Health Canada Santé Canada

Therapeutic Products Directorate

Drug Submission Performance Quarterly Report

April - June

2021

Canada

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Direction des produits thérapeutiques - Rapport trimestriel du rendement des présentations de drogue - avril - juin 2021

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OVERVIEW

The Therapeutic Products Directorate's (TPD) Quarterly Drug Submission Performance Report reflects pharmaceutical drug submission review activity over five consecutive quarters: from April - June 2020 to April - June 2021. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

Several significant events occurred during the spring of 2020 including the COVID-19 Pandemic and the implementation of revised fees in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*.

- Health Canada employees shifted from working in their offices to working remotely from home. Fortunately, in 2019, HPFB had implemented new forms to take advantage of the gateway for transmission of regulatory transactions in electronic format.[1] This method is more efficient than sending transactions on physical media by courier and is mandatory as of October 1, 2020.

- The publication of the Quarterly Drug Submission Performance Report was cancelled for two quarters (there were no reports published for Q4 Jan-Mar 2020 and Q1 Apr-June 2020), however figures for the past three quarters are provided in this report.

- An Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19 was approved and on August 13, 2020 the Minister of Health approved the Order respecting certain time limits under the Food and Drug Regulations temporarily extending the default period to review clinical trial applications and amendments from 30 days to 45 days to allow Health Canada to expedite the influx of COVID-19 related clinical trial applications. The order extending the default period expired on November 16, 2020. The number of CTA and CTA-As received under orders are included in this report.

- The Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD Interim Order) was approved by the Governor in Council on September 25, 2020. This interim order was introduced, in part, to create a new authorization pathway to help expedite the authorization of drugs and vaccines for COVID-19. The number of applications and amendments filed, the number of applications and amendments in review, and the number of authorizations issued under the ISAD Interim Order are included in this report.

[1] The Regulatory Enrolment Process (REP) and the Common Electronic Submissions Gateway (CESG)

- There was a significant increase in the volume of Drug Identification Number Applications for Disinfectant products (DIND) received (see the Quarterly Drug Submission Performance Report for the Natural and Non-Prescription Health Products Directorate (NNHPD)).

- On April 1, 2020, revised fees were implemented in accordance with the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)*. In addition, submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug are now submitted as an SNDS or SANDS (and not as an NC).

- Decisions made in 2020-2021 included submissions filed under both the pre-2020 and post-2020 cost recovery framework.

General Information

There are several steps involved in the drug submission review[2] and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on the last day of the quarter. **"Backlog"** is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

Approvals[3] are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

Authorization means an authorization issued under section 5 of the ISAD Interim Order.

A **review cycle completion**[4] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken to complete a cycle (excluding any pause days[5]) is compared to a set performance standard which is based on the type of submission, class and cycle (status).

Performance for all submissions or applications filed after April 1, 2020 is tracked individually.

[2] For further clarification, refer to the Guidance for Industry: Management of Drug Submissions.

[3] Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-Cs are not included in the SNDS Approval figures. For further clarification, refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

[4] Review cycles include all types e.g. Review 1, Review 2, Review QN, Review Post Jr. The total number of "review decisions" may surpass the total number of review cycle completions as they include cancellations/withdrawals that occur while the submission is 'inactive'. For example, a withdrawal can be issued when a company fails to respond to a notice of non-compliance within the allotted time frame. A 'Cancelled by Company' is counted as a review decision when a company sends a cancellation letter after the submission's original materials have been accepted for review.

[5] In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance (effective date: April 1, 2020).

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude "refiled"[6] submissions.

Any questions or comments on this report should be forwarded to:

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Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: osip-bppi@hc-sc.gc.ca

[6] For further clarification, refer to the Guidance for Industry: Management of Drug Submissions.

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
COV19	-	Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
COV19A	-	Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application - Amendment
DINA	-	Application for a Drug Identification Number for a pharmaceutical product, including non-prescription products attesting to a Labelling Standard
DINB	-	Application for a Drug Identification Number for a biological product
DIND	-	Application for a Drug Identification Number for a disinfectant product
DINF	-	Application for a Drug Identification Number for a Category IV Monograph Product
EUANDS	-	Abbreviated Extraordinary Use New Drug Submission
EUNDS	-	Extraordinary Use New Drug Submission
EUSANDS	-	Supplement to an Abbreviated Extraordinary Use New Drug Submission
EUSNDS	-	Supplement to an Extraordinary Use New Drug Submission
MPNDS	-	Pre-Submission Meeting New Drug Submission
MPSNDS	-	Pre-Submission Meeting Supplement to a New Drug Submission
NC	-	Notifiable Change
NDS	-	New Drug Submission
NDS-D	-	New Drug Submission for Disinfectant products
PDC	-	Post-authorization Division 1 Change for a pharmaceutical product
PDC-B	-	Post-authorization Division 1 Change for a biologic drug product
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission

SANDS	-	Supplement to an Abbreviated New Drug Submission
SANDS-c	-	Supplement to an Abbreviated New Drug Submission - Confirmatory
SNDS	-	Supplement to a New Drug Submission
SNDS-c	-	Supplement to a New Drug Submission - Confirmatory
SNDS-D	-	Supplement to a New Drug Submission for Disinfectant products

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
IO_NOA	-	Notice of Authorization
IO_NOA_TC	-	Notice of Authorization with Terms and Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to changes (Prescription to Non-Prescription)
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter

Fee Categories

Fee Category	Description
New active substance	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph
Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance
Comparative studies	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance
Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance
Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance
Switch status from prescription drug to non-prescription drug	Submissions based only on data that support the modification or removing of a medicinal ingredient listed in Schedule F of the Food and Drug Regulations (i.e. identical claim for existing drug) - Category discontinued
Labelling only	Submissions, other than those described in item 9, 12 or 13, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data)

Fee Category	Description
Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment
Administrative submission	Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the Food and Drugs Act)
Disinfectant – full review	Submissions, other than those described in item 12, that include data in support of a disinfectant
Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacture's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug
Drug identification number application - labelling standards	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data
Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance - Category discontinued

For further information, please consult the Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications .

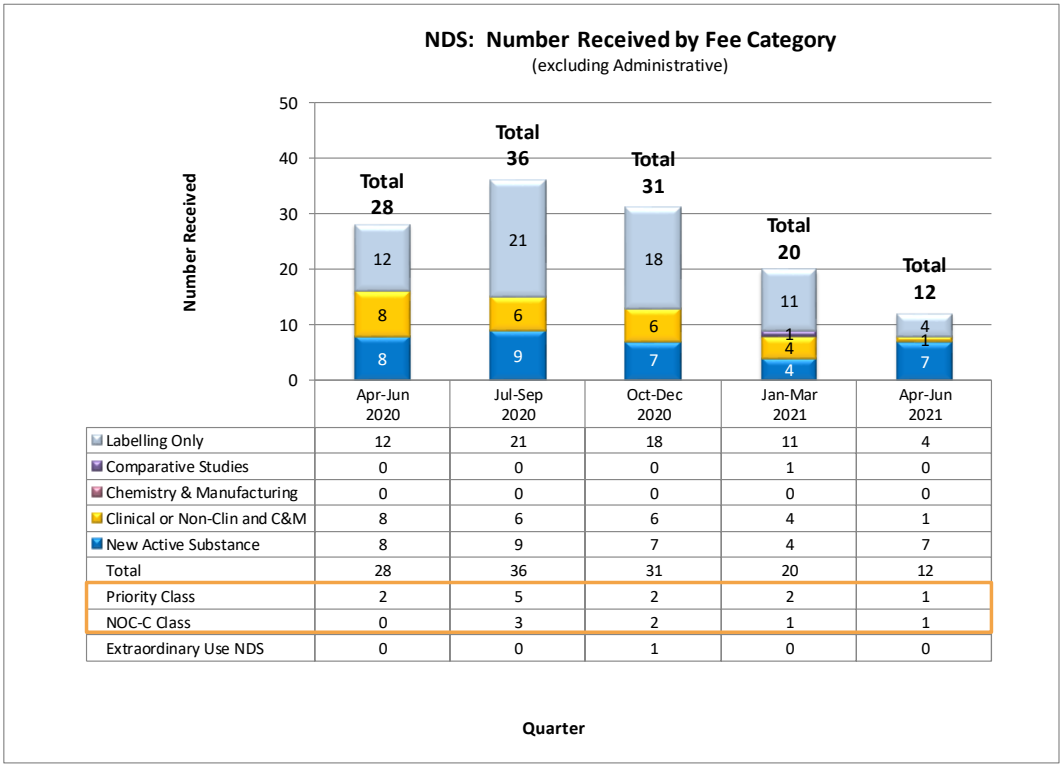
NEW DRUG SUBMISSION (NDS)

&

SUPPLEMENT TO A NEW DRUG SUBMISSION (SNDS)

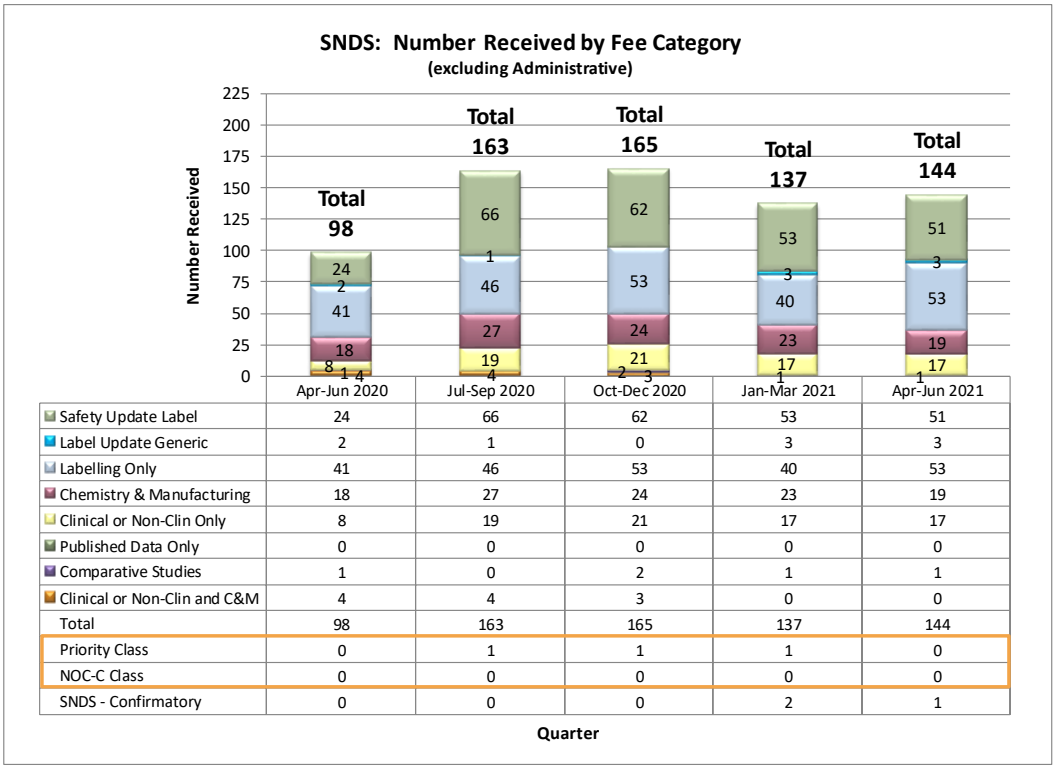
SUBMISSIONS RECEIVED [7]

NDS: Number Received by Fee Category



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Labelling Only	12	21	18	11	4
Comparative Studies	0	0	0	1	0
Chemistry & Manufacturing	0	0	0	0	0
Clinical or Non-Clin and C&M	8	6	6	4	1
New Active Substance	8	9	7	4	7
Total	28	36	31	20	12
Priority Class	2	5	2	2	1
NOC-C Class	0	3	2	1	1
Extraordinary Use NDS	0	0	1	0	0

SNDS: Number Received by Fee Category

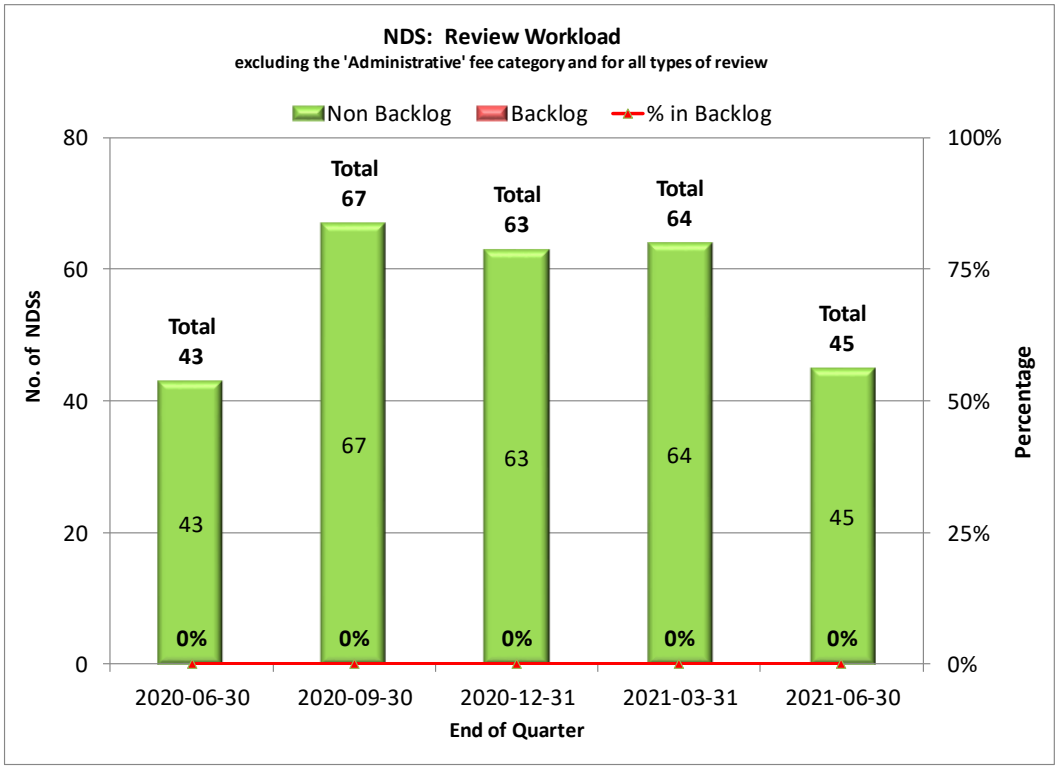


	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Safety Update Label	24	66	62	53	51
Label Update Generic	2	1	0	3	3
Labelling Only	41	46	53	40	53
Chemistry & Manufacturing	18	27	24	23	19
Clinical or Non-Clin Only	8	19	21	17	17
Published Data Only	0	0	0	0	0
Comparative Studies	1	0	2	1	1
Clinical or Non-Clin and C&M	4	4	3	0	0
Total	98	163	165	137	144
Priority Class	0	1	1	1	0
NOC-C Class	0	0	0	0	0
SNDS - Confirmatory	0	0	0	2	1

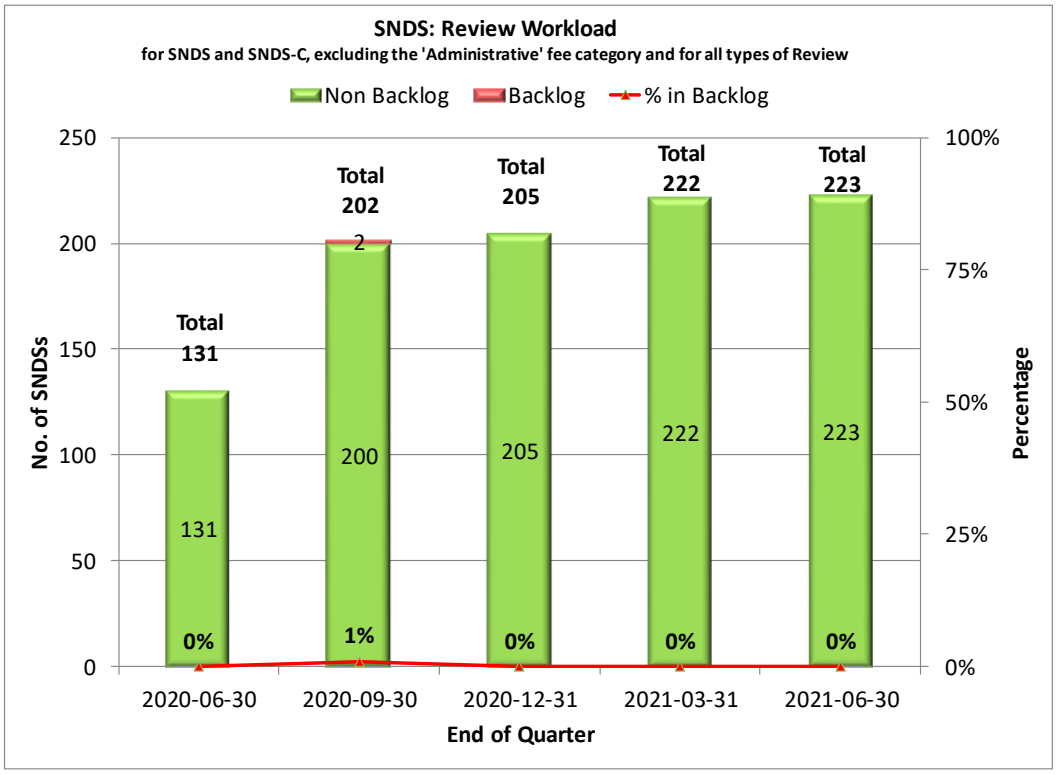
[7] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

WORKLOAD

NDS: Review Workload



SNDS: Review Workload



WORKLOAD

NDS: Review Workload by Fee Category

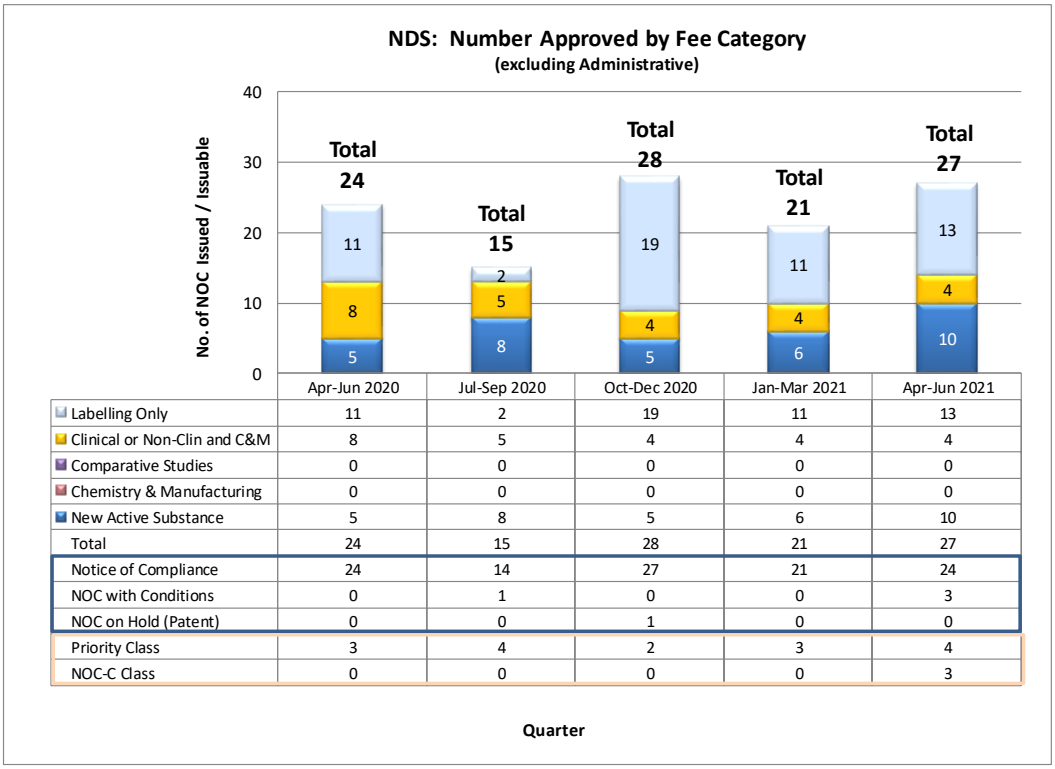
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2020-06-30**	**2020-09-30**	**2020-12-31**	**2021-03-31**	**2021-06-30**
Labelling Only	**4**	**23**	**16**	**17**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**16**	**20**	**20**	**22**	**19**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**22**	**24**	**27**	**25**	**17**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**43**	**67**	**63**	**64**	**45**
Non Backlog	**43**	**67**	**63**	**64**	**45**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**6**	**5**	**7**	**6**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

SNDS: Review Workload by Fee Category

SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Labelling Only	**19**	**48**	**47**	**49**	**47**
Backlog	*0*	*1*	*0*	*0*	*0*
Comparative Studies	**5**	**4**	**0**	**1**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**35**	**43**	**37**	**47**	**45**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**47**	**37**	**44**	**53**	**61**
Backlog	*0*	*1*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**9**	**10**	**11**	**9**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**3**	**2**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	**1**	**0**	**0**	**2**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	**12**	**58**	**65**	**61**	**61**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**131**	**202**	**205**	**222**	**223**
Non Backlog	**131**	**200**	**205**	**222**	**223**
Backlog	**0**	**2**	**0**	**0**	**0**
% in Backlog	**0%**	**1%**	**0%**	**0%**	**0%**
Priority (subset)	**3**	**3**	**1**	**2**	**2**
Backlog	*0*	*1*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**0**	**0**	**0**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

