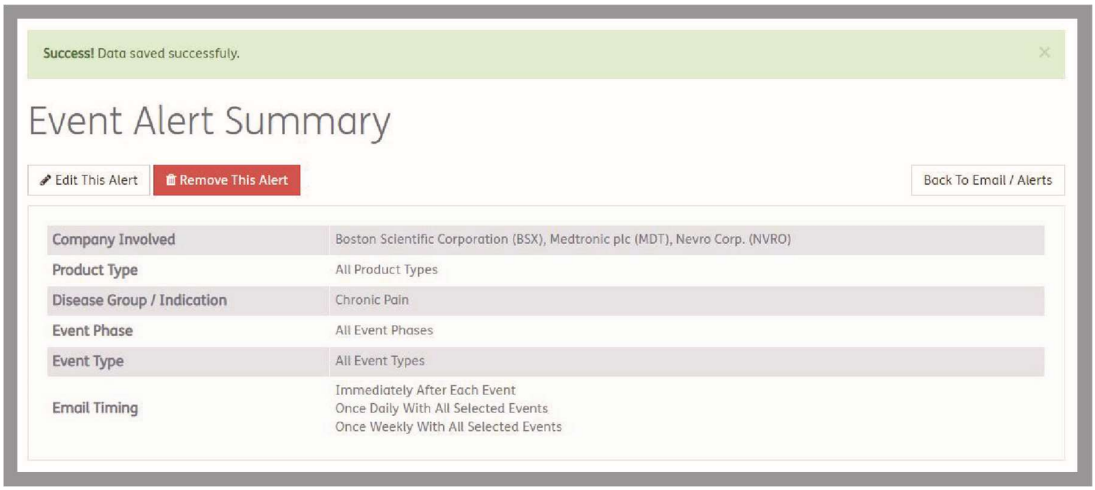


If you need to edit your alert settings at any time, you can return to the Email Alert Settings in My Account and make changes.



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How do I save a search so I can come back to it easily?

You can save a new search from the results of any Advanced Search.

Click Save This Search and give your search a name.

You can access all of your saved searches from the Saved Searches button on the Advanced Searches, from your My Account page, or from the Advanced Search drop-down menu. From your Saved Searches page, you can rename, load, or delete your searches.

My Profile | Email and Alerts | Saved Searches | Report Library | Purchase History

Search Name *click to run	Search Description	Search Type	Created	Updated	Actions		
510k/PMA	trials for prods in 510k PMA phase	Trial Search	10/25/18	10/25/18	Rename	Load	Delete
510k/PMA endo meta derm		Trial Search	10/25/18	10/25/18	Rename	Load	Delete
Cardio and Endocrine Trial Announcements		Catalyst Search	10/24/18	10/25/18	Rename	Load	Delete
Cardio Trial Cats	Trial announcements and Trial Data	Catalyst Search	10/24/18	10/24/18	Rename	Load	Delete
Inhalers		Combination Product Search	10/25/18	10/25/18	Rename	Load	Delete
Inhalers - AZN, Boeh		Combination Product Search	10/25/18	11/8/18	Rename	Load	Delete
Inhalers - AZN, Boeh, GSK		Combination Product Search	11/8/18	11/8/18	Rename	Load	Delete
Private CE Mark		Product Search	11/8/18	11/8/18	Rename	Load	Delete

In order to modify a search, just load the search and change your filters. You can either save that search as a new search or update the selected saved search.

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What are Meddevicetracker's Research Standards?

