Third Party Review Organization Performance Report

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Introduction and Review Timeline Description

The Accredited Persons Program was created by the FDA Modernization Act of 1997 (FDAMA) to improve the efficiency and timeliness of FDA's 510(k) process. Under the program, FDA accredits Third Parties (Accredited Persons) that are authorized to conduct the primary review of 510(k)s for eligible devices. Under MDUFA V, the FDA committed to publishing the performance of individual accredited Third Parties with at least five completed submissions on the Web (e.g., rate of NSE, average number of holds, average time to SE) . A summary of Third Party Performance Metrics will be posted on a quarterly basis. This report contains data from FY 2023, Q1 (October 1, 2022, through December 31, 2022). The number of Third Party Review Organizations with at least 5 completed submissions for each Fiscal Year is shown below:

FY2023	FY2024	FY2025	FY2026	FY2027
1	0	0	0	0

The cumulative number of Third Party 510(k) submissions accepted by Quarter for each Fiscal Year is shown below:

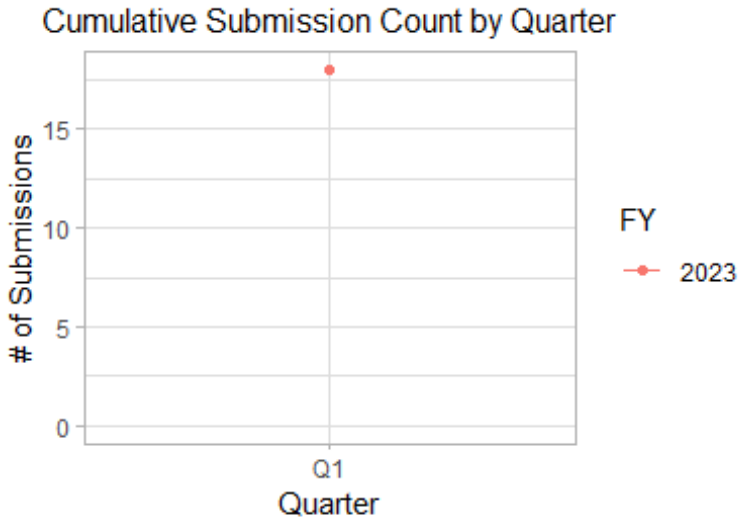
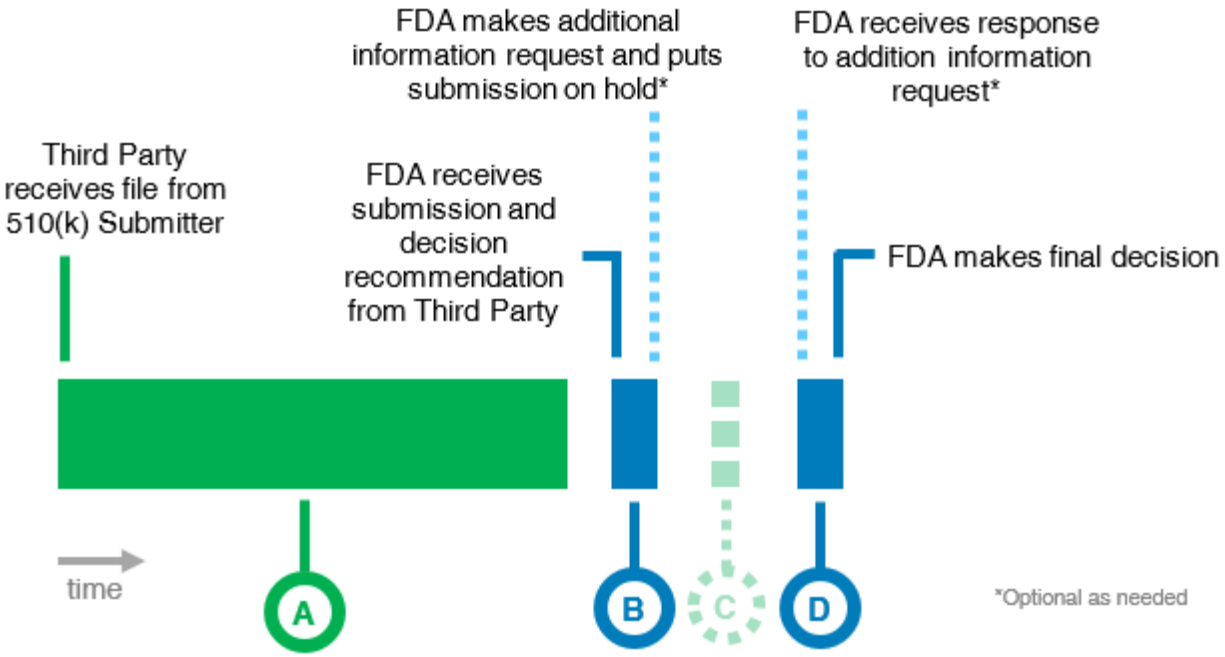


Figure 1

A Third Party 510(k) submission goes through four different stages before a final decision is made by FDA.

- Stage A - The Third Party receives the file from the 510(k) Submitter, reviews the file, and sends the file and its decision recommendation to FDA.
- Stage B - FDA reviews the submission to ensure that the Third Party has submitted all the information needed to make a final decision. If more information is needed, FDA makes a request of additional information, notifies the Third Party, and puts the submission on hold.
- Stage C (Optional) - The Third Party reviews FDA's request for additional information and notifies the 510(k) submitter. The Third Party responds to FDA's deficiencies, updating the review memo and submission as necessary. The submission is considered on hold until FDA receives a complete response to its request for additional information.
- Stage D - FDA reviews the additional information, if requested and subsequently provided, and makes a final decision.



Definitions

1) **Initial Third Party Review Time**:

= Date FDA receives Third Party submission
- Date Third Party receives the file from the 510(k) Submitter

Elapsed time in days for the Third Party to review the 510(k) Submitter's file and determine its decision recommendation for a final MDUFA V decision (SE or NSE). The elapsed time includes the time needed for the 510(k) Submitter to resolve deficiencies. The Third Party provides the Submitter's file, its associated Third Party review documentation and its decision recommendation to FDA.

2) **Third Party Hold Time**:

= Date FDA receives response to request for additional information
- Date FDA makes decision to put submission on hold

Elapsed time in days for the Third Party to respond to a request for additional information from FDA for a final MDUFA V decision (SE or NSE). If the Third Party does not receive a request for additional information, *Third Party Hold Time* is set to 0 days. If the file is placed on hold more than once, this is the total number of days the file has been on hold.