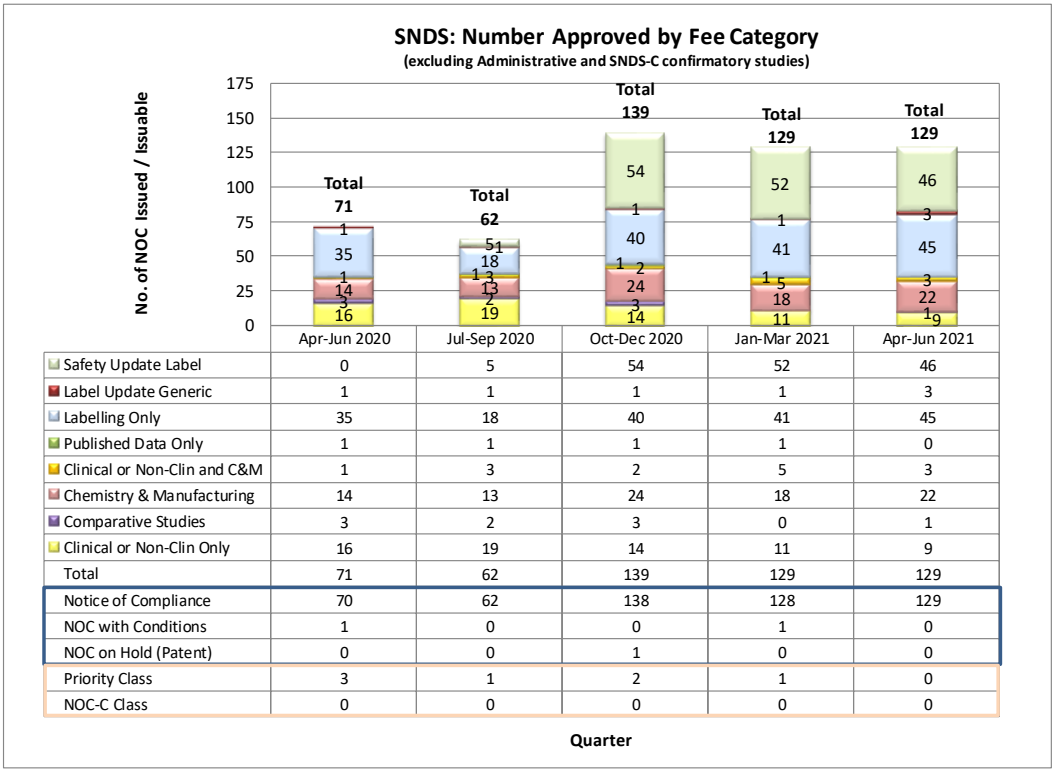
APPROVALS [8]

NDS: Number Approved by Fee Category and by NOC Type



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Labelling Only	11	2	19	11	13
Clinical or Non-Clin and C&M	8	5	4	4	4
Comparative Studies	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
New Active Substance	5	8	5	6	10
Total	24	15	28	21	27
Notice of Compliance	24	14	27	21	24
NOC with Conditions	0	1	0	0	3
NOC on Hold (Patent)	0	0	1	0	0
Priority Class	3	4	2	3	4
NOC-C Class	0	0	0	0	3

SNDS: Number Approved by Fee Category and by NOC Type



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Safety Update Label	0	5	54	52	46
Label Update Generic	1	1	1	1	3
Labelling Only	35	18	40	41	45
Published Data Only	1	1	1	1	0
Clinical or Non-Clin and C&M	1	3	2	5	3
Chemistry & Manufacturing	14	13	24	18	22
Comparative Studies	3	2	3	0	1
Clinical or Non-Clin Only	16	19	14	11	9
Total	71	62	139	129	129
Notice of Compliance	70	62	138	128	129
NOC with Conditions	1	0	0	1	0
NOC on Hold (Patent)	0	0	1	0	0
Priority Class	3	1	2	1	0
NOC-C Class	0	0	0	0	0

[8] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

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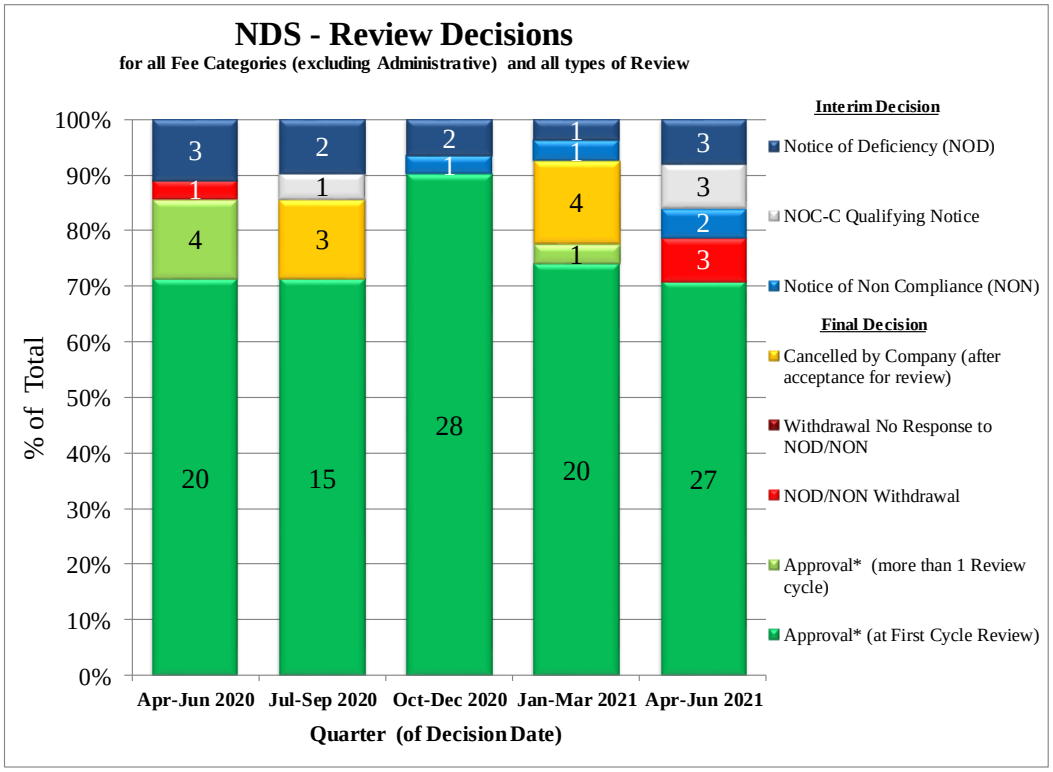
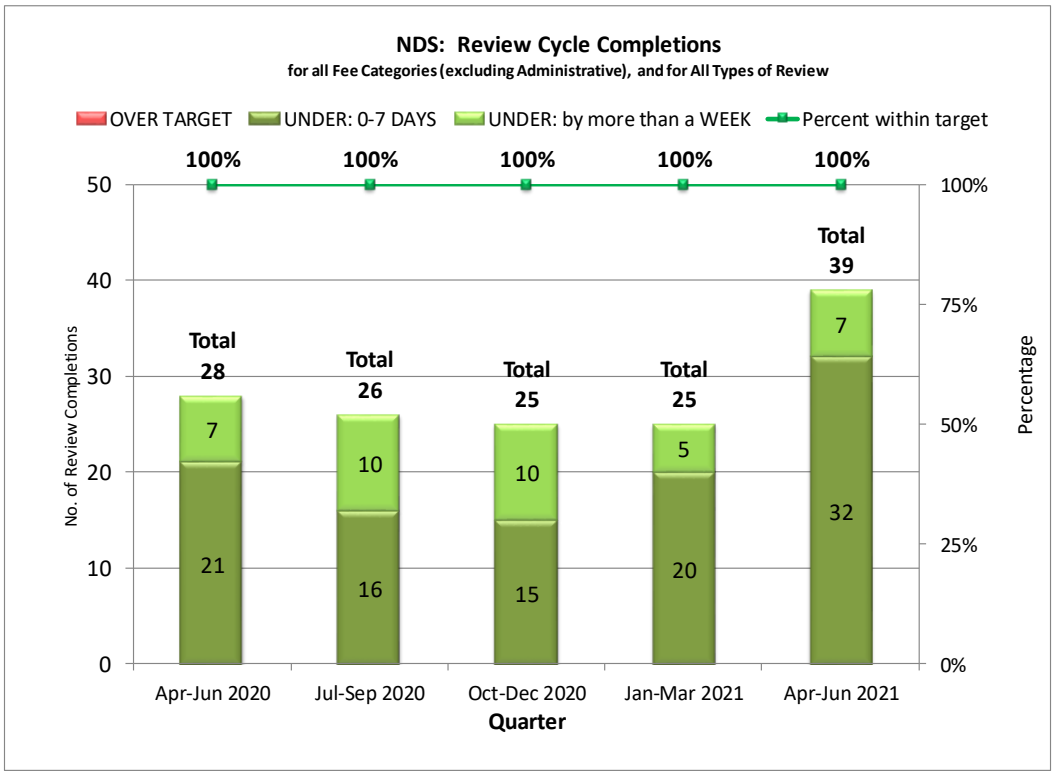
REVIEW PERFORMANCE

