Santé Canada Health Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Quarterly Report

April - June

2019

Canada

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Direction des produits biologiques et des thérapies génétiques – Rapport trimestriel du rendement des présentations de drogue – avril - juin 2019

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OVERVIEW

The Biologics and Genetic Therapies Directorate (BGTD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from April - June 2018 to April - June 2019. Statistics are provided by Submission Type and show the number received the number in workload, the number of decisions and the number of approvals.

General Information

There are several steps involved in the drug submission review[1] 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[2] 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.

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

[2] 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-C are not included in the SNDS Approval figures. For further Clarification refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

A **review cycle completion**[3] 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 is compared to a set performance standard[4] which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review 1 and 90 days for Review 2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

"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"[5] submissions.

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

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101 Tunney's Pasture Driveway, Tunney's Pasture
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[3] Review cycles include all types e.g. Review 1, Review 2, Review QN. 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.

[4] Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the Guidance for Industry: Management of Drug Submissions. This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

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

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
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
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
YBPR	-	Yearly Biologic Product Report

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with 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

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Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
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 NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission	Submissions in support of a manufacturer or product name change.
Disinfectants[7]	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications

[6] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling

[7] 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 on in a separate NNHPD Drug Submission Performance Report.

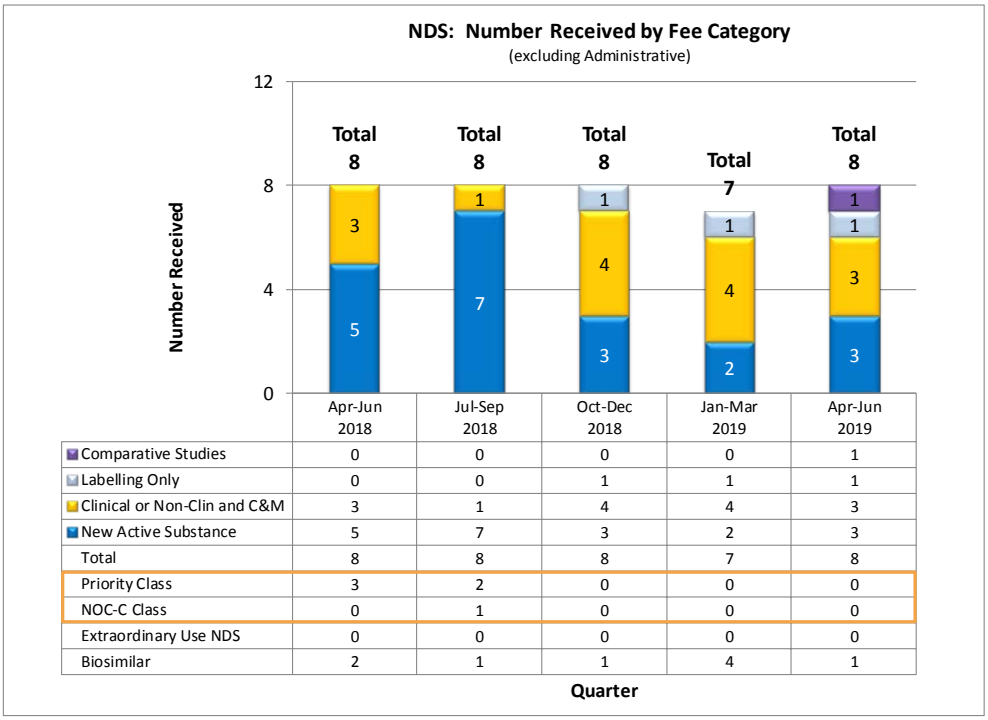
New Drug Submissions (NDS)

&

Supplemental New Drug Submissions (SNDS)

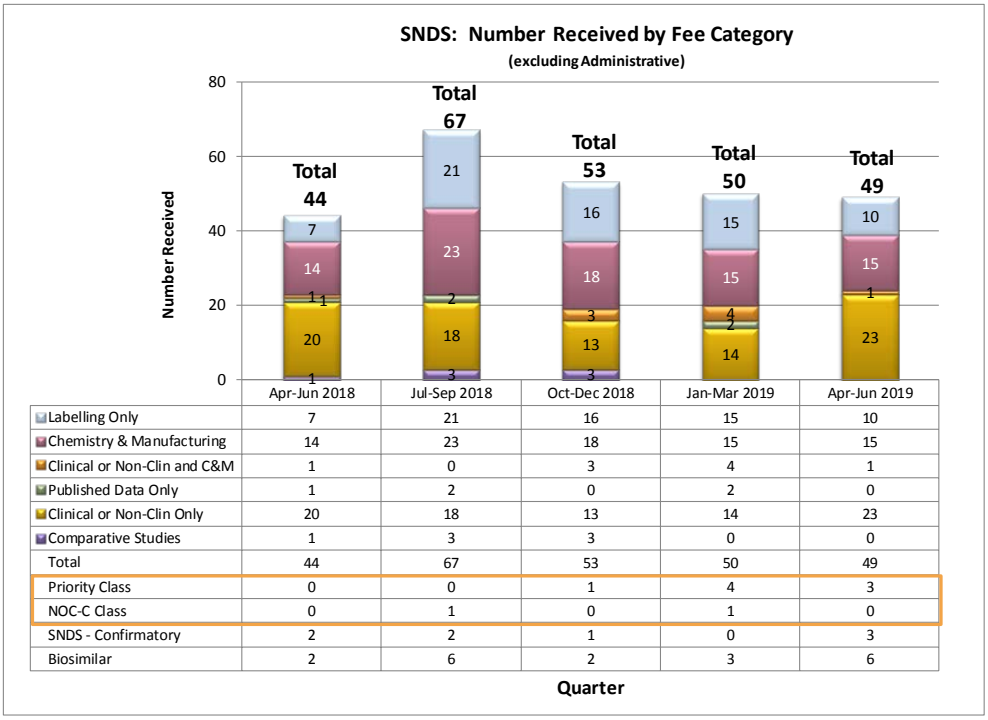
SUBMISSIONS RECEIVED[8][9]