3) **Total Third Party Review Time**:

= *Initial Third Party Review Time* + *Third Party Hold Time*

Elapsed time in days for a Third Party to review a file from a 510(k) Submitter, including the time it is on hold for a final MDUFA V decision (SE or NSE).

4) **Total FDA Review Time**:

= Date FDA makes Final Decision - Date FDA receives Third Party Submission
- *Third Party Hold Time*

Elapsed time in days for FDA to provide a final MDUFA V decision (SE or NSE) to a Third Party submission. By statute, FDA must provide a final MDUFA V decision in 30 days. *Total FDA Review Time* does not include the number of days that a submission is on hold waiting for additional information from the Third Party.

5) **Total Time to Decision from FDA Receipt**:

= *Total FDA Review Time* + *Third Party Hold Time*

Elapsed time in days between FDA's receipt of a Third Party submission and FDA's final MDUFA V decision (SE or NSE). *Total Time to Decision from FDA Receipt* includes *Third Party Hold Time*, while *Total FDA Review Time* does not. For non-Third Party files, *Total Time to Decision from FDA Receipt* is called Total Time to Decision (TTD).

6) **Total Time to Decision from Third Party Receipt**:

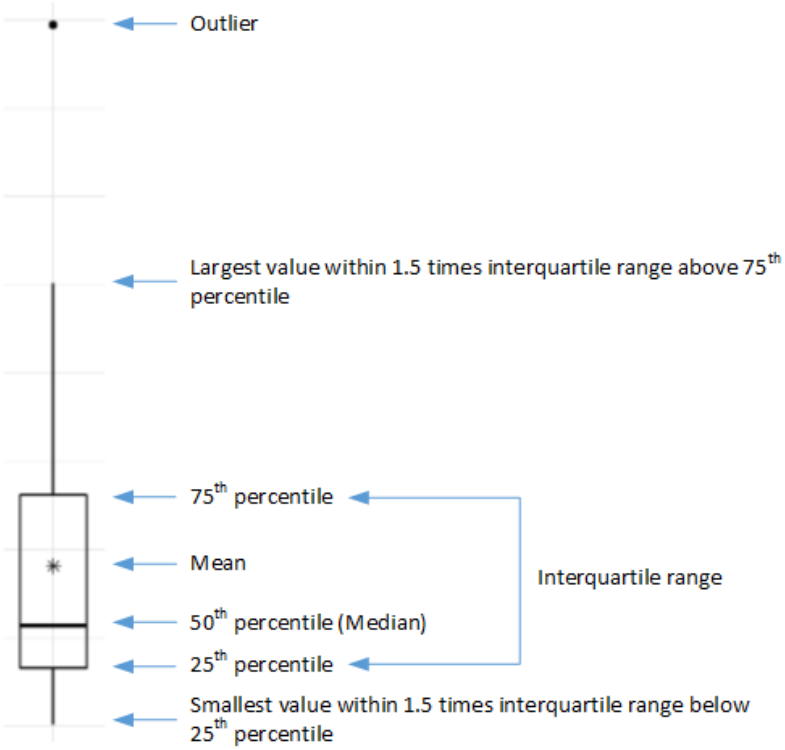
= *Total Third Party Review Time + Total FDA Review Time*

Elapsed time in days for FDA and a Third Party to provide a final MDUFA V decision (SE or NSE) to a submitter. *Total Time to Decision from Third Party Receipt* spans the entire lifecycle of a TP submission.

Names of Third Party Review Organizations

All 3PROs	All Third Party Review Organizations
AABB	AABB
BSV	BeanStock Ventures
CMSI	Center for Measurement Standards of Industrial
COLA	COLA, Inc.
GQRS	Global Quality and Regulatory Services
NYSDOH	New York State Department of Health
RTS	Regulatory Technology Services, LLC
SGS	SGS North America
TPRG	Third Party Review Group, LLC

Box Plot Legend:



Box Plot Sources:
Tukey (John W. Tukey (1977). Exploratory Data Analysis. Addison-Wesley.)
H. Wickham. ggplot2: Elegant Graphics for Data Analysis. Springer-Verlag New York, 2016.

