Third Party Review Organization Performance Report

Correction: The FY18, Q1 and FY18, Q2 Third Party Review Organization Performance Reports released on 1/26/18 and 4/18/18, respectively, included incorrect calculations of *Total Third Party Review Time* (Report Definition 2). As a result of the calculation error, *Total Third Party Review Time* was reported to be shorter than actual in some cases and longer than actual in others. All other metrics were calculated and reported correctly – the error did not affect measures that include the time 3PROs spend reviewing submissions, such as the *Total Time to Decision from Third Party Receipt.*

The calculation of *Total Third Party Review Time* has been corrected as of FY18, Q3. In addition, we are releasing corrected versions of the FY18, Q1 and FY18, Q2 Reports. For FY18, Q1 and FY18, Q2, please only use data from the corrected reports. Corrections are highlighted in grey below.

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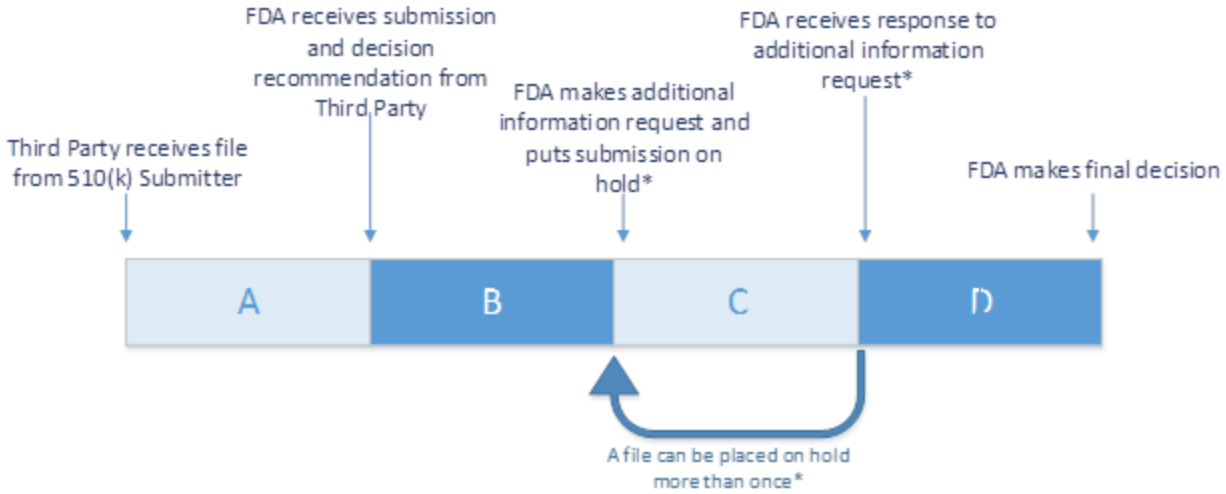
Introduction and Review Timeline Description

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 IV, the FDA committed to publishing the performance of individual accredited Third Parties with at least five completed submissions on the Web (e.g., average number of holds, average time to final decision). A summary of Third Party Performance Metrics will be posted on a quarterly basis. This report contains data from FY 2018, Q1 (October 1, 2017 through December 31, 2017). At this time, there is one Third Party Review Organization with at least 5 completed submissions.

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 and makes a final decision.



1) Third Party Initial Review Time = A
2) Third Party Total Review Time = A + C
3) Total FDA Days = B + D
4) Third Party Hold Time = C*
5) Cumulative Time to Decision from FDA Receipt Date = B + C + D
6) Cumulative Time to Decision from TP Receipt Date = A + B + C + D

*This data may not be present for all third party submissions.

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. 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. 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.

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 IV decision (SE or NSE) to a Third Party submission. By statute, FDA must provide a final MDUFA IV 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 IV decision. *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 IV decision 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

AABB
CMSI: Center for Measurement Standards of Industrial
NYSDOH: New York State Department of Health
NIOM: Nordic Institute of Dental Materials
RTS: Regulatory Technology Services, LLC
TPRG: Third Party Review Group, LLC
TUV: TUV SUD America Inc.