NDS: Received by Fee Category



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Comparative Studies	0	0	0	0	1
Labelling Only	0	0	1	1	1
Clinical or Non-Clin and C&M	3	1	4	4	3
New Active Substance	5	7	3	2	3
Total	8	8	8	7	8
Priority Class	3	2	0	0	0
NOC-C Class	0	1	0	0	0
Extraordinary Use NDS	0	0	0	0	0
Biosimilar	2	1	1	4	1

SNDS: Received by Fee Category



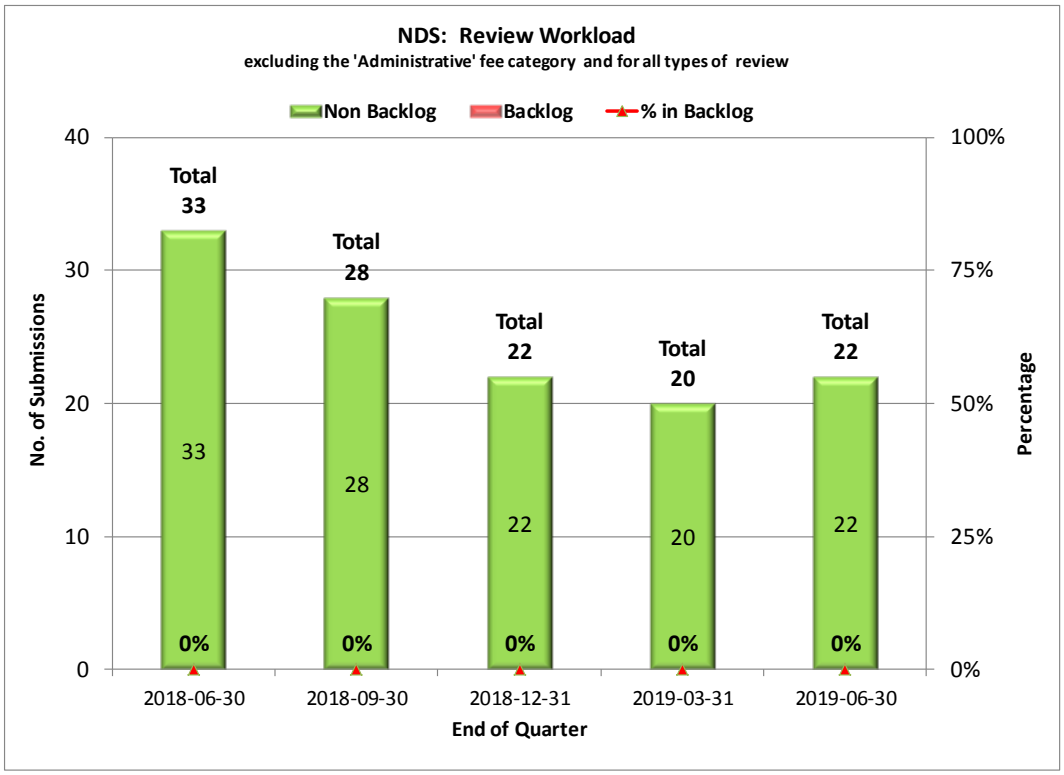
	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Labelling Only	7	21	16	15	10
Chemistry & Manufacturing	14	23	18	15	15
Clinical or Non-Clin and C&M	1	0	3	4	1
Published Data Only	1	2	0	2	0
Clinical or Non-Clin Only	20	18	13	14	23
Comparative Studies	1	3	3	0	0
Total	44	67	53	50	49
Priority Class	0	0	1	4	3
NOC-C Class	0	1	0	1	0
SNDS - Confirmatory	2	2	1	0	3
Biosimilar	2	6	2	3	6

