Meddevicetracker Catalyst Definitions

Meddevicetracker
Pharma Intelligence

Catalyst Type Group	Catalyst Type	Definition
Company	Analyst/R&D Update	This catalyst type monitors upcoming analyst or R&D days within the pharma/biotech space.
Company	Divestment/Spinoff	Company announces that a portion of its business will be divested/spun-off
Company	Earnings Announcement	This catalyst type tracks all upcoming earnings announcement of public companies.
Conference	Investor Conference	This catalyst type monitors an upcoming investor conference
Conference	Medical Conference	This catalyst type monitors an upcoming medical conference
Other	Other	Any catalyst that does not fall into any other specified category
Partnership	Acquisition Completion	Upcoming completion of transaction or deal of company acquiring another company or drug
Partnership	New	A company publically anounces they are seeking a partnership.
Partnership	New (Emerging Markets)	A company publically anounces they are seeking a partnershipin an emerging market.
Partnership	Option Exercise Decision	A decision made by a company to exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology
Partnership	Option Exercise Decision (Emerging Markets)	A decision made by a company to exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology that happens outside of the major markets (i.e. BRIC, etc.)
Patent	Examination Update	An update from the examination of a patent application
Patent	Expiration	Upcoming date in which the patent (or pediatric exclusivity period) expires or is no longer valid
Patent	Litigation Update	Court decisions and rulings
Patent	Litigation Update (Emerging Markets)	Court decisions and rulings within the emerging markets
Patent	USPTO Action	A USPTO action is written correspondence from the patent examiner that requires a properly signed written response from the applicant in order for prosecution of the application to continue. Examples of Office actions include a restriction requirement, a non-final Office action, and a final Office action.
Progress Update	Development Review	Progress of overall clinical development program, relates to its path to registration
Progress Update	Development Review (Emerging Markets)	Progress of overall clinical development program, relates to its path to registration in the emerging markets

Progress Update	Hospital/Health System Product Launch	As opposed to a “Progress Update - Product Launch” catalyst, this is used when a company plans to launch a product noting a specific hospital or healthcare system instead of a broader commercial availability. Often used for larger device systems.
Progress Update	Manufacturing/Supply	Company update on issues regarding the ability to produce or supply drug. Often pertains to manufacturing plant issues and resulting contamination.
Progress Update	Manufacturing/Supply (Emerging Markets)	Company update on issues regarding the ability to produce or supply drug in a nonmajor market (i.e. BRIC, etc.) Often pertains to manufacturing plant issues and resulting contamination.
Progress Update	Product Launch	Company anticipates launch of approved drug for sale in an unspecified region or market
Progress Update	Product Launch (Australia)	Company anticipates launch of approved drug for sale in Australia
Progress Update	Product Launch (Canada)	Company anticipates launch of approved drug for sale in Canada
Progress Update	Product Launch (Emerging Markets)	Company anticipates launch of approved drug for sale in the emerging markets
Progress Update	Product Launch (Europe)	Company anticipates launch of approved drug for sale in Europe
Progress Update	Product Launch (Europe) - Individual Country	Company anticipates launch of approved drug for sale in an individual country in Europe
Progress Update	Product Launch (Japan)	Company anticipates launch of approved drug for sale in Japan
Progress Update	Product Launch (U.S.)	Company anticipates launch of approved drug for sale in the US
Progress Update	Product Relaunch	If product was previously removed from market temporarily for any reason, this catalyst tracks the upcoming relaunch
Regulatory	510(k) Clearance	This catalyst type tracks an upcoming 510(k) clearance for a specific device.
Regulatory	510(k) Filing	This catalyst type tracks an upcoming 510(k) filing for a specific device, as specified by the company.
Regulatory	510(k)/PMA Approval Decision	This catalyst type tracks an upcoming 510(k) or PMA approval decision for a specific device. This catalyst is used when the company does not specify the type of filing.
Regulatory	510(k)/PMA Filing	This catalyst type tracks an upcoming 510(k) or PMA filing for a specific device. This catalyst is used when the company does not specify the type of filing.
Regulatory	Approval (Australia)	Anticipated approval by the Australian Health Practitioner Regulation Agency of a New Drug Submission
Regulatory	Approval (Canada)	Anticipated approval by Health Canada of a New Drug Submission

