Meddevicetracker

Pharma Intelligence

Meddevicetracker

Methodology and editorial process

Below you will find an overview of the methodology and process around our Medtech coverage available in Meddevicetracker, combined with Meddevicetracker Reports. These have been broken into four key parts to help you understand the types of content we have and strength of coverage.

Coverage Areas

1) Inclusion Criteria

2) Meddevicetracker Reports,
previously known as Medtech Insight Reports

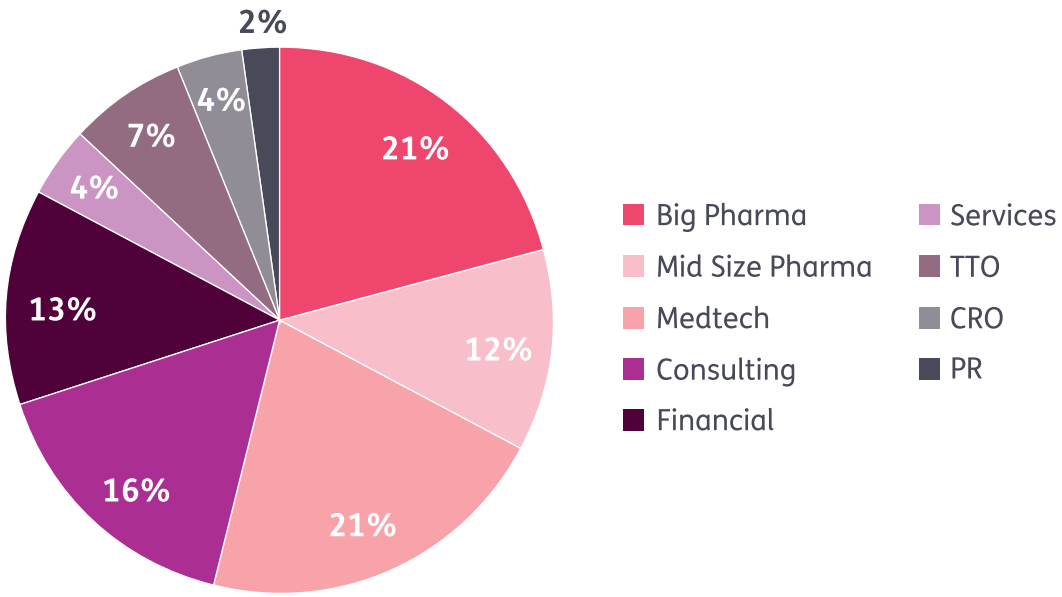
3) Medtech Publication Connection

Coverage Areas

Meddevicetracker, with the addition of Meddevicetracker Reports, was launched in May 2016 with information and analysis covering: Cardiovascular, Oncology (with specialization in companion diagnostics), CNS disorders (with specialization in neuro-stimulation), Autoimmune (with specialization in wound care), Drug Delivery Technology (DDT), Orthopedics, Diabetes and Obesity, and Women's Health. Additional Reports coverage includes: Diagnostics, Dermatology/Aesthetics, Infectious Diseases, Ophthalmology, and Surgical/Robotics.

