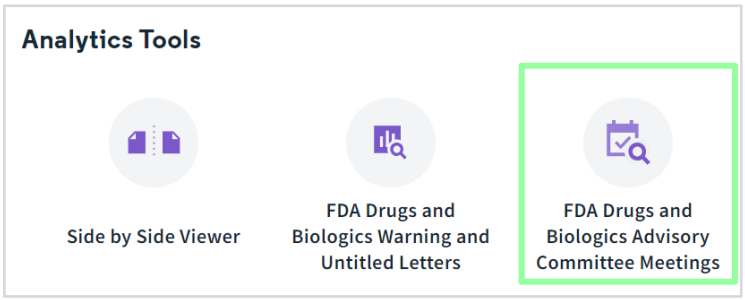
FDA ADCOM Meeting Analytics in Cortellis

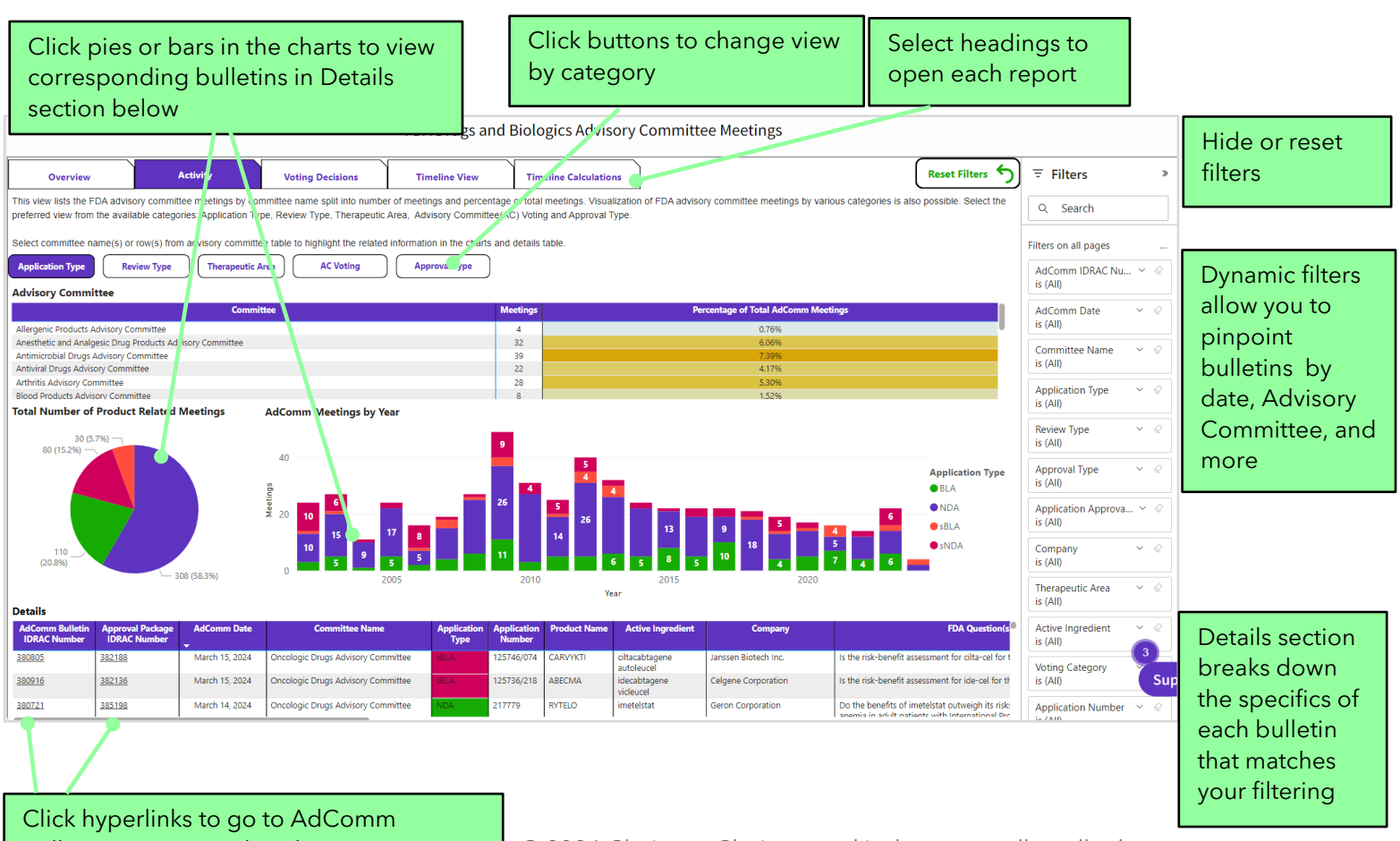
These analytics help you quickly pinpoint the Cortellis FDA Advisory Committee Meeting Bulletins for products similar to yours, making it easier to prepare to go before an advisory committee with your products. Filter by date, type of product, committee, indication and more.