NDS: Review Decisions by Type

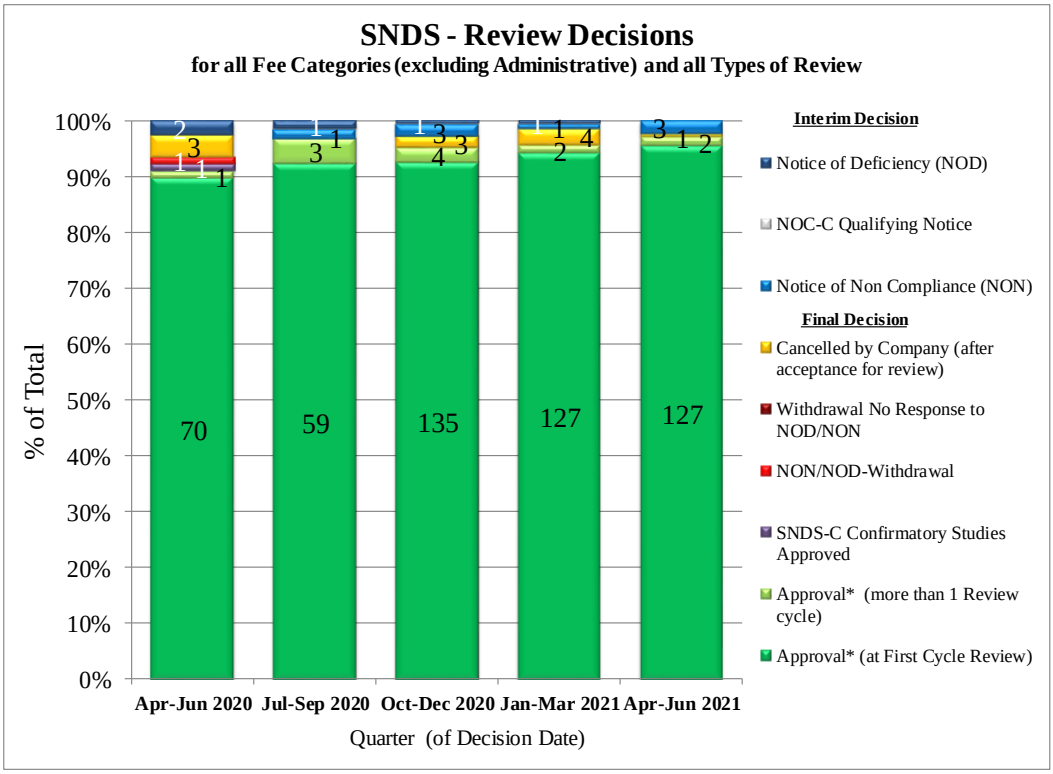


NDS: Review Cycle Completions

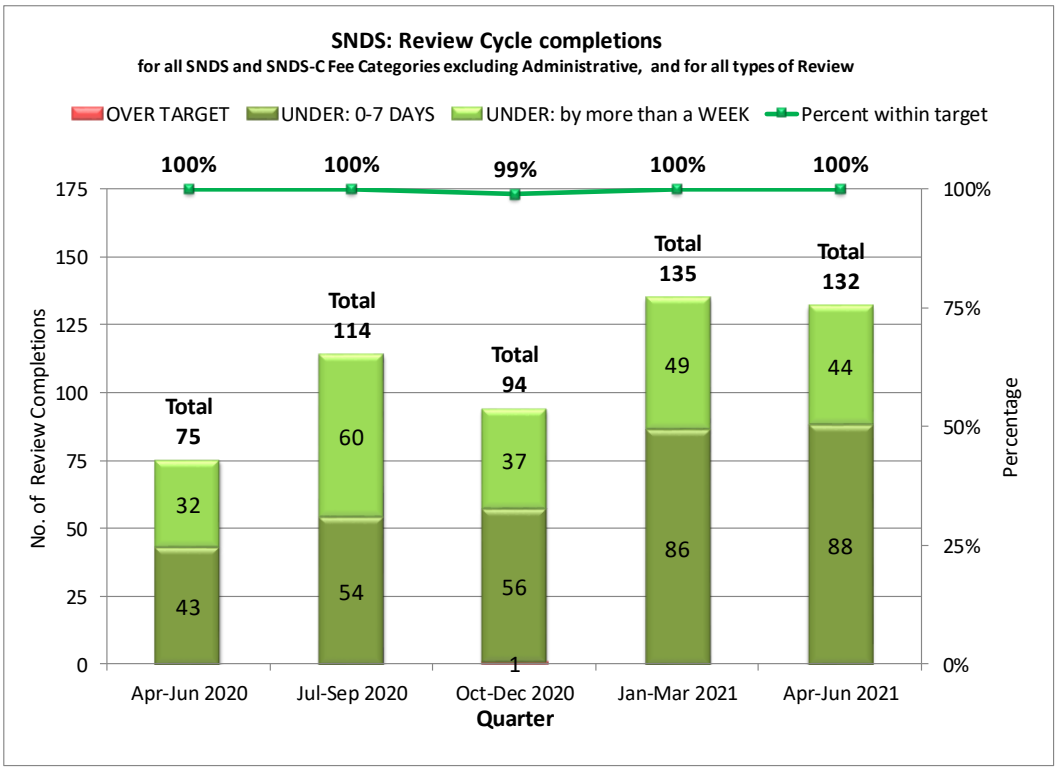


REVIEW CYCLE DECISIONS

SNDS: Review Decisions by Type

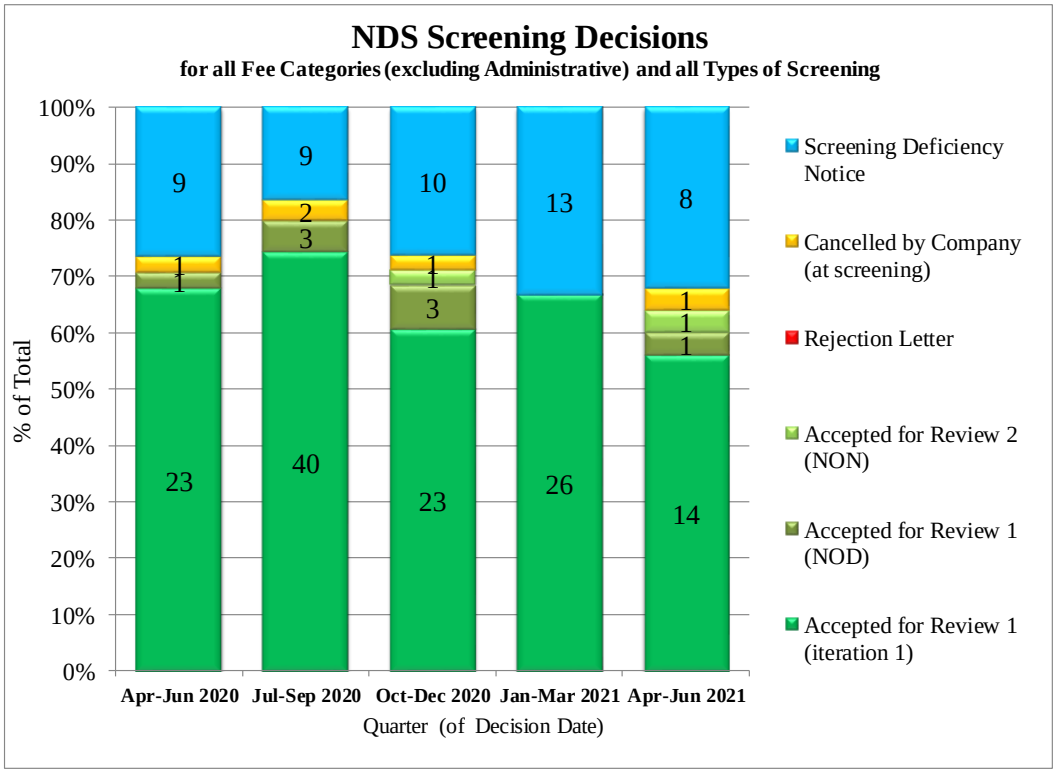


SNDS: Review Cycle Completions

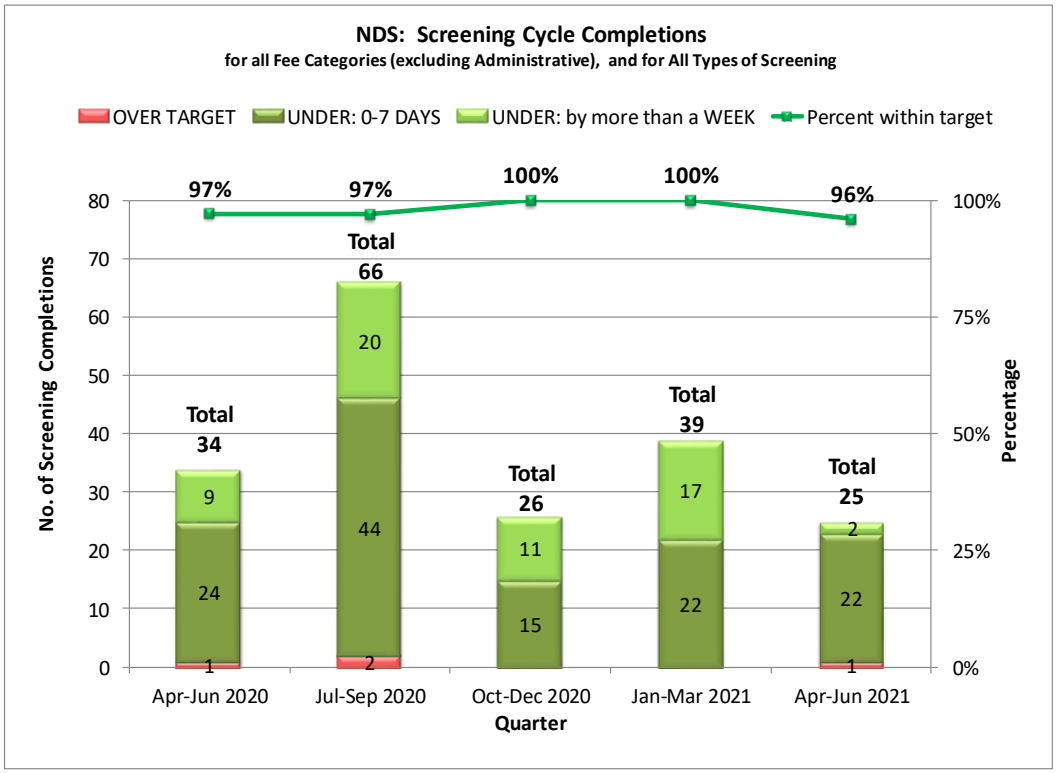


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

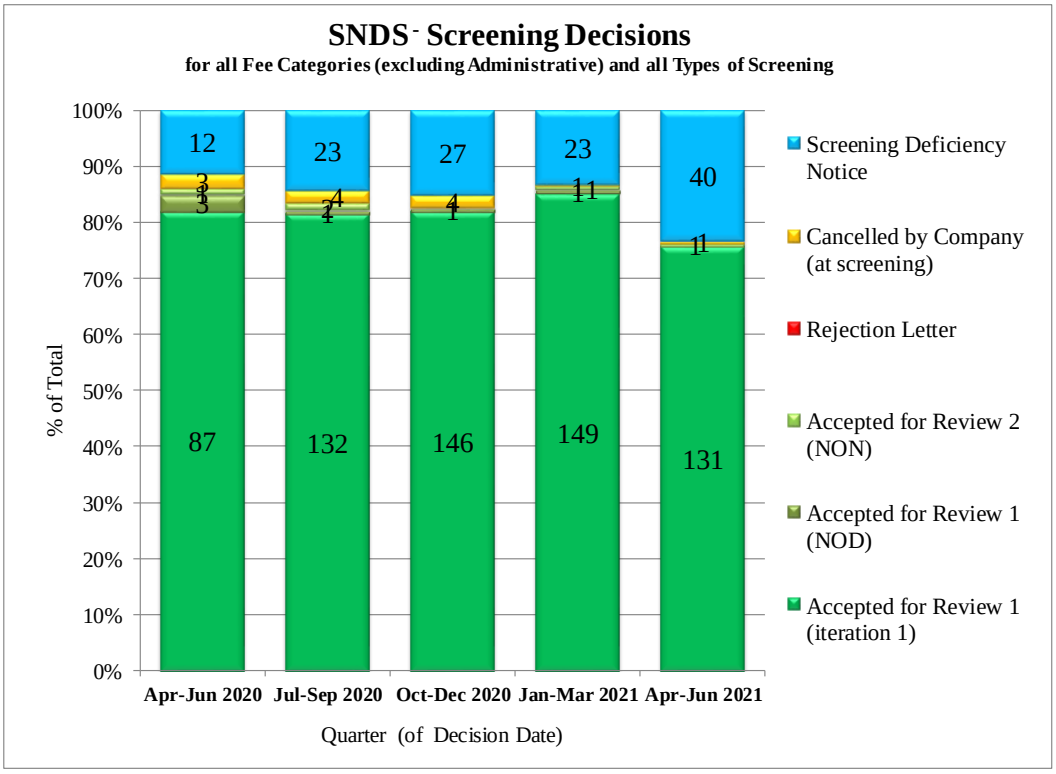


NDS: Screening Cycle Completions

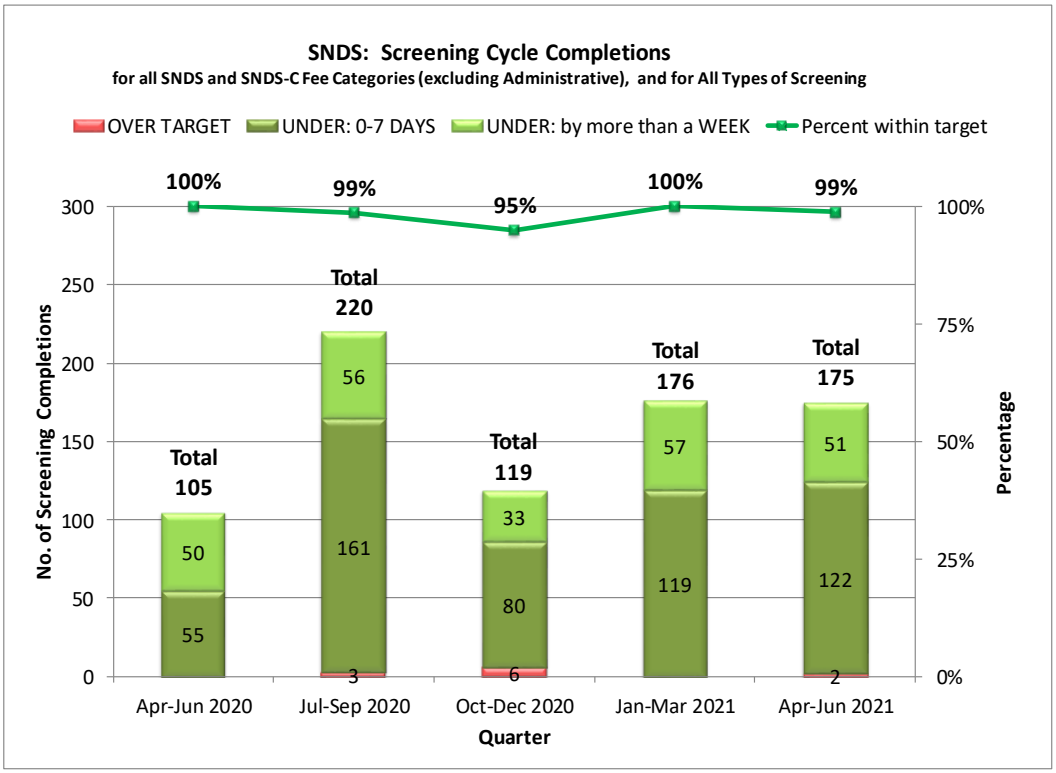


SCREENING CYCLE DECISIONS

SNDS: Screening Decisions by Type



SNDS: Screening Cycle Completions



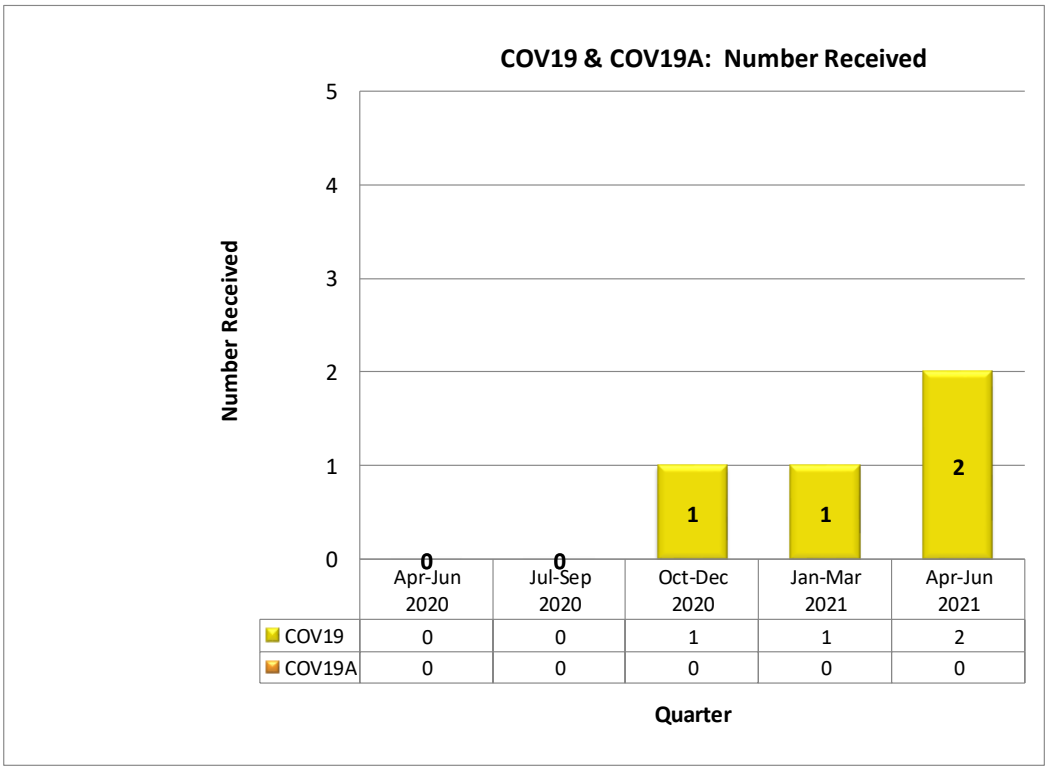
Application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19)

&

Application for an amendment to an application under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (COV19A)

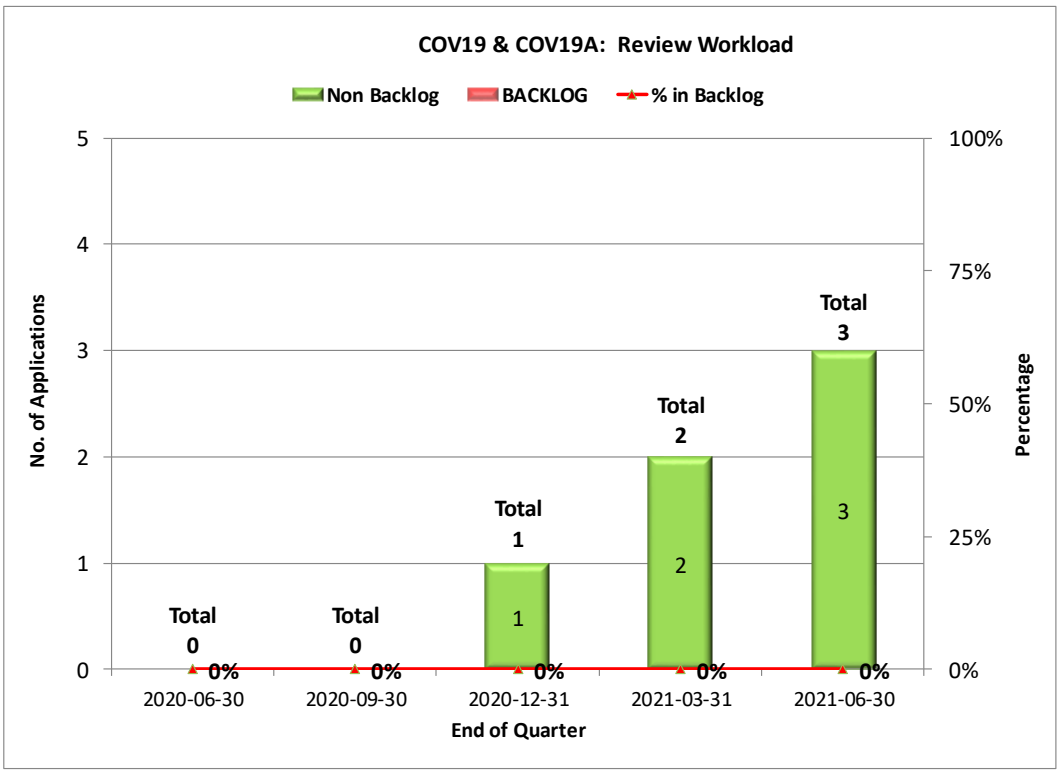
RECEIVED

COV19 & COV19A: Number Received



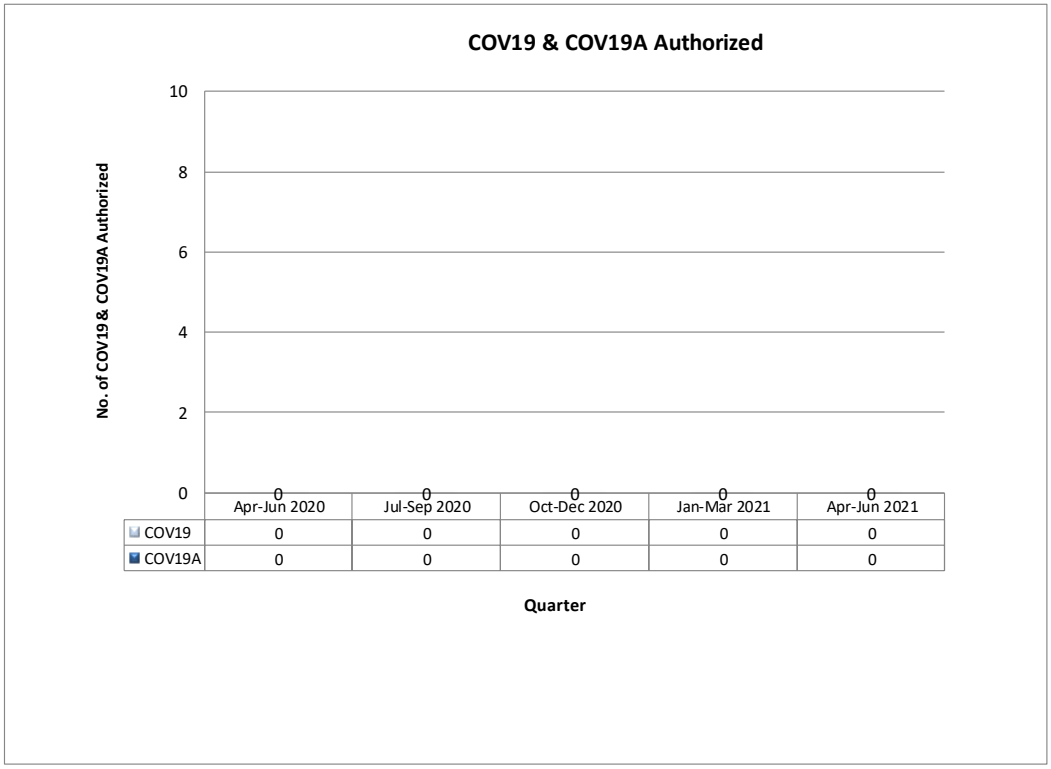
WORKLOAD

COV19 & COV19A: Review Workload



AUTHORIZATIONS

COV19 & COV19A: Number Authorized



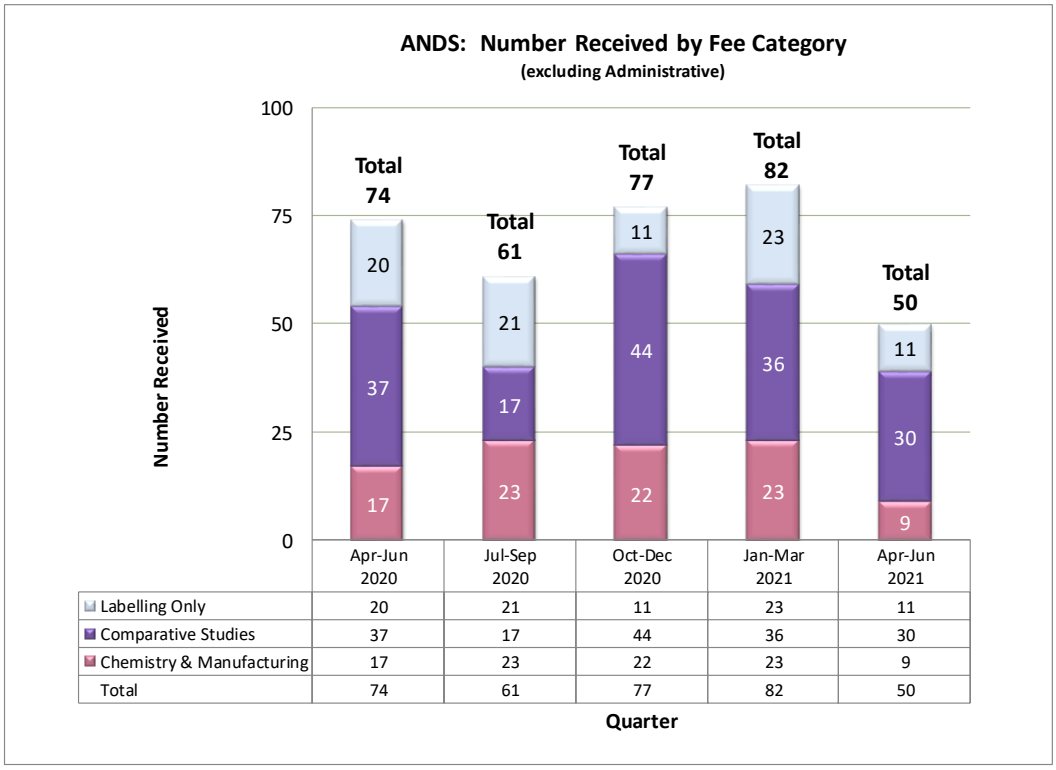
Abbreviated New Drug Submissions (ANDS)

&

Supplement to an Abbreviated New Drug Submissions (SANDS)

SUBMISSIONS RECEIVED

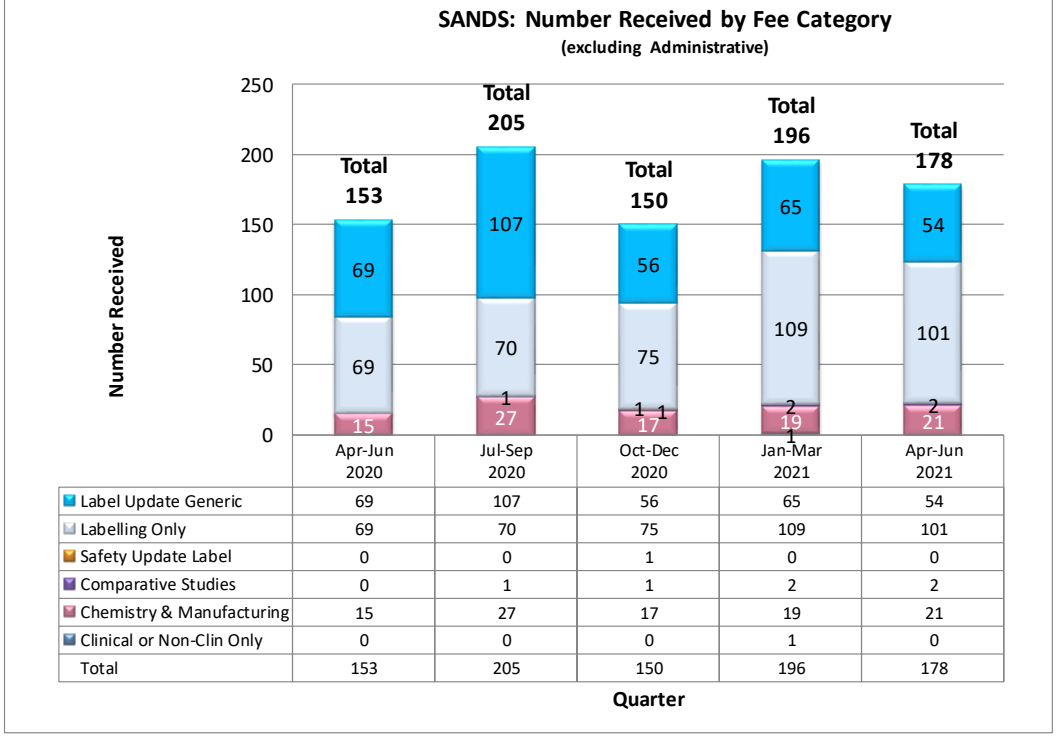
ANDS: Number Received by Fee Category



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Labelling Only	20	21	11	23	11
Comparative Studies	37	17	44	36	30
Chemistry & Manufacturing	17	23	22	23	9
Total	74	61	77	82	50

Quarter

SANDS: Number Received by Fee Category

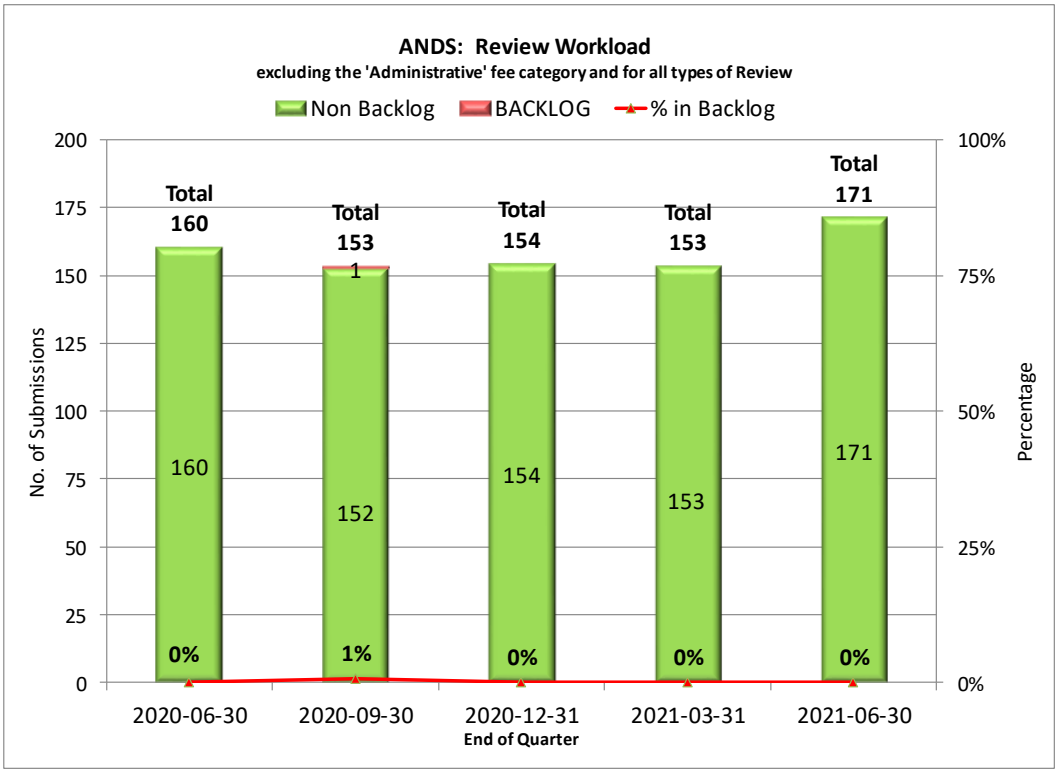


	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Label Update Generic	69	107	56	65	54
Labelling Only	69	70	75	109	101
Safety Update Label	0	0	1	0	0
Comparative Studies	0	1	1	2	2
Chemistry & Manufacturing	15	27	17	19	21
Clinical or Non-Clin Only	0	0	0	1	0
Total	153	205	150	196	178