Third Party Performance Data

Initial Third Party Review Time

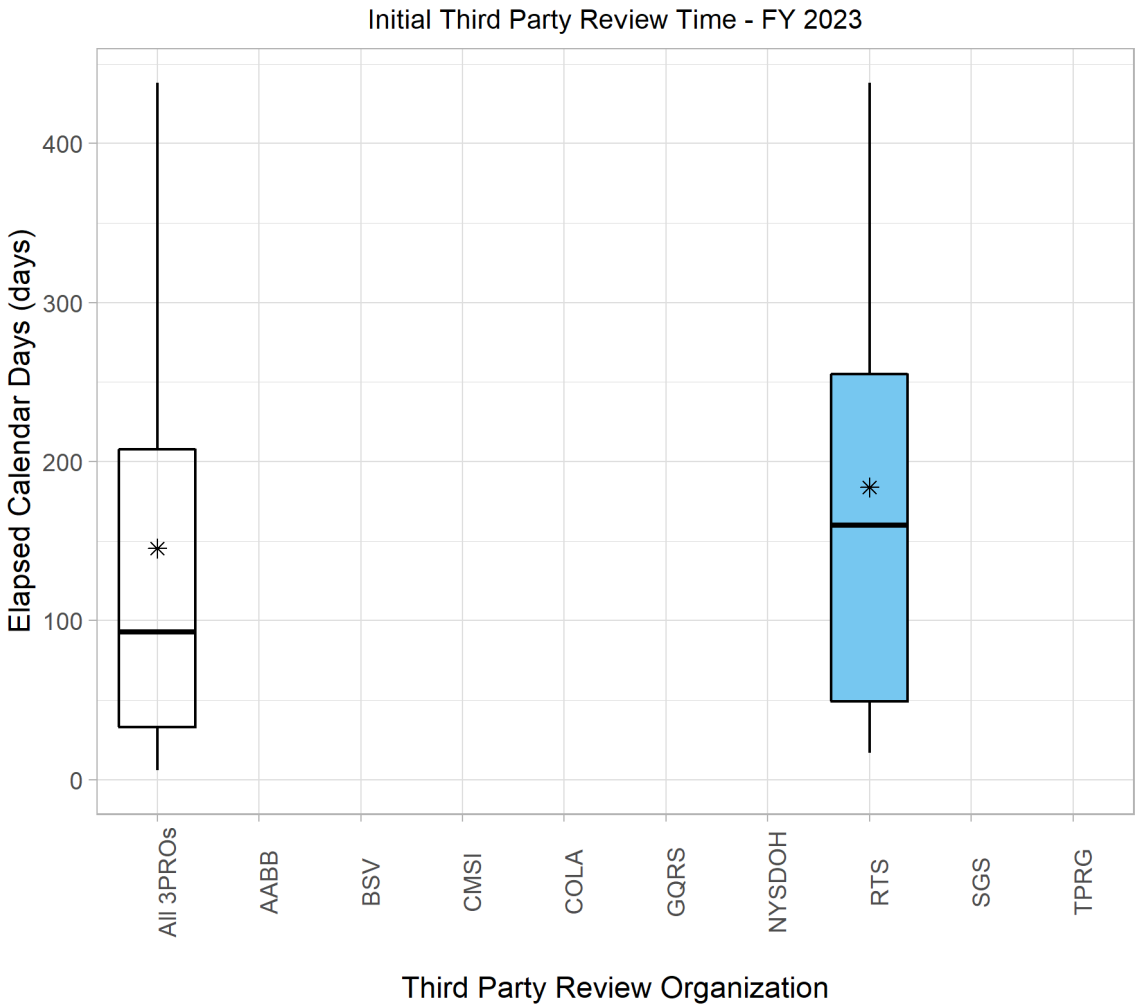


Figure 2

Third Party Hold Time

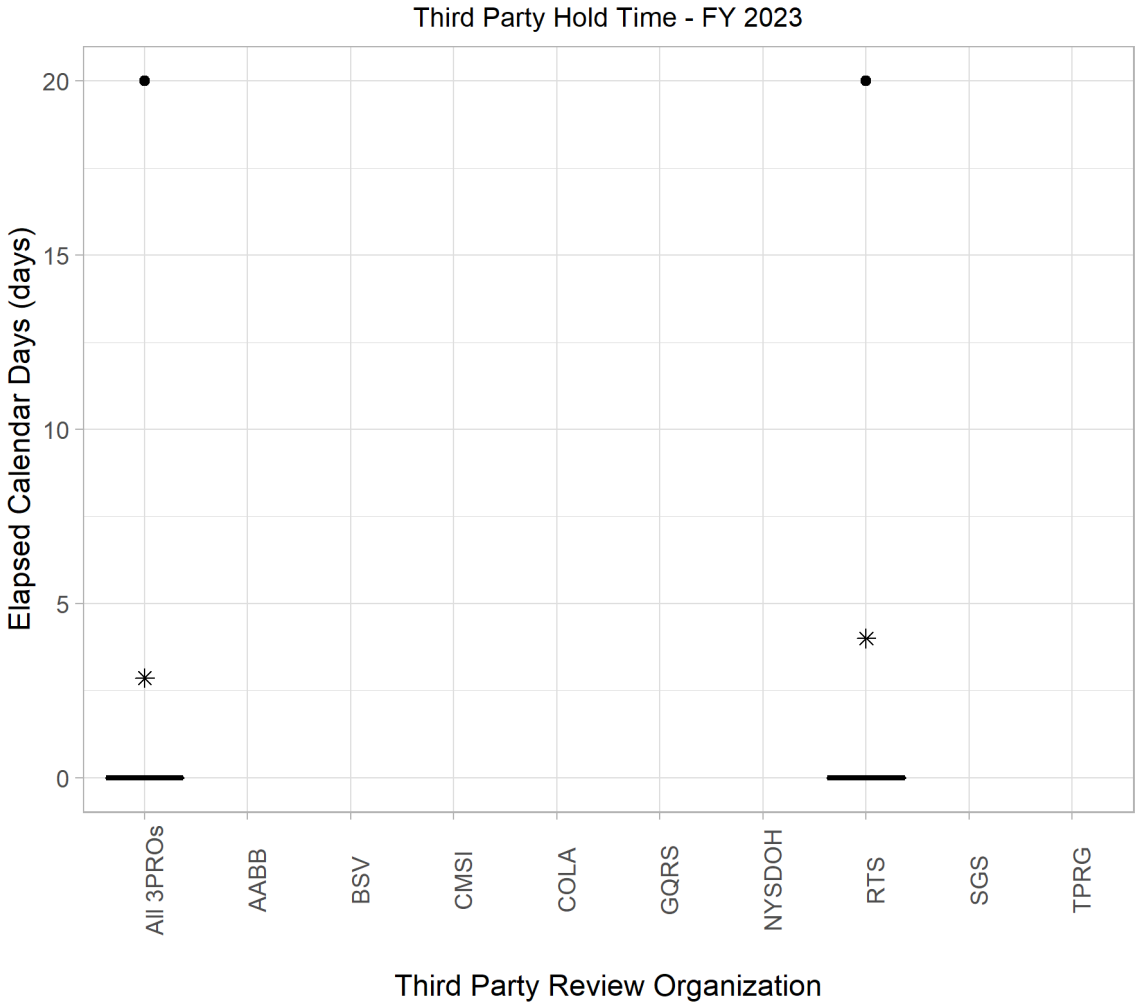


Figure 3