[8] **Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

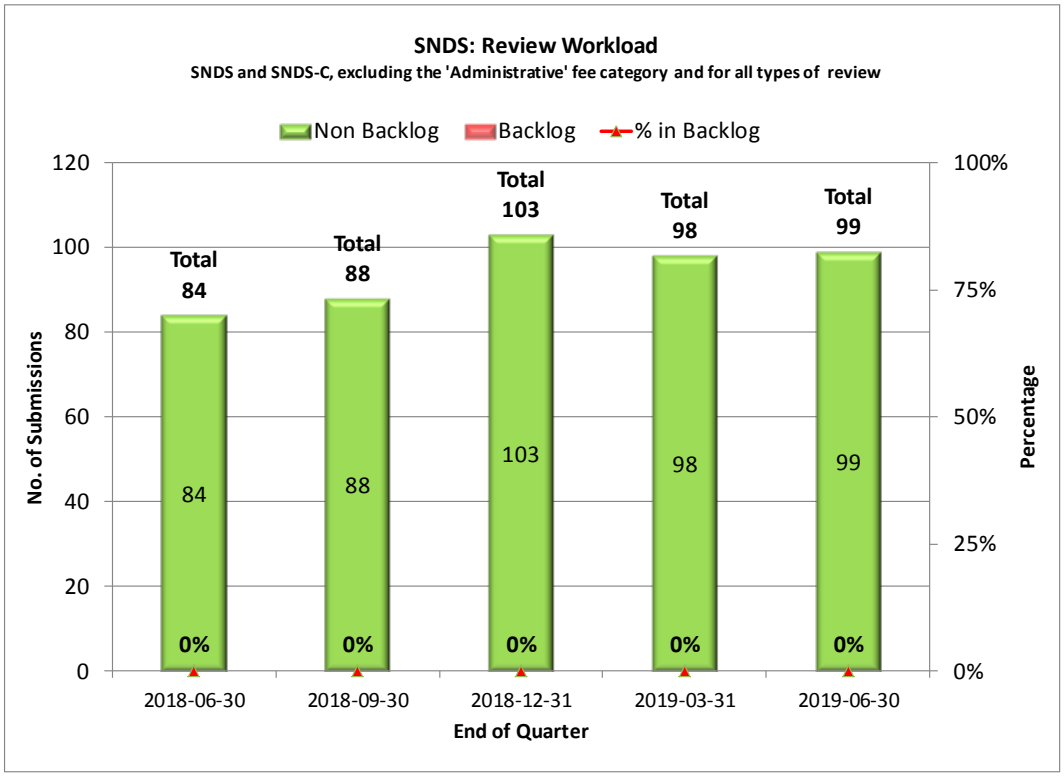
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

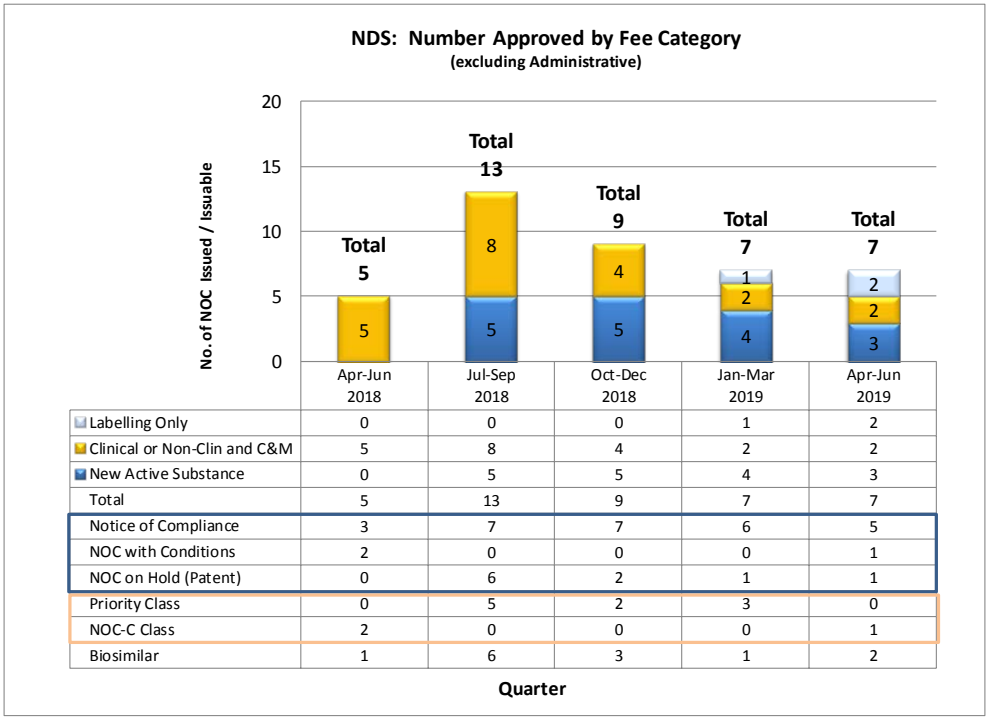
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	**2018-06-30**	**2018-09-30**	**2018-12-31**	**2019-03-31**	**2019-06-30**
Clinical or Non-Clin and C&M	**21**	**14**	**9**	**10**	**12**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**12**	**14**	**12**	**10**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**33**	**28**	**22**	**20**	**22**
Non Backlog	**33**	**28**	**22**	**20**	**22**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**7**	**5**	**3**	**0**	**0**
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	**2018-06-30**	**2018-09-30**	**2018-12-31**	**2019-03-31**	**2019-06-30**
Comparative Studies	**1**	**3**	**6**	**4**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**26**	**22**	**29**	**26**	**25**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**48**	**48**	**48**	**49**	**54**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**4**	**2**	**4**	**6**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**2**	**1**	**3**	**3**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**3**	**12**	**13**	**10**	**9**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**84**	**88**	**103**	**98**	**99**
Non Backlog	**84**	**88**	**103**	**98**	**99**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**2**	**0**	**1**	**4**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**2**	**6**	**6**	**5**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*