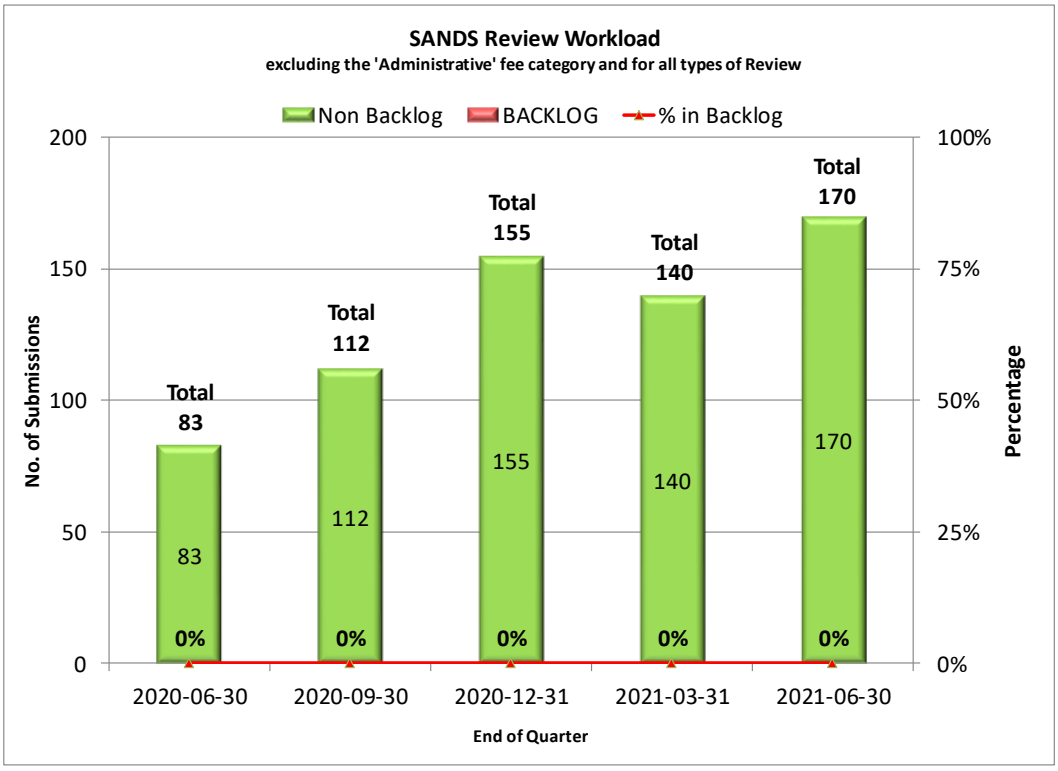
Quarter

WORKLOAD

ANDS: Review Workload



SANDS: Review Workload



WORKLOAD

ANDS: Review Workload by Fee Category

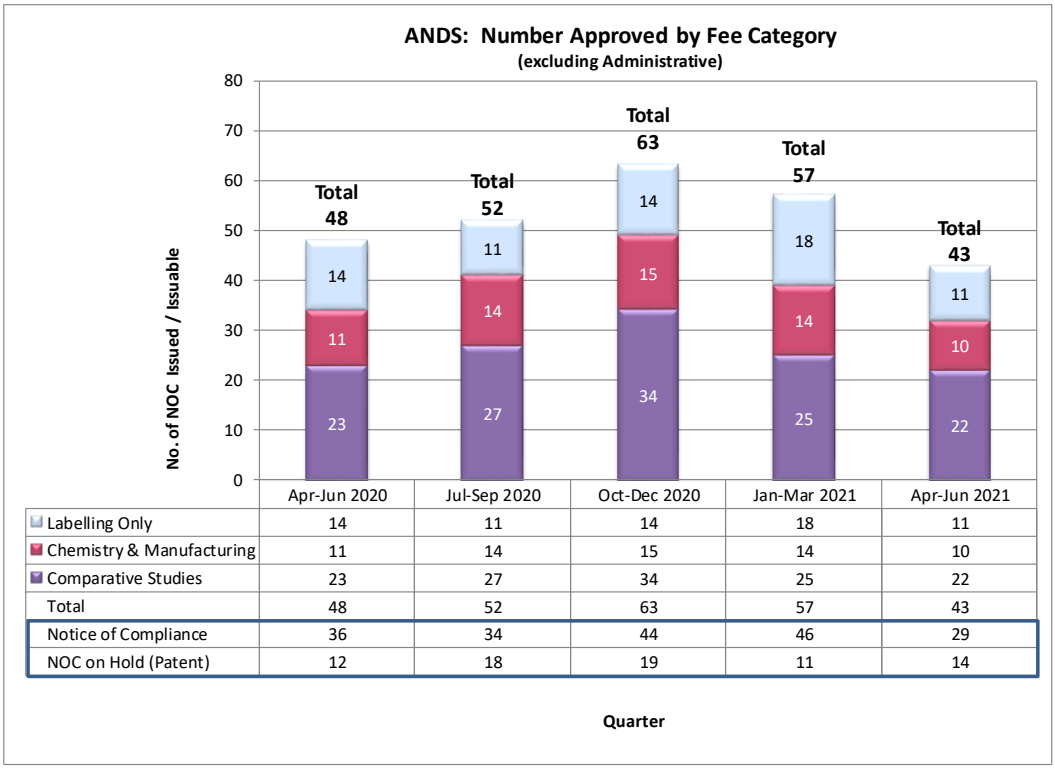
ANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Chemistry & Manufacturing	47	51	54	53	51
Backlog	*0*	*1*	*0*	*0*	*0*
Comparative Studies	103	84	79	89	98
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	10	18	21	11	22
Backlog	*0*	*0*	*0*	*0*	*0*
Total	160	153	154	153	171
Non Backlog	160	152	154	153	171
BACKLOG	0	1	0	0	0
% in Backlog	0%	1%	0%	0%	0%

SANDS: Review Workload by Fee Category

SANDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
Chemistry & Manufacturing	28	37	40	30	34
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	1	0	0	1	5
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	31	54	85	91	119
Backlog	*0*	*0*	*0*	*0*	*0*
Label Update Generic	23	21	29	18	12
Backlog	*0*	*0*	*0*	*0*	*0*
Safety Update Label	0	0	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	83	112	155	140	170
Non Backlog	83	112	155	140	170
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

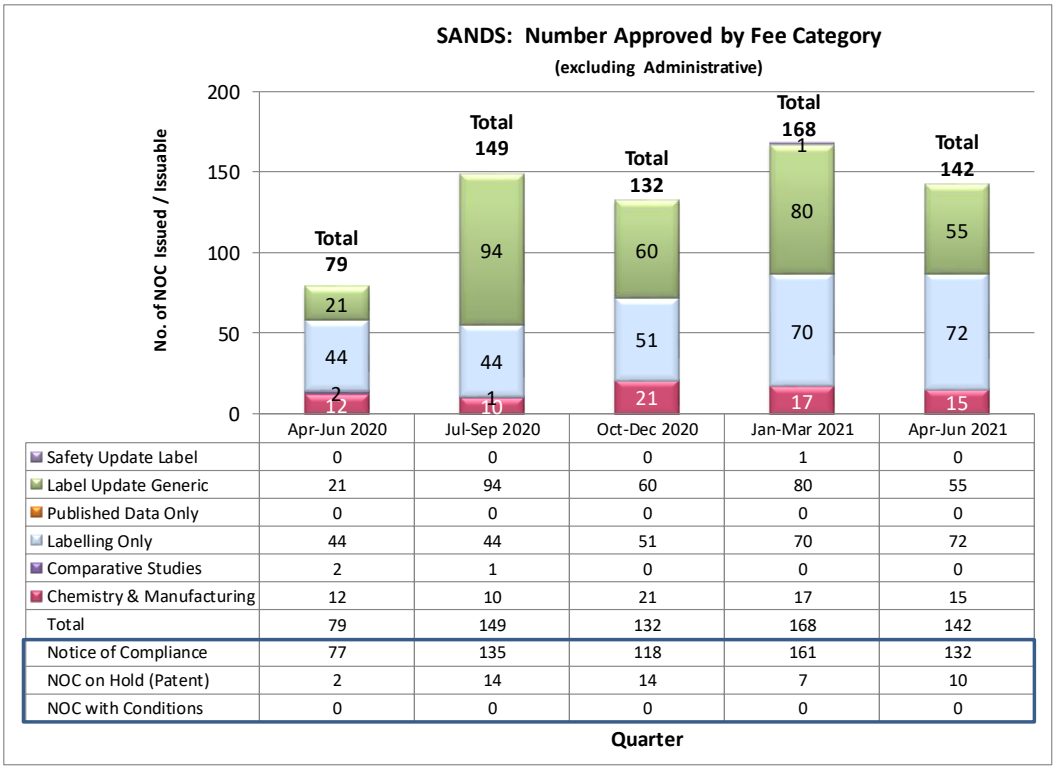
APPROVALS

ANDS: Number Approved by Fee Category and by NOC Type



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Labelling Only	14	11	14	18	11
Chemistry & Manufacturing	11	14	15	14	10
Comparative Studies	23	27	34	25	22
Total	48	52	63	57	43
Notice of Compliance	36	34	44	46	29
NOC on Hold (Patent)	12	18	19	11	14

SANDS: Number Approved by Fee Category and by NOC Type



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Safety Update Label	0	0	0	1	0
Label Update Generic	21	94	60	80	55
Published Data Only	0	0	0	0	0
Labelling Only	44	44	51	70	72
Comparative Studies	2	1	0	0	0
Chemistry & Manufacturing	12	10	21	17	15
Total	79	149	132	168	142
Notice of Compliance	77	135	118	161	132
NOC on Hold (Patent)	2	14	14	7	10
NOC with Conditions	0	0	0	0	0

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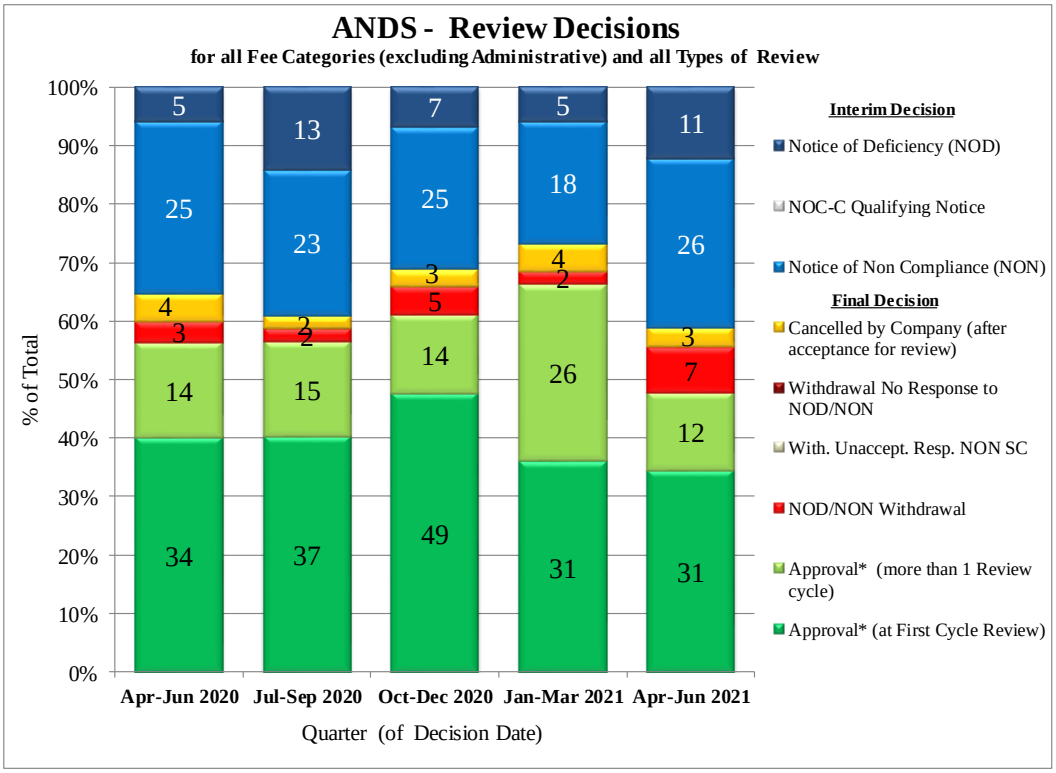
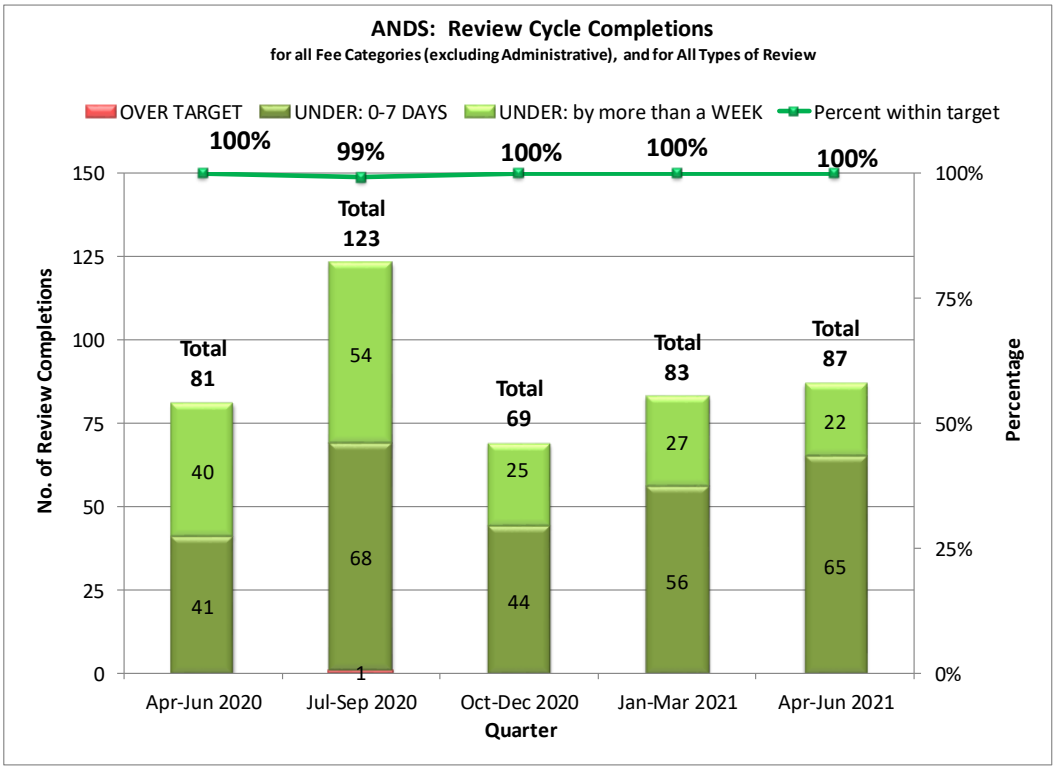
REVIEW PERFORMANCE

