Third Party Review Organization Performance Report

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Introduction and Review Timeline Description

The Third Party (3P) 510(k) Program, formally known as the Accredited Persons Program, was created by the FDA Modernization Act (FDAMA) in 1997 to improve the efficiency and timeliness of FDA's 510(k) process. Under the program, FDA accredits Third Party Review Organizations (ROs) that are authorized to conduct the primary review of 510(k)s for eligible devices.

Under MDUFA IV and MDUFA V, the FDA committed to publishing the performance of accredited Third Party Review Organizations 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 2023, Q1 through FY 2026, Q3 (October 1, 2022 through June 30, 2026). 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
2	2	2	2	0

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

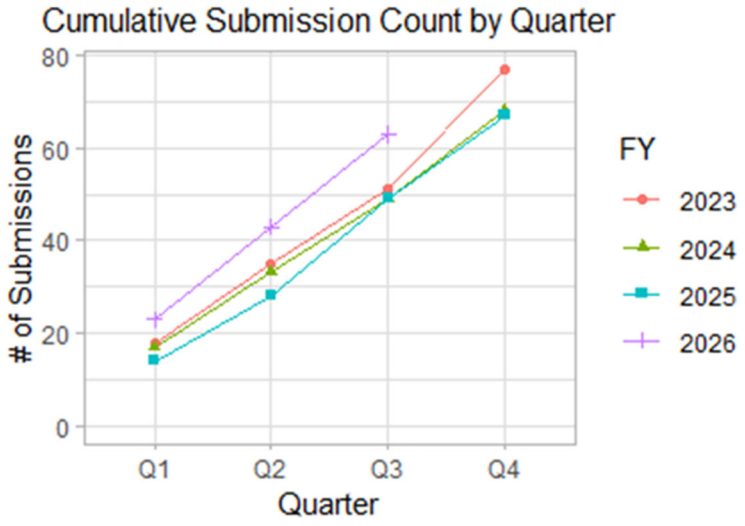
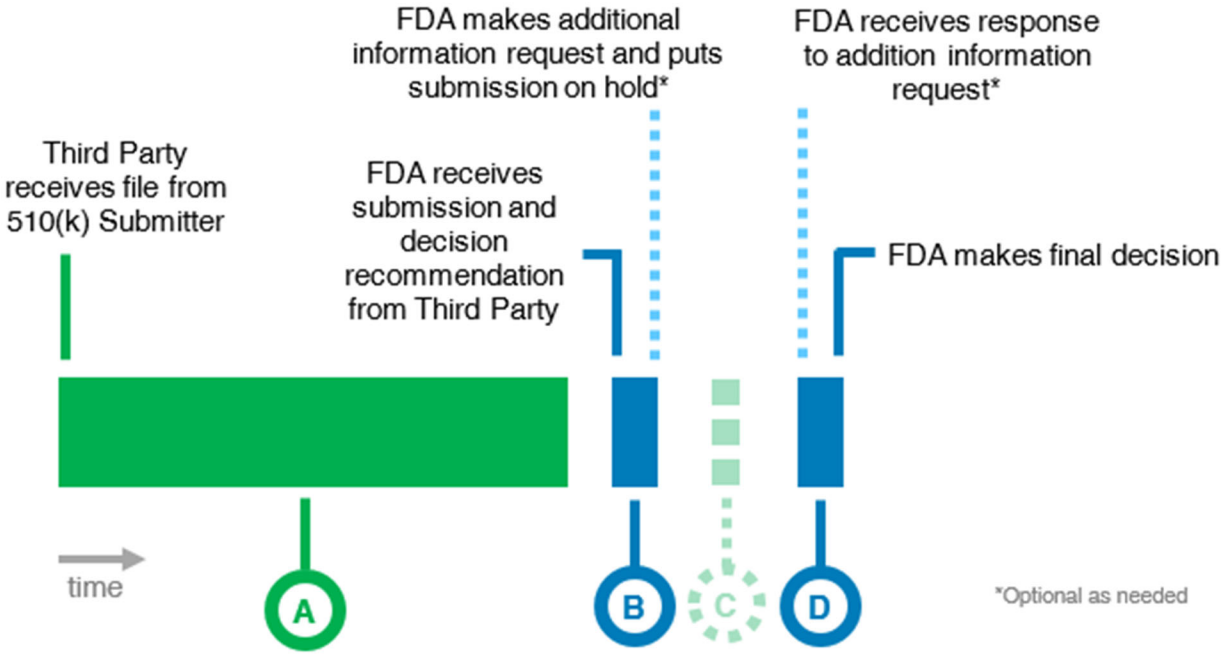