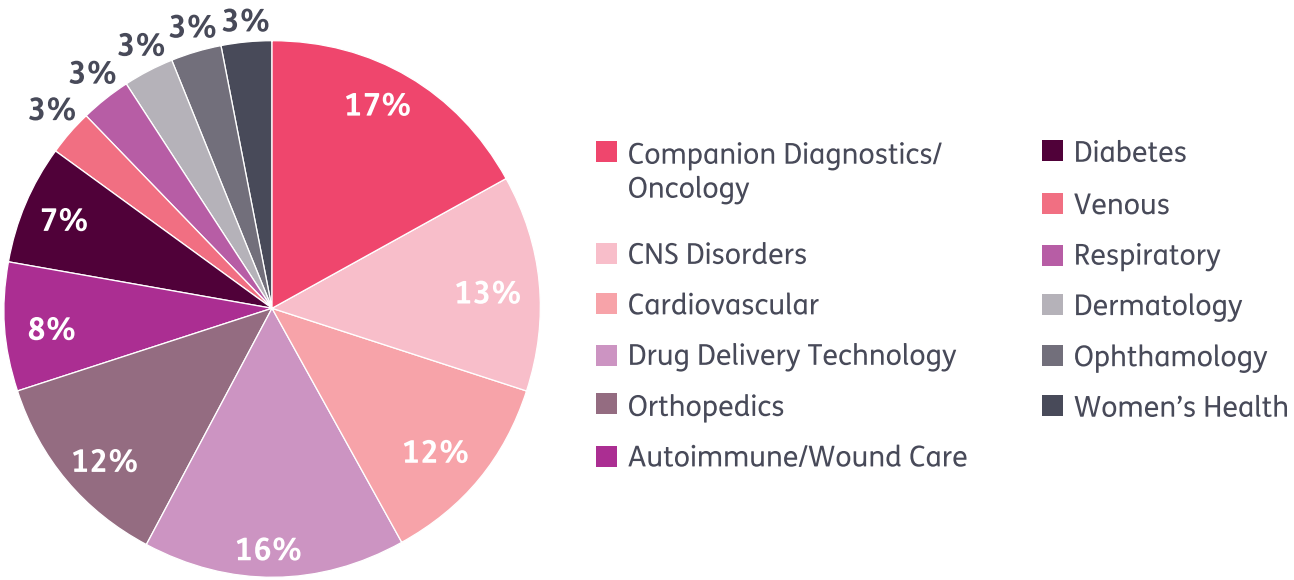
We have conducted extensive client research s to determine which coverage areas and content are most important to our clients' needs. We interviewed over 100 clients from across the industry (shown in the chart below), which has led to our current editorial plan.

Meddevicetracker Feedback: By Client Type



Our market and client research has indicated the following levels of interest in various content areas:

Meddevicetracker: Client Feedback



This feedback has contributed to the 2017 integrated content plan.

Inclusion Criteria

Coverage

Meddevicetracker tracks the development and regulatory process of various devices as well as diagnostic machines and assays. Coverage includes global device and diagnostic development, but focuses on the US, EU, and Japanese markets, Company profiles include company locations, subsidiaries, acquisitions, and earnings and ticker information if public. Product coverage includes development history, trial information, agency interactions, filings and approvals (particularly 510(k) and PMA), advisory panel meetings, various types of trial data, reimbursements, patents, financial offerings, and various other development milestones. MDT specializes in 'real-time' event tracking to have the most up-to-date developments where users can be kept informed through customized email alerts. In addition, Meddevicetracker has the widest breadth and most transparent coverage of catalysts, which are used to map out future milestones that will impact a product's development.

Product coverage includes class II and III devices being developed by public and private companies Product coverage does not include class I devices, or "research use only" devices. Class I devices typically present little to no potential harm to the patient and require much less regulatory oversight compared to II and III. Coverage also includes HDE, de novo, companion diagnostic, laboratory developed tests (LDTs) and other types of diagnostics. Prioritization is given to those that will make the most commercial impact.

Editorial Process

All information and analysis inputted into the Meddevicetracker is gathered, analyzed, entered, and quality-controlled by a team of in-house analysts. These analysts undergo an extensive three-month training period 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 Meddevicetracker 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 read through the Q&A with investment banks to gain valuable insight you can't get through web-scraping and an off-shore team. We follow medical conferences, R&D days, industry reports and speak with the IR departments of companies to gain more insight.

Our in-house team and processes allow us to be very nimble and adapt to client requests and the market quickly.

Sources

The majority of daily updates are accumulated through news releases, earnings calls, SEC filings, company websites, regulatory sites, journals, publications, etc.

New approvals, for example, 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. We prioritize the adding of these profiles based on our timeline of content development.

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. We use www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm for recently approved devices and the monthly listings.