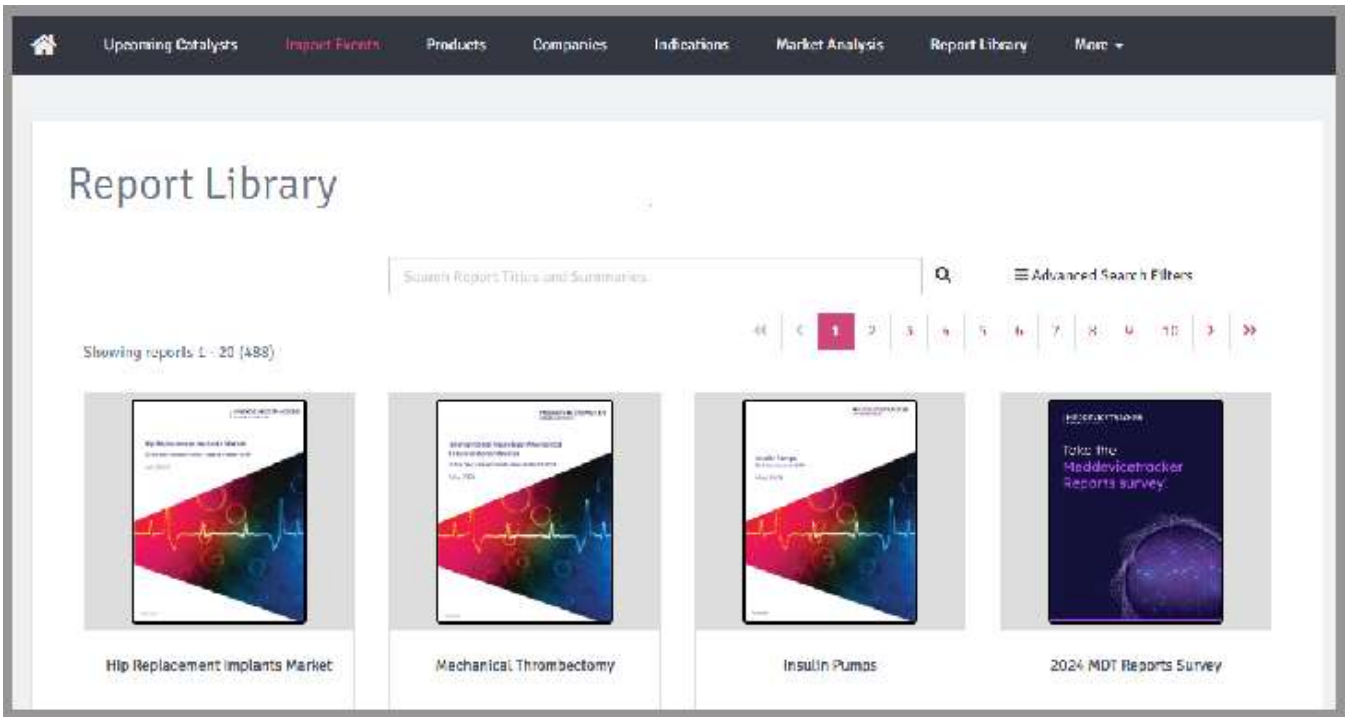
All information and analysis inputted into the Meddevicetracker is gathered, analyzed, entered, and qualitycontrolled by a team of in-house analysts. These analysts undergo extensive training to understand the Medtech market, development processes, regulatory functions, who the players are, where to find the information, and more. Each day we follow all the market events and filter them into what is important for development. This information is entered real-time into the system by our analysts and quality controlled by a senior analyst so as to ensure consistency and accuracy across the platform. We follow over 200 earnings calls on a quarterly basis and analyze the Q&A with investment banks to gain valuable insight you can't get through web-scraping. We follow medical conferences, R&D days, industry reports and speak with the IR departments of companies to gain more insight.

What are Meddevicetracker Reports and where can I access them?

Meddevicetracker Reports are comprehensive analyses of the devices, technologies, procedures, and companies shaping the global medical technology market. These reports are driven by the industry's most talented and highly respected researchers and authors, spanning over 25 years of experience in healthcare and medical products marketing and business development.

The reports contain product analysis by competitor, new and emerging products by competitor, expected approvals, clinical trials and results, competitive analysis and market analysis.

You can access the Meddevicetracker Reports in the 'Reports' tab and via the report gallery.



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What are Meddevicetracker Reports Research Standards?

Multiple qualitative and quantitative techniques are used to develop market segment forecasts, allowing estimates to be cross-checked to ensure accuracy. All our forecasts are reviewed and verified by our team of medical device industry analysts and are benchmarked with device companies own data where possible.

Meddevicetracker Reports analysts also have exclusive access to content from leading proprietary Medtech/ healthcare intelligence services and the industry analysts who produce them. These services include Medtech Insight, Datamonitor Healthcare, Biomedtracker, Meddevicetracker and In Vivo.

Primary research may be conducted to validate the major qualitative and quantitative trends discussed in the report. Interviews are conducted with manufacturers and distributors, among others. Data derived from interviewees are verified and corroborated by other primary sources and by reliable secondary sources (see below), to ensure any bias is removed from the resulting forecasts.

Secondary sources for statistical and technological information include organizations such as the American Cancer Society, the National Cancer Institute, the National Institutes of Health, the US Food and Drug Administration, WHO, Import/Export data and publications in the scientific and trade literature. While these are believed to be the best secondary sources of data, the estimation of trends from these data is complicated by periodic changes in reporting and classification methods. Figures cited are for the most years publicly available.

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