Figure 1

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

- Stage A - The Third Party Review Organization 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 Review Organization 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 Review Organization, and puts the submission on hold.
- Stage C – If FDA makes a request of additional information, the Third Party Review Organization reviews FDA's request and notifies the 510(k) Submitter. The Third Party Review Organization 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.



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 (Substantially Equivalent (SE) or Not Substantially Equivalent (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 Third Party submission.

Names of Third Party Review Organizations

Abbreviation	Full Name
AABB	Association for the Advancement of Blood & Biotherapies
BSC	BeanStock Consulting
CMSI	Center for Measurement Standards of Industrial
COLA	COLA, Inc.
GQRS	Global Quality and Regulatory Services
RTS	Regulatory Technology Services, LLC
Scarlet NB B.V.	Scarlet NB B.V.
SMO India	SMO India
TPRG	Third Party Review Group, LLC

Third Party Performance Data

All Third Party Review Organizations

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	77	68	67	63	
Non-MDUFA V Final Decisions: Withdrawn, Deleted, or Other (%)	9 (12%)	6 (9%)	7 (10%)	2 (3%)	
MDUFA V Final Decisions: SE or NSE (%)	68 (88%)	61 (90%)	55 (82%)	41 (65%)	
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	12 (19%)	
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	1 (1%)	5 (7%)	8 (13%)	
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 FDA Days (%)	87%	84%	71%	93%	
Average Holds					
Third Party Submission with a Final Decision	77	67	62	43	
Total # Requests for Additional Information (Holds)	19	19	20	10	
Average # Requests for Additional Information per Submission	0.25	0.28	0.32	0.23	
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	77	67	62	43	
Third Party SE Recommendations	77	67	62	43	
Third Party NSE Recommendations	0	0	0	0	
Third Party SE Recommendations with a Final Decision	77	67	62	43	
MDUFA V Final Decision					
SE	64	60	51	41	
NSE	4	1	4	0	
Non-MDUFA V Final Decision					
Withdrawn	5	6	5	2	
Deleted	3	0	2	0	
Other	1	0	0	0	
Third Party NSE Recommendations with a Final Decision	0	0	0	0	
MDUFA V Final Decision					
SE	0	0	0	0	
NSE	0	0	0	0	
Non-MDUFA V Final Decision					
Withdrawn	0	0	0	0	
Deleted	0	0	0	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 (Days)	102	96	74	80	
25th Percentile Initial Third Party Review Time	35	47	38	36	
50th Percentile Initial Third Party Review Time	65	81	57	49	
75th Percentile Initial Third Party Review Time	136	126	103	98	
Maximum Initial Third Party Review Time	438	544	258	349	
Average Third Party Hold Time (Days)	26	25	27	7	
25th Percentile Third Party Hold Time	0	0	0	0	
50th Percentile Third Party Hold Time	0	0	0	0	
75th Percentile Third Party Hold Time	3	20	32	0	
Maximum Third Party Hold Time	323	180	180	94	
Average Total Third Party Review Time (Days)	128	121	101	86	
25th Percentile Total Third Party Review Time	42	56	41	37	
50th Percentile Total Third Party Review Time	88	97	92	56	
75th Percentile Total Third Party Review Time	189	137	143	110	
Maximum Total Third Party Review Time	526	544	276	349	
Average Total FDA Review Time (Days)	31	29	41	15	
25th Percentile Total FDA Review Time	12	16	20	1	
50th Percentile Total FDA Review Time	27	27	28	12	
75th Percentile Total FDA Review Time	30	30	57	28	
Maximum Total FDA Review Time	217	163	200	47	
Average Total Time to Decision from FDA Receipt (Days)	56	53	68	22	
25th Percentile Total TTD from FDA Receipt	12	16	20	1	
50th Percentile Total TTD from FDA Receipt	28	28	28	12	
75th Percentile Total TTD from FDA Receipt	32	56	92	29	
Maximum Total TTD from FDA Receipt	540	302	317	129	
Average Total Time to Decision from Third Party Receipt (Days)	158	149	141	101	
25th Percentile Total TTD from Third Party Receipt	55	72	65	44	
50th Percentile Total TTD from Third Party Receipt	109	126	116	76	
75th Percentile Total TTD from Third Party Receipt	214	167	197	127	
Maximum Total TTD from Third Party Receipt	743	545	409	377	