Third Party Performance Data

Initial Third Party Review Time – FY 2018

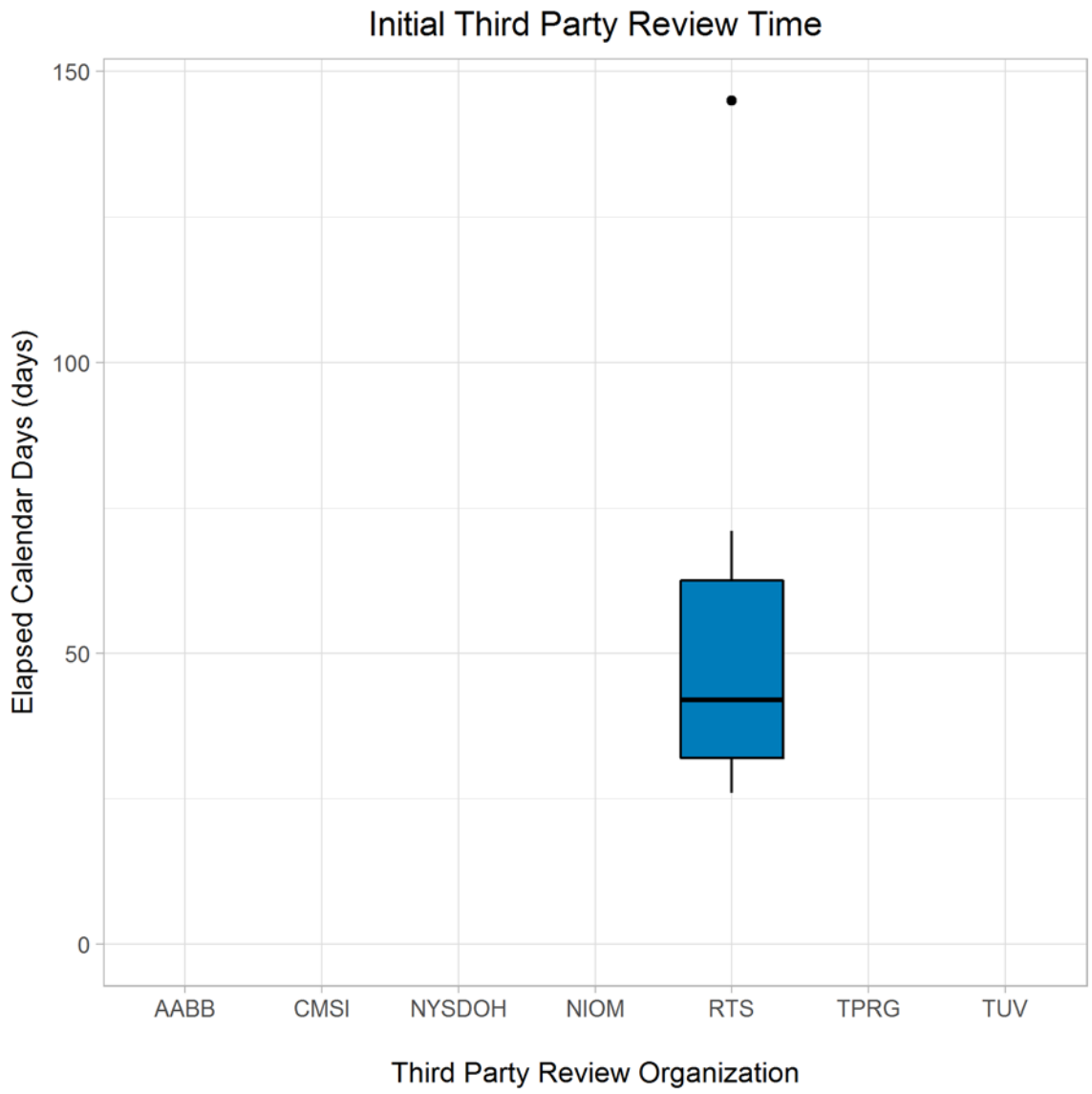


Figure 1. Initial Third Party Review Time.

