

PDUFA Performance Dashboard Performance Dashboard app Instruction Manual

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PDUFA Performance Dashboard Performance Dashboard app

INSTRUCTION MANUAL

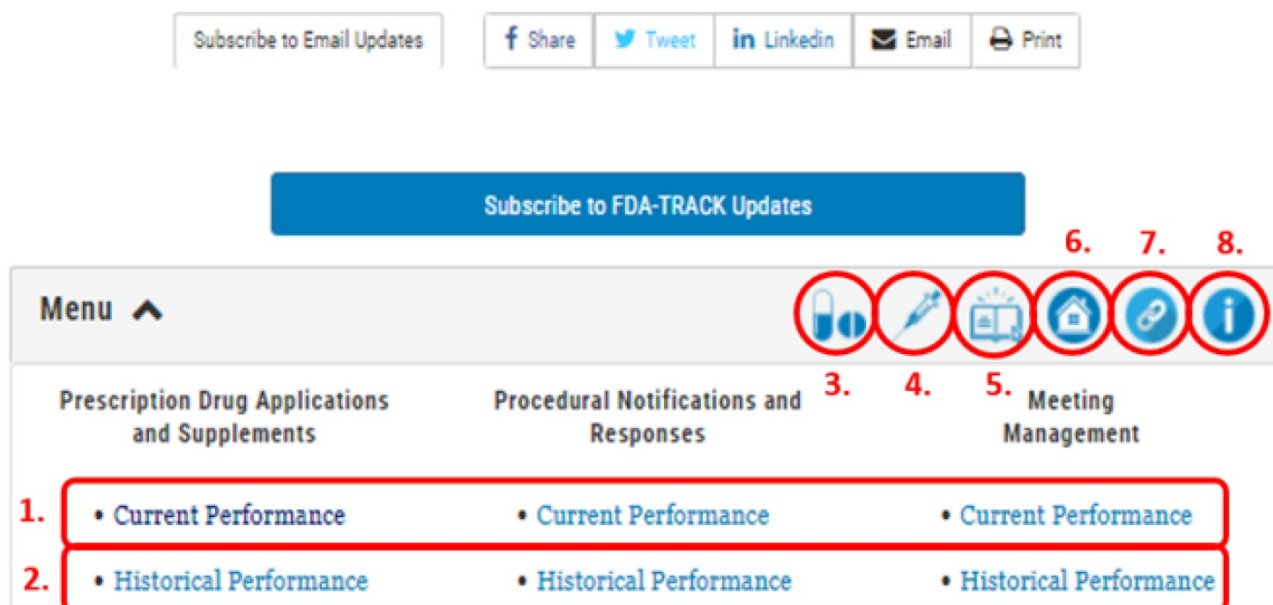
Navigation and Relevant Information

The [PDUFA Performance Dashboards](#) are organized into three categories: 1) Prescription Drug Applications and Supplements; 2) Procedural Notifications and Responses; and 3) Meeting Management. Each category includes a Current and Historical Performance Dashboard with a navigation menu and icons at the top of each dashboard. The menu and icons include information to:

1. PDUFA Current Performance Dashboards for each category showing the two most recent years of performance for each goal
2. PDUFA Historical Performance Dashboards for each category showing the historical performance for each goal
3. FDA-TRACK Drugs Home Page

4. FDA-TRACK Biologics Home Page
5. PDUFA Dashboard User Guide
6. FDA-TRACK Home Page
7. Relevant Links about PDUFA
8. General background about PDUFA

FDA-TRACK: PDUFA Performance



Current Performance

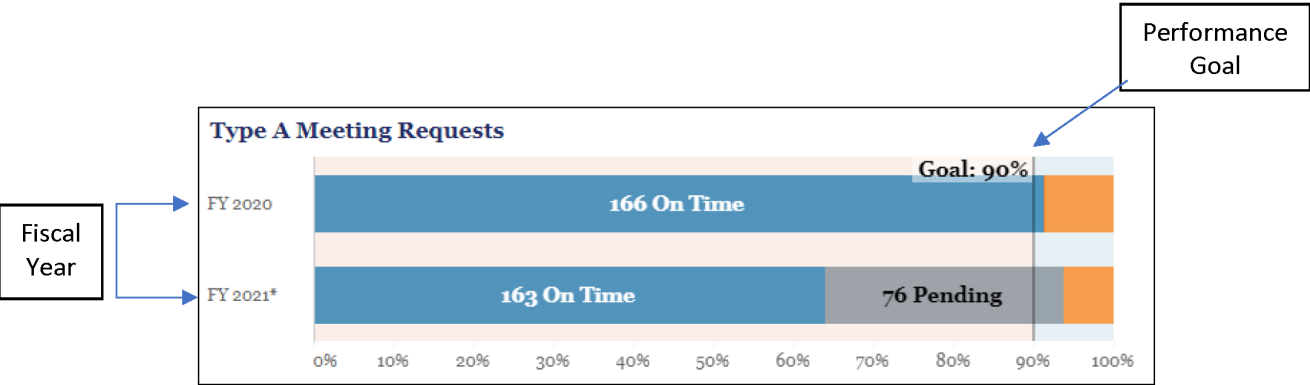
The Current Performance page of the PDUFA Performance Dashboard shows the two most recent years of performance for each established goal and the most recent year of performance for newly implemented goals established under PDUFA VII. When more than one year of data is reported, the first year's data is final, and the second year's data is preliminary with some actions still pending.