Association for the Advancement of Blood & Biotherapies (AABB)

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

BeanStock Consulting (BSC)

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.

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.

Regulatory Technology Services, LLC (RTS)

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	54	40	41	36	
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	7 (13%)	3 (8%)	3 (7%)	1 (3%)	
MDUFA V Final Decisions: SE or NSE (%)	47 (87%)	36 (90%)	35 (85%)	24 (67%)	
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	5 (14%)	
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	1 (2%)	3 (7%)	6 (17%)	
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 FDA Days (%)	90%	84%	72%	92%	
Average Holds					
Third Party Submission with a Final Decision	54	39	38	25	
Total # Requests for Additional Information (Holds)	12	10	10	7	
Average # Requests for Additional Information per Submission	0.22	0.26	0.26	0.28	
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	54	39	38	25	
Third Party SE Recommendations	54	39	38	25	
Third Party NSE Recommendations	0	0	0	0	
Third Party SE Recommendations with a Final Decision	54	39	38	25	
MDUFA V Final Decision					
SE	44	36	33	24	
NSE	3	0	2	0	
Non-MDUFA V Final Decision					
Withdrawn	4	3	2	1	
Deleted	3	0	1	0	
Third Party NSE Recommendations with a Final Decision	0	0	0	0	
MDUFA V Final Decision					
SE	0	0	0	0	
NSE	0	0	0	0	
Non-MDUFA V Final Decision					
Withdrawn	0	0	0	0	
Deleted	0	0	0	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 (Days)	94	84	85	88	
25th Percentile Initial Third Party Review Time	33	48	37	37	
50th Percentile Initial Third Party Review Time	55	72	73	65	
75th Percentile Initial Third Party Review Time	110	123	120	107	
Maximum Initial Third Party Review Time	438	249	258	349	
Average Third Party Hold Time (Days)	31	21	27	4	
25th Percentile Third Party Hold Time	0	0	0	0	
50th Percentile Third Party Hold Time	0	0	0	0	
75th Percentile Third Party Hold Time	0	10	36	2	
Maximum Third Party Hold Time	323	118	180	48	
Average Total Third Party Review Time (Days)	124	105	111	92	
25th Percentile Total Third Party Review Time	34	59	40	42	
50th Percentile Total Third Party Review Time	76	82	112	67	
75th Percentile Total Third Party Review Time	174	131	158	121	
Maximum Total Third Party Review Time	526	351	276	349	
Average Total FDA Review Time (Days)	31	30	41	21	
25th Percentile Total FDA Review Time	12	22	20	7	
50th Percentile Total FDA Review Time	26	28	28	26	
75th Percentile Total FDA Review Time	30	30	44	29	
Maximum Total FDA Review Time	217	163	200	47	
Average Total Time to Decision from FDA Receipt (Days)	62	50	67	25	
25th Percentile Total TTD from FDA Receipt	12	22	20	7	
50th Percentile Total TTD from FDA Receipt	26	28	28	28	
75th Percentile Total TTD from FDA Receipt	30	44	90	30	
Maximum Total TTD from FDA Receipt	540	265	317	89	
Average Total Time to Decision from Third Party Receipt (Days)	155	134	152	112	
25th Percentile Total TTD from Third Party Receipt	53	72	67	65	
50th Percentile Total TTD from Third Party Receipt	98	109	133	81	
75th Percentile Total TTD from Third Party Receipt	194	160	222	156	
Maximum Total TTD from Third Party Receipt	743	514	409	377	

Scarlet NB B.V.