Third Party Hold Time – FY 2018

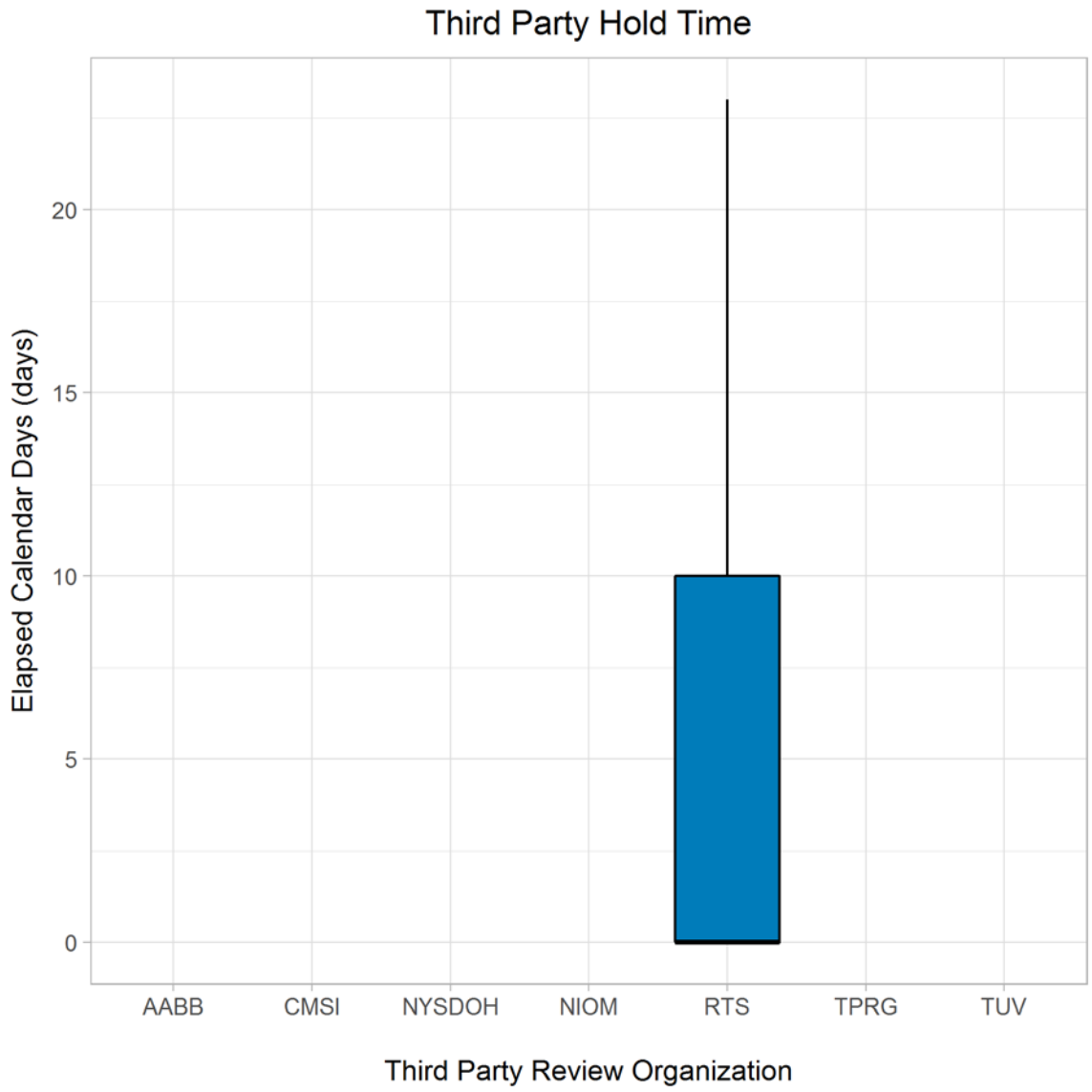


Figure 2. Third Party Hold Time.