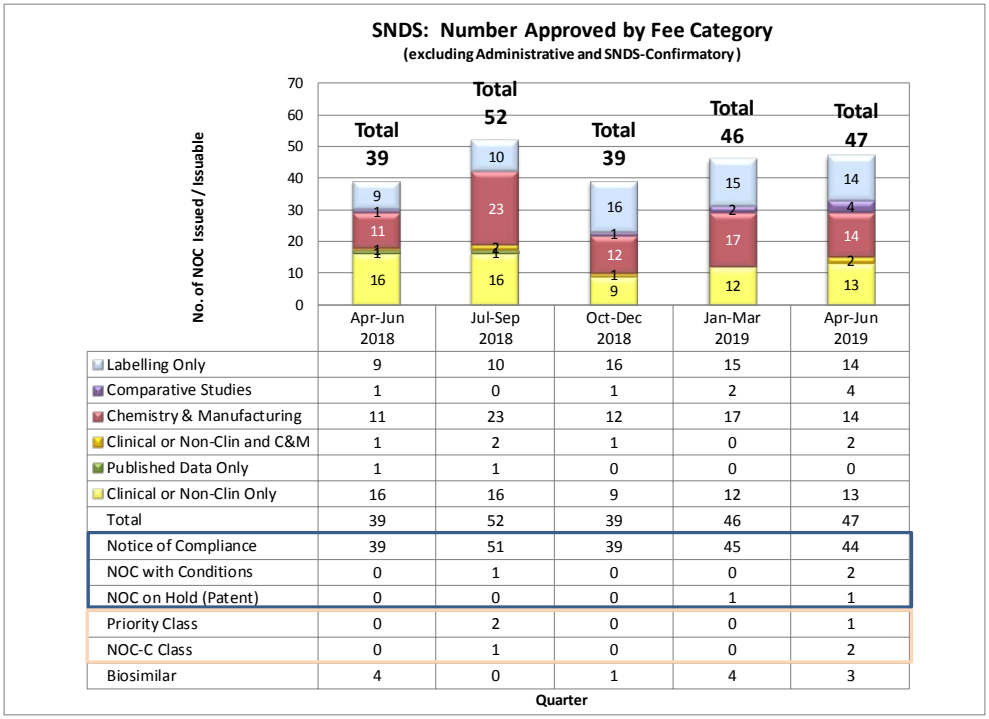
APPROVALS [10] [11]

NDS: Number Approved by Fee Category and NOC Type



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Labelling Only	0	0	0	1	2
Clinical or Non-Clin and C&M	5	8	4	2	2
New Active Substance	0	5	5	4	3
Total	5	13	9	7	7
Notice of Compliance	3	7	7	6	5
NOC with Conditions	2	0	0	0	1
NOC on Hold (Patent)	0	6	2	1	1
Priority Class	0	5	2	3	0
NOC-C Class	2	0	0	0	1
Biosimilar	1	6	3	1	2

SNDS: Number Approved by Fee Category and NOC Type



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Labelling Only	9	10	16	15	14
Comparative Studies	1	0	1	2	4
Chemistry & Manufacturing	11	23	12	17	14
Clinical or Non-Clin and C&M	1	2	1	0	2
Published Data Only	1	1	0	0	0
Clinical or Non-Clin Only	16	16	9	12	13
Total	39	52	39	46	47
Notice of Compliance	39	51	39	45	44
NOC with Conditions	0	1	0	0	2
NOC on Hold (Patent)	0	0	0	1	1
Priority Class	0	2	0	0	1
NOC-C Class	0	1	0	0	2
Biosimilar	4	0	1	4	3

[10] 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 .

[11] **Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

BIOSIMILARS: NDS & SNDS Market Authorizations

Biosimilars: Number of NDS & SNDS that were issued an NOC by Quarter

Submission Type	Class	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
NDS	CLIN/C&M	4	0	1	0	1
NDS Total		**4**	**0**	**1**	**0**	**1**
SNDS	C&M ONLY	1	0	0	2	1
	C&M/LABELLING	0	0	0	0	0
	CLIN ONLY	1	0	0	1	1
	CLIN/C&M	0	0	0	0	0
	COMP/C&M	0	0	1	0	0
	LABELLING ONLY	2	0	0	0	0
SNDS Total		**4**	**0**	**1**	**3**	**2**

