



Data Driven Insights Dashboard User Guide

Original Oncology Approvals 2013–Present



Introduction

Friends developed [this publicly available interactive dashboard](#) to explore data on new oncology drugs approved by the US Food and Drug Administration (FDA) since 2013.

The data are updated daily to reflect review and approval timelines, User Fee goal dates, use of expedited programs and Oncology Center of Excellence (OCE) pilot programs, drug classes, indications, and other drug approval information.

This guide includes several use cases that highlight key features of the dashboard users can interact with to gain data-driven insights on the landscape of oncology drugs approved over the last decade.

Please submit feedback and questions to info@focr.org



Interactive Features



Select A Trend

By Group ▼

Over time

By Group

Select a Trend – Changes how approvals are grouped on the X-Axis (by year of approval or by group selected).

Select A Group

Expedited vs. Traditional ▼

Expedited vs. Traditional

All Expedited Programs

Combined Expedited Programs

All Pilot Programs

Combined Pilot Programs

Select a Group – Changes the legend/how approvals are categorized.

Carvykti	3.8
Kimtrak	10.0

Kimtrak (tebentafusp-tebn)
for treatment of Skin Cancer

Approved **1/25/2022**, 29 day(s) before the PDUFA Goal Date.

Development Time: **9.4 Years**
Review Time: **7.1 Months**
Drug Class: **Bispecific Antibodies**
Expedited Programs Used: **BTD & PR**
Pilot Programs Used: **AAid, Orbis, & RTOR**

Details – Hover your mouse over elements on the graph or the table to the right for additional details on the datapoint/approval.

Filter By

First-in-class
(All) ▼

Drug Class
(All) ▼

Indication
(All) ▼

PDUFA Timing
(All) ▼

Filters – Include/exclude drugs based on approval characteristics.

Elements on the graph can also be selected to filter the table of approvals on the right.

Undo/redo last action

Reset dashboard

View full screen

Download an image of the dashboard

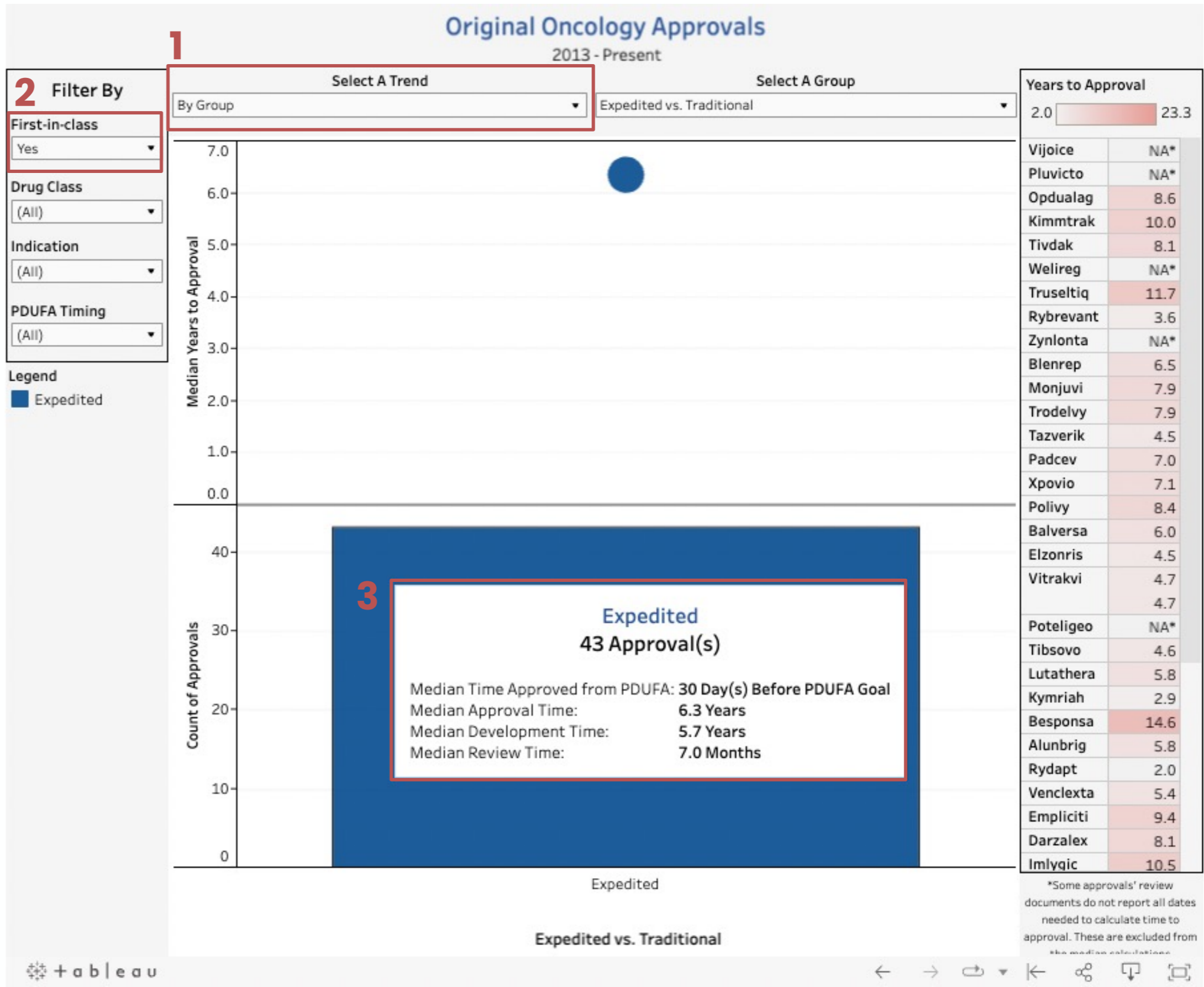


Use Case #1: How do expedited programs support approvals of first-in-class drugs?