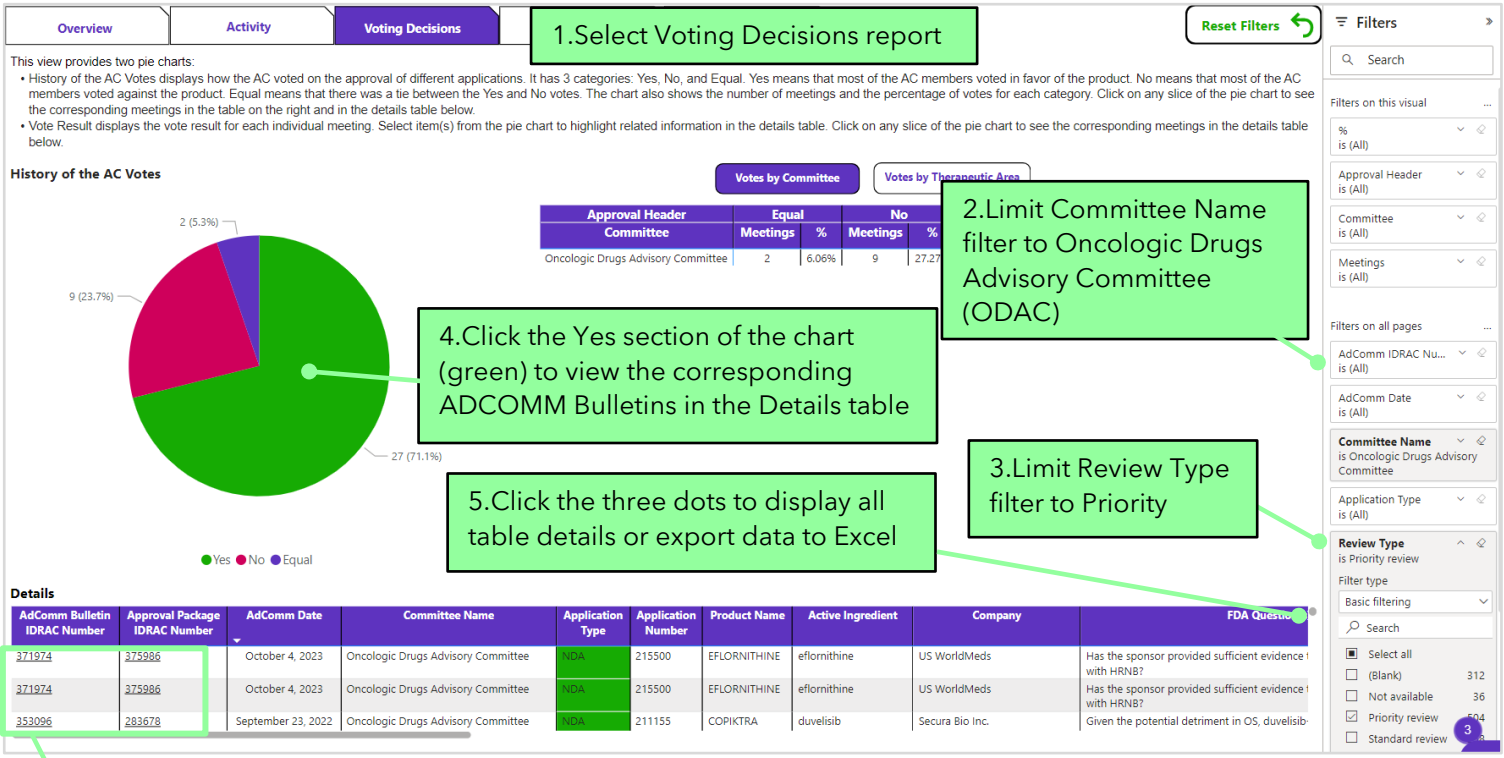
1. Access the FDA Analytics at the bottom of the Regulatory Home Page and **select FDA Drugs and Biologics Advisory Committee Meetings.**