Biosimilars: List of NDS & SNDS issued an NOC during FY 2019-20 by Quarter

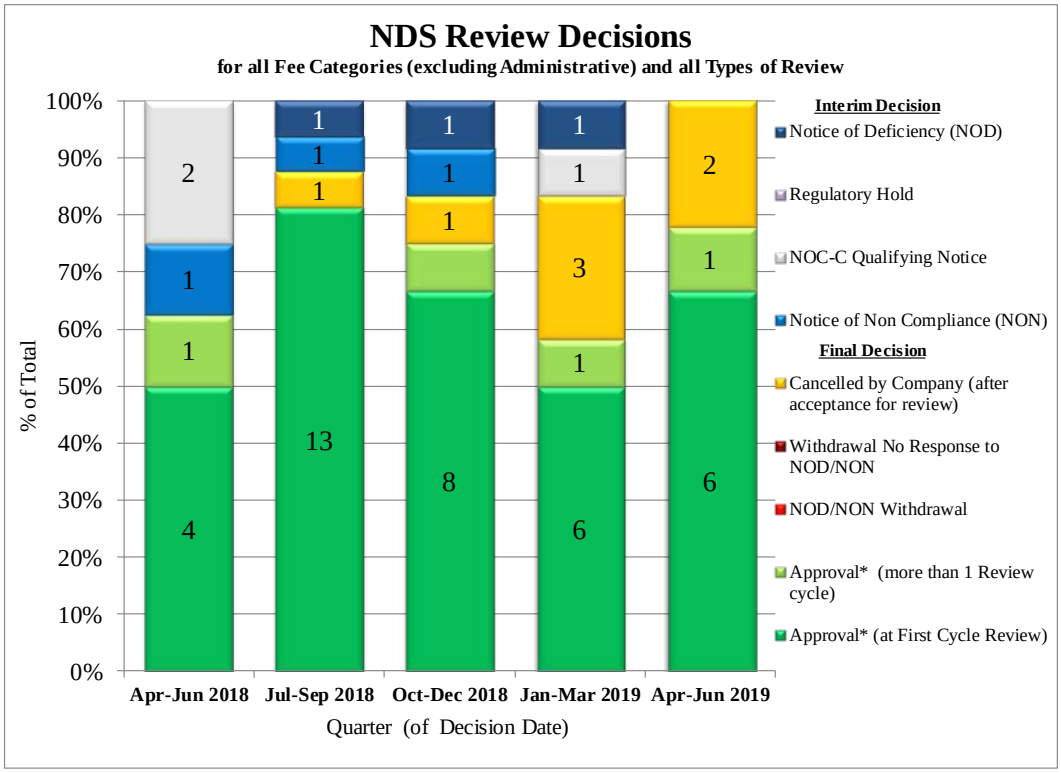
Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2019-20	Notice of Compliance (NOC) Date
NDS	ZIRABEV	CLIN/C&M	PFIZER CANADA ULC	BEVACIZUMAB	Q1	2019-Jun-14
New Drug Submission Total						**1**
SNDS	MVASI	C&M ONLY	AMGEN CANADA INC.	BEVACIZUMAB	Q1	2019-Apr-02
	MVASI	CLIN ONLY	AMGEN CANADA INC.	BEVACIZUMAB	Q1	2019-Jun-05
Supplemental New Drug Submission Total						**2**

Please note: Approved Biosimilars that remain on Intellectual Property Hold are not included.

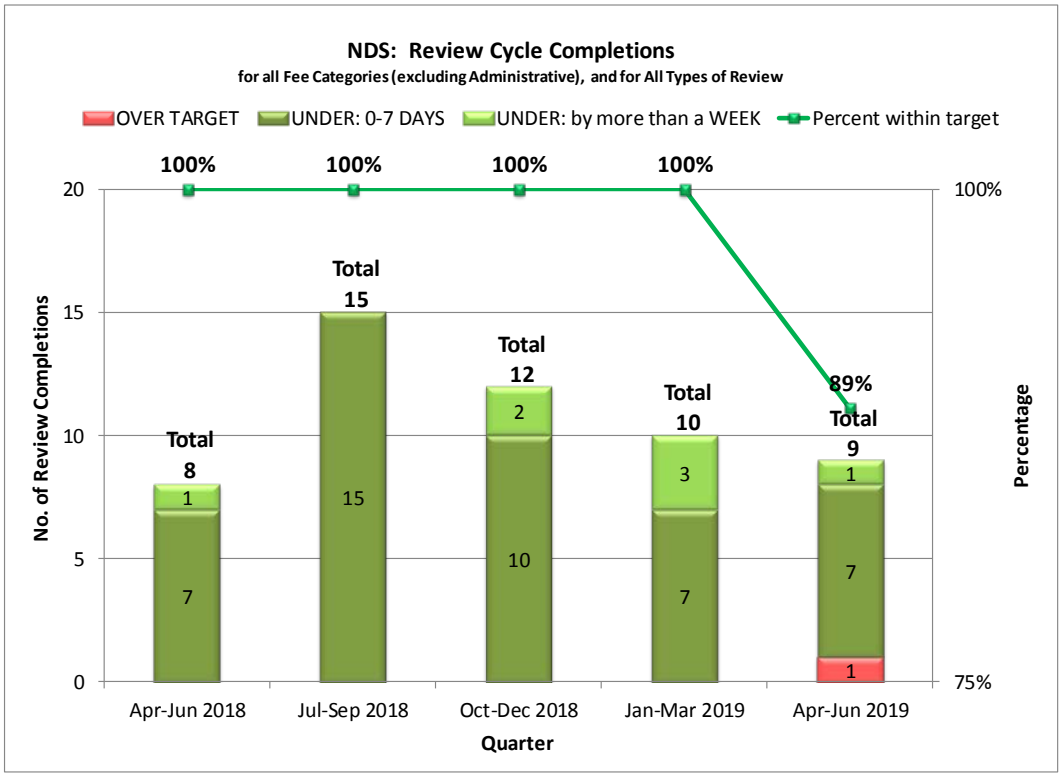
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