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

SMO India

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)

Table 3.1: Third Party 510(k) MDUFA V Decision Performance Goals - Third Party Review Group, LLC (TPRG).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	21	24	24	24	
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	1 (5%)	3 (12%)	4 (17%)	1 (4%)	
MDUFA V Final Decisions: SE or NSE (%)	20 (95%)	21 (88%)	20 (83%)	15 (62%)	
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	6 (25%)	
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)	
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 FDA Days (%)	85%	81%	70%	94%	
Average Holds					
Third Party Submission with a Final Decision	21	24	24	16	
Total # Requests for Additional Information (Holds)	6	9	10	2	
Average # Requests for Additional Information per Submission	0.29	0.38	0.42	0.12	
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	21	24	24	16	
Third Party SE Recommendations	21	24	24	16	
Third Party NSE Recommendations	0	0	0	0	
Third Party SE Recommendations with a Final Decision	21	24	24	16	
MDUFA V Final Decision					
SE	19	20	18	15	
NSE	1	1	2	0	
Non-MDUFA V Final Decision					
Withdrawn	1	3	3	1	
Deleted	0	0	1	0	
Third Party NSE Recommendations with a Final Decision	0	0	0	0	
MDUFA V Final Decision					
SE	0	0	0	0	
NSE	0	0	0	0	
Non-MDUFA V Final Decision					
Withdrawn	0	0	0	0	
Deleted	0	0	0	0	

Table 3.2: Third Party 510(k) MDUFA V Decision Performance Goals - Third Party Review Group, LLC (TPRG).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Days)	118	121	54	75	
25th Percentile Initial Third Party Review Time	58	34	39	24	
50th Percentile Initial Third Party Review Time	94	97	47	41	
75th Percentile Initial Third Party Review Time	148	151	65	91	
Maximum Initial Third Party Review Time	371	544	142	266	
Average Third Party Hold Time (Days)	9	37	29	7	
25th Percentile Third Party Hold Time	0	0	0	0	
50th Percentile Third Party Hold Time	0	0	0	0	
75th Percentile Third Party Hold Time	3	29	32	0	
Maximum Third Party Hold Time	81	180	180	94	
Average Total Third Party Review Time (Days)	127	157	83	81	
25th Percentile Total Third Party Review Time	69	60	41	24	
50th Percentile Total Third Party Review Time	94	108	60	41	
75th Percentile Total Third Party Review Time	166	191	101	91	
Maximum Total Third Party Review Time	405	544	206	291	
Average Total FDA Review Time (Days)	28	27	41	6	
25th Percentile Total FDA Review Time	10	1	17	1	
50th Percentile Total FDA Review Time	29	27	28	1	
75th Percentile Total FDA Review Time	30	30	72	4	
Maximum Total FDA Review Time	118	122	127	35	
Average Total Time to Decision from FDA Receipt (Days)	37	64	70	13	
25th Percentile Total TTD from FDA Receipt	10	1	17	1	
50th Percentile Total TTD from FDA Receipt	29	29	29	1	
75th Percentile Total TTD from FDA Receipt	32	57	92	4	
Maximum Total TTD from FDA Receipt	199	302	304	129	
Average Total Time to Decision from Third Party Receipt (Days)	155	184	124	87	
25th Percentile Total TTD from Third Party Receipt	91	87	61	36	
50th Percentile Total TTD from Third Party Receipt	123	134	107	44	
75th Percentile Total TTD from Third Party Receipt	215	215	155	97	
Maximum Total TTD from Third Party Receipt	475	545	333	326	