ANDS: Review Decisions by Type

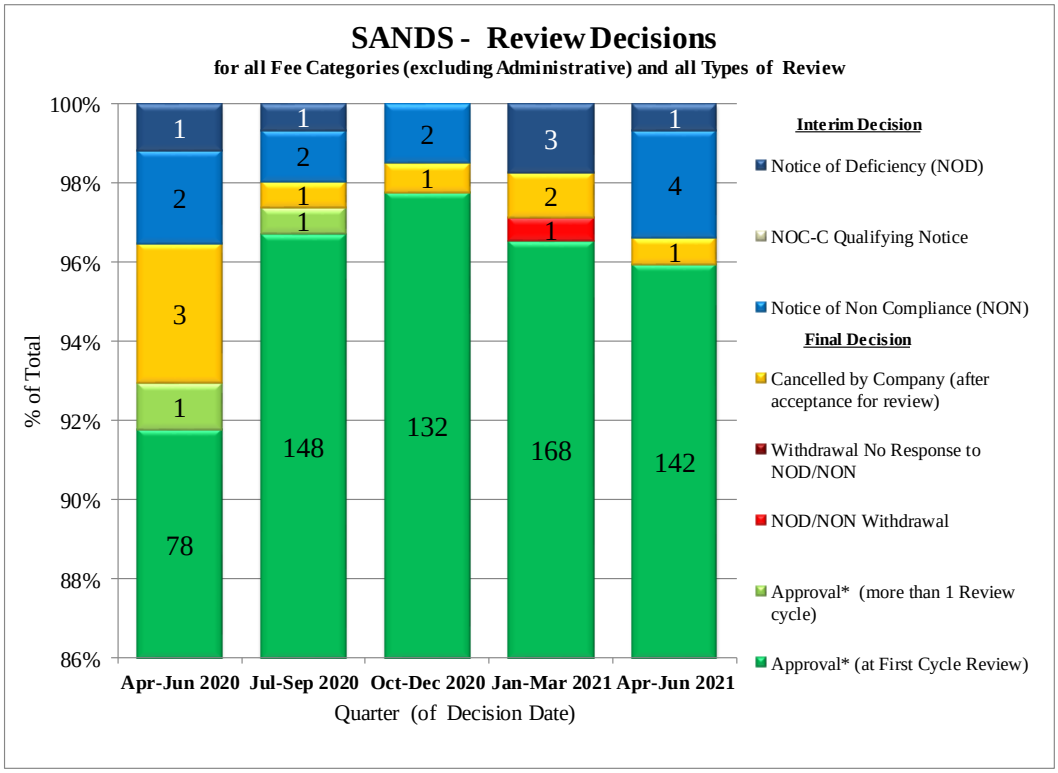


ANDS: Review Cycle Completions

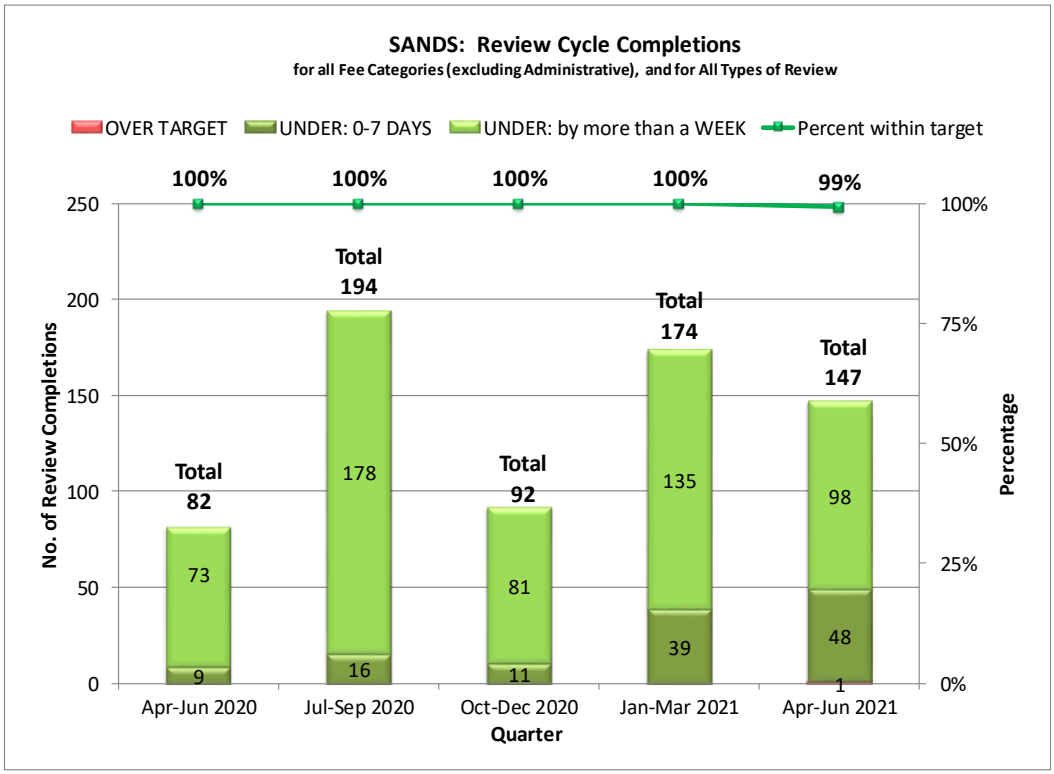


REVIEW PERFORMANCE

SANDS: Review Decisions by Type

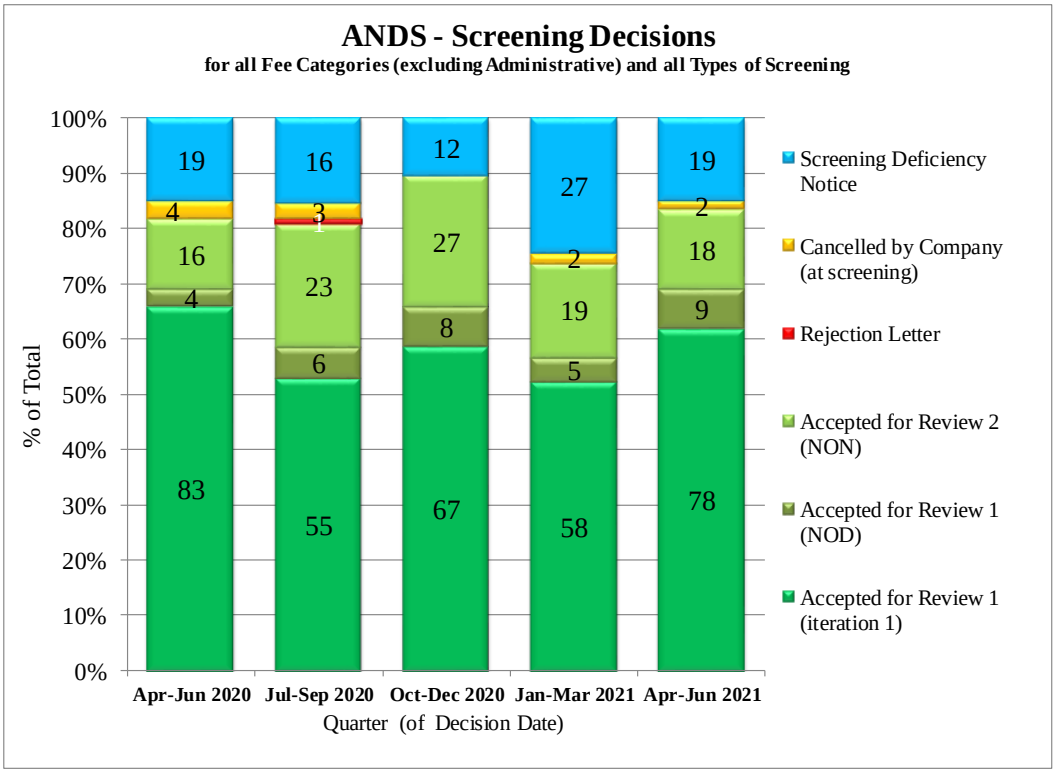


SANDS: Review Cycle Completions

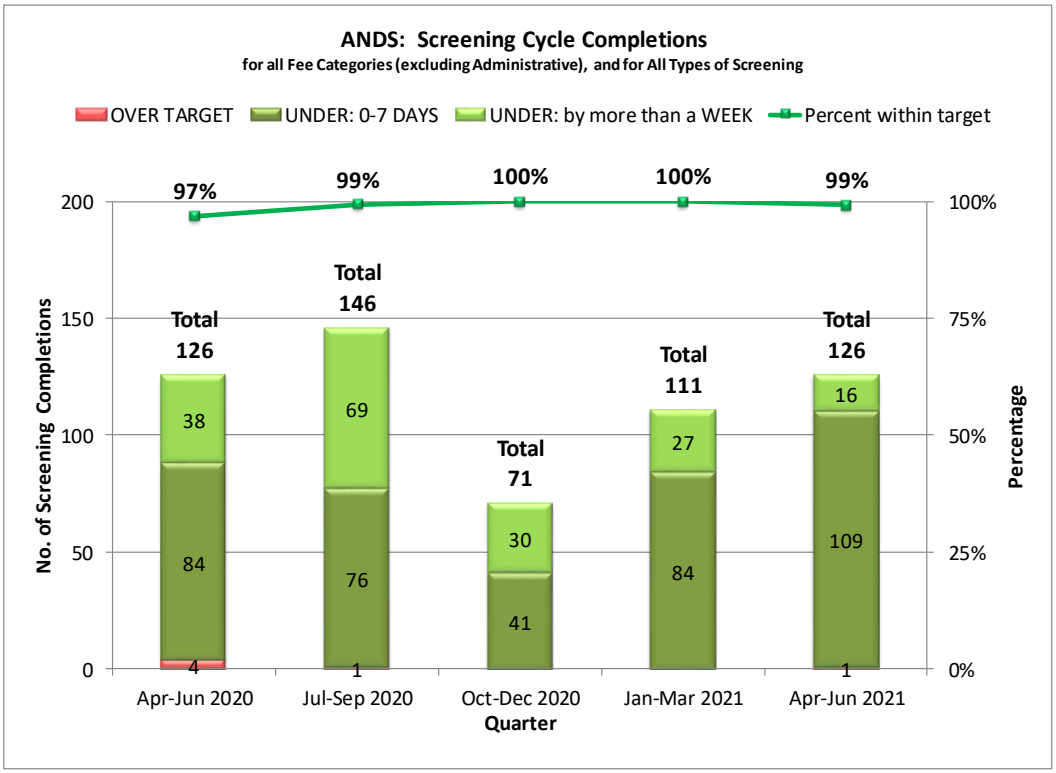


SCREENING PERFORMANCE

ANDS: Screening Decisions by Type

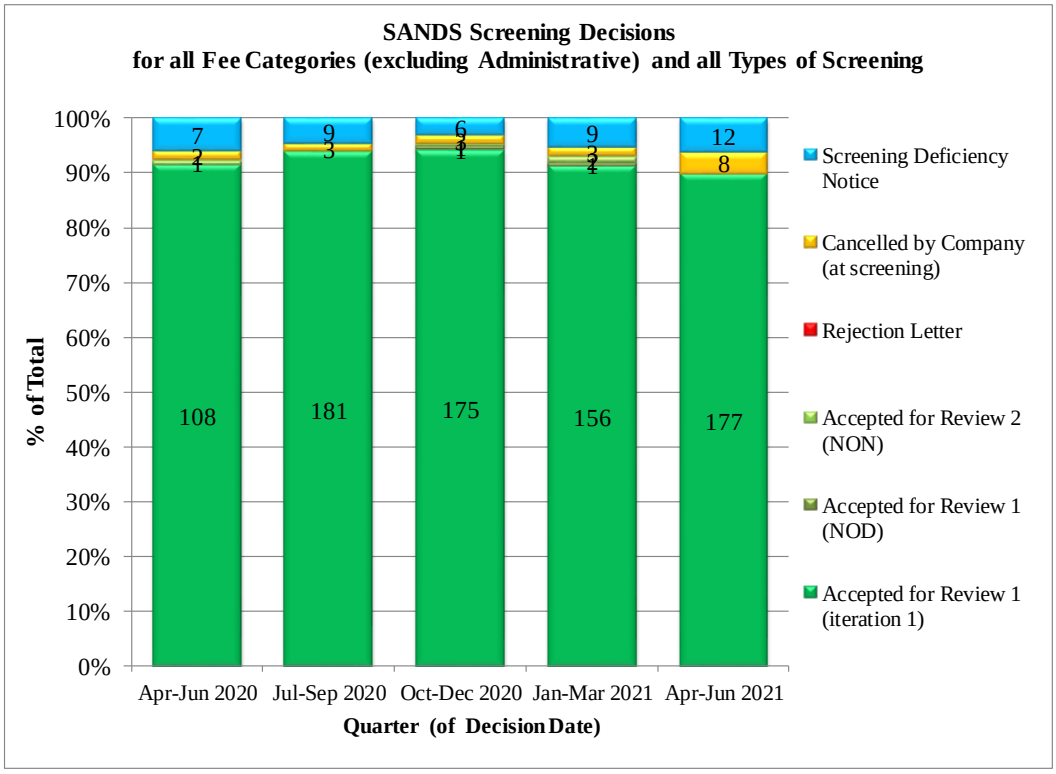


ANDS: Screening Cycle Completions

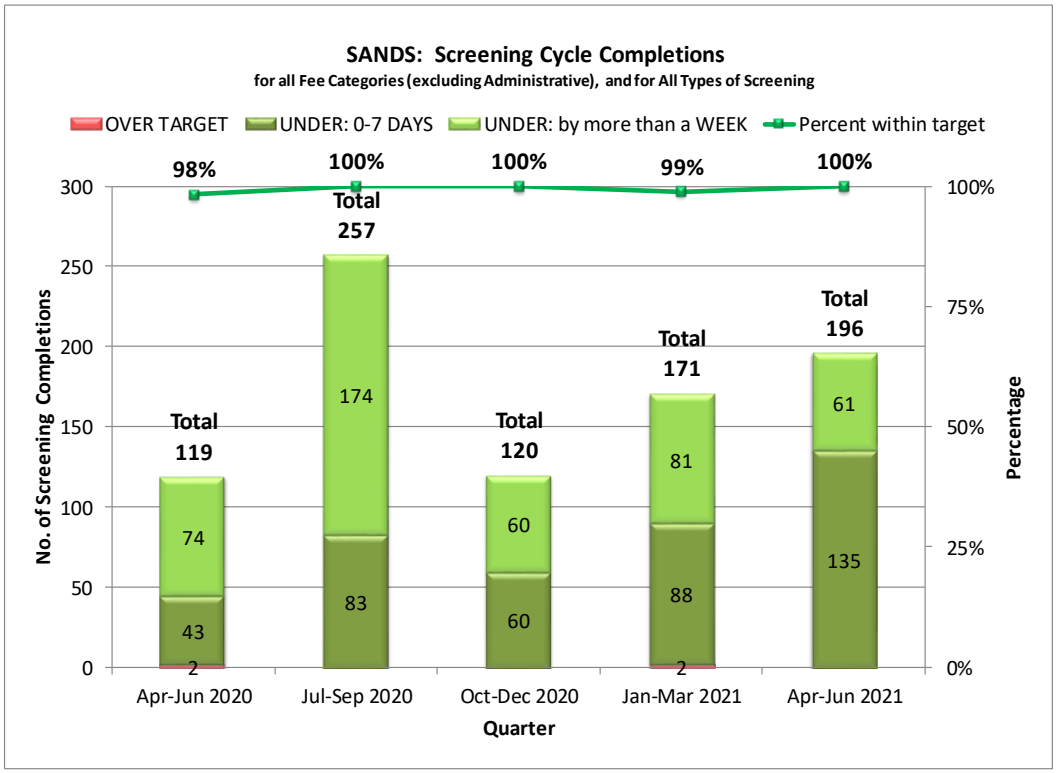


SCREENING PERFORMANCE

SANDS: Screening Decisions by Type

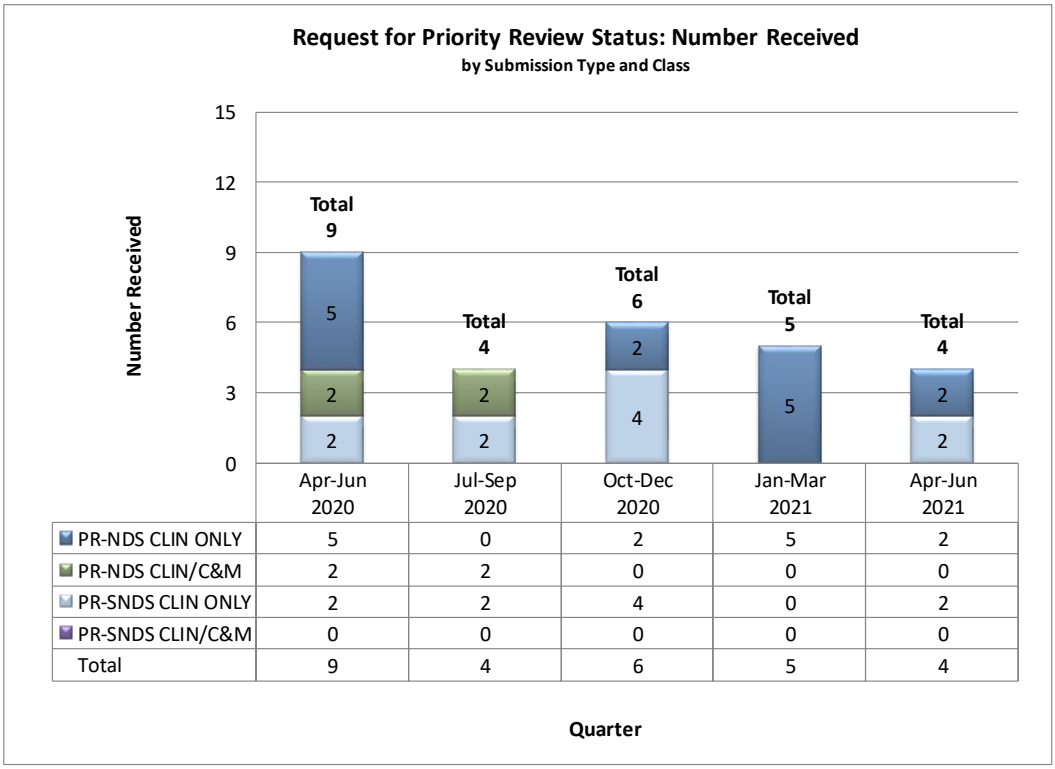


SANDS: Screening Cycle Completions



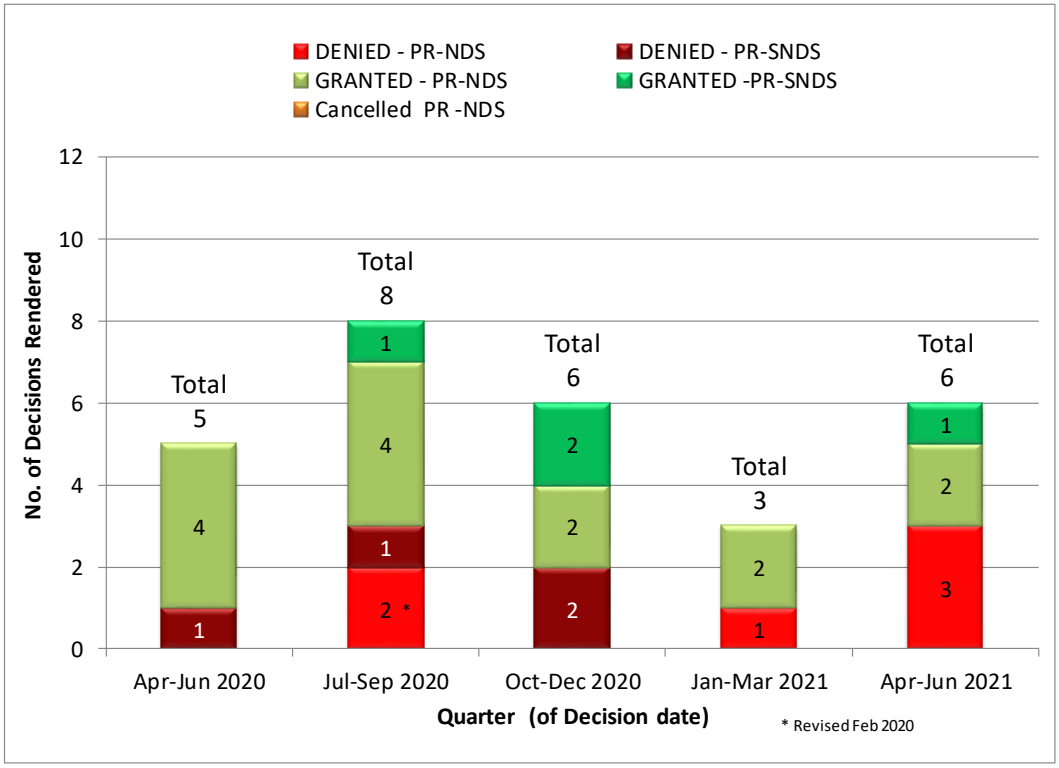
REQUEST FOR PRIORITY REVIEW STATUS (for NDS & SNDS)

Request for Priority Review Status: Number Received

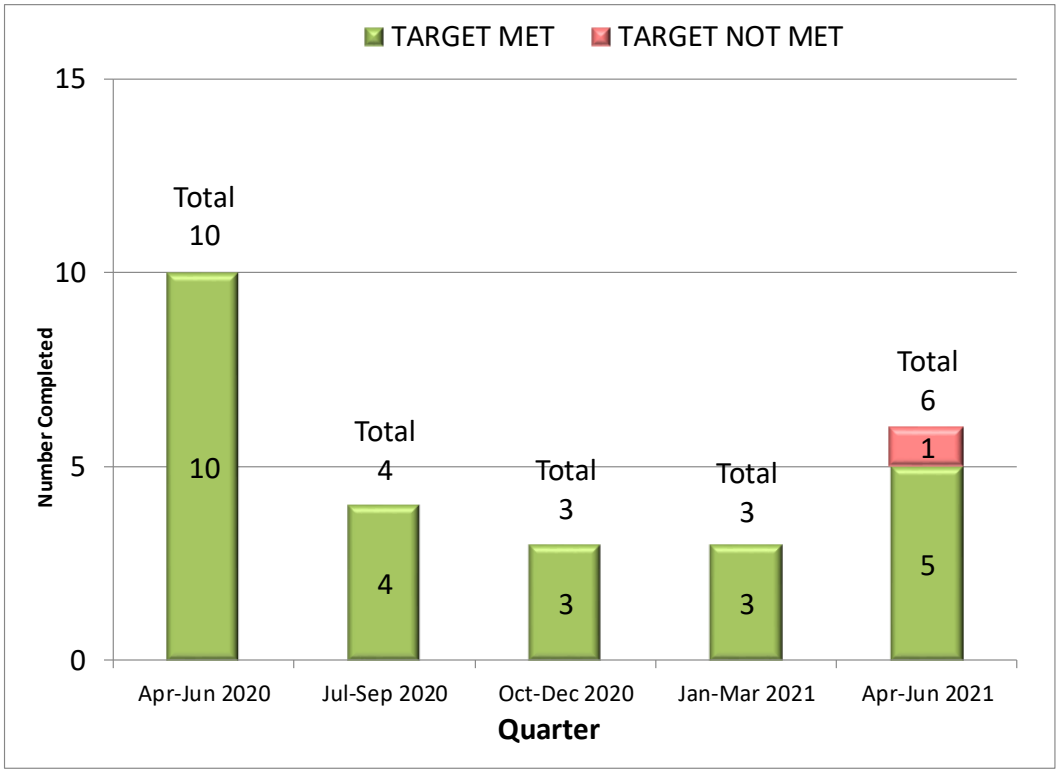


	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
PR-NDS CLIN ONLY	5	0	2	5	2
PR-NDS CLIN/C&M	2	2	0	0	0
PR-SNDS CLIN ONLY	2	2	4	0	2
PR-SNDS CLIN/C&M	0	0	0	0	0
Total	9	4	6	5	4

Request for Priority Review Status: Decisions Rendered



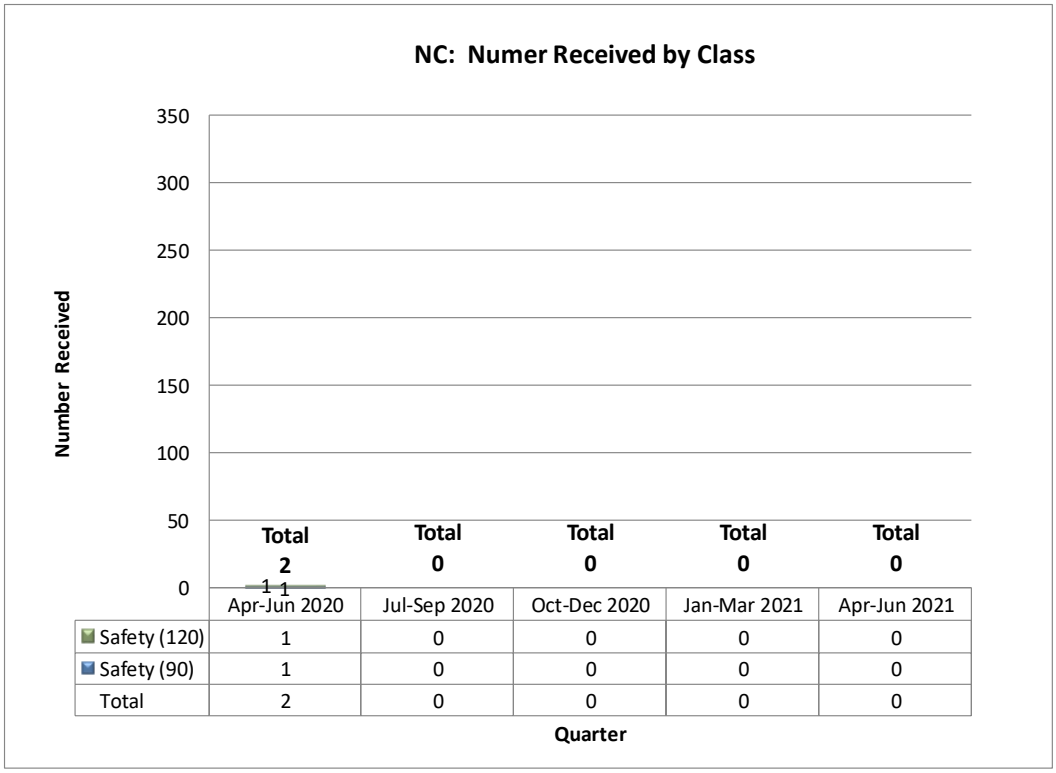
Request for Priority Review Status: Performance



