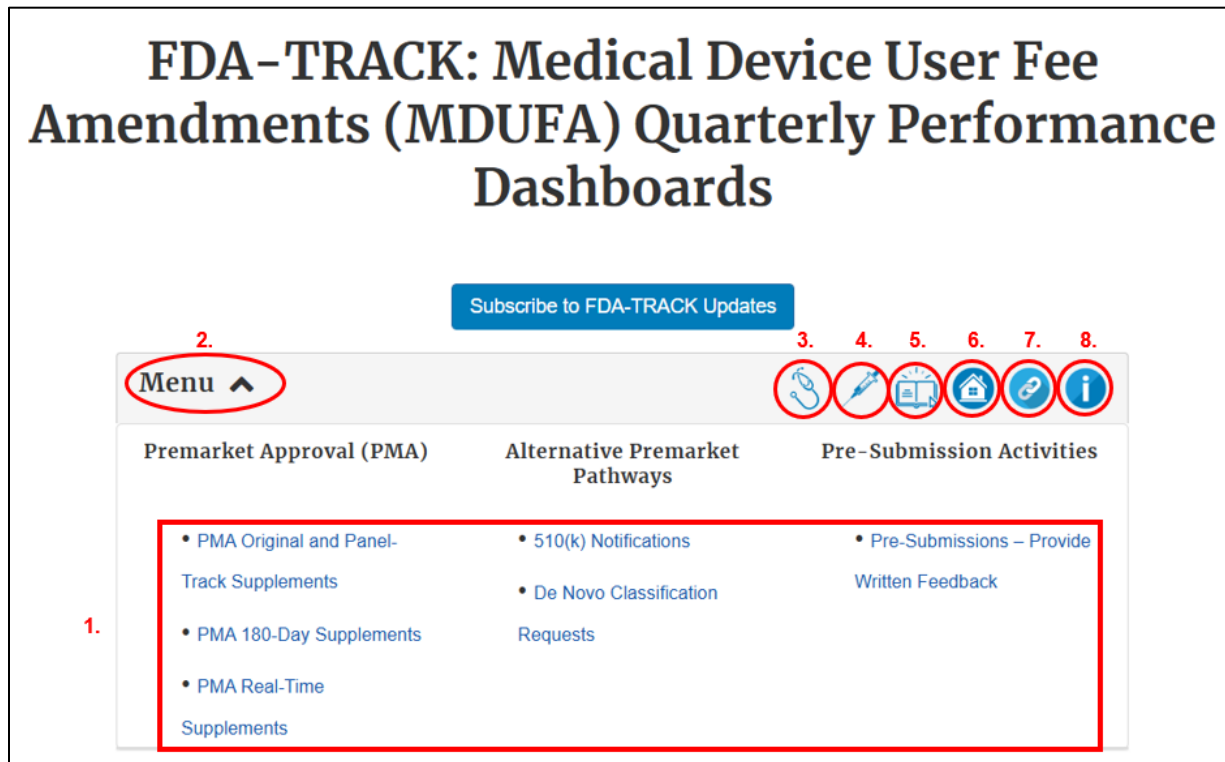


MDUFA Quarterly Performance Dashboards User Guide

Navigation and Relevant Information

The [MDUFA Quarterly Performance Dashboards](#) are organized into three categories: 1) Premarket Approval (PMA); 2) Alternative Premarket Pathways; and 3) Pre-Submission Activities. Each category includes a navigation menu and icons at the top of each dashboard. The menu and icons include information on:

1. MDUFA Quarterly Dashboards for each category showing the four most recent years of performance for each goal
2. Click here to collapse the menu or return to dashboard navigation
3. FDA-TRACK Medical Devices Home Page
4. FDA-TRACK Biologics Home Page
5. MDUFA Performance Dashboards User Guide
6. FDA-TRACK Home Page
7. Relevant Links about MDUFA
8. General background about MDUFA