Regulatory	Approval (Europe) - Individual Country	Anticipated approval in single European country where company has filed application (decentralized procedure)
Regulatory	Approval Decision (Emerging Markets)	Anticipated approval decision by a regulatory body to market a drug in a nonmajor market (i.e. BRIC, etc.)
Regulatory	Approval Decision (Europe)	Anticipated approval decision by the EMA
Regulatory	Approval Decision (Japan)	Anticipated approval decision by the MHLW or PMDA of a Japanese marketing application
Regulatory	CE Mark Approval	Anticipated approval of the CE mark indicating a product's compliance with EU legislation and enabling the free movement of products within the European market.
Regulatory	CE Mark Filing	Anticipated filing of the CE mark, a mandatory conformity marking for certain products sold within the European Economic Area (EEA)
Regulatory	CLIA Waiver Designation	Clinical Laboratory Improvement Amendments (CLIA) are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. Tests and test systems that meet risk, error, and complexity requirements are issued a CLIA certificate of waiver.
Regulatory	CLIA Waiver Submission	Anticipated submission of CLIA waiver so that clinical tests can become available for use in physician offices, clinics and other public health settings as well.
Regulatory	De Novo Approval Decision	Anticipated decision on the De Novo application filed for approval of a new device that has no predicate device to use for approval (different process than PMA and 510k)
Regulatory	De Novo Request Filing	A request for the FDA to make a risk-based evaluation for classification of the device into Class I or II
Regulatory	European Regulatory Communication	A letter or a press release issued by CHMP relating to the review of a drug
Regulatory	FDA Advisory Panel Brief	Briefing documents from FDA site for upcoming Advisory Committee meeting
Regulatory	FDA Advisory Panel Meeting	A meeting held by an FDA Advisory Committee to discuss an NDA/BLA and the drug's risk-benefit profile. At the end of the meeting, the panel votes on recommending approval
Regulatory	FDA Response	FDA issues a response to communication from Company. Does not include formal FDA meetings
Regulatory	Filing for Approval (Australia)	Anticipated filing for approval in Australia
Regulatory	Filing for Approval (Canada)	Anticipated filing for approval in Canada
Regulatory	Filing for Approval (Emerging Markets)	Anticipated filing for approval in a nonmajor market (i.e. BRIC, etc.)

Regulatory	HDE Approval Decision	Humanitarian device exemption (HDE) application is approved by the FDA. An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
Regulatory	HDE Modular Filing	The modular HDE review process is based on a submission of individual sections or “modules” that constitute a complete HDE submission once all have been submitted. The modular approach allows the FDA to review each module separately, allowing the applicant to receive timely feedback and potentially resolve any deficiencies earlier in the review process compared to a traditional HDE application. Upon receipt of the final module, the FDA will make a filing decision that, if positive, triggers the HDE 75-day review clock for an approval decision.
Regulatory	HDE Modular Filing Completed	The modular HDE review process is based on a submission of individual sections or “modules” that constitute a complete HDE submission once all have been submitted. The modular approach allows the FDA to review each module separately, allowing the applicant to receive timely feedback and potentially resolve any deficiencies earlier in the review process compared to a traditional HDE application. Upon receipt of the final module, the FDA will make a filing decision that, if positive, triggers the HDE 75-day review clock for an approval decision.
Regulatory	HDE Submission	Humanitarian device exemption (HDE) application filing to the FDA. An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
Regulatory	IDE Approval Decision	FDA approval of an IDE submission allows the initiation of subject enrollment in a clinical investigation of a significant risk device. This guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE as well as a general explanation of the reasons for those decisions.
Regulatory	IDE Request for Additional Information	Additional information required by the FDA to be submitted before making a decision on the IDE application.