Total Third Party Review Time – FY 2018

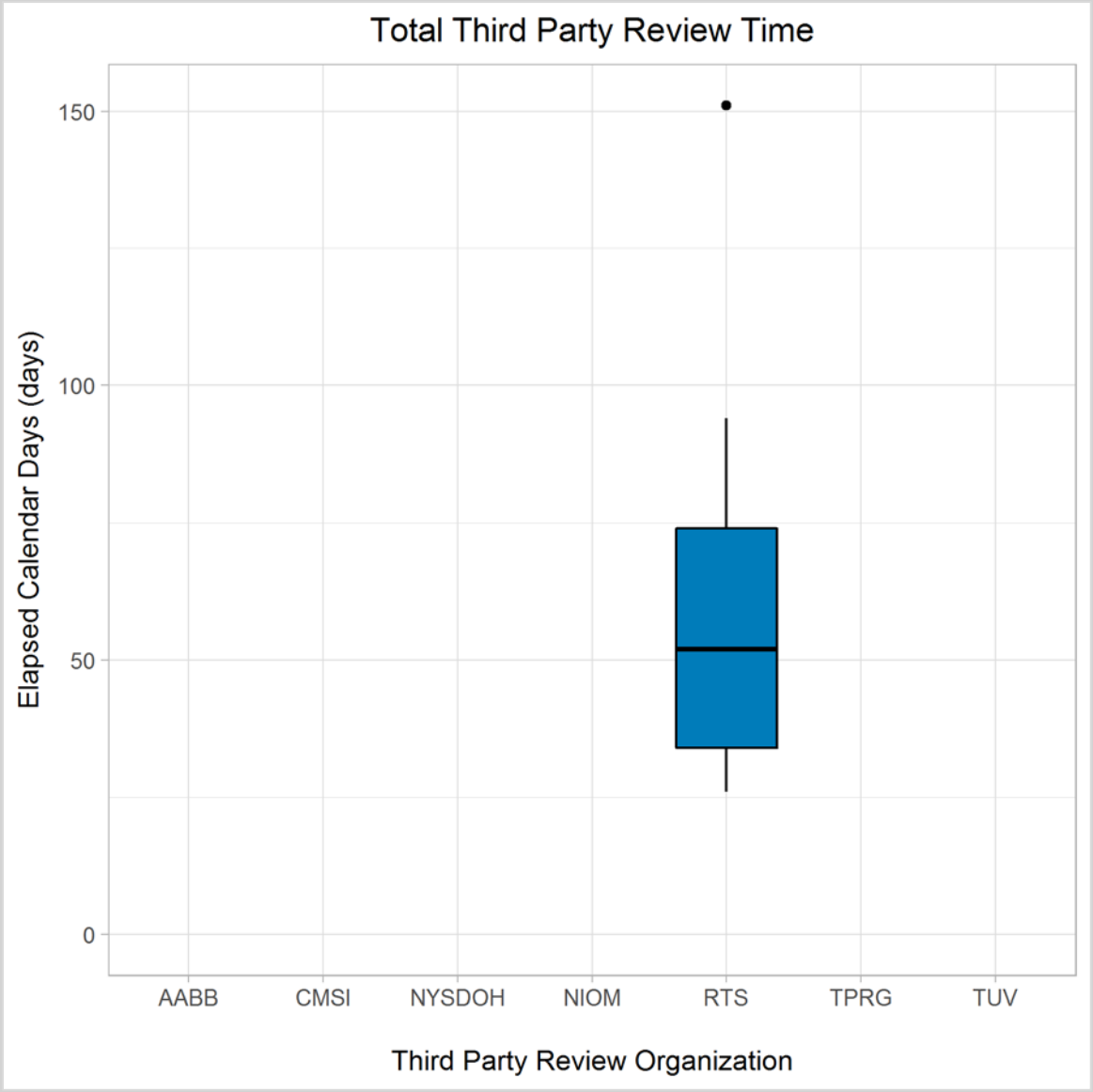


Figure 3. Total Third Party Review Time (Corrected in this version, see Page 1 for details).