The Current Performance page displays a stacked bar chart for each year of performance:

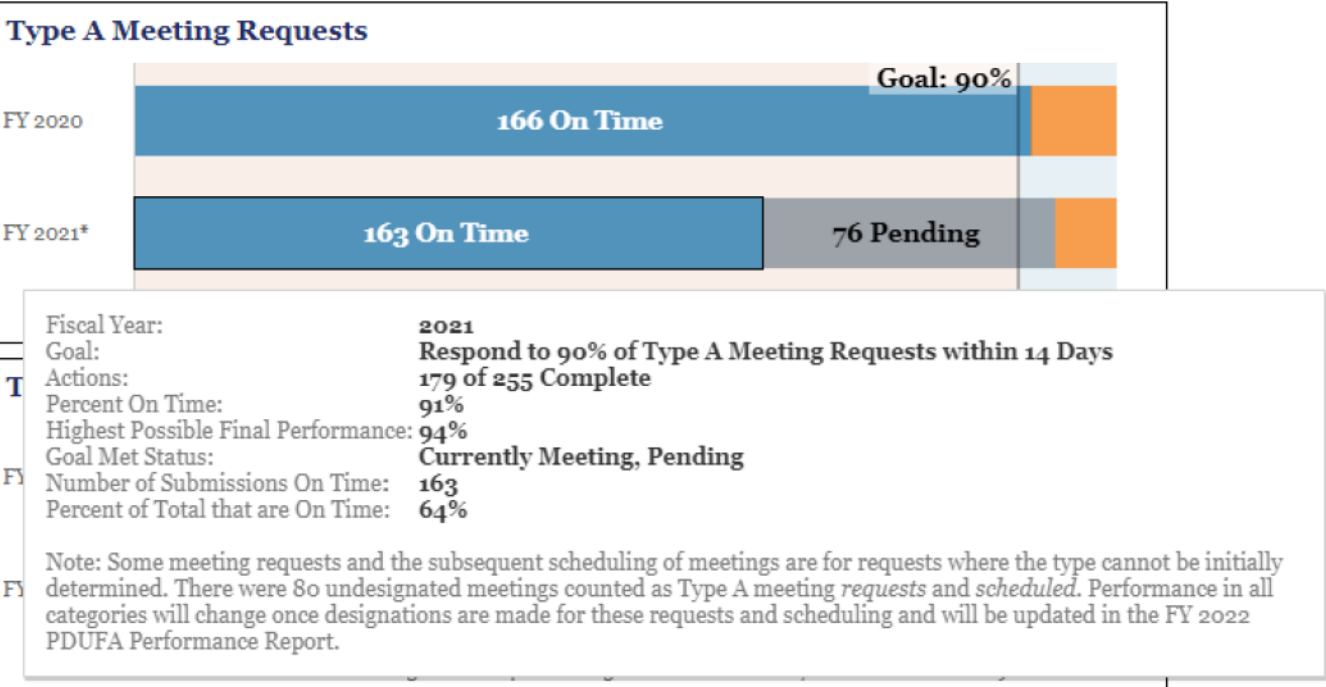
- The color of each segment of the bar represents status:
 - Blue represents actions completed “On Time,” or within goal;
 - Gray represents actions “Pending,” or within goal and where no action has been taken;
 - Orange represents actions “Overdue,” where action was taken after the goal date, or no action was taken and is past the goal date.
- Each bar is labeled with the number of actions in that status, except in cases where the volume of actions with that status is extremely small. In some instances, the label for the review status will not display in the graph due to space. This is an automatic default setting in the visualization software. If you hover the cursor over the section of the graph where the label is missing, the label details will appear in the Tooltip.
- The “Performance Goal” is shown as a solid vertical line on the graph:
 - If the blue bar reaches the performance goal line from the left, the goal status is “Goal Met”, or “Will Meet Goal.”
 - If the gray bar crosses the performance goal line and the Percent On Time meets or exceeds the

performance goal, the goal status is “Currently Meeting, Pending.” If the gray bar crosses the performance goal line and the Percent On Time is below the goal, the goal status is “Currently Not Meeting, Pending.” If the orange bar reaches the performance goal line from the right, the goal status is “Goal Not Met” or “Will Not Meet Goal.”