Meddevicetracker (formerly Medtech Insight) Reports

What's Included

1. **Executive Summary/ Market Overview – key findings of the report and key data**

2. **Product Analysis**
   a. Lead Products by Competitor [Inc. Product Portfolio Table with Brief Description, Benefits/Core Advantages, Approvals (FDA/CE Mark]
   b. New/Emerging Products by Competitor [New Products/Innovations Table), Expected Approvals]
   c. Clinical Trials/Results

3. **Competitive Analysis**
   a. Company Revenues [Inc Tables of Net Sales & Segment Sales if available – US, 5EU (France, Germany, Italy, Spain & UK), Japan and RoW]
   b. Market Share: US, 5EU, Japan and RoW
   c. Corporate Growth Strategies for each competitor
   d. Strategic Partnerships/Acquisitions
   e. Expected next FY growth by segment

4. **Market Analysis**
   a. 5-year procedure volume forecasts
   b. 5-year Market Forecasts (US, 5EU, Japan and RoW)
   c. Overall Market Growth, plus Segment Growth text/trends/impact new technologies, etc.
   d. Market Drivers/Limiters

Editorial Process

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.

Medtech Insight 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, Medtrack, Meddevicetracker and Strategic Transactions.

Market Forecasts

A combination of regression and cause-and-effect analysis of the data (of different growth driver and resistor events) is used to provide forecasts for market sizing. Prices used in projections of market revenues are average prices paid by the end-user for the products and are derived via supplier and user quotations or estimates based on typical industry discounts from list prices where available. Data concerning unit shipments, market values, growth rates, and market share are incorporated into our forecasting and market share analysis models, which are used to derive market estimates for future years. A rate factor is utilized to determine the speed with which the market develops, which is similar to that observed for markets for other medical products and is adjusted to match historic data for the market under analysis.

Primary Research

Primary research is conducted to validate the major qualitative and quantitative trends discussed in the report. Interviews are conducted with manufacturers and distributors, physicians, and hospital purchase departments, among others. The key questions asked include market sizing details, growth opportunities and challenges as well as factors affecting purchasing decisions. Data derived from interviewees are verified and corroborated by other primary sources and/or from reliable secondary sources (see below), to ensure any bias is removed from the resulting forecasts.

Secondary Research

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 recent years publicly available.

In addition to the use of corporate annual and quarterly reports, financial information for this report was obtained from company prospectuses and press releases, Forms 10-K and 10-Q, investment analysts' reports, product catalogues and price lists.

Other Informa products used in the development of Medtech Insight Reports include:

- **Medtech Insight** https://medtech.pharmaintelligence.informa.com/
- **In Vivo** https://invivo.pharmaintelligence.informa.com/
- **Strategic Transactions** https://www.pharmamedtechbi.com/deals
- **Biomedtracker** https://www.biomedtracker.com/
- **Meddevicetracker** https://www.meddevicetracker.com/

Insight Connection

As well as the extensive Medtech intelligence data from Meddevicetracker and Meddevicetracker Reports, our medical device and diagnostics coverage includes news and analysis from Medtech Insight. Together, these are the leading source of regulatory, market and competitor information for the medical devices and diagnostics industries.

Long-established and reputable, with a strong and extensive network across the industry, our experts provide insight on regulation, policy, technology and business critical issues. Readers find opportunities to grow their business and to keep informed of regulatory and policy developments impacting the worldwide Medtech industry.

As of end of June 2016, all of our medical device and diagnostics publications (Clinica, Gray Sheet, Medtech Insight, Start Up) were integrated under a single brand: Medtech Insight. With a new easy to use platform available on desktop, tablets and phones subscribers are connected with the latest news and analysis from our experienced team.

Our Medtech Insight team provide in depth coverage that includes:

- Country specific regulatory issues (US, Europe, Asia, RoW)
- Analysis of pre- and post-market issues
- Emerging technologies
- Clinical trial requirements
- Approval/registration processes
- Product launch strategies
- Quality control, surveillance, recalls and post-market regulation
- Evaluation of licensing and investment opportunities
- Financing strategies, venture and other early stage funding sources