Development Statuses

Meddevicetracker covers industry-led development of products from research through commercialization. Primary coverage is focused on the US, EU and Japanese markets. Should a product also be developed in markets outside these core areas, coverage may be provided, however, it is not comprehensive. Discontinued products are retained in the platform and reason(s) for suspension are provided when available.

Trial Information

Meddevicetracker covers planned, ongoing or completed clinical trials designed to support commercialization. Trial profiles contain detailed trial design information and previous/upcoming milestones. Results data are captured for laboratory and clinical studies. Trial sites and individual investigator details are excluded.

Regulatory and Marketing Information

Meddevicetracker covers regulatory filings, approvals and launches. Voting outcomes from FDA Advisory Committee meetings are captured.

Inclusions:
- PMA / 510(k)
- De Novo and Humanitarian Device Exemption (HDE) approvals
- CE Mark approvals
- Japanese approvals

Exclusions:
- Manufacturing approvals
- Post-marketing requirements

Licensing Information

Meddevicetracker covers licensing and regional distribution agreements in which development and/or commercialization rights are exchanged. Mergers and acquisitions between companies or for a specific product are also covered.

Event and Catalyst Types

Meddevicetracker is built on historical events as well as forward-looking events (or catalysts). Events are categorized by the specific type of information reported in the public domain, such as regulatory, trial data or trial announcements. A complete list of Meddevicetracker event and catalysts types along with their definitions is available in the 'Resources' section of the site.

Questions?

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