In the example below, 182 submissions were filed in FY 2020. Of those submissions, 91% (166) met the performance goal, while 9% (16) did not. Since the orange bar does not reach the performance goal line from the left, the status of that goal is “Goal Met.” In FY 2021, 255 submissions were filed; 64% (163) were on time, 30% (76) were still pending, and 6% (16) were overdue. Since the gray bar reaches the goal line, the status of that goal is “Currently Meeting, Pending.”



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:

- 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.

- Actions:
 - For final data, the number of actions out of the total that were on time.
 - For preliminary data, the number of actions that are completed, regardless of whether they were on time or overdue, out of all potential actions.
- Percent on Time: The percent of actions that met the goal.
- Highest Possible Performance: The highest performance that can be achieved if all “Pending” within goal submissions are acted upon within goal.
- Goal Met Status: The statuses are “Goal Met,” “Will Meet Goal,” “Currently Meeting, Pending,” “Currently Not Meeting, Pending,” “Will Not Meet Goal,” or “Goal Not Met.”
- Number of Submissions: For a specified status, the number of submissions included in that status.
- Percent of Total: For a specified status, the percentage portion of submissions in relation to the total (100%).
- Additional Notes: Any additional pertinent information about how a specific performance goal is measured.

Historical Performance

The Historical Performance page of the PDUFA Performance Dashboard shows the past six years of data for each performance goal. The past five years of data are final and the past year of data, which may include newly implemented goals, is preliminary with actions still pending. The Performance Goal Filter above the chart allows for the selection of a goal as seen in the example below.

FDA-TRACK: PDUFA Historical Performance – Prescription Drug Applications and Supplements

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Prescription Drug Applications
and Supplements

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Procedural Notifications and
Responses

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Meeting
Management

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Review Workload: FY 2016 to FY 2021

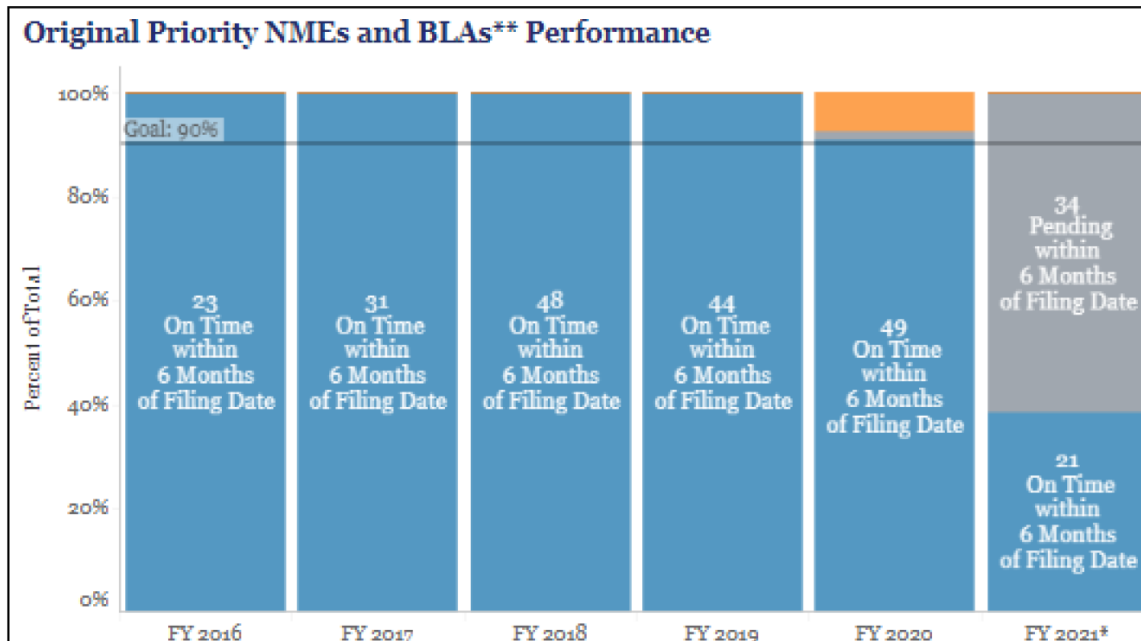
In the charts below, preliminary workload numbers from FY 2021 are compared to the previous 5-year averages for the review goals which include: NDAs and BLAs, resubmissions, and supplements. FDA saw an increase between FY 2020 and FY 2021 in the number of original priority NMEs and BLAs, original priority non-NME NDAs, original standard non-NME NDAs, and NDA and BLA manufacturing supplements requiring prior approval.

Submission type definitions and other terms are found in Appendix E of the annual PDUFA Performance Report. The data presented in these charts represent receipts by FDA of the submission types.