Total Third Party Review Time

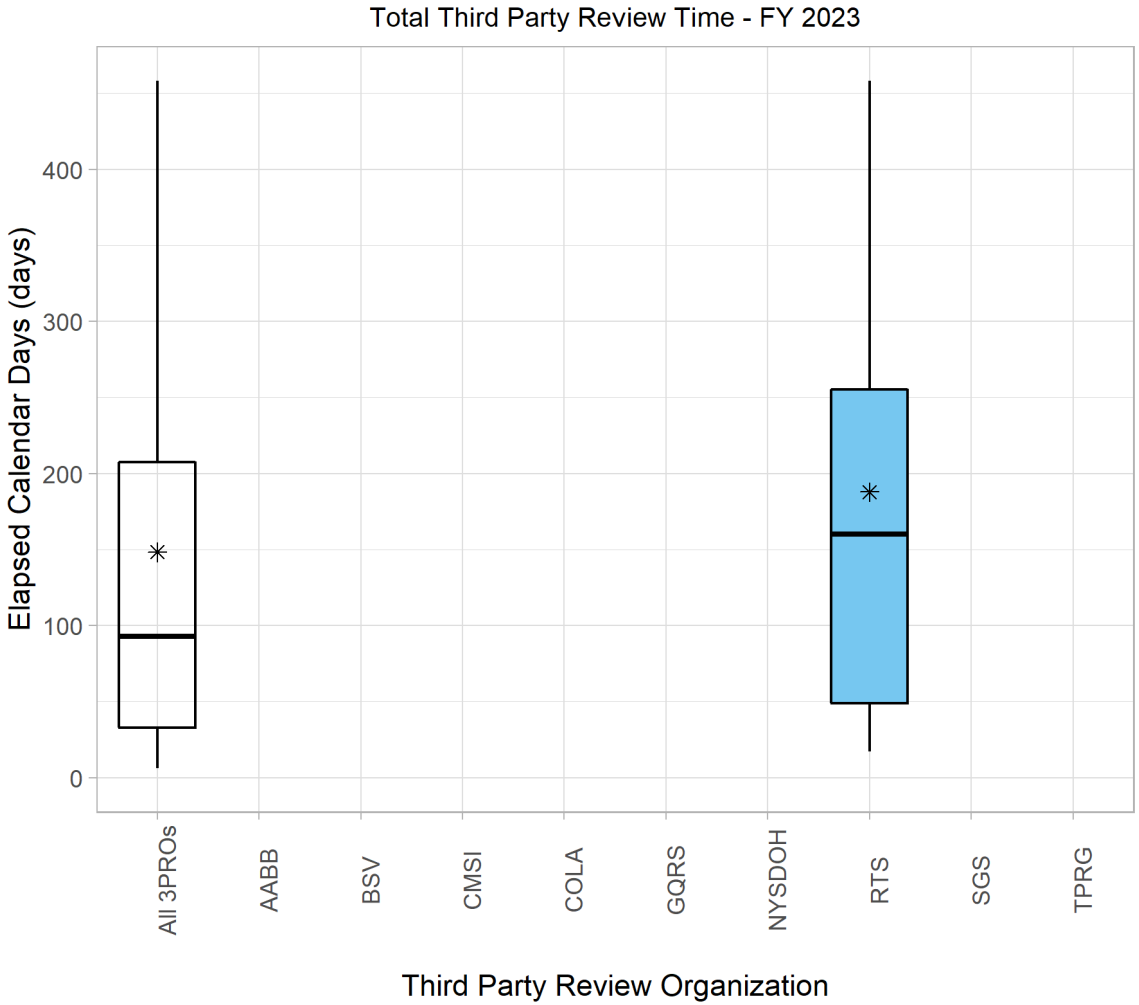


Figure 4

Total FDA Review Time

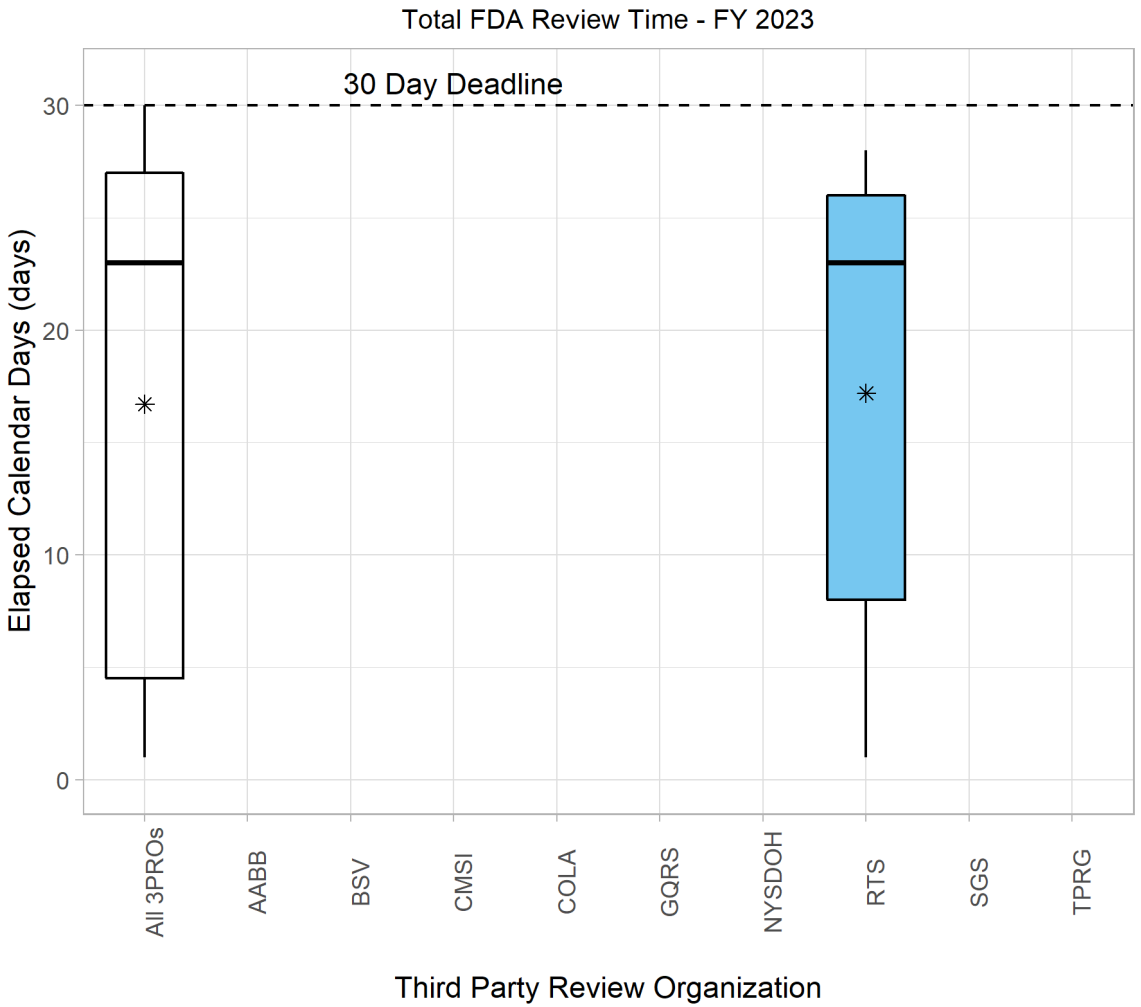


Figure 5

Total Time to Decision from FDA Receipt