Regulatory	IDE Submission	Anticipated submission of IDE, which if approved, allows the initiation of subject enrollment in a clinical investigation of a significant risk device.
Regulatory	Market Removal Hearing	Advisory committee meeting on removal of an approved drug and/or indication from the market
Regulatory	Meeting with European Medicines Agency	Any meeting occurring with the EU regulatory authority
Regulatory	Meeting with FDA	Any meeting occurring with the FDA, includes but is not limited to end of Phase II meetings
Regulatory	Other	An anticipated regulatory update that does not fall into any other specified regulatory category
Regulatory	PMA Approval Decision	An approved Premarket Approval Application (PMA) like an approved New Drug Application (NDA) is, in effect, a private license granted to the applicant for marketing a particular medical device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).
Regulatory	PMA Approval Decision (Japan)	The Pharmaceuticals and Medical Devices Agency (PMDA) is the regulatory body in Japan which controls the marketing of medical devices. The regulatory pathway for “highly controlled medical devices” requires the submission of a Premarket Approval Application with the PMDA, a review, and approval before a device can be brought to market.
Regulatory	PMA Filing	Anticipated filing of a Premarket Approval Application (PMA) to the FDA. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to begin an indepth review. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed. The letter will include the PMA reference number and the date FDA filed the PMA. Expedited review status, if appropriate, may be communicated at this time. The date of filing is the date that a PMA accepted for filing was received by the agency. The 180day period for review of a PMA starts on the date of filing.
Regulatory	PMA Filing (Japan)	The Pharmaceuticals and Medical Devices Agency (PMDA) is the regulatory body in Japan which controls the marketing of medical devices. The regulatory pathway for “highly controlled medical devices” requires the submission of a Premarket Approval Application with the PMDA, a review, and approval before a device can be brought to market.
Regulatory	PMA Modular Filing	In a Modular PMA the complete contents of a PMA are broken down into well delineated components (or module) and each component is submitted to FDA as soon as the applicant has completed the module, compiling a complete PMA over time. The PMA is viewed as a compilation of sections or "modules," such as preclinical, clinical, manufacturing, that together become a complete application. This method is recommended for products that are in early stages of clinical study. This method is not appropriate when the applicant is very close to being ready to submit a PMA or when the device design is in a state of flux or likely to change.

Regulatory	PMA Modular Filing Completed	The process begins with a PMA Shell which lays out the plan for submission of the modules. The shell is an outline of modules and identifies information necessary to support the filing and approval of a specific Class III product through a combined IDE-PMA process. The review team will work with applicants to develop a customized shell for each specific product that includes module contents and suggested timelines. It is developed individually with the manufacturer for a specific device.
Regulatory	PMA Supplemental Approval Decision	A PMA supplement approval is the FDA approval of the submission required for a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA; additional information provided to FDA for PMA supplement under review are amendments to a supplement
Regulatory	PMA Supplemental Filing	A PMA supplement filing is the submission required for a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA; additional information provided to FDA for PMA supplement under review are amendments to a supplement
Regulatory	Pre-IDE FDA Response	In order to facilitate the initiation of clinical trials under the IDE regulation, the Food and Drug Administration (FDA) encourages sponsors to begin communicating with the ODE reviewing division prior to the submission of the original IDE application. This communication may take the form of a “PreIDE” meeting and/or a “PreIDE” submission. The FDA response refers to the FDA's communication.
Regulatory	Pre-IDE Submission	FDA Response In order to facilitate the initiation of clinical trials under the IDE regulation, the Food and Drug Administration (FDA) encourages sponsors to begin communicating with the ODE reviewing division prior to the submission of the original IDE application. This communication may take the form of a “PreIDE” meeting and/or a “PreIDE” submission.
Regulatory	Progress Update	Any regulatory update that does not fall into any other specified event types
Regulatory	Progress Update (Emerging Markets)	Any regulatory update in a nonmajor market that does not fall into any other specified event types
Regulatory	Treatment Guidelines Announcement	An announcement sometimes issued by company or assiciation/organization relating to changes in treatment recommendations or instructions
Reimbursement	Individual Country (Emerging Markets) Decision	Specific Emerging Market Country health care organization or private insurer deciding whether to pay for a drug’s costs, in part or in full.
Reimbursement	Individual Country (Europe) Decision	Any European Country (excluding the UK’s NICE) national health insurance deciding whether to cover a drug’s cost, or limiting/reducing the reimbursement previously allotted (e.g. IQWIG, SMC, AWMSG)
Reimbursement	Individual Country (Other) Decision	A non-EU and Non-Emerging Market country’s health insurer or private payer deciding whether to reimburse a drug's cost, or limit/reduce the previously stated reimbursement (e.g. Canada, Australia, etc.)

