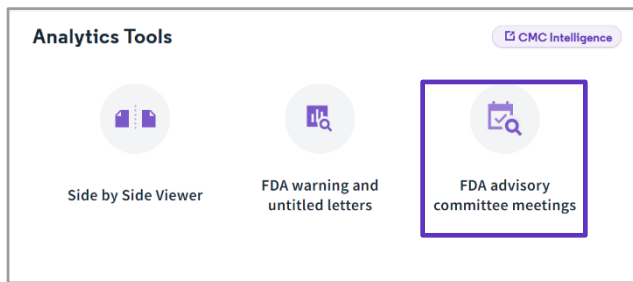


FDA ADCOM Meeting Analytics in Cortellis

These analytics help you quickly pinpoint the Cortellis FDA Advisory Committee Meeting Bulletins for products similar to yours, making it easier to prepare to go before an advisory committee with your products. Filter by date, type of product, committee, indication and more.



1. Access the FDA Analytics at the bottom of the Regulatory Home Page and **select FDA advisory committee meetings.**
2. The Analytic opens in a new tab.

Click bars in the table to view corresponding bulletins in Details section below

Select tabs to open each report

Hide or reset filters

Use drop down to change graph colors

Dynamic filters allow you to pinpoint bulletins by date, Advisory Committee, and more

Details section breaks down the specifics of each bulletin that matches your filtering

Total Number of Product Related Meetings

296	95	78	492
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Annual Breakdown

Year	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Count	24	29	13	25	16	19	30	56	33	27	41	32	24	22	24	23	21	19	14

Details

AdComm ID/RAC Number	Committee Name	Company	Product Name	Therapeutic Area	Active Ingredient	ATC Code	Indication
102618	Oncologic Drugs (ODAC)	ChemGenex Pharmaceuticals	Omapro	Cancer	Omacetaxine mesesuccinate	L01XX40	For the treatment of adults with chronic myeloid leukemia who have failed prior therapy with imatinib
102464	Oncologic Drugs (ODAC)	Cell Therapeutics	Pixuvi	Cancer	Pixantrone dimaleate	L01DB11	As a single agent treatment for patients with recurring or refractory (difficult to treat), aggressive acute myeloid leukemia
106159	Pulmonary-Allergy Drugs (PADAC)	Forest Research Institute	Daliresp	Respiratory disorders	Roflumilast	R03DX07	To reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis
107234	Anesthetic and Analgesic Drug	Acura Pharmaceuticals	Acurox	Pain	Oxycodone hydrochloride	N02AA55	For relief from moderate to severe pain where use of an immediate-release, orally administered formulation is not appropriate
107265	Anti-Infective Drugs	World Health	Artesunate	Infections	Artesunate	P01BE03	For the initial management of acute malaria in patients with severe malaria

Example: You are going before ODAC soon with a priority review oncology product and want to find ADCOMM bulletins for those products that received a Yes vote at committee and then later received an approval letter.

1. Select Voting versus FDA Decisions report

2. Limit Advisory Committee filter to ODAC

3. Limit Review Type filter to Priority

4. Click the Yes section of the chart (green) to view the corresponding ADCOMM Bulletins in the Details table

5. Right click anywhere in the Details table to export to Excel

Number of Advisory Committee Meetings Followed by an FDA Decision

Decision Type	Count
Approval Letter (Green)	28
FDA Decision Pending (Yellow)	11
Complete Response Letter (Red)	9
Withdrawn (Grey)	49

FDA Decisions following Advisory Committee Votes

AC Vote	Final Decision	Percentage
Yes	Approval Letter	91%
Yes	Complete Response Letter	9%
No	Approval Letter	24%
No	Complete Response Letter	47%
No	Withdrawn	24%
Empty	Approval Letter	10%
Empty	Complete Response Letter	40%
Empty	Withdrawn	50%

AdComm IDRAC Number	Committee Name	Company	Product Name	Therapeutic Area	Active Ingredient	ATC Code	Indication
169683	Oncologic Drugs (ODAC)	Genentech	Perjeta	Cancer	Pertuzumab	L01XC13	In combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with human epidermal growth factor receptor 2-positive locally advanced or metastatic breast cancer.
126290	Oncologic Drugs (ODAC)	Seattle Genetics	Adcetris	Cancer	Brentuximab vedotin	L01XC12	For treatment of patients with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior systemic therapy.
126242	Oncologic Drugs (ODAC)	Seattle Genetics	Adcetris	Cancer	Brentuximab Vedotin	L01XC12	For treatment of patients with Hodgkin lymphoma (HL) after failure of autologous stem cell transplantation.
122254	Oncologic Drugs (ODAC)	Novartis	Afinitor	Cancer	Everolimus	L01XE10	For the treatment of progressive neuroendocrine tumors of pancreatic origin.
122270	Oncologic Drugs (ODAC)	CP	Sutent	Cancer	Sunitinib maleate	L01XE04	For the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with a WHO performance grade of 0 or 1.
116532	Oncologic Drugs (ODAC)					L01XE12	For the treatment of symptomatic or progressive medullary thyroid cancer in patients with a WHO performance grade of 0 or 1.

AdComm IDRAC Number
169683
126290
126242
122254
122270
116532

6. Search the IDRAC numbers in Cortellis to find the corresponding ADCOMM Bulletins.

Search: 169683

Filter: Country/Region, Topic, Document Type, Document Category, Date Filter, Last Updated, All other filters, Reset Filters

For more information contact Customer Service at **LS Product Support**.