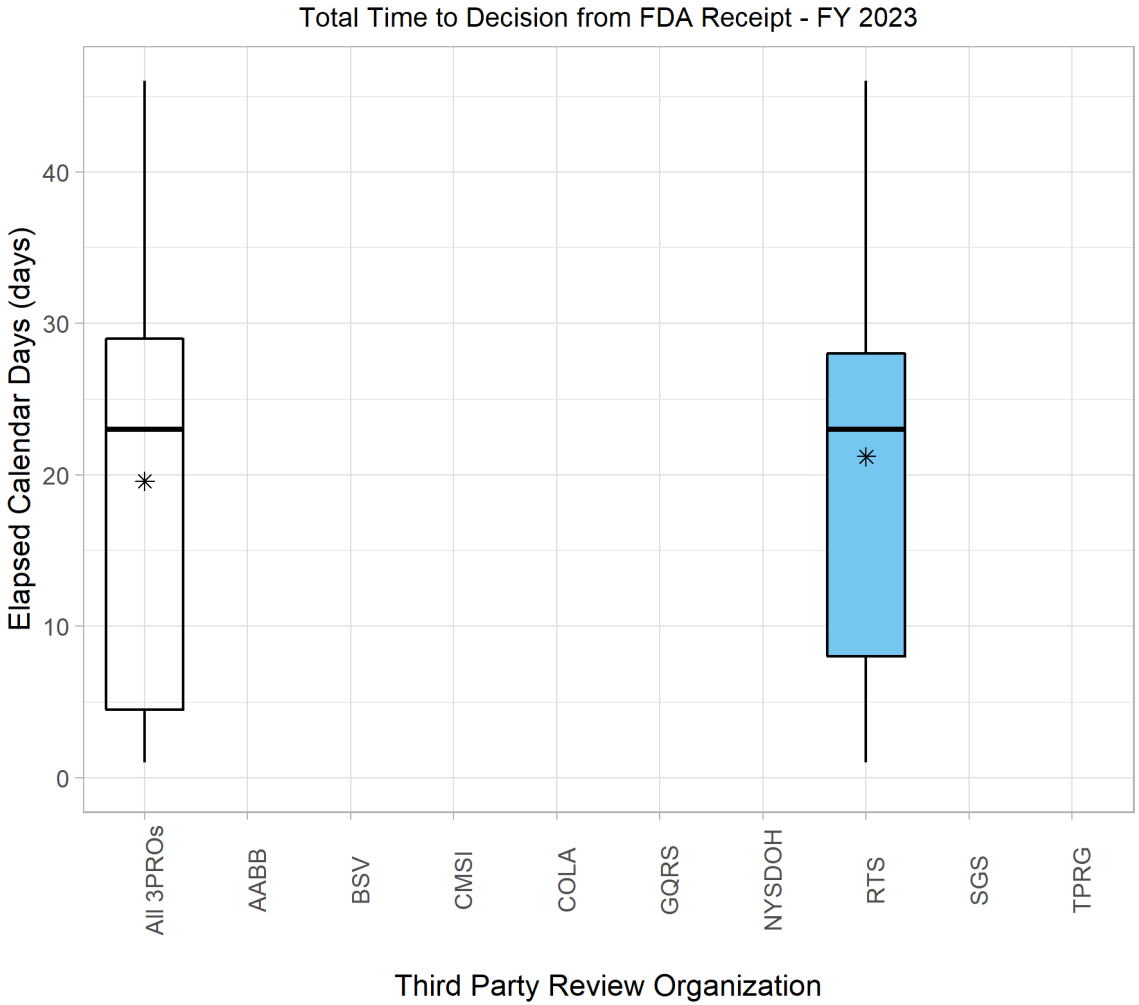


Figure 6

Total Time to Decision from Third Party Receipt

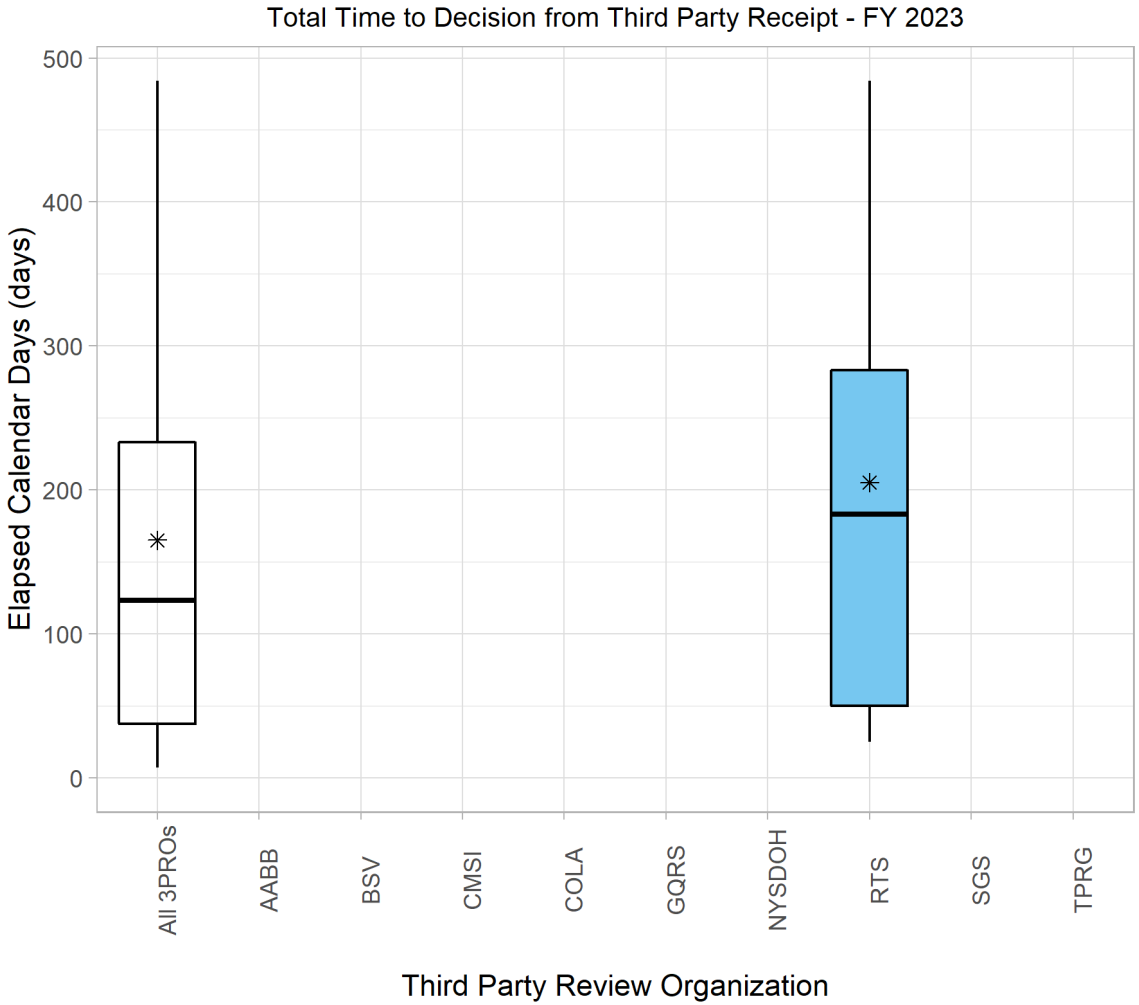


Figure 7

All Third Party Review Organizations