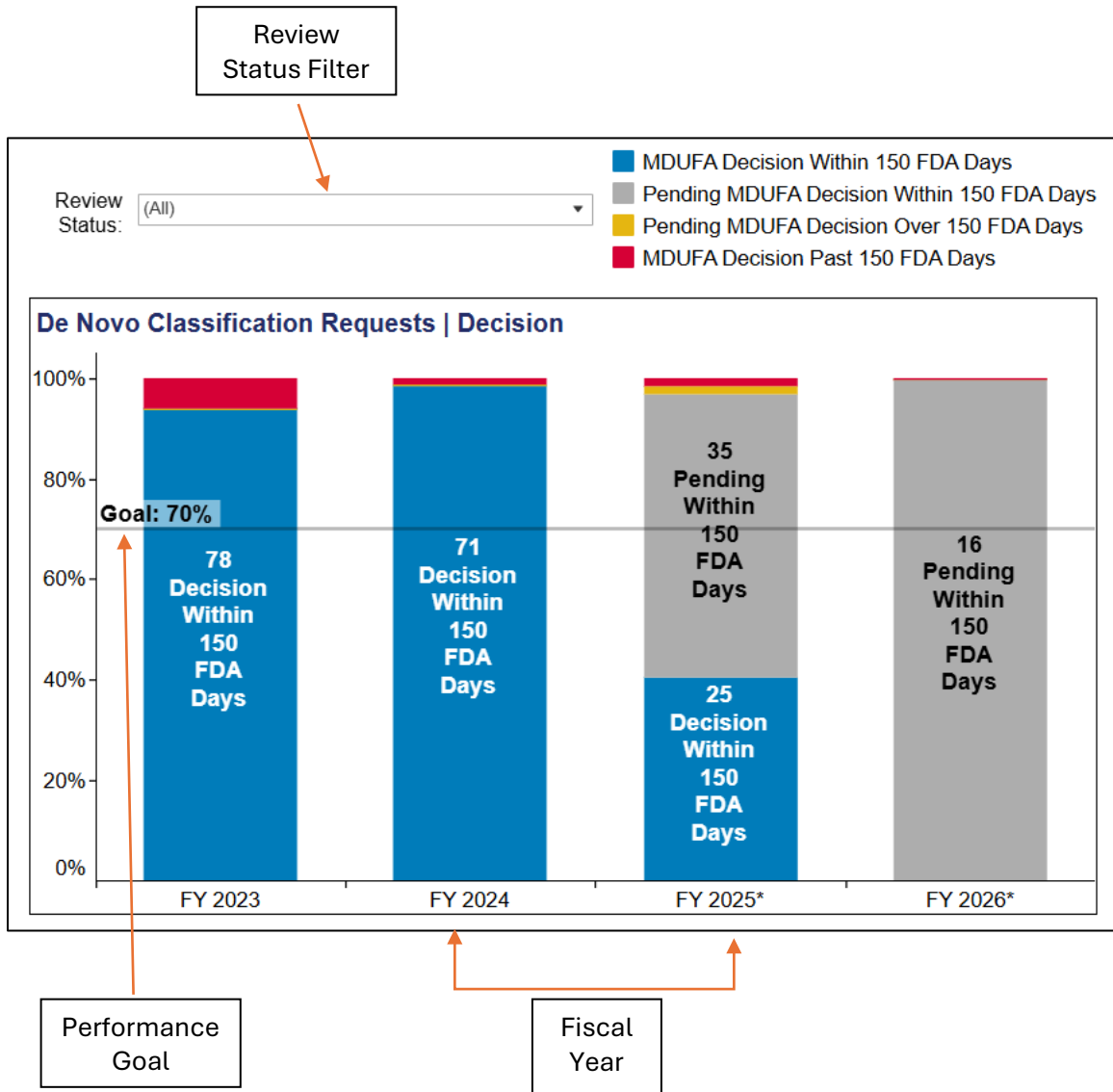


The MDUFA Quarterly Performance Dashboards show the four most recent years of performance on submissions received. The first two years' data is final or updated due to review timelines that can extend beyond the fiscal year. The third- and fourth-year data are preliminary and updated quarterly, as actions may be pending.