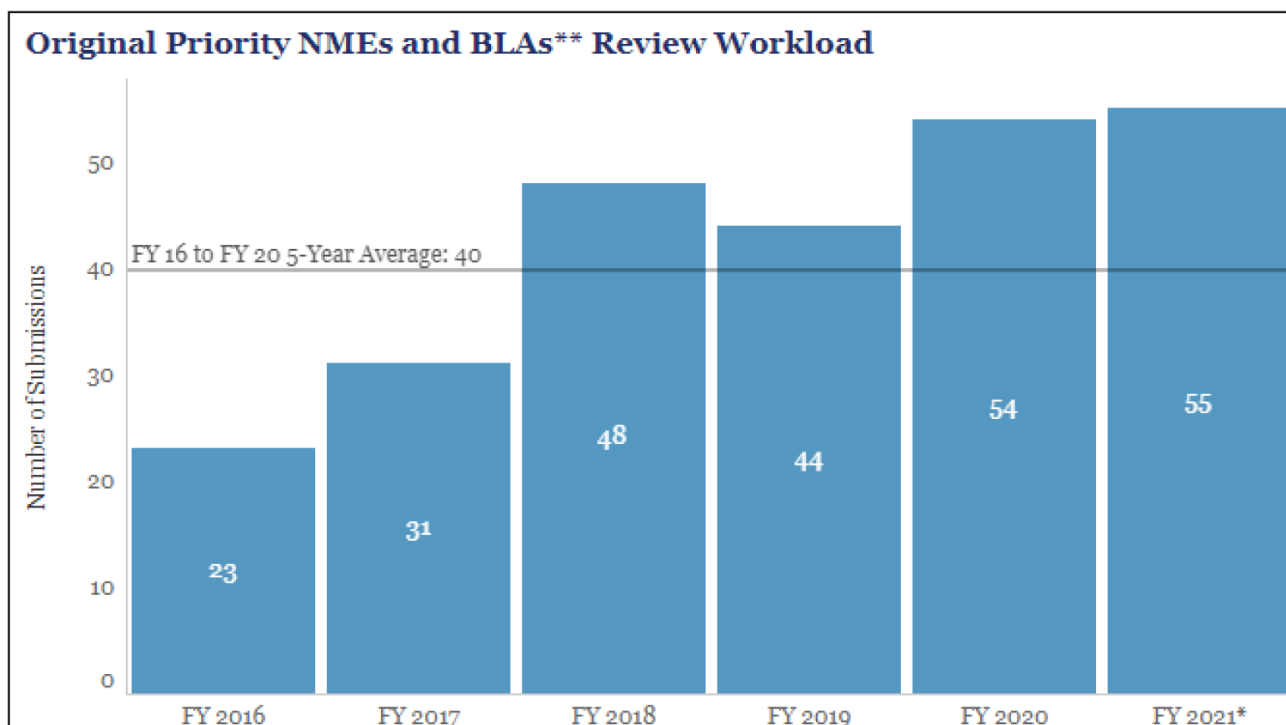
Performance Goal:

Original Priority NMEs and BLAs**

Review Status: ■ Overdue ■ Pending ■ On Time



Workload data represents the number of submissions subject to the specific goals during the drug review process. The “average” line through the graph represents the average number of submissions over the five-year period of final performance data, excluding the preliminary data.



Datasets and Footnotes

The data in each dashboard can be downloaded by selecting the dataset button below each dashboard, as shown below for the Current Performance for the Prescription Drug Applications and Supplements Dashboard.

[Download Prescription Drug Applications and Supplements Dataset](#)

Footnotes are provided below each dashboard showing relevant information, for example, noting whether there were changes in the performance goals, or whether data is preliminary.

Footnotes:

* Performance is currently preliminary due to pending submissions.

*** The most recent FY workload and performance data includes applications that are identified as undesignated, which means they are still within the 60-day filing date and have not yet had a review designation, standard or priority, made.

Specifications:

- Categories: Prescription Drug Applications and Supplements, Procedural Notifications and Responses, Meeting Management
- Performance Dashboards: Current and Historical for each category
- Features: Navigation menu, icons for easy access to information

FAQ

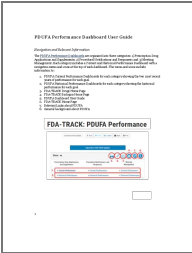
Q: How can I download the data from the dashboards?

A: You can download the data by selecting the dataset button below each dashboard.

Q: What does the average line in the graph represent?

A: The average line represents the average number of submissions over the five-year period of final performance data, excluding preliminary data.

Documents / Resources

	<p>PDUFA Performance Dashboard Performance Dashboard app [pdf] Instruction Manual</p> <p>Performance Dashboard app, Performance, Dashboard app, app</p>
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References

- [User Manual](#)

[Manuals+](#), [Privacy Policy](#)

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