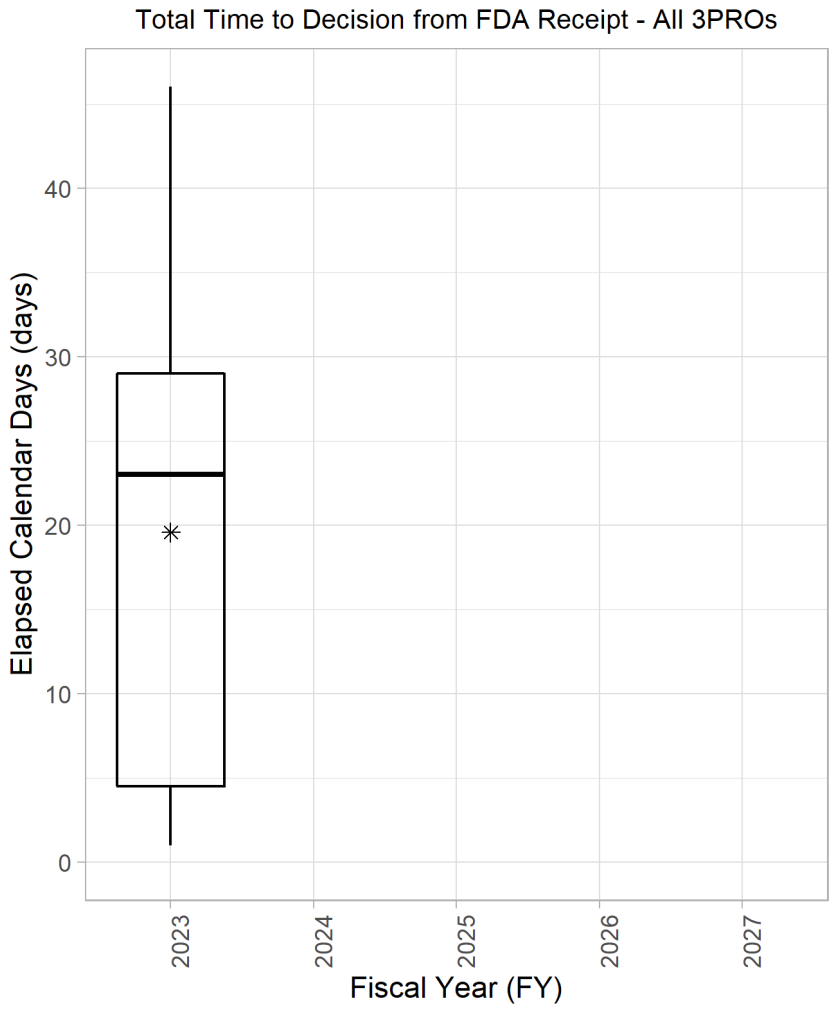


Figure 8

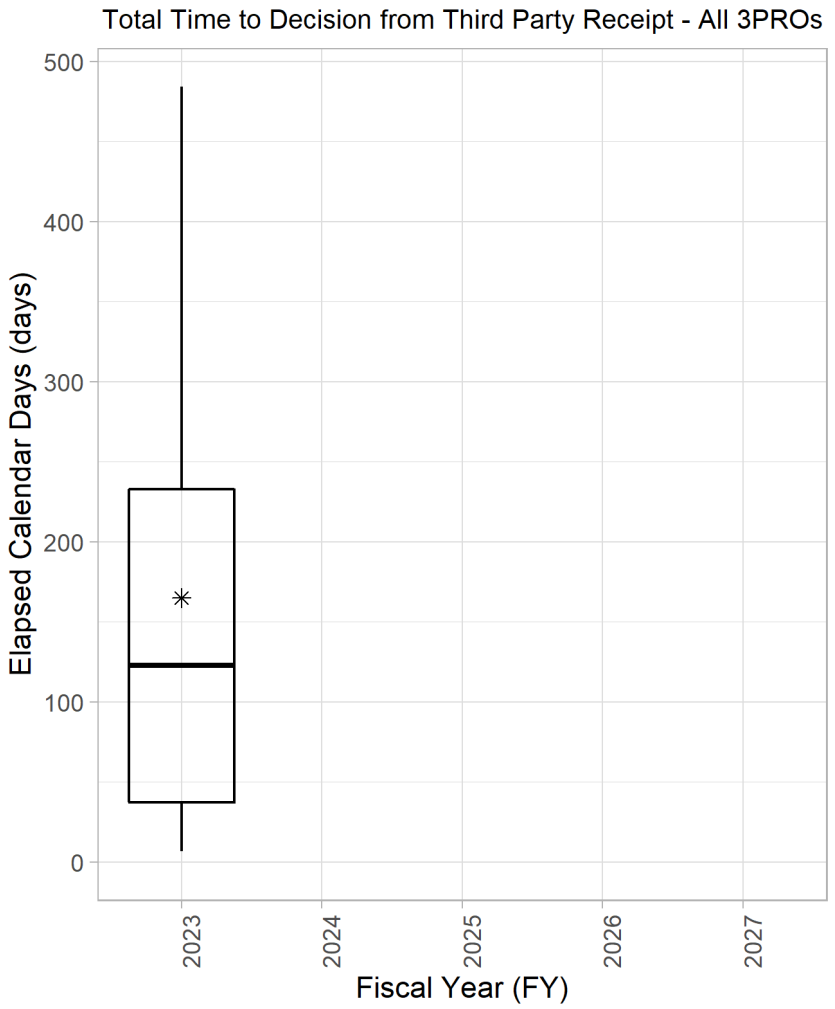


Figure 9

Table 1.1: Third Party 510(k) MDUFA V Decision Performance Goals - All Third Party Review Organizations.