1. Show approvals grouped by expedited vs. traditional by changing the "Select a Trend" parameter to "By Group".
2. Show only first-in-class approvals by selecting "Yes" under the first-in-class filter.
3. Hover mouse over bar graph for details.

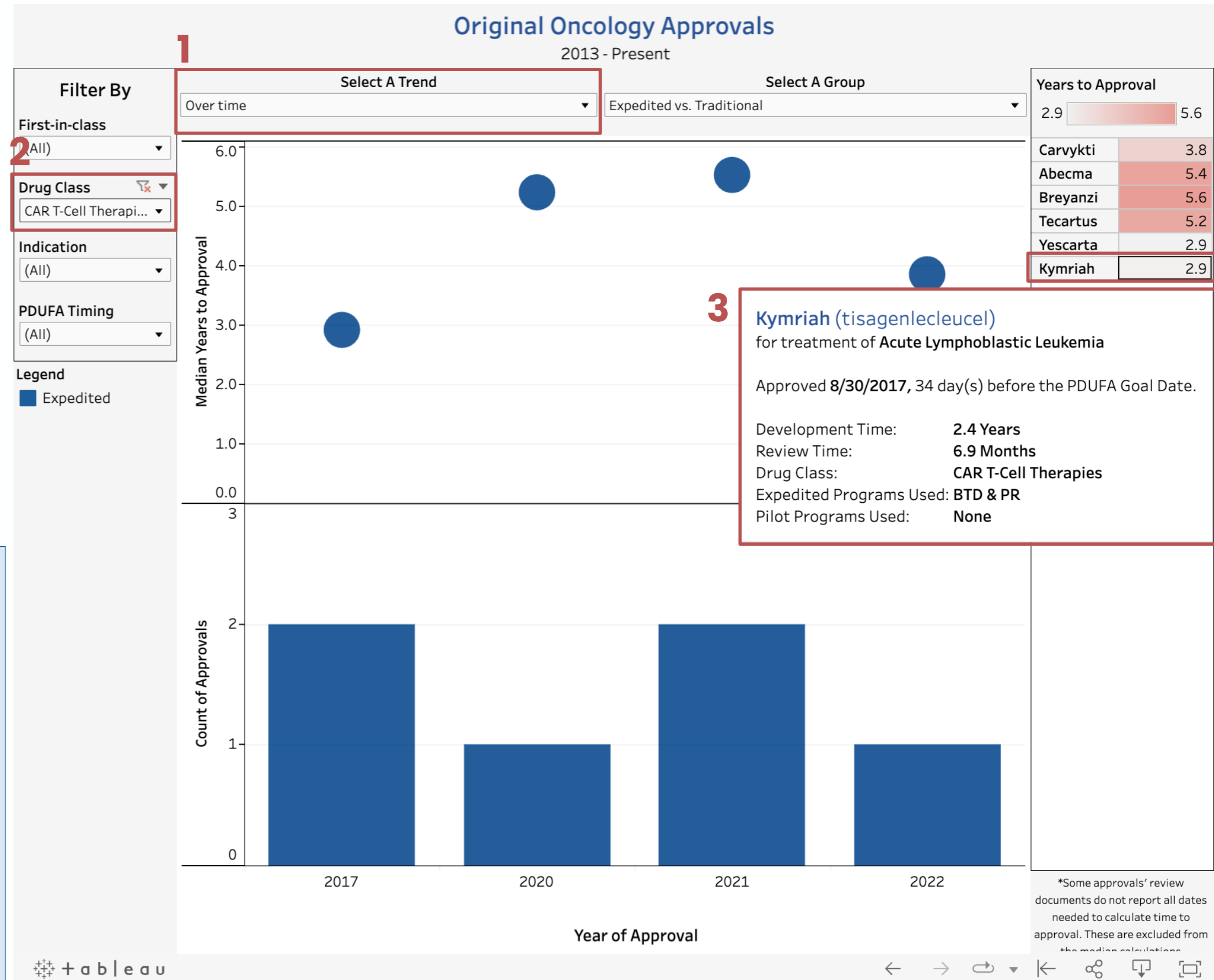
Insights

- There have been 43 first-in-class drugs approved since 2013.
- All first-in-class drugs approved used at least one expedited program.
- Expedited programs helped get first-in-class drugs approved in a median of 6.3 years.



Use Case #2: How many cell/gene therapies have been approved since 2013 and for which indications?

1. Select "Over time."
2. Filter "Drug Class" by CAR T Cell Therapies.
3. Hover over the list on the right to view details (including indications) about each approval.



Insights

- 6 CAR T Cell therapies have been approved since 2013.
- 3 drugs were approved to treat Non-Hodgkin Lymphoma, 2 for multiple myeloma, and 1 for Acute Lymphoblastic Leukemia.
- All 6 approvals were granted Breakthrough Therapy Designation.

Use Case #3: What drugs were approved in 2020 using Accelerated Approval, Breakthrough Therapy Designation, & Priority Review?

1. Select "Overtime"
2. Select "Combined Expedited Programs."
3. Select "AA, BT, & PR" to highlight the group in the graph.
4. Select the portion of the bar in 2020 that is highlighted to filter the list on the right.
5. Use the list of approvals on the right to explore details about these approvals.