Total FDA Review Time – FY 2018

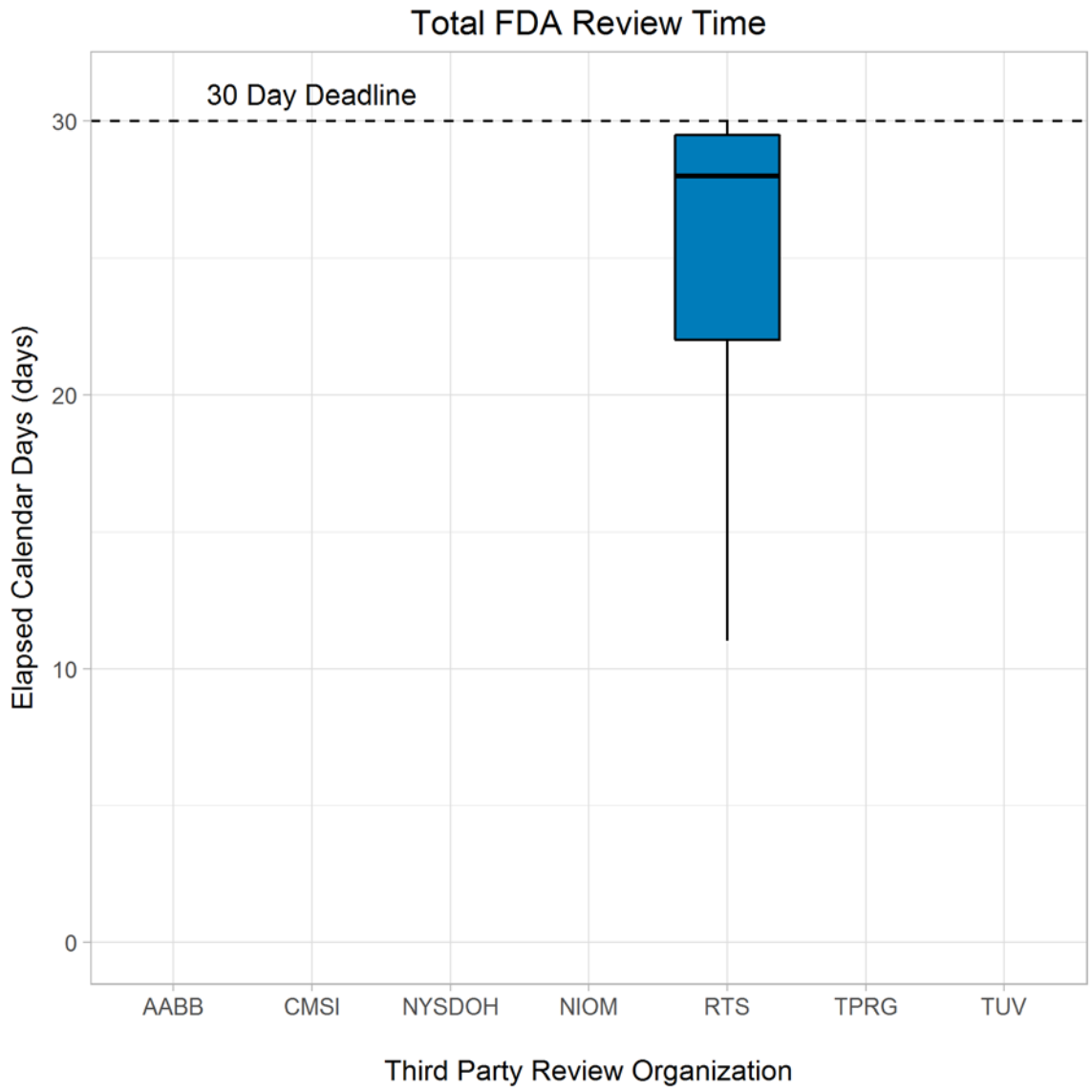


Figure 4. Total FDA Review Time.