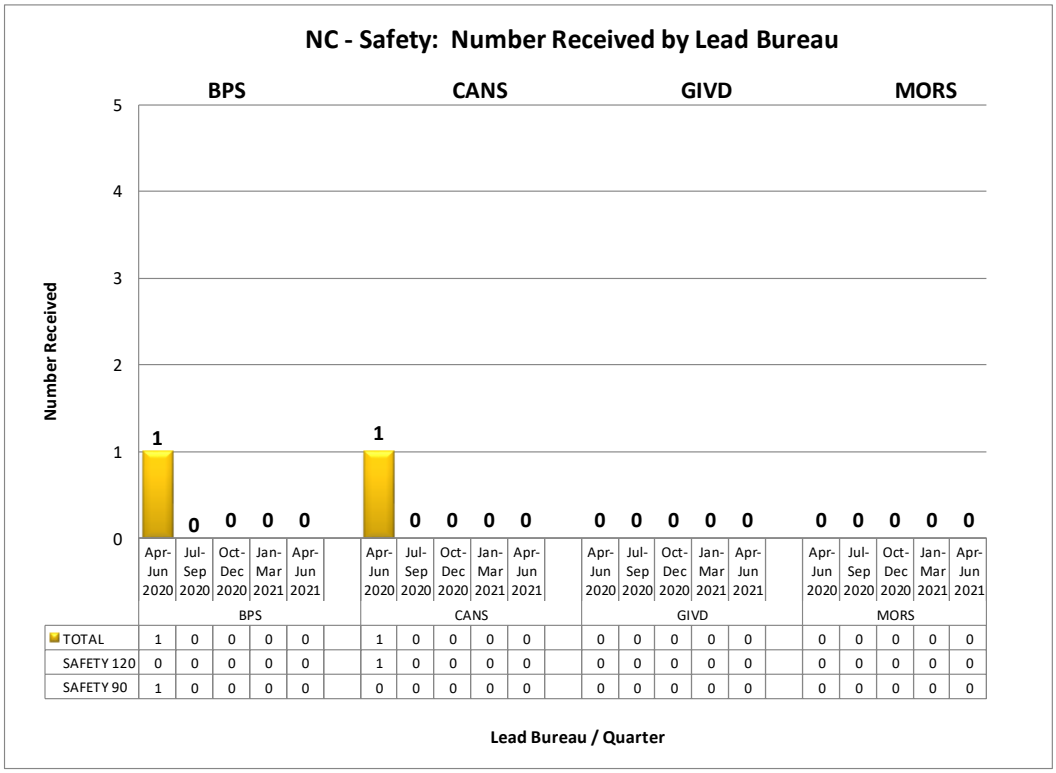
NC: NOTIFIABLE CHANGE

NOTIFIABLE CHANGE
RECEIVED

NC: Number Received by Class

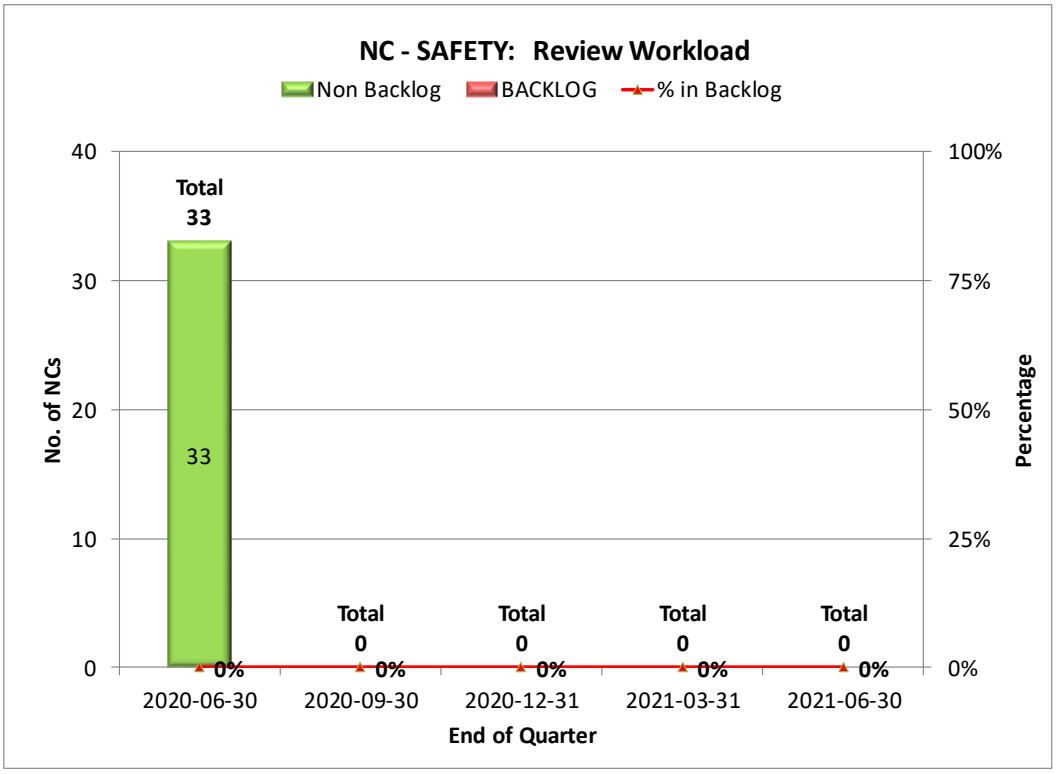


NC-SAFETY: Number Received by Lead Bureau



WORKLOAD

NC-SAFETY: Review Workload

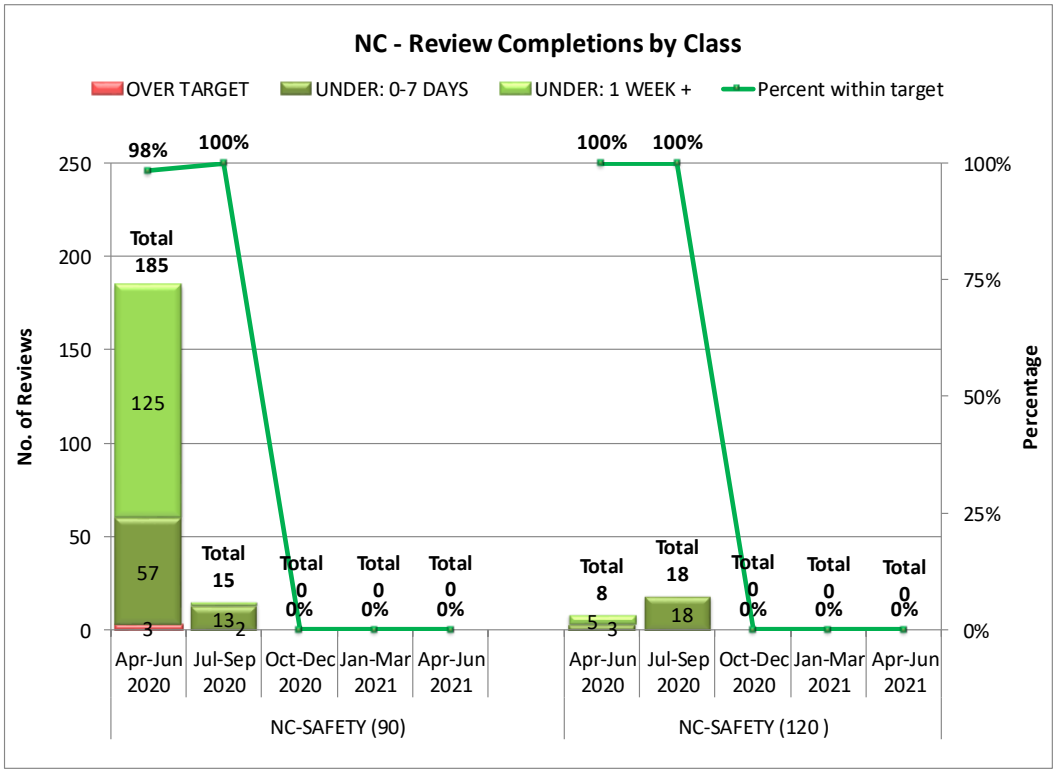


NC-SAFETY: Review Workload by Class

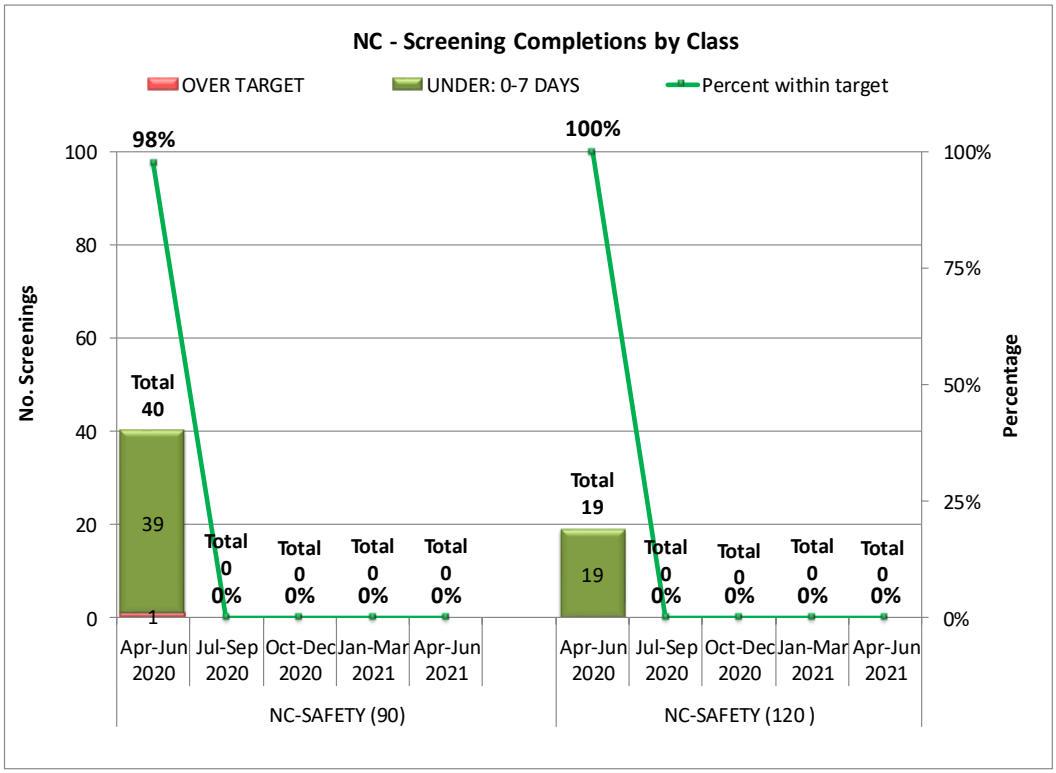
TPD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2020-06-30	2020-09-30	2020-12-31	2021-03-31	2021-06-30
SAFETY - 90 day	15	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	18	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	33	0	0	0	0
Non Backlog	33	0	0	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NC–SAFETY: Review Completions by Class



NC–SAFETY: Screening Completions by Class



NC-SAFETY: Number of Decisions by Class

NC - SAFETY (90)					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	181	15	1	4	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	5	0	0	0	0
CANCELLED BY COMPANY	6	0	0	0	0
NC - HOLD (PATENT)	1	0	0	0	0

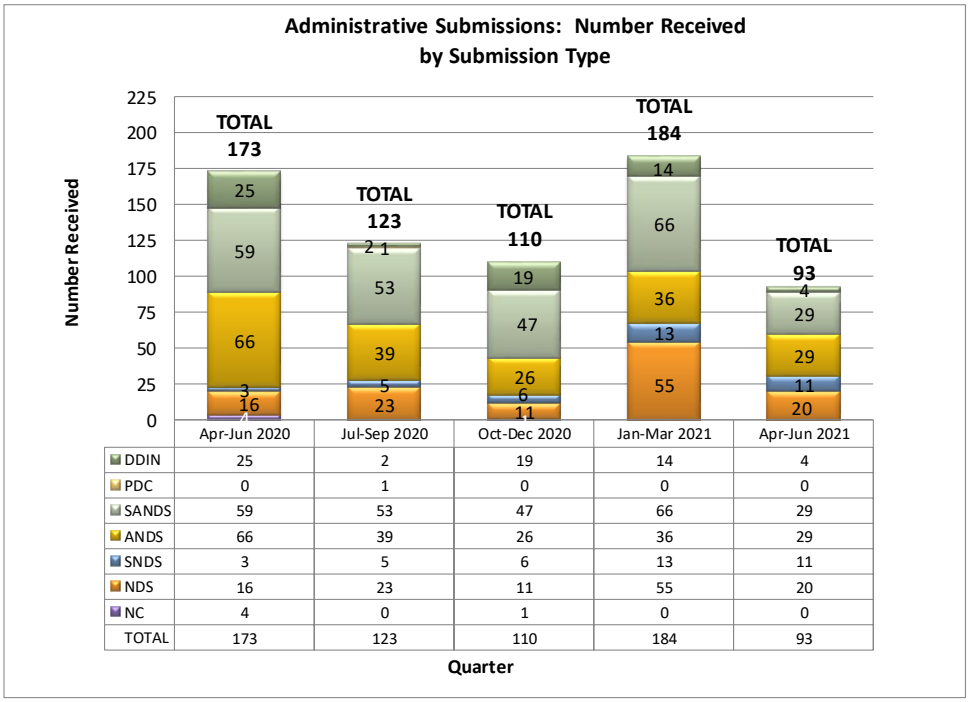
NC - SAFETY (120)					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	8	18	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	0	0
CANCELLED BY COMPANY	1	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes)[9]

RECEIVED

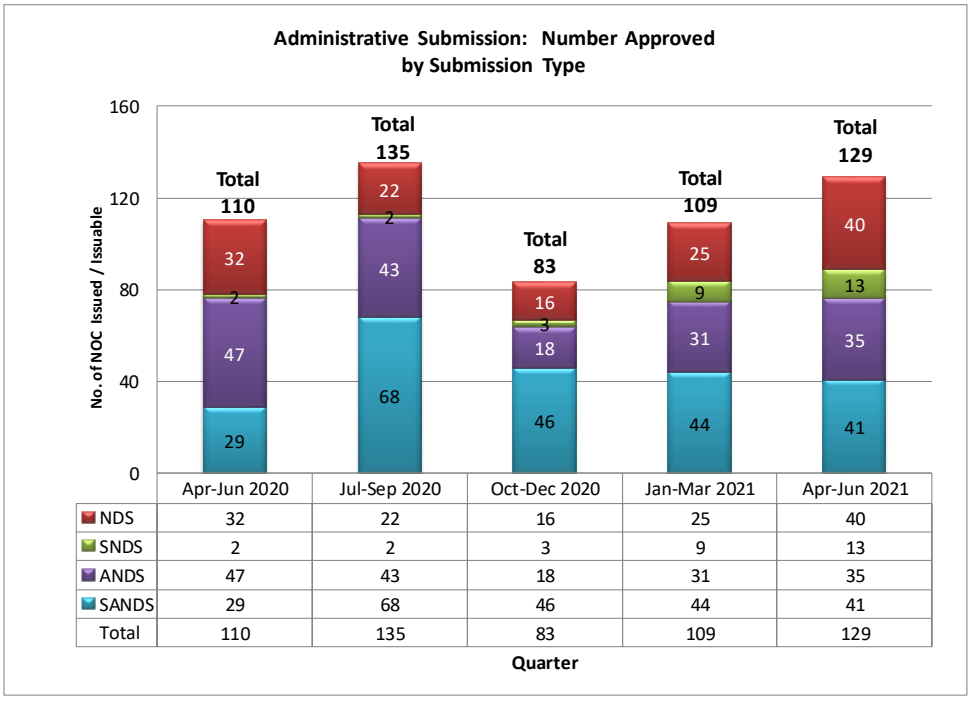
Administrative Submissions: Number Received by Submission Type



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
DDIN	25	2	19	14	4
PDC	0	1	0	0	0
SANDS	59	53	47	66	29
ANDS	66	39	26	36	29
SNDS	3	5	6	13	11
NDS	16	23	11	55	20
NC	4	0	1	0	0
TOTAL	173	123	110	184	93

APPROVALS

Administrative Submissions: Number Approved (NDS, SNDS, ANDS and SANDS)



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
NDS	32	22	16	25	40
SNDS	2	2	3	9	13
ANDS	47	43	18	31	35
SANDS	29	68	46	44	41
Total	110	135	83	109	129

[9] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

ADMINISTRATIVE SUBMISSIONS

(Manufacturer and/or Product Name Changes) [10]

DECISIONS

Administrative Submissions/Applications: Number of Decisions by Submission Type

NDS	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
NOTICE OF COMPLIANCE	32	22	16	25	40
SCREENING DEFICIENCY NOTICE	0	0	1	1	0
CANCELLATION LETTER	1	0	0	2	2
PROCESSING HOLD LETTER	6	6	2	2	2
SNDS	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTICE OF COMPLIANCE	2	2	3	9	13
SCREENING DEFICIENCY NOTICE	0	0	0	1	1
CANCELLATION LETTER	0	2	0	0	5
PROCESSING HOLD LETTER	0	2	1	0	0
ANDS	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTICE OF COMPLIANCE	47	42	18	30	35
NOC ON IP HOLD	0	1	0	1	0
SCREENING DEFICIENCY NOTICE	1	2	0	0	0
CANCELLATION LETTER	6	5	2	1	2
PROCESSING HOLD LETTER	13	3	7	0	2
SANDS	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTICE OF COMPLIANCE	29	68	46	44	41
NOC ON IP HOLD	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	1
CANCELLATION LETTER	4	2	0	6	1
PROCESSING HOLD LETTER	10	4	5	1	0
NC	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	1	1	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0
CANCELLATION LETTER	4	0	0	0	0
PROCESSING HOLD LETTER	0	0	2	0	0
SCREENING DEFICIENCY NOTICE	0	0	1	0	0
DINA	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTIFICATION FORM / DIN ISSUED	12	12	15	7	13
NO OBJECTION LETTER	1	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	1
CANCELLATION LETTER	8	2	1	0	0
PROCESSING HOLD LETTER	4	0	0	0	0
PDC	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	0	0	0	0	0
CANCELLATION LETTER	0	1	0	0	0
PROCESSING HOLD LETTER	0	0	0	0	0

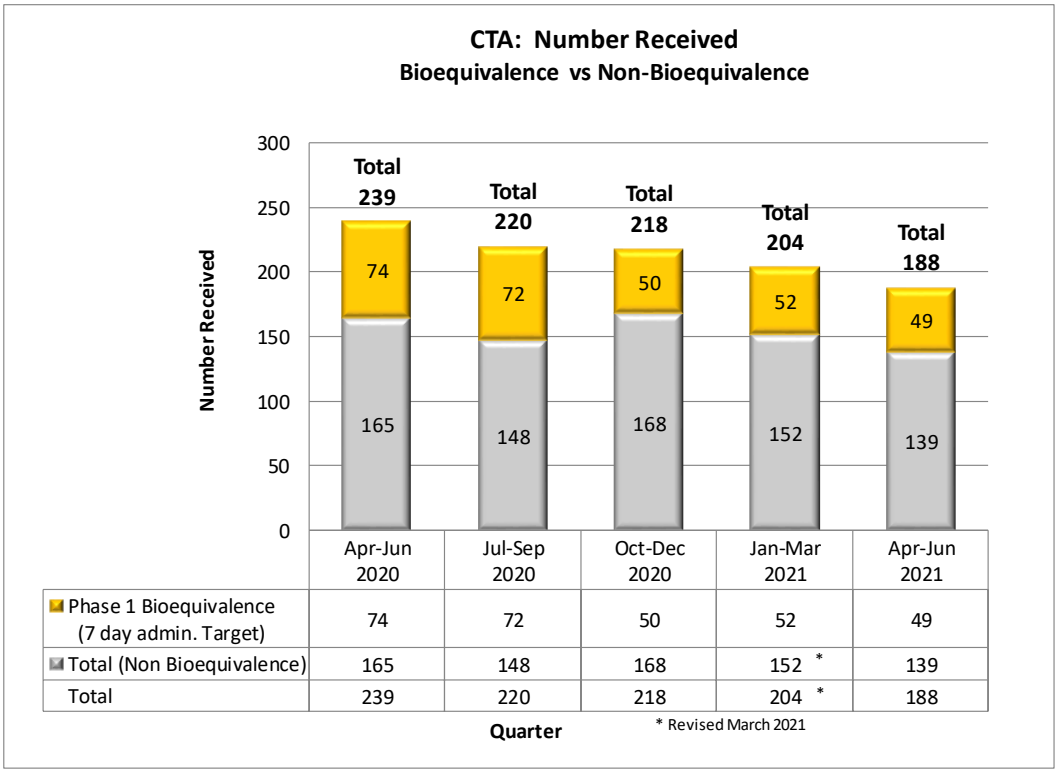
[10] The screening functions for Administrative submissions and the review functions for Labelling Only submissions with an Administrative component were moved from the Office of Submissions and Intellectual Property (OSIP) to the labelling area of the Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) at TPD in December 2018.

Clinical Trial Applications and Amendments

(CTA & CTA-A)

CTA: CLINICAL TRIAL APPLICATIONS

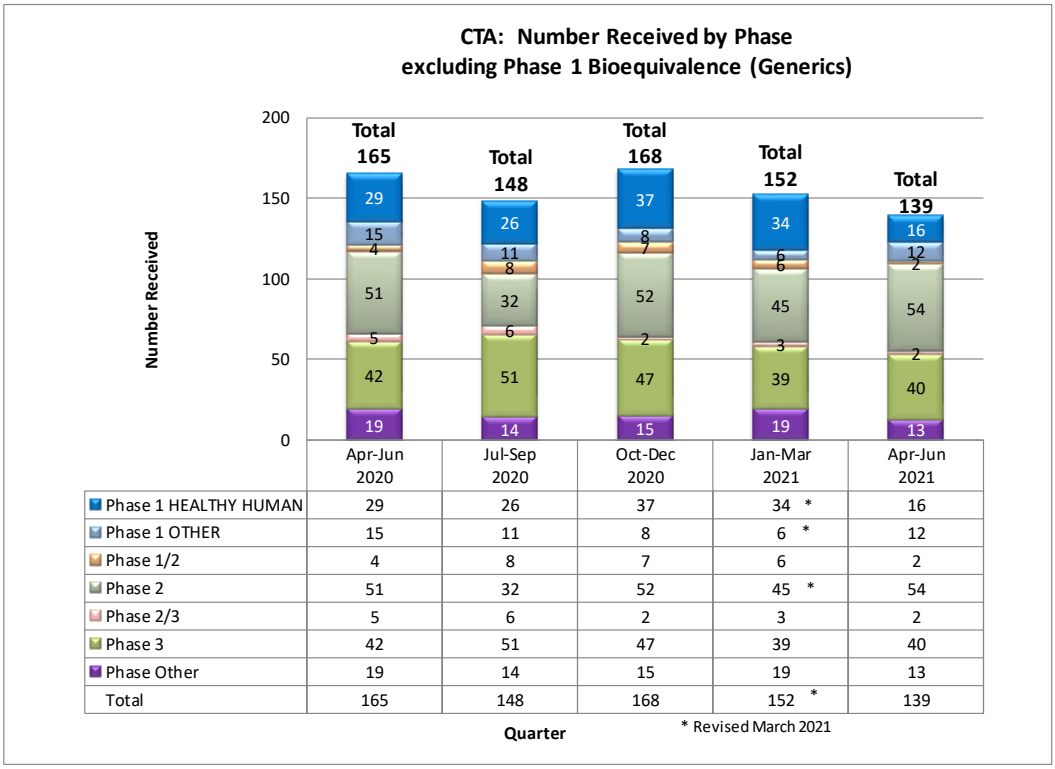
CTA: Number Received



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Phase 1 Bioequivalence (7 day admin. Target)	74	72	50	52	49
Total (Non Bioequivalence)	165	148	168	152 *	139
Total	239	220	218	204 *	188

* Revised March 2021

CTA: Number Received by Phase



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Phase 1 HEALTHY HUMAN	29	26	37	34 *	16
Phase 1 OTHER	15	11	8	6 *	12
Phase 1/2	4	8	7	6	2
Phase 2	51	32	52	45 *	54
Phase 2/3	5	6	2	3	2
Phase 3	42	51	47	39	40
Phase Other	19	14	15	19	13
Total	165	148	168	152 *	139