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	18				
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	0 (0%)				
MDUFA V Final Decisions: SE or NSE (%)	7 (39%)				
Pending Final Decision for less than 30 FDA days (%)	9 (50%)				
Pending Final Decision for more than 30 FDA days (%)	2 (11%)				
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 FDA Days (%)	100%				
Average Holds					
Third Party Submission with a Final Decision	7				
Total # Requests for Additional Information (Holds)	1				
Average # Requests for Additional Information per Submission	0.14				
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	7				
Third Party SE Recommendations	7				
Third Party NSE Recommendations	0				
Third Party SE Recommendations with a Final Decision	7				
MDUFA V Final Decision					
SE	7				
NSE	0				
Non-MDUFA V Final Decision					
Withdrawn	0				
Deleted	0				
Third Party NSE Recommendations with a Final Decision	0				
MDUFA V Final Decision					
SE	0				
NSE	0				
Non-MDUFA V Final Decision					
Withdrawn	0				
Deleted	0				

Table 1.2: Third Party 510(k) MDUFA V Decision Performance Goals - All Third Party Review Organizations.

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Calendar Days)	146				
25th Percentile Initial Third Party Review Time	33				
50th Percentile Initial Third Party Review Time	93				
75th Percentile Initial Third Party Review Time	208				
Maximum Initial Third Party Review Time	438				
Average Third Party Hold Time (Calendar Days)	3				
25th Percentile Third Party Hold Time	0				
50th Percentile Third Party Hold Time	0				
75th Percentile Third Party Hold Time	0				
Maximum Third Party Hold Time	20				
Average Total Third Party Review Time (Calendar Days)	149				
25th Percentile Total Third Party Review Time	33				
50th Percentile Total Third Party Review Time	93				
75th Percentile Total Third Party Review Time	208				
Maximum Total Third Party Review Time	458				
Average Total FDA Review Time (Calendar Days)	17				
25th Percentile Total FDA Review Time	5				
50th Percentile Total FDA Review Time	23				
75th Percentile Total FDA Review Time	27				
Maximum Total FDA Review Time	30				
Average Total Time to Decision from FDA Receipt (Calendar Days)	20				
25th Percentile Total TTD from FDA Receipt	5				
50th Percentile Total TTD from FDA Receipt	23				
75th Percentile Total TTD from FDA Receipt	29				
Maximum Total TTD from FDA Receipt	46				
Average Total Time to Decision from Third Party Receipt (Calendar Days)	165				
25th Percentile Total TTD from Third Party Receipt	38				
50th Percentile Total TTD from Third Party Receipt	123				
75th Percentile Total TTD from Third Party Receipt	233				
Maximum Total TTD from Third Party Receipt	484				

AABB (AABB)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

BeanStock Ventures (BSV)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Center for Measurement Standards of Industrial (CMSI)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

COLA, Inc. (COLA)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Global Quality and Regulatory Services (GQRS)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

New York State Department of Health (NYSDOH)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Regulatory Technology Services, LLC (RTS)

