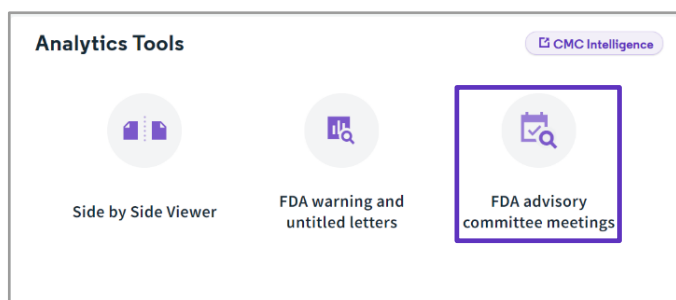


FDA ADCOM Meeting Analytics in Cortellis

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.



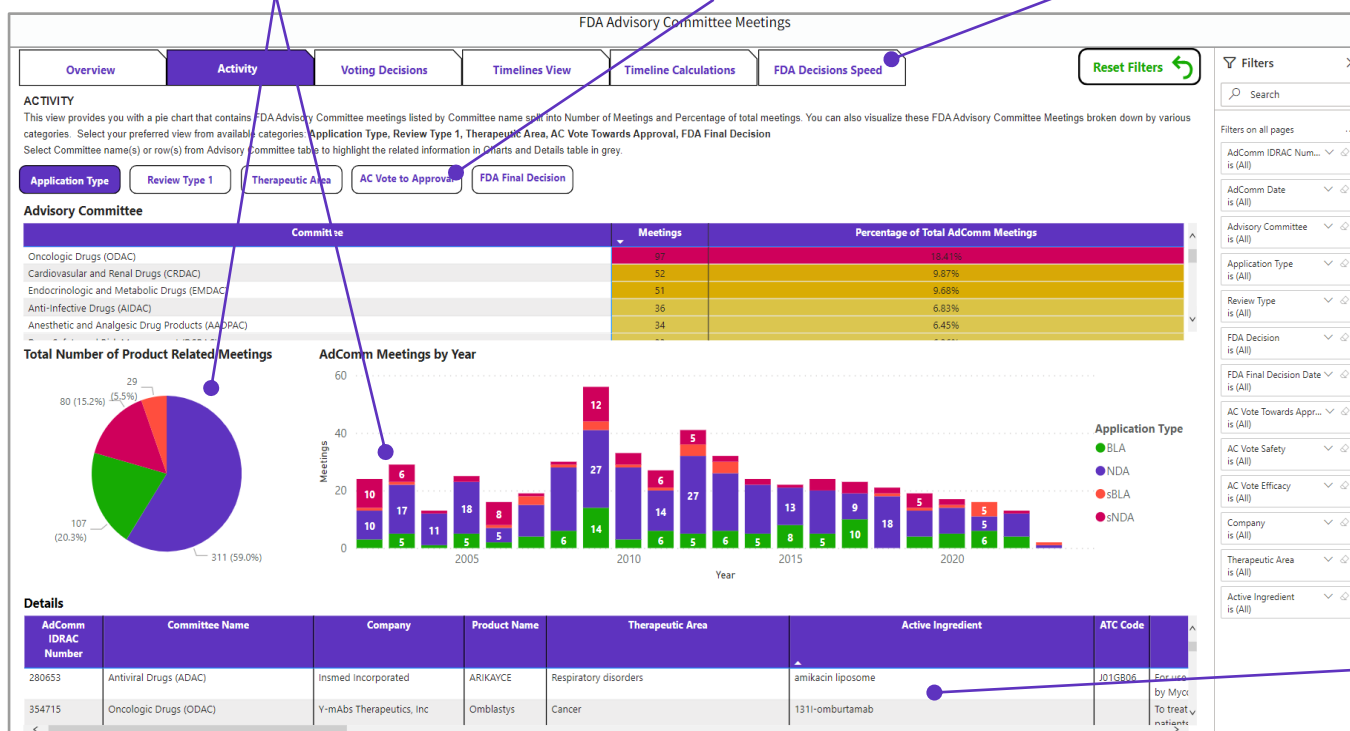
1. Access the FDA Analytics at the bottom of the Regulatory Home Page and **select FDA advisory committee meetings**.
2. The Analytic opens in a new tab. The **Overview** section provides information about the analytic's scope, terminologies and rules.
3. Click the **heading of interest** (e.g. Activity)

Click pies or bars in the charts to view corresponding bulletins in Details section

Click buttons to change view by category

Select headings to open each report

Hide or reset filters



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

Details section breaks down the specifics of each bulletin that matches

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.

Overview

Activity

Voting Decisions

Decisions Speed

1. Select Voting Decisions

2. Limit Advisory Committee filter to ODAC

3. Limit Review Type filter to Priority

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

5. Click the three dots to display all table details or export data to Excel

Reset Filters

Filters

Search

Filters on all pages

AdComm IDrac Num...

is (All)

AdComm Date

is (All)

Advisory Committee

is Oncologic Drugs (ODAC)

Filter type

Basic filtering

Search

Application Type

is (All)

Review Type

is Priority

Filter type

Basic filtering

Search

Select all

(Blank)

Accelerated Approval

1

2

15

54

Sort descending

Sort ascending

Sort by

VOTING DECISIONS

This view provides a Votes pie chart that contains a breakdown of:

• AC Vote Towards Approval: Outcome of Committee vote includes number of meetings and relevant percentage by votes by committee name

• FDA Final Decision: Breakdown of FDA Decisions following Advisory Committee Vote

Select Item(s) from Votes pie chart or Votes by Advisory Committee table to highlight related information in other Charts and Details table

Votes Towards Approval

Votes by Committee

Votes by Therapy Area

AC Vote to Approval

Committee

01 - Yes

Meetings

%

20

100.0%

Oncologic Drugs (ODAC)

17 (31.5%)

20 (37.0%)

17 (31.5%)

Yes

No

Not Available

FDA Decisions following Advisory Committee Votes

01 - Yes

02 - No

04 - Not Available

Meetings

20

10

0

Approvable Letter

Approval Letter

Complete Response Letter

Non-Approvable Letter

Withdrawn

Details

AdComm IDrac Number	Committee Name	Company	Product Name	Therapeutic Area	Active Ingredient	ATC Code	Indication	Application
95657	Oncologic Drugs (ODAC)	Schering-Plough	Sylatron	Cancer	Peginterferon alfa-2b	L03AB10	Adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.	sBLA
90316	Oncologic Drugs (ODAC)	Genentech	Avastin	Cancer	Bevacizumab	L01XC07	As a single agent for the treatment of previously treated glioblastoma multiforme.	sBLA

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

All

Comparison Tables

Intelligence Reports

Regulatory Summaries

Source Documents

Search

95657

Search

Advanced search

Filter

Country/Region

Topic

Document Type

Document Category

Date

Translation Status

All other filters

Reset Filters

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