REVIEW PERFORMANCE

NDS: Review Decisions by Type

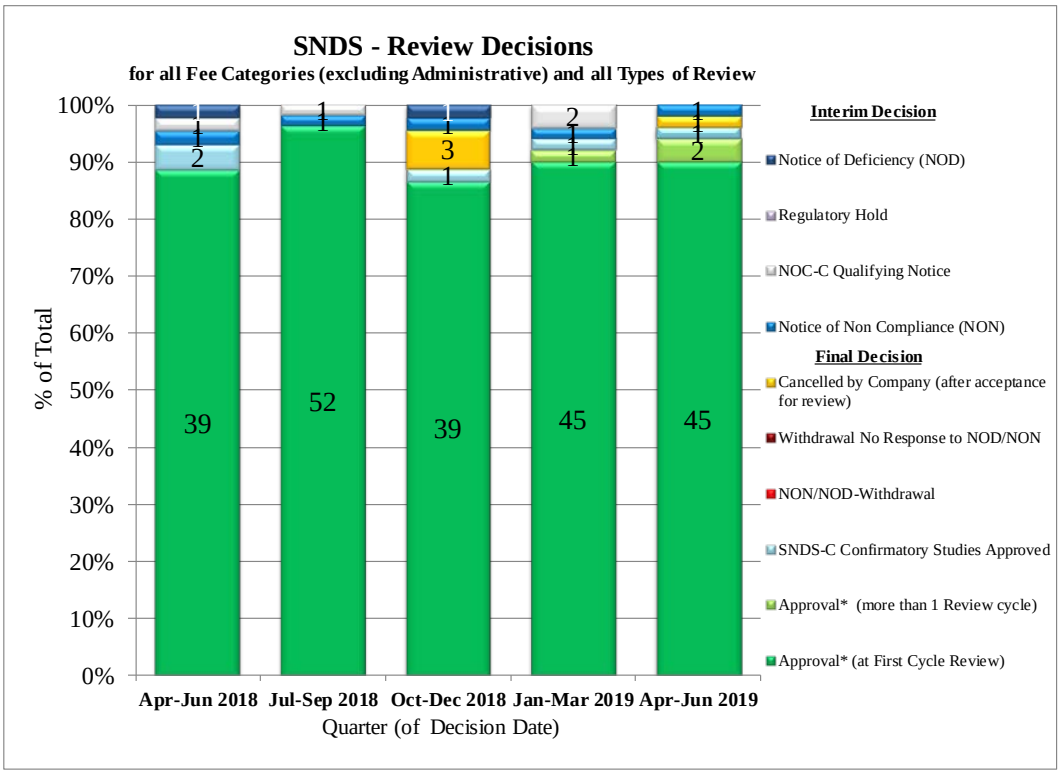


NDS: Review Cycle Completions

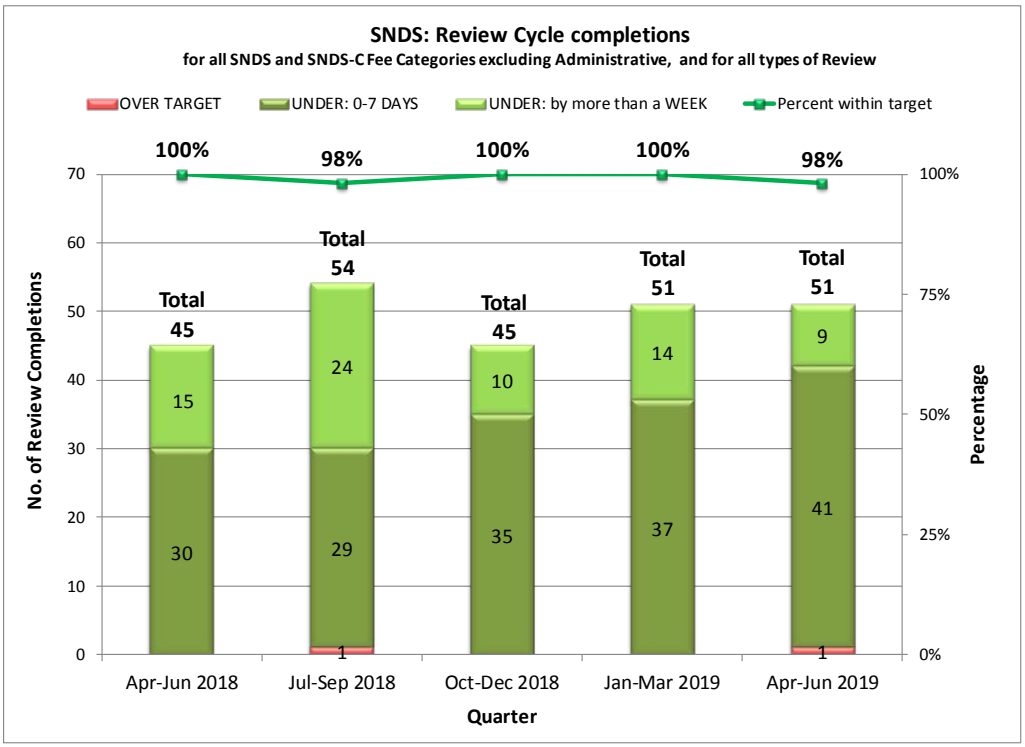


REVIEW PERFORMANCE