* Revised March 2021

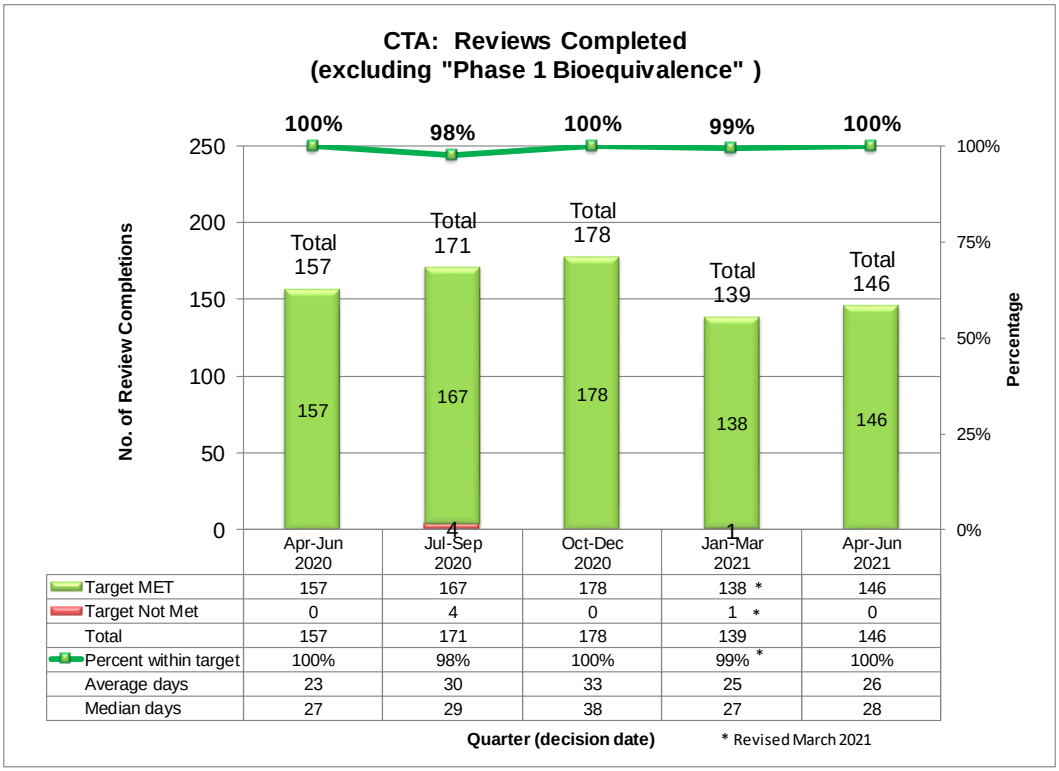
DECISION DOCUMENTS

CTA: Number of Decisions by Type

CTA					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	215	185	217	186	188
CANCELLED BY COMPANY DURING REVIEW	18	8	14	7	9
CANCELLED BY COMPANY AT PROCESSING	5	4	1	2	6
NOTICE OF AUTHORIZATION	1	2	6	0	1

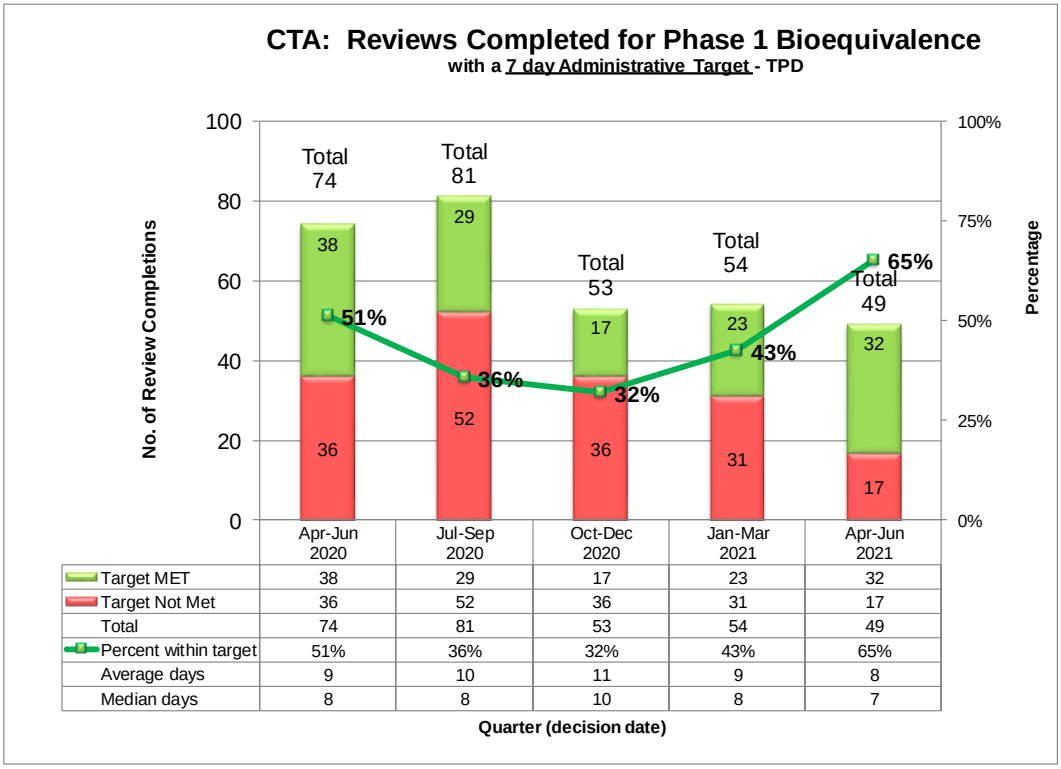
PERFORMANCE

CTA: Reviews Completed (excluding Phase 1 Bioequivalence)



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Target MET	157	167	178	138 *	146
Target Not Met	0	4	0	1 *	0
Total	157	171	178	139	146
Percent within target	100%	98%	100%	99% *	100%
Average days	23	30	33	25	26
Median days	27	29	38	27	28

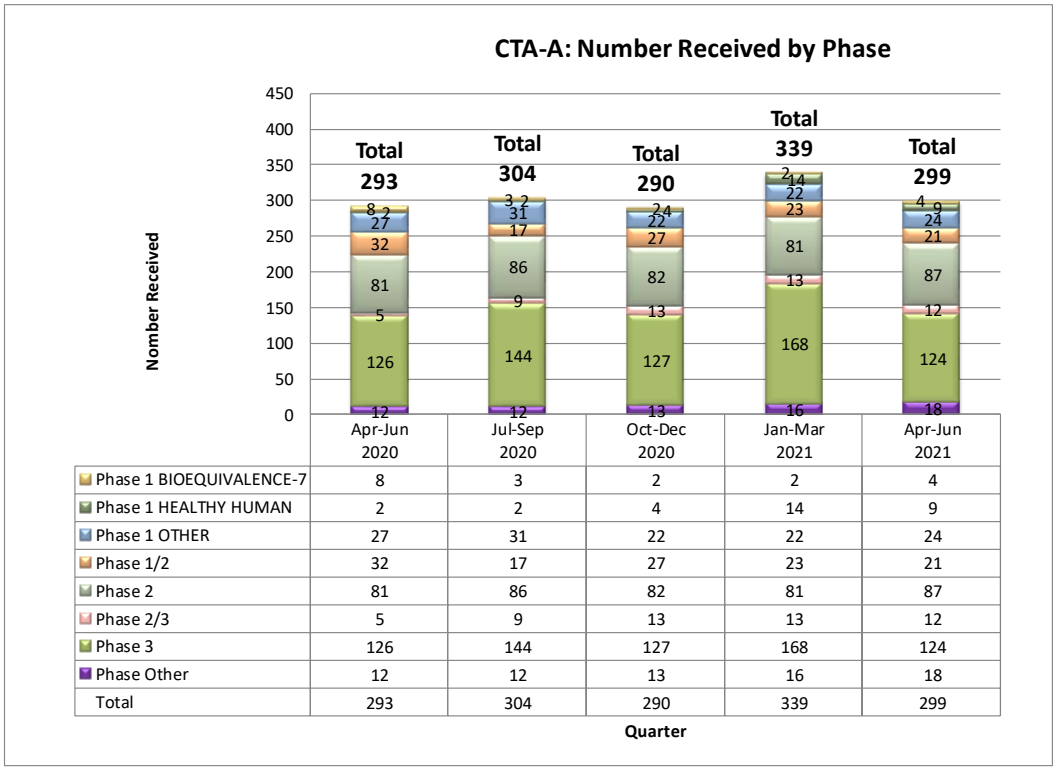
CTA: Reviews Completed for Phases with a 7 Day Administrative Target



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Target MET	38	29	17	23	32
Target Not Met	36	52	36	31	17
Total	74	81	53	54	49
Percent within target	51%	36%	32%	43%	65%
Average days	9	10	11	9	8
Median days	8	8	10	8	7

CTA-A: CLINICAL TRIAL APPLICATION-AMENDMENTS

CTA-A: Number Received by Phase



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Phase 1 BIOEQUIVALENCE-7	8	3	2	2	4
Phase 1 HEALTHY HUMAN	2	2	4	14	9
Phase 1 OTHER	27	31	22	22	24
Phase 1/2	32	17	27	23	21
Phase 2	81	86	82	81	87
Phase 2/3	5	9	13	13	12
Phase 3	126	144	127	168	124
Phase Other	12	12	13	16	18
Total	293	304	290	339	299

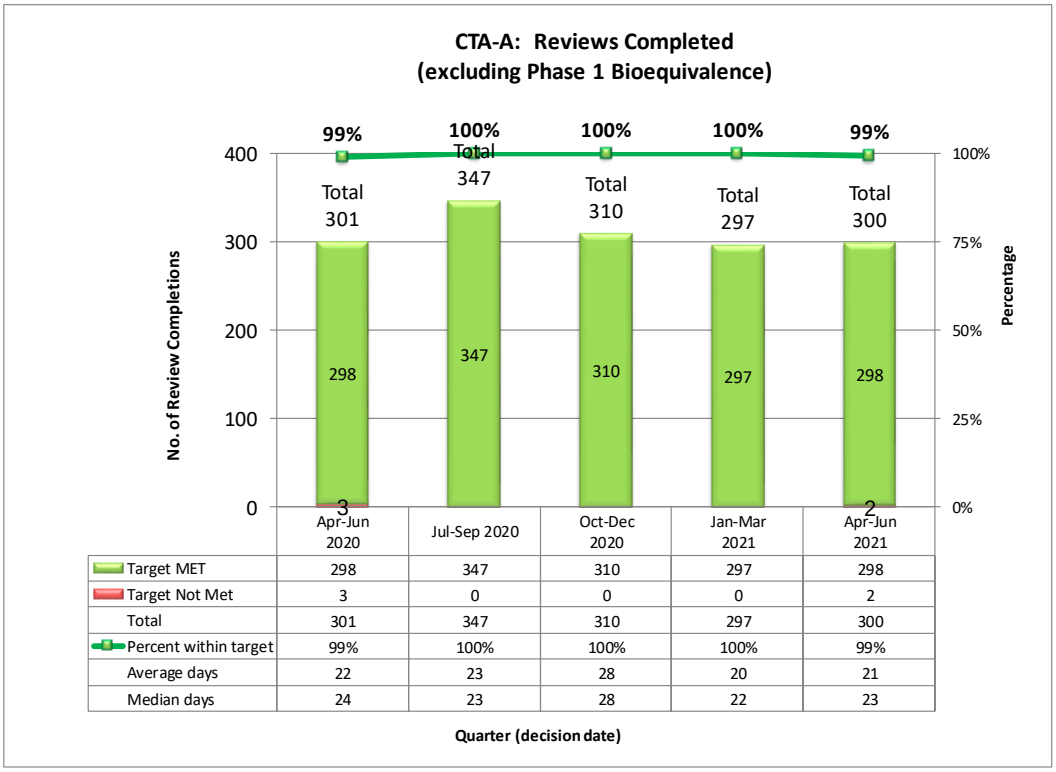
DECISIONS

CTA-A: Number of Decisions by Type

CTA-A (excluding administrative)					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NO OBJECTION LETTER	307	259	301	293	303
CANCELLED BY COMPANY DURING REVIEW	5	2	7	2	2
CANCELLED BY COMPANY AT PROCESSING	7	14	8	21	9
NOT SATISFACTORY NOTICE	0	0	0	0	0
NOTICE OF AUTHORIZATION	0	0	2	4	2
NOTICE OF AUTHORIZA AMEND	0	0	0	0	2

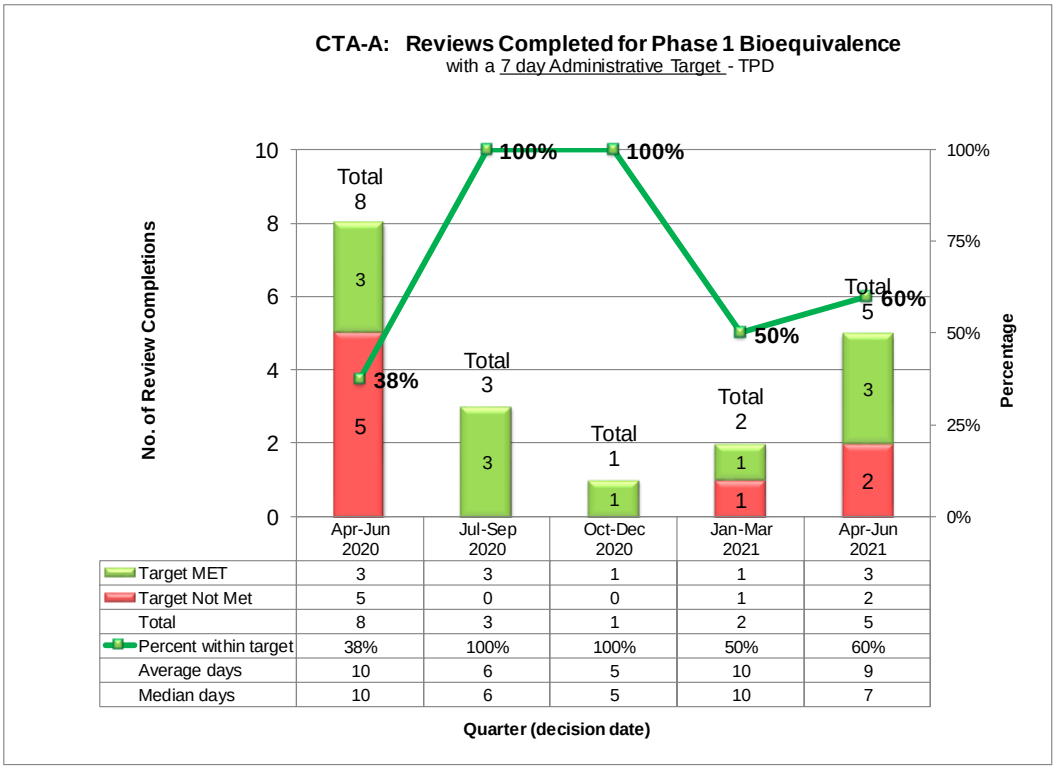
PERFORMANCE

CTA-A: Reviews Completed (excluding Phase 1 Bioequivalence)



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Target MET	298	347	310	297	298
Target Not Met	3	0	0	0	2
Total	301	347	310	297	300
Percent within target	99%	100%	100%	100%	99%
Average days	22	23	28	20	21
Median days	24	23	28	22	23

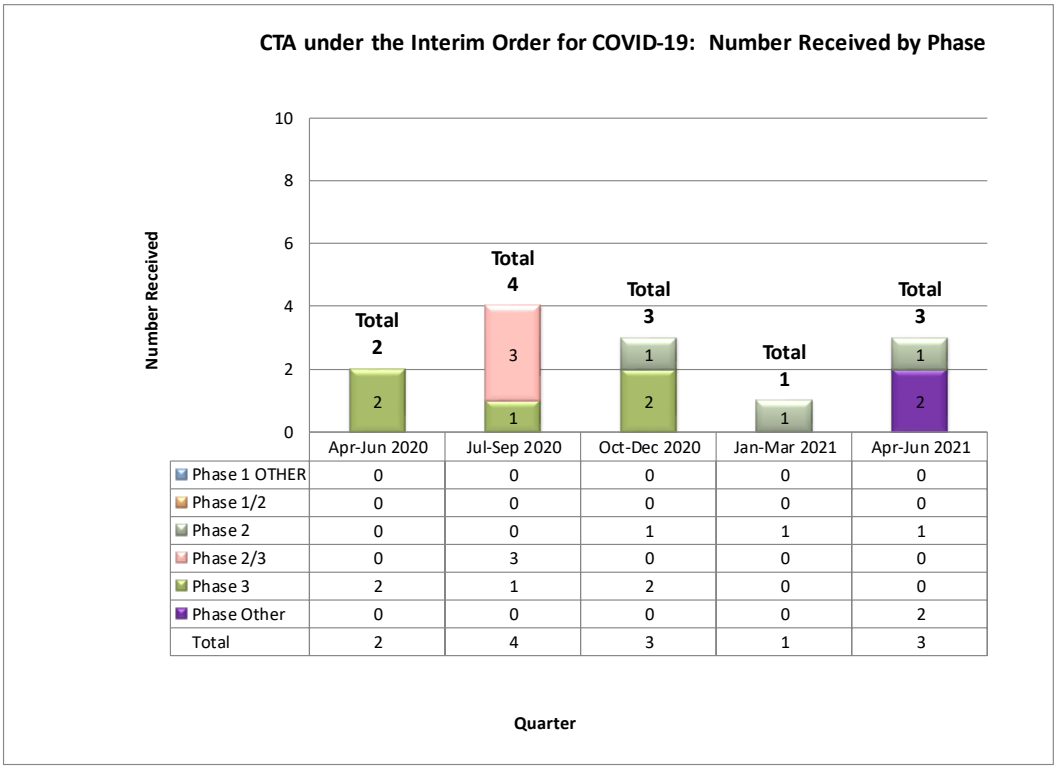
CTA-A: Reviews Completed for Phases with a 7 Day Administrative Target



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Target MET	3	3	1	1	3
Target Not Met	5	0	0	1	2
Total	8	3	1	2	5
Percent within target	38%	100%	100%	50%	60%
Average days	10	6	5	10	9
Median days	10	6	5	10	7

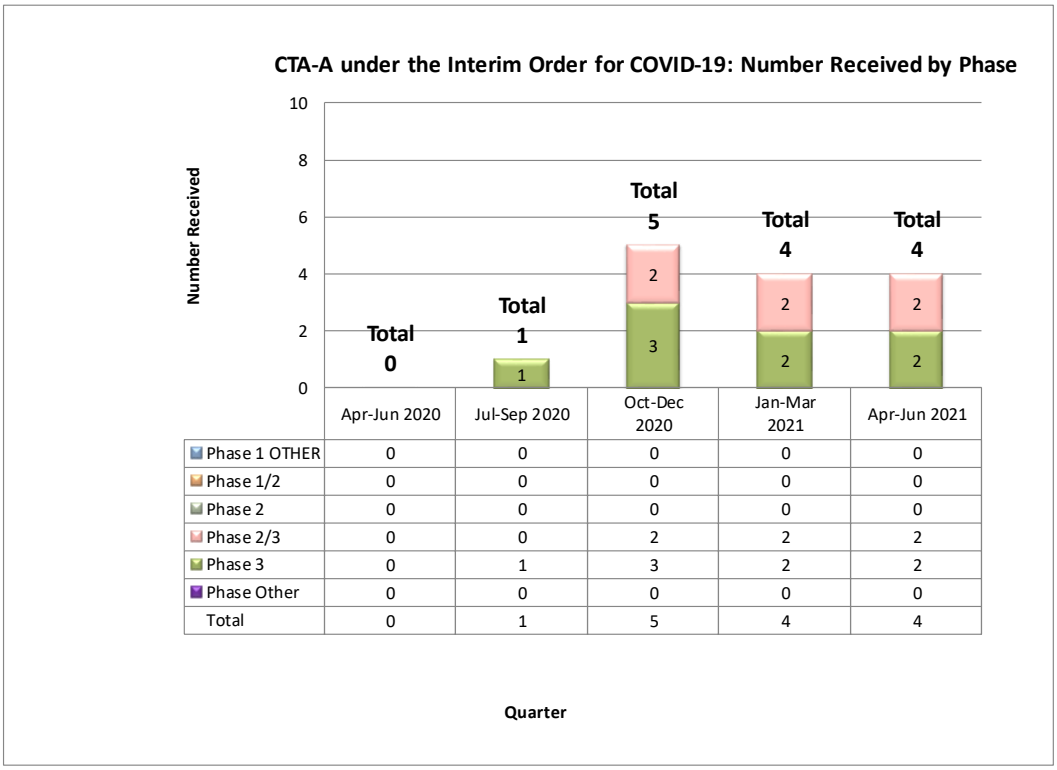
CTA & CTA-A RECEIVED UNDER THE INTERIM ORDER COVID 19

CTA: Number Received under the Interim Order Covid-19 by phase



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Phase 1 OTHER	0	0	0	0	0
Phase 1/2	0	0	0	0	0
Phase 2	0	0	1	1	1
Phase 2/3	0	3	0	0	0
Phase 3	2	1	2	0	0
Phase Other	0	0	0	0	2
Total	2	4	3	1	3

CTA-A: Number Received under the Interim Order Covid-19 by phase



	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Phase 1 OTHER	0	0	0	0	0
Phase 1/2	0	0	0	0	0
Phase 2	0	0	0	0	0
Phase 2/3	0	0	2	2	2
Phase 3	0	1	3	2	2
Phase Other	0	0	0	0	0
Total	0	1	5	4	4

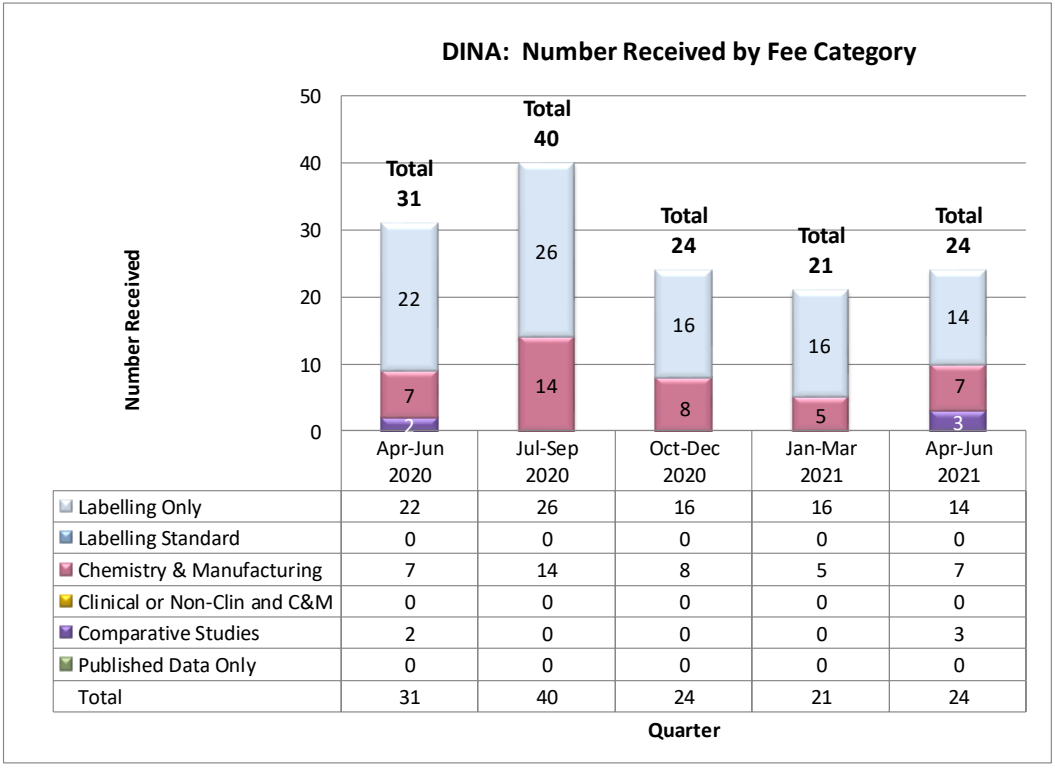
These figures are a subset of the total CTA and CTA-A received.