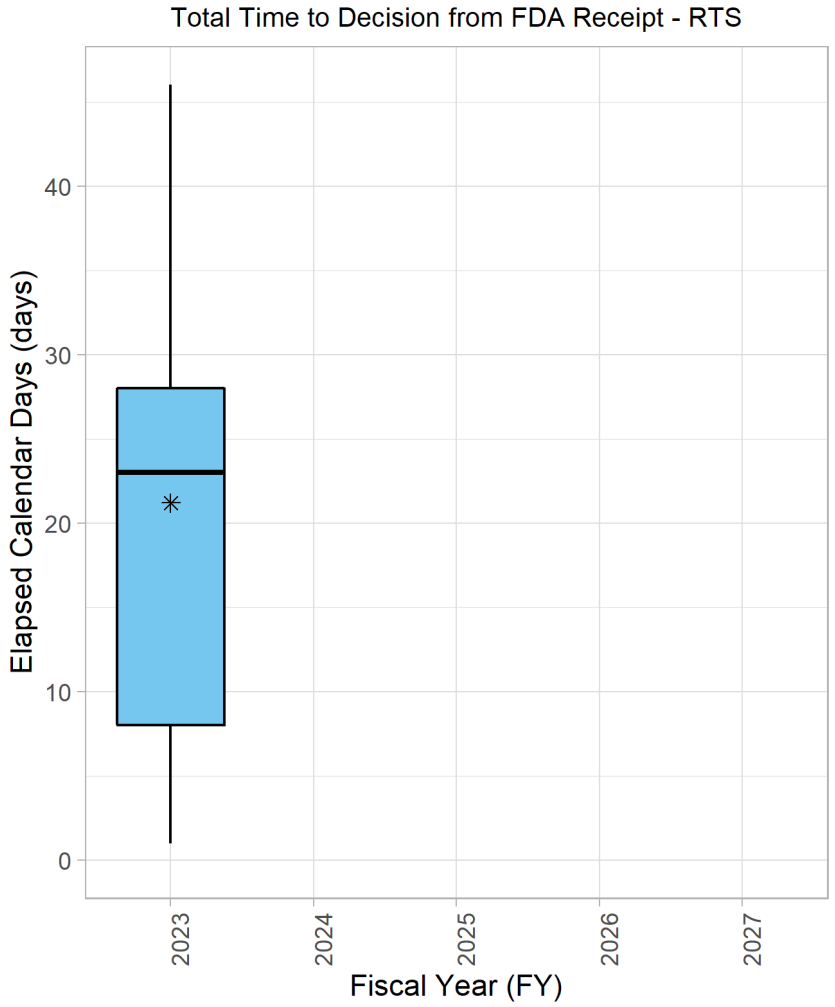


Figure 10

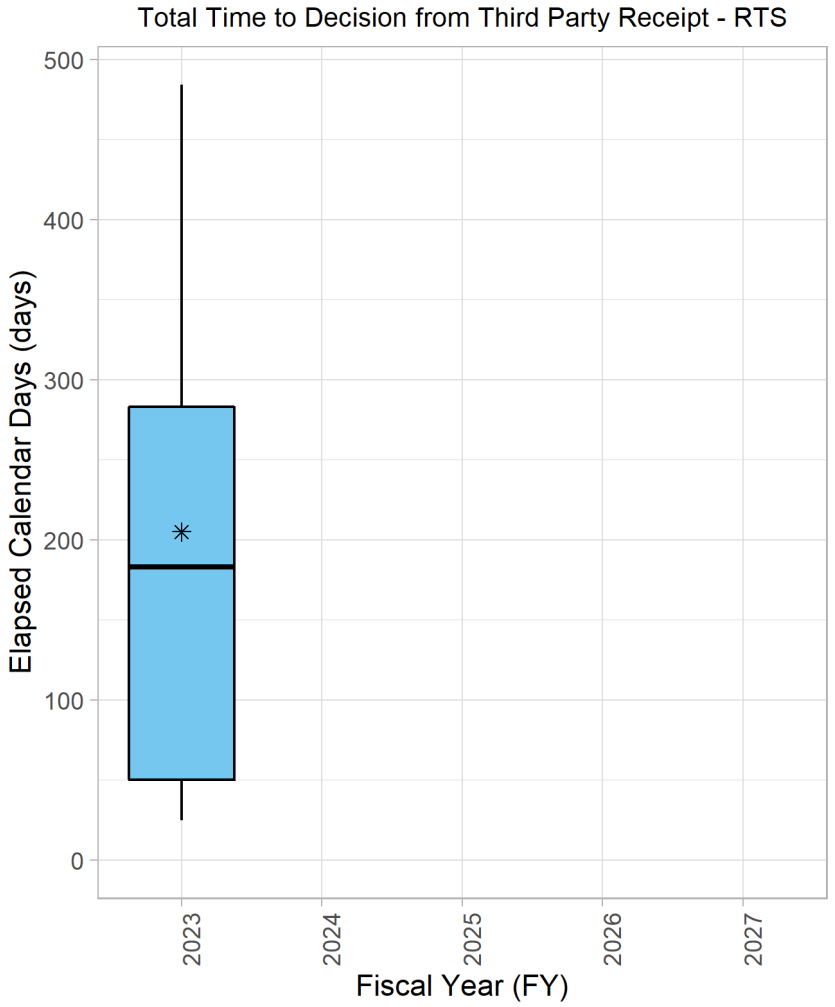


Figure 11

Table 2.1: Third Party 510(k) MDUFA V Decision Performance Goals - Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	12				
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	0 (0%)				
MDUFA V Final Decisions: SE or NSE (%)	5 (42%)				
Pending Final Decision for less than 30 FDA days (%)	6 (50%)				
Pending Final Decision for more than 30 FDA days (%)	1 (8%)				
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 FDA Days (%)	100%				
Average Holds					
Third Party Submission with a Final Decision	5				
Total # Requests for Additional Information (Holds)	1				
Average # Requests for Additional Information per Submission	0.2				
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	5				
Third Party SE Recommendations	5				
Third Party NSE Recommendations	0				
Third Party SE Recommendations with a Final Decision	5				
MDUFA V Final Decision					
SE	5				
NSE	0				
Non-MDUFA V Final Decision					
Withdrawn	0				
Deleted	0				
Third Party NSE Recommendations with a Final Decision	0				
MDUFA V Final Decision					
SE	0				
NSE	0				
Non-MDUFA V Final Decision					
Withdrawn	0				
Deleted	0				

Table 2.2: Third Party 510(k) MDUFA V Decision Performance Goals - Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Calendar Days)	184				
25th Percentile Initial Third Party Review Time	49				
50th Percentile Initial Third Party Review Time	160				
75th Percentile Initial Third Party Review Time	255				
Maximum Initial Third Party Review Time	438				
Average Third Party Hold Time (Calendar Days)	4				
25th Percentile Third Party Hold Time	0				
50th Percentile Third Party Hold Time	0				
75th Percentile Third Party Hold Time	0				
Maximum Third Party Hold Time	20				
Average Total Third Party Review Time (Calendar Days)	188				
25th Percentile Total Third Party Review Time	49				
50th Percentile Total Third Party Review Time	160				
75th Percentile Total Third Party Review Time	255				
Maximum Total Third Party Review Time	458				
Average Total FDA Review Time (Calendar Days)	18				
25th Percentile Total FDA Review Time	8				
50th Percentile Total FDA Review Time	23				
75th Percentile Total FDA Review Time	26				
Maximum Total FDA Review Time	28				
Average Total Time to Decision from FDA Receipt (Calendar Days)	22				
25th Percentile Total TTD from FDA Receipt	8				
50th Percentile Total TTD from FDA Receipt	23				
75th Percentile Total TTD from FDA Receipt	28				
Maximum Total TTD from FDA Receipt	46				
Average Total Time to Decision from Third Party Receipt (Calendar Days)	205				
25th Percentile Total TTD from Third Party Receipt	50				
50th Percentile Total TTD from Third Party Receipt	183				
75th Percentile Total TTD from Third Party Receipt	283				
Maximum Total TTD from Third Party Receipt	484				

SGS North America (SGS)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Third Party Review Group, LLC (TPRG)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Change Log

Date	Description
2018-January	Initial Report
2018-October	Added new 3PRO - ADAS
2018-October	Added boxplot legend
2019-January	Added new 3PRO - BDC
2019-January	Updated timeline graphic
2019-January	Added reporting by Fiscal Year and plots for individual 3PROs
2019-February-14	Process change for new second hold policy requiring concurrence from the 510(k) Third Party FDA staff. This change may affect Average Holds and the rate of NSE decisions.
2019-April	Added cumulative submission count graph
2019-April	Clarified definitions to state reporting is for MDUFA decisions (SE or NSE)
2020-July	Added new 3PRO - COLA
2021-January	Added new 3PROs - BSV and SGS
2021-April	Name change for BDC to GQRS
2021-August	As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews
2022-January	FY 2022 reporting information and graphics incorporated
2023-January	Updated to reflect MDUFA V, and removed ADAS, NIOM and TUV from the 3PRO list