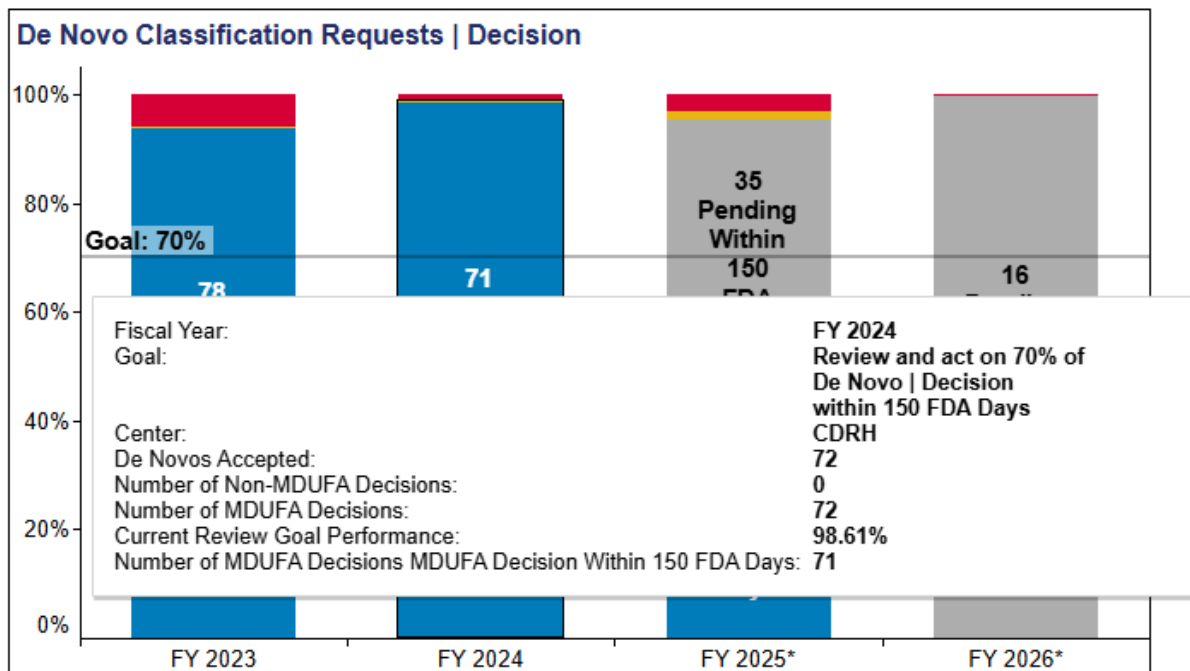
The Performance Dashboard pages display a stacked bar chart for each year of performance:

- The color of each segment of the bar represents review status:
 - Blue represents actions completed “Goal Met,” or within the MDUFA goal date.
 - Gray represents actions “Pending Within Goal,” where no action has been taken and submissions are within the MDUFA goal date.
 - Yellow represents actions “Pending Past Goal,” where no action has been taken and submissions are past the MDUFA goal date.
 - Red represents actions “Goal Not Met” or “Past Goal,” where action was taken after the MDUFA goal date.
- Each bar is labeled with the total number of submissions in the review statuses described above.
- A review status filter is available above each dashboard to improve data visibility, especially when there is a large number of submissions in one status and a relatively small number in others.
- The “Performance Goal” is shown as a solid horizontal line on the graph.

In the example below, 72 submissions were accepted in FY 2024. Of those submissions, 71 or 98.61% were within the MDUFA goal date. Since the red bar does not reach the performance goal line from the top and the blue bar passes it, the goal was met. In FY 2025, 62 submissions were accepted. Excluding pending submissions, the current performance is 92.59%. The grey bar reaches the performance goal line, while the blue bar remains below it, indicating that the goal is currently being met but may change depending on the outcome of pending submissions.



To see a “Tooltip” that displays additional information, hover the cursor over each status on a bar, as shown in the example below.



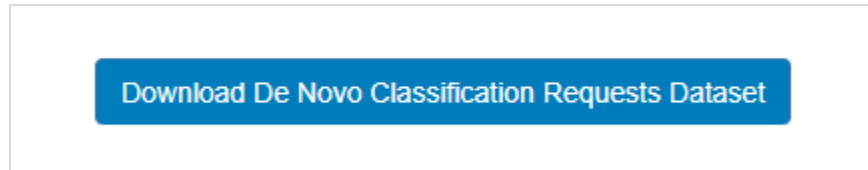
The Tooltip provides several useful pieces of information. These include:

- Submissions Accepted Submissions are complete and can be processed for review.
- Fiscal Year: The Fiscal Year of the receipt of the submission subject to the goal.
- Goal: The performance goal, type of action, and review time of the goal.
- Center: The FDA Center responsible for the review.
- Submission Metrics: Information about submissions received, accepted, or eligible for review under the goal
- Number of Non-MDUFA Decisions: The number of submissions that are not subject to MDUFA.
- Number of MDUFA Decisions: The number of submissions that are subject to MDUFA
- Current Review Goal Performance: The percentage of submissions with a final decision issued by the MDUFA goal date.
- Number of Submissions per Review Status: For a specific status, the total number of submissions included in that status.

Note: The specific metrics displayed vary by submission type and dashboard.

Datasets and Footnotes

The data in each dashboard can be downloaded by selecting the dataset button below each dashboard, as shown below for the De Novo Classification Requests Dashboard.



Footnotes are provided below each dashboard showing relevant information, for example, noting whether data is preliminary, or clarifying differences in data inclusion criteria for specific goals.

Footnotes:

* FY 2025 and FY 2026 includes preliminary performance as of 12/31/2025.