Total Time to Decision from FDA Receipt – FY 2018

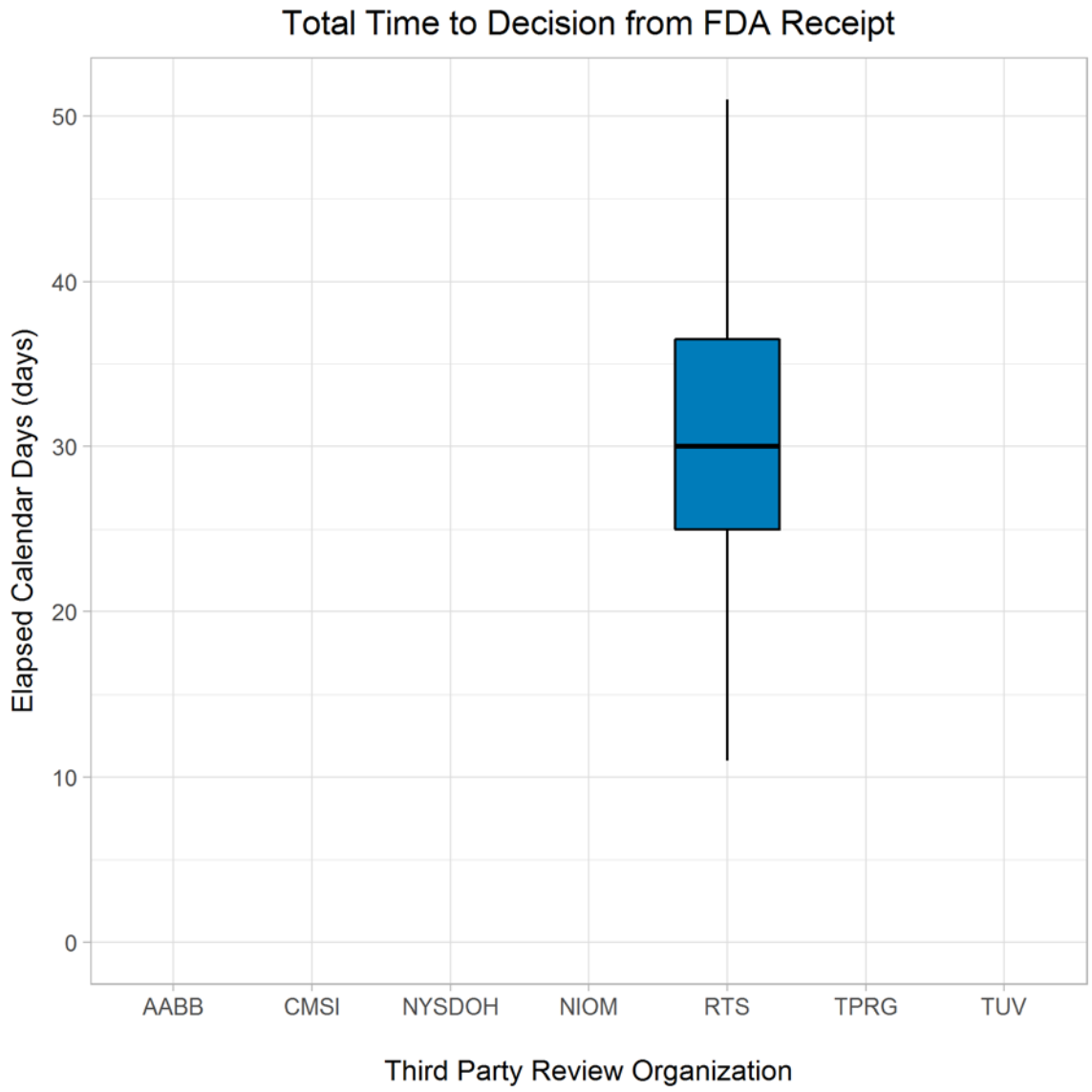


Figure 5. Total Time to Decision from FDA Receipt.