SNDS: Review Decisions by Type

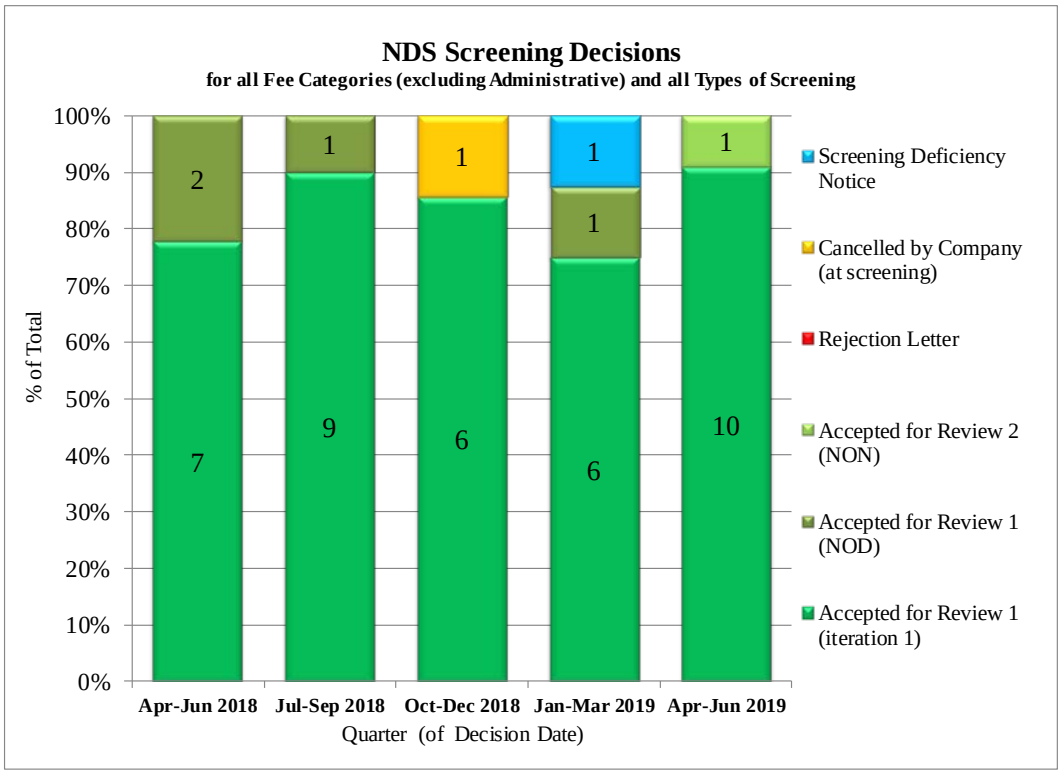


SNDS: Review Cycle Completions

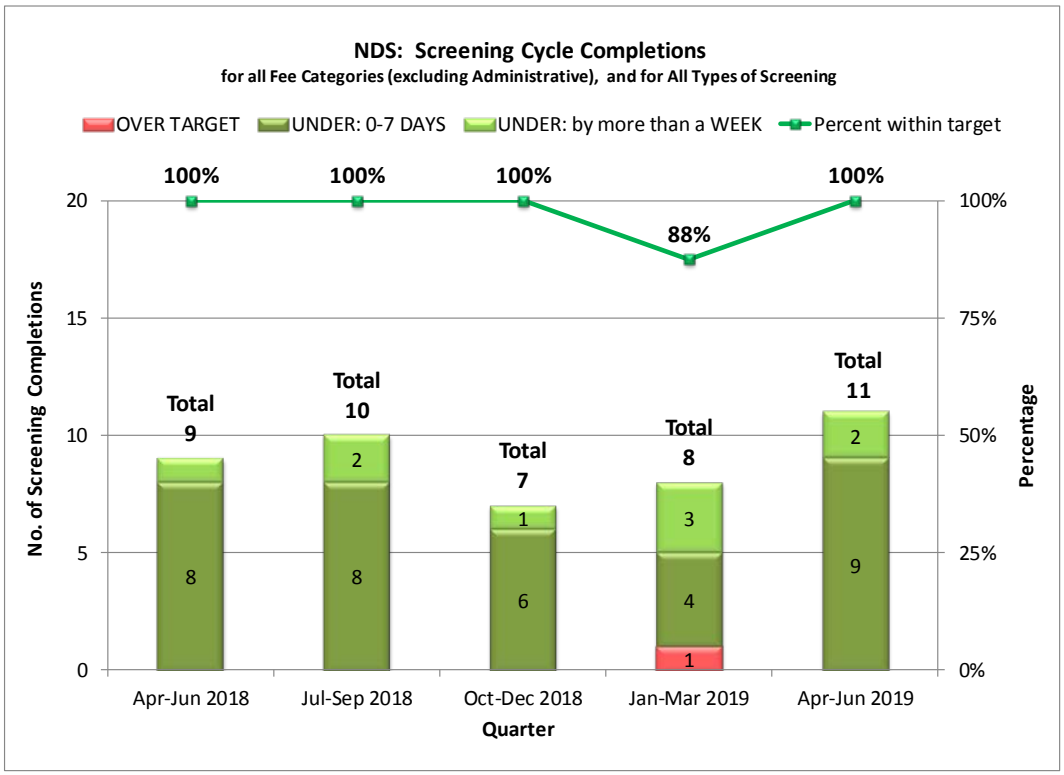


SCREENING PERFORMANCE

NDS: Screening Decisions by Type