Reimbursement	Medicare/Payer (US) Decision	Medicare, large private health insurance payer (Aetna etc.) or other payment agency or body in the U.S. (VA Hospitals VANF) deciding whether to reimburse a drug's care, or reduce the previously allotted amount for reimbursement
Reimbursement	NICE (UK) Guidance	National Institute for Clinical Excellence (NICE), the U.K. health care agency, deciding whether to reimburse a drug's costs. This includes draft guidance or final decision.
Reimbursement	Progress Update	Anything related to a decision being made by a health care insurer or government agency that is not a positive or negative decision. This could include a Medicare proceeding on reimbursement, a statement that a payer will reexamine a decision or any other nondeciding reimbursement event
Reimbursement	Reimbursement Decision (Japan)	Japan's health insurance agencies deciding whether to reimburse a drug's cost, or expand the already allotted reimbursement (e.g. Added to NHI price listing)
Trial Announcement	Dosing Completed	Time at which all enrolled patients have completed full treatment in study
Trial Announcement	Data Monitoring Board Analysis	Interim analyses of trial data conducted by medical, surgical and statistical experts selected by company to serve as an independent monitoring board, will make recommendations to continue or stop trial
Trial Announcement	Expanded Access Program	Designed to make products available as early in the device evaluation process as possible to patients without therapeutic options, either because they have exhausted or are intolerant of approved therapies
Trial Announcement	First-In-Human Implant	When a company expects to perform an implant of a device (ie. stent, scaffold, valve, etc.) for the first time in humans.
Trial Announcement	Go/No-Go Decision	Anticipated decision from the Company regarding the advancement of a clinical program or trial
Trial Announcement	Hold Lifted	A clinical hold is an order issued by FDA to the company to delay a proposed clinical investigation (subjects may not be given investigational drug) or to suspend an ongoing investigation (no new subjects may be recruited and placed on investigational drug/patients already in study should be taken off therapy involving investigational drug) unless specifically permitted by FDA in the interest of patient safety. FDA may lift the hold when the grounds for the hold no longer apply
Trial Announcement	Initiation	Anticipated start of a clinical trial, where the first patient is enrolled or dosed
Trial Announcement	Initiation (Emerging Markets)	Anticipated start of a clinical trial in a nonmajor market (i.e. BRIC, etc.), where the first patient is enrolled or dosed
Trial Announcement	Other	Any trial announcement that does not fall into any other specified category
Trial Announcement	Patient Enrollment Completed	Anticipated completion of full accrual or enrollment goal for a trial

Trial Announcement	Resume Trial	Anticipated reinitiation of a trial that had been halted or suspended
Trial Announcement	Trial Completion	Anticipation of all patients in trial have completed the trial, including followup
Trial Announcement	Trial Completion (Emerging Markets)	Anticipation of all patients in a trial in a nonmajor market (i.e. BRIC, etc.) have completed the trial, including followup
Trial Data	Final Results	Upcoming data that can be explicitly stated as “final analysis”
Trial Data	Other	Any upcoming data that does not fall under any other specified category. Often used for preclinical data or vaguely described data
Trial Data	Published Results	Any upcoming data that is published in a journal or publication, this will typically be a “final analysis”
Trial Data	Top-Line Results	Anticipated first mention of clinical efficacy data, falls under “interim analysis”
Trial Data	Updated Results	Upcoming updated clinical data from topline, also falls under “interim analysis”, can include more patients, longer treatment, followup, etc.
Trial Data	Trial Data (Emerging Markets)	Any upcoming data for a trial that is being conducted in a nonmajor market (i.e. BRIC, etc.)