Total Time to Decision from Third Party Receipt – FY 2018

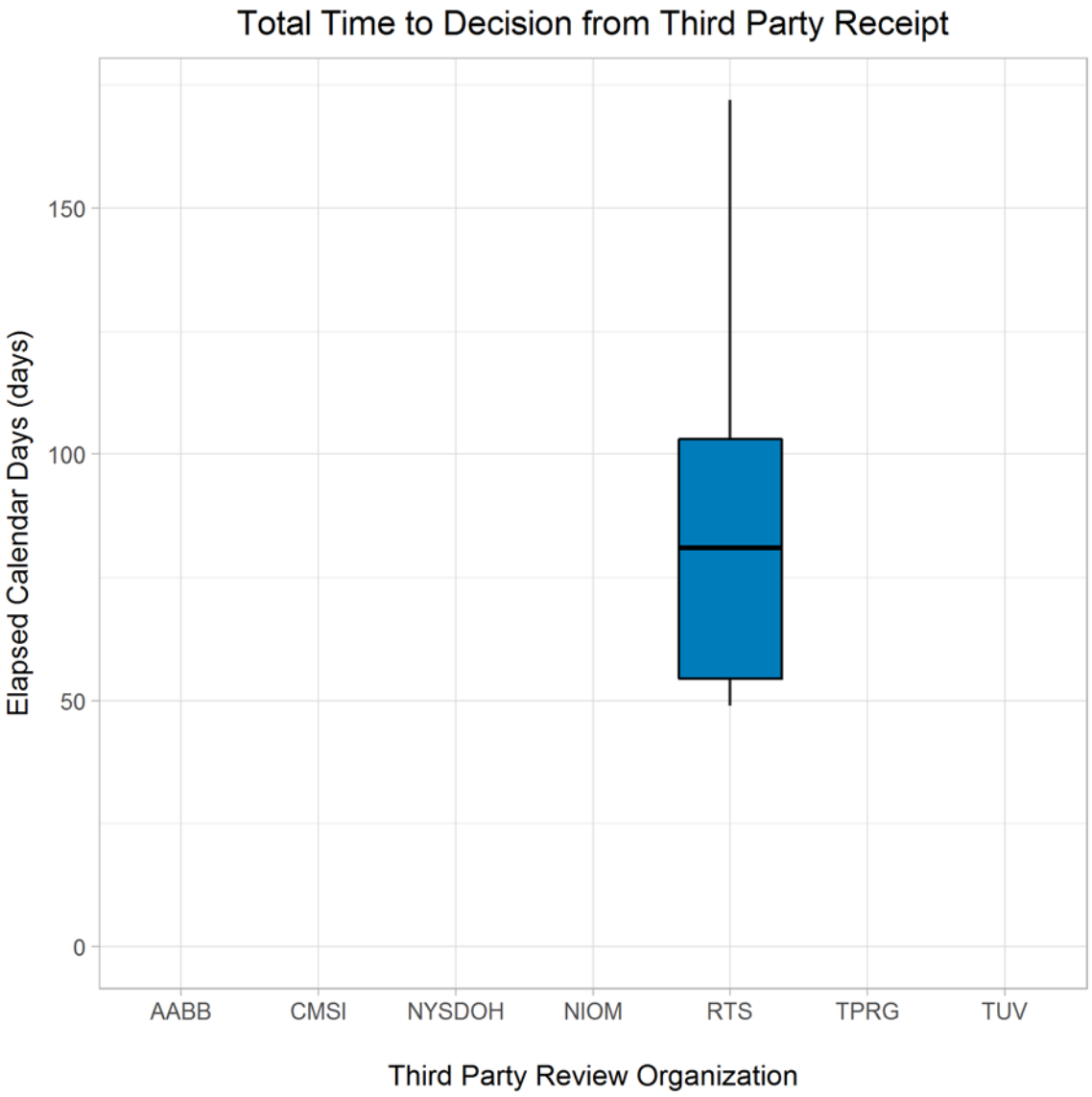


Figure 6. Total Time to Decision from Third Party Receipt.

All Third Party Review Organizations

Table 1.1. All: Third Party 510(k) MDUFA IV Decision Performance Goals.

Performance Metric	FY2018
Total Third Party 510(k) Submissions Accepted	18
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	8 (44%)
Pending Final Decision for less than 30 FDA days (%)	9 (50%)
Pending Final Decision for more than 30 FDA days (%)	1 (6%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	100%
Average Holds	
Third Party Submission with a Final Decision	8
Total # Requests for Additional Information (Holds)	4
Average # Requests for Additional Information per Submission	0.5
Third Party Recommendation and Final Decision Agreement	
Third Party Submissions with a Final Decision	8
Third Party SE Recommendations	8 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	8
MDUFA IV Final Decision	
SE	8 (100%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	0 (0%)
Third Party NSE Recommendations with a Final Decision	0
MDUFA IV Final Decision	
SE	0 (0%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	0 (0%)

Table 1.2. All: Third Party 510(k) Review Time Performance Metrics.