DINA

Application for a Drug Identification Number

DINA: APPLICATION FOR A DRUG IDENTIFICATION NUMBER [11]

DINA: Number Received by Fee Category

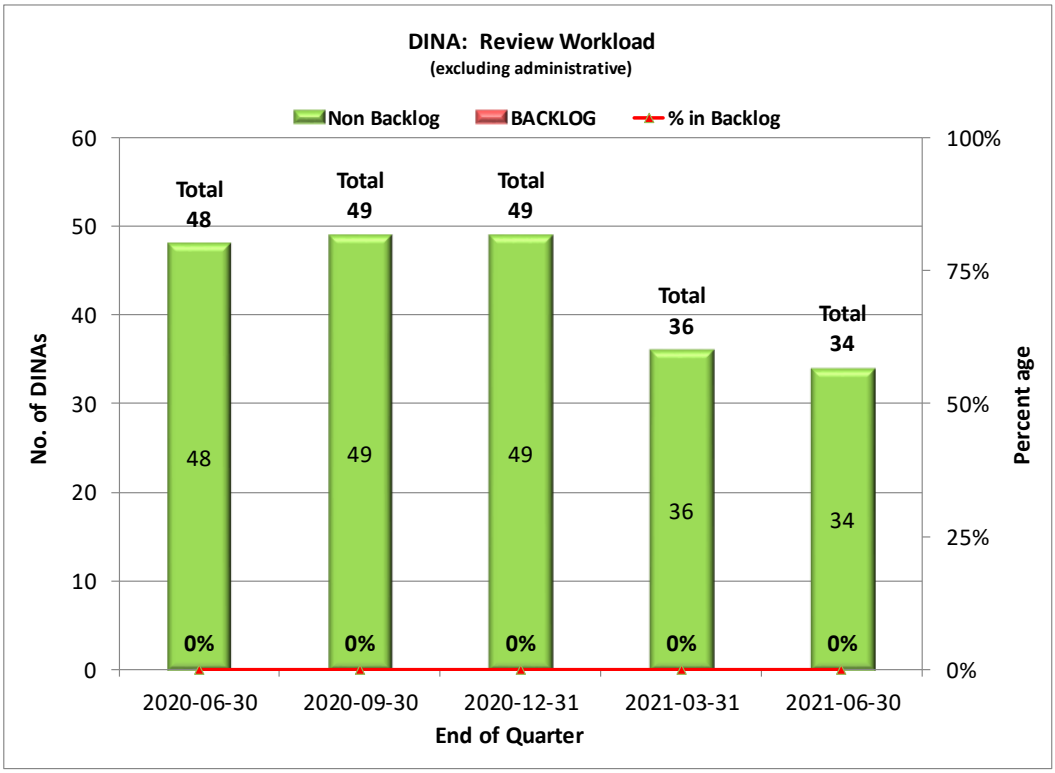


	Apr-Jun 2020	Jul-Sep 2020	Oct-Dec 2020	Jan-Mar 2021	Apr-Jun 2021
Labelling Only	22	26	16	16	14
Labelling Standard	0	0	0	0	0
Chemistry & Manufacturing	7	14	8	5	7
Clinical or Non-Clin and C&M	0	0	0	0	0
Comparative Studies	2	0	0	0	3
Published Data Only	0	0	0	0	0
Total	31	40	24	21	24

[11] The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported in a separate NNHPD Drug Submission Performance Report as of October 1, 2015.

REVIEW WORKLOAD

DINA: Review Workload

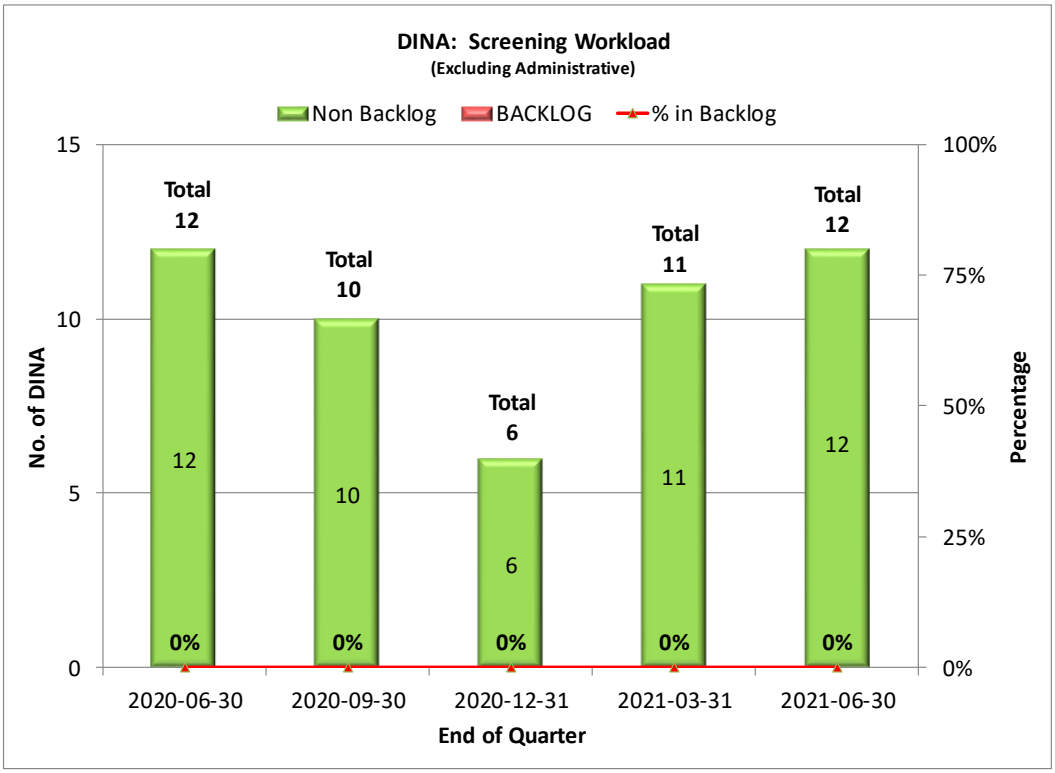


DINA: Review Workload by Fee Category

DINA: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2020-06-30**	**2020-09-30**	**2020-12-31**	**2021-03-31**	**2021-06-30**
Labelling Only	**35**	**36**	**29**	**16**	**14**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**12**	**11**	**18**	**19**	**18**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**2**	**1**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**48**	**49**	**49**	**36**	**34**
Non Backlog	**48**	**49**	**49**	**36**	**34**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

DINA: Screening Workload



DINA: Screening Workload by Fee Category

DINA: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2020-06-30**	**2020-09-30**	**2020-12-31**	**2021-03-31**	**2021-06-30**
Labelling Only	**8**	**2**	**3**	**7**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Standard	**0**	**2**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**3**	**6**	**3**	**4**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Comparative Studies	**1**	**0**	**0**	**0**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**12**	**10**	**6**	**11**	**12**
Non Backlog	**12**	**10**	**6**	**11**	**12**
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINA: Number of Decisions by Fee Category

DINA - LABELLING ONLY					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTIFICATION FORM/DIN ISSUED	4	5	2	8	1
NO OBJECTION LETTER	13	22	19	17	13
CANCELLED BY COMPANY	2	3	0	1	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	1	0	0	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	2	0	0	1	0

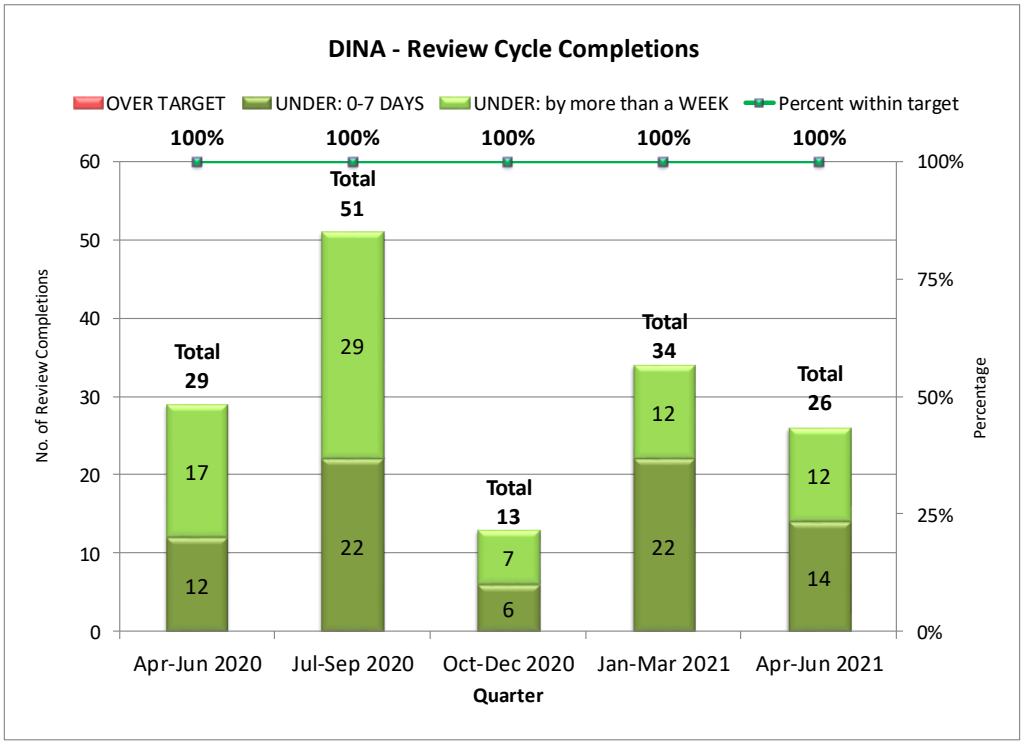
DINA - CHEMISTRY AND MANUFACTURING					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTIFICATION FORM/DIN ISSUED	6	4	0	3	6
NO OBJECTION LETTER	3	5	4	5	1
NOD WITHDRAWAL LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	1
NOTICE OF NON-COMPLIANCE	0	0	2	0	3
NEW DRUG LETTER REVIEW	0	0	0	0	0
NEW DRUG LETTER SCREEN	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	5	5	7	3	0
CANCELLED BY COMPANY	0	1	0	0	0

DINA - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
NOTIFICATION FORM/DIN ISSUED	0	0	0	1	0
NOTICE OF DEFICIENCY	0	0	1	0	0
NOTICE OF NON-COMPLIANCE	0	0	0	0	0
NO OBJECTION LETTER	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

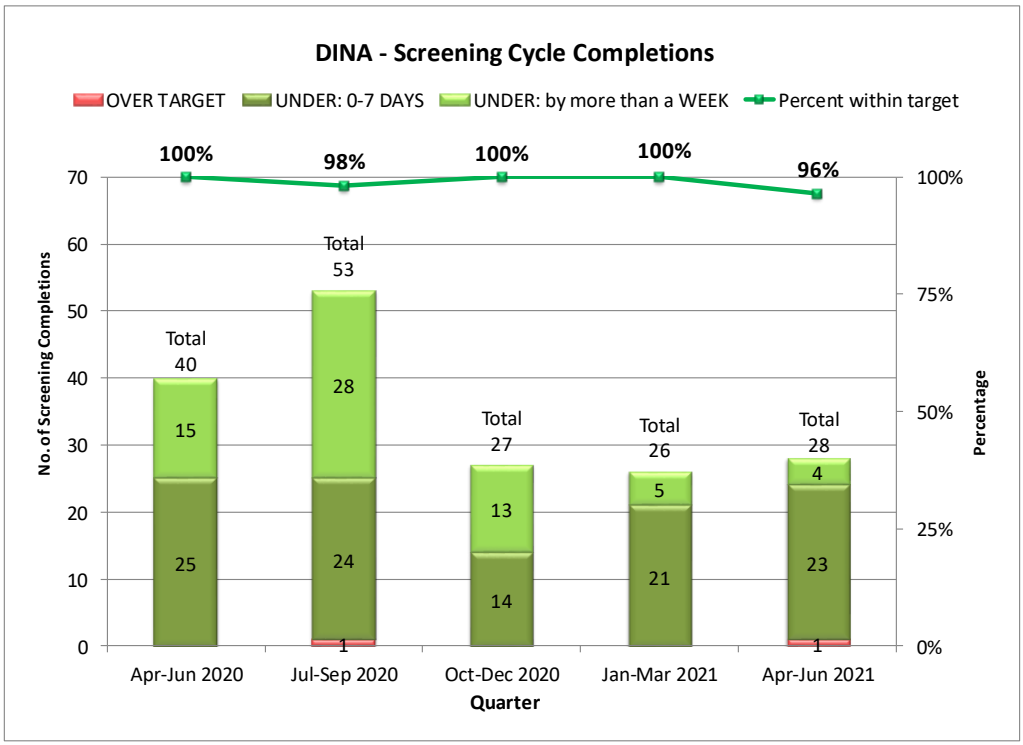
DINA - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
CANCELLED BY COMPANY	0	0	0	0	0
NOTICE OF NON-COMPLIANCE	1	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NON WITHDRAWAL LETTER	0	0	0	0	1

PERFORMANCE

DINA: Review Cycle Completions

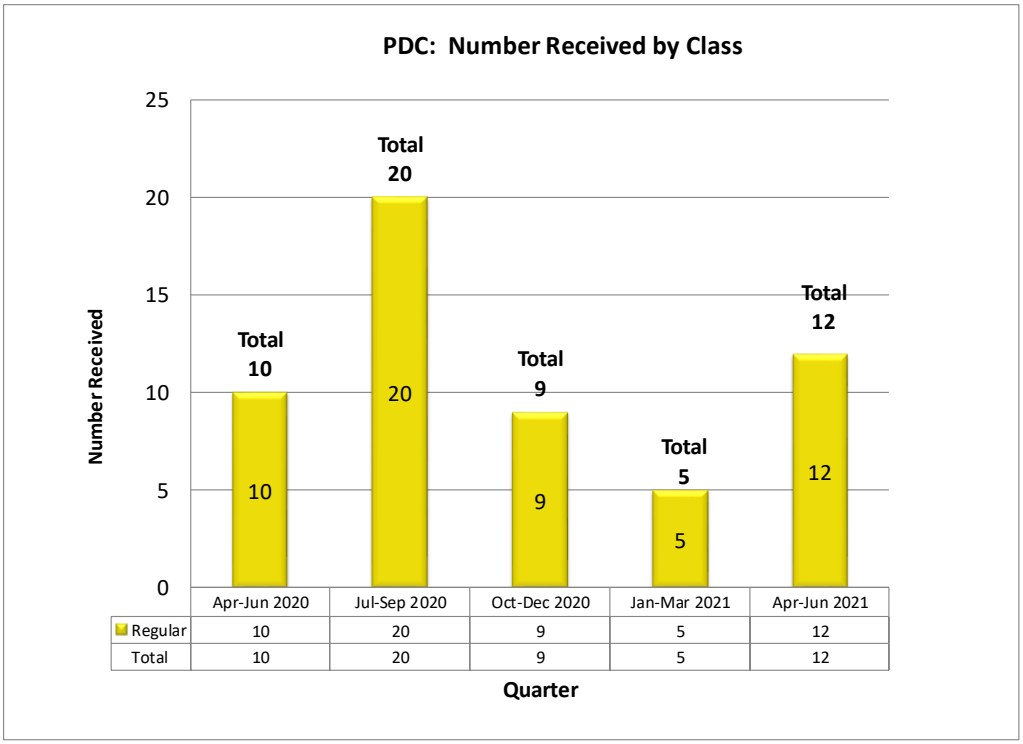


DINA: Screening Cycle Completions



PDC: POST-AUTHORIZATION DIVISION 1 CHANGE

PDC: Number Received

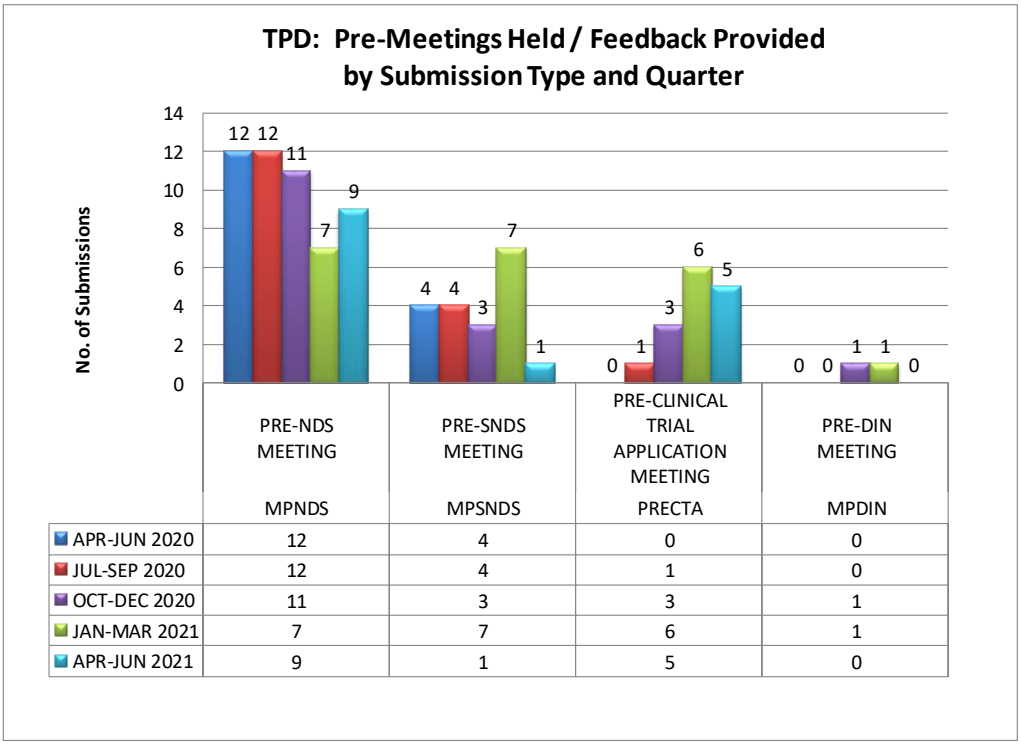


PDC: Number of Decisions by Type

PDC					
DOCUMENT TYPE	**Apr-Jun 2020**	**Jul-Sep 2020**	**Oct-Dec 2020**	**Jan-Mar 2021**	**Apr-Jun 2021**
REGULAR					
CANCELLED BY COMPANY	2	8	3	4	6
NO OBJECTION LETTER	9	7	11	4	1
NOT SATISFACTORY NOTICE	1	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

APPENDIX A: PRE-SUBMISSION MEETINGS [12]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING (MPNDS)	PRE-SNDS MEETING (MPSNDS)	PRE-CLINICAL TRIAL APPLICATION MEETING (PRECTA)	PRE-DIN MEETING (MPDIN)
APR-JUN 2020	12	4	0	0
JUL-SEP 2020	12	4	1	0
OCT-DEC 2020	11	3	3	1
JAN-MAR 2021	7	7	6	1
APR-JUN 2021	9	1	5	0

[12] Prior to filing a submission, the sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission. For further information, refer to the Management of Drug Submissions Guidance.