2. The Analytic opens in a new tab. The **Overview** section provides information about the analytic's scope, terminologies and rules.

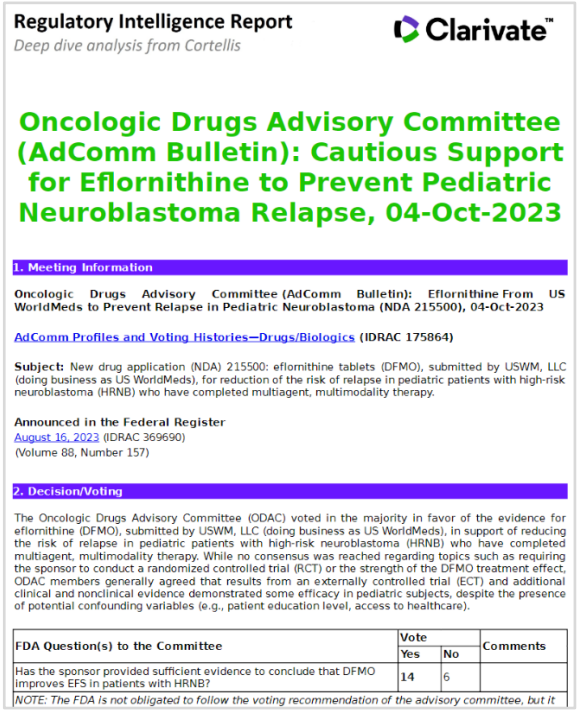
3. Click the **heading of interest** (e.g. Activity)



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.



6. Click the hyperlinks to open the AdComm Bulletins or Approval Packages directly from the Details section.



Regulatory Intelligence Report

Deep dive analysis from Cortellis

Clarivate™

Oncologic Drugs Advisory Committee (AdComm Bulletin): Cautious Support for Eflornithine to Prevent Pediatric Neuroblastoma Relapse, 04-Oct-2023

1. Meeting Information

Oncologic Drugs Advisory Committee (AdComm Bulletin): Eflornithine From US WorldMeds to Prevent Relapse in Pediatric Neuroblastoma (NDA 215500), 04-Oct-2023

AdComm Profiles and Voting Histories—Drugs/Biologics (IDRAC 175864)

Subject: New drug application (NDA) 215500: eflornithine tablets (DFMO), submitted by USWM, LLC (doing business as US WorldMeds), for reduction of the risk of relapse in pediatric patients with high-risk neuroblastoma (HRNB) who have completed multiagent, multimodality therapy.

Announced in the Federal Register

August 16, 2023 (IDRAC 369690)
(Volume 88, Number 157)

2. Decision/Voting

The Oncologic Drugs Advisory Committee (ODAC) voted in the majority in favor of the evidence for eflornithine (DFMO), submitted by USWM, LLC (doing business as US WorldMeds), in support of reducing the risk of relapse in pediatric patients with high-risk neuroblastoma (HRNB) who have completed multiagent, multimodality therapy. While no consensus was reached regarding topics such as requiring the sponsor to conduct a randomized controlled trial (RCT) or the strength of the DFMO treatment effect, ODAC members generally agreed that results from an externally controlled trial (ECT) and additional clinical and nonclinical evidence demonstrated some efficacy in pediatric subjects, despite the presence of potential confounding variables (e.g., patient education level, access to healthcare).

FDA Question(s) to the Committee	Vote		Comments
	Yes	No	
Has the sponsor provided sufficient evidence to conclude that DFMO improves EFS in patients with HRNB?	14	6	

NOTE: The FDA is not obligated to follow the voting recommendation of the advisory committee, but it

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