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	51
25th Percentile Initial Third Party Review Time	26
50th Percentile Initial Third Party Review Time	40
75th Percentile Initial Third Party Review Time	59
Maximum Initial Third Party Review Time	145
Average Third Party Hold Time (Calendar Days)	6
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	8
Maximum Third Party Hold Time	23
Average Total Third Party Review Time (Calendar Days)	56
25th Percentile Total Third Party Review Time	26
50th Percentile Total Third Party Review Time	47
75th Percentile Total Third Party Review Time	64
Maximum Total Third Party Review Time	151
Average Total FDA Review Time (Calendar Days)	25
25th Percentile Total FDA Review Time	21
50th Percentile Total FDA Review Time	26
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	30
Average Total Time to Decision from FDA Receipt (Calendar Days)	30
25th Percentile Total TTD from FDA Receipt	23
50th Percentile Total TTD from FDA Receipt	29
75th Percentile Total TTD from FDA Receipt	34
Maximum Cumulative TTD from FDA Receipt Date	51
Average Total Time to Decision from Third Party Receipt (Calendar Days)	80
25th Percentile Total TTD from Third Party Receipt	52
50th Percentile Total TTD from Third Party Receipt	69
75th Percentile Total TTD from Third Party Receipt	94
Maximum Total TTD from Third Party Receipt	172

Highlighted information has been corrected in this version (see Page 1 for details).

AABB

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.

Center for Measurement Standards of Industrial (CMSI)

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.

New York State Department of Health (NYSDOH)

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.

Nordic Institute of Dental Materials (NIOM)

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.

Regulatory Technology Services, LLC (RTS)

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

Performance Metric	FY2018
Total Third Party 510(k) Submissions Accepted	11
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	7 (64%)
Pending Final Decision for less than 30 FDA days (%)	3 (27%)
Pending Final Decision for more than 30 FDA days (%)	1 (9%)
Current Performance: Third Party Submissions that received MDUFA IV 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)	4
Average # Requests for Additional Information per Submission	0.57
Third Party Recommendation and Final Decision Agreement	
Third Party Submissions with a Final Decision	7
Third Party SE Recommendations	7 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	7
MDUFA IV Final Decision	
SE	7 (100%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	0 (0%)
Third Party NSE Recommendations with a Final Decision	0
MDUFA IV Final Decision	
SE	0 (0%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	0 (0%)

Table 2.2. RTS: Third Party 510(k) Review Time Performance Metrics. Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	58
25th Percentile Initial Third Party Review Time	32
50th Percentile Initial Third Party Review Time	42
75th Percentile Initial Third Party Review Time	63
Maximum Initial Third Party Review Time	145
Average Third Party Hold Time (Calendar Days)	7
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	10
Maximum Third Party Hold Time	23
Average Total Third Party Review Time (Calendar Days)	64
25th Percentile Total Third Party Review Time	34
50th Percentile Total Third Party Review Time	52
75th Percentile Total Third Party Review Time	74
Maximum Total Third Party Review Time	151
Average Total FDA Review Time (Calendar Days)	25
25th Percentile Total FDA Review Time	22
50th Percentile Total FDA Review Time	28
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	30
Average Total Time to Decision from FDA Receipt (Calendar Days)	31
25th Percentile Total TTD from FDA Receipt	25
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	37
Maximum Cumulative TTD from FDA Receipt Date	51
Average Total Time to Decision from Third Party Receipt (Calendar Days)	89
25th Percentile Total TTD from Third Party Receipt	55
50th Percentile Total TTD from Third Party Receipt	81
75th Percentile Total TTD from Third Party Receipt	103
Maximum Total TTD from Third Party Receipt	172

Highlighted information has been corrected in this version (see Page 1 for details).

Third Party Review Group, LLC (TPRG)

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.

TUV SUD America Inc. (TUV)

This Third Party Review Organization had fewer than 5 submissions in the current reporting period.