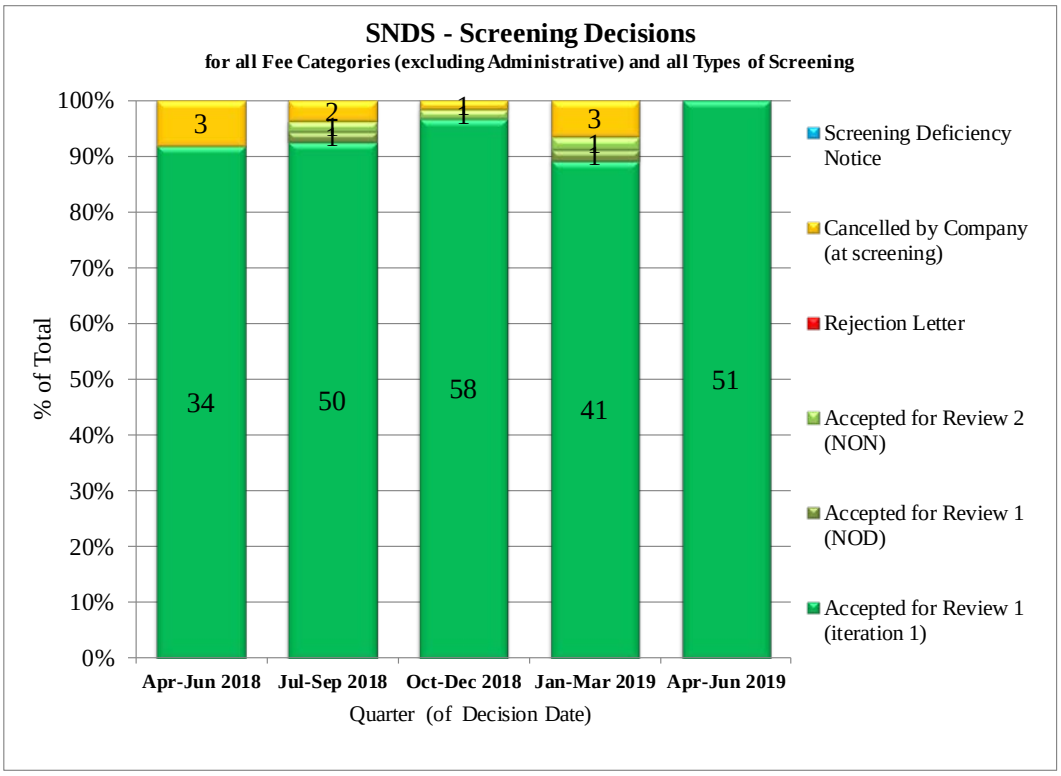


NDS: Screening Cycle Completions

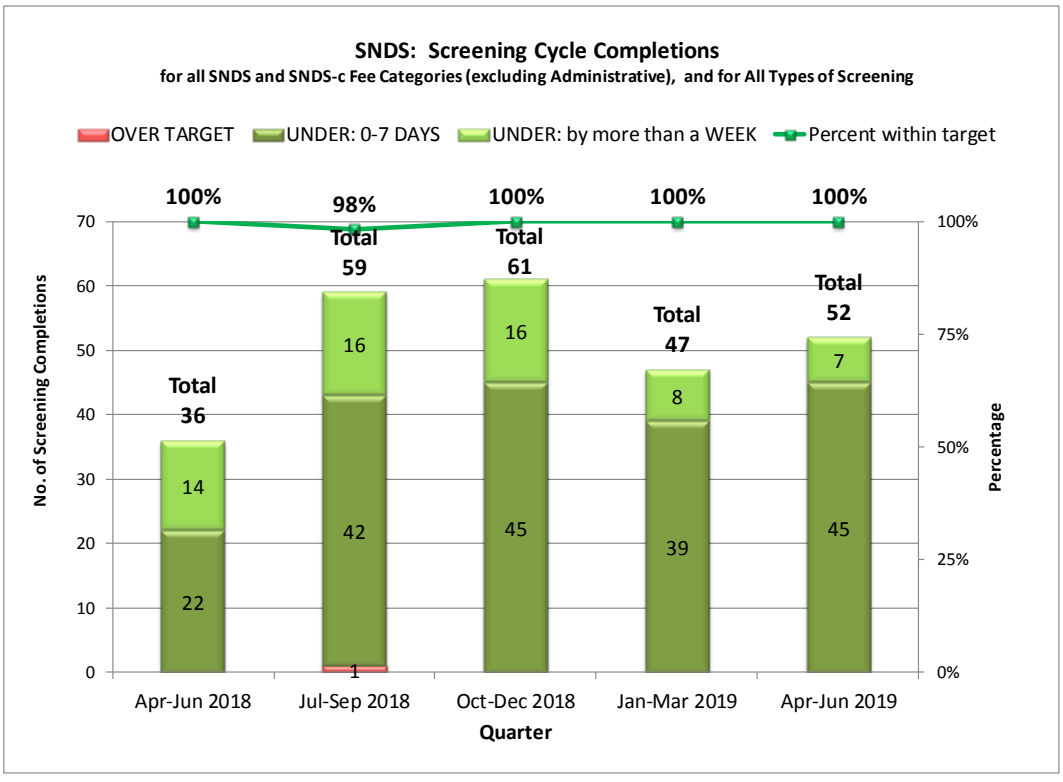


SCREENING PERFORMANCE

SNDS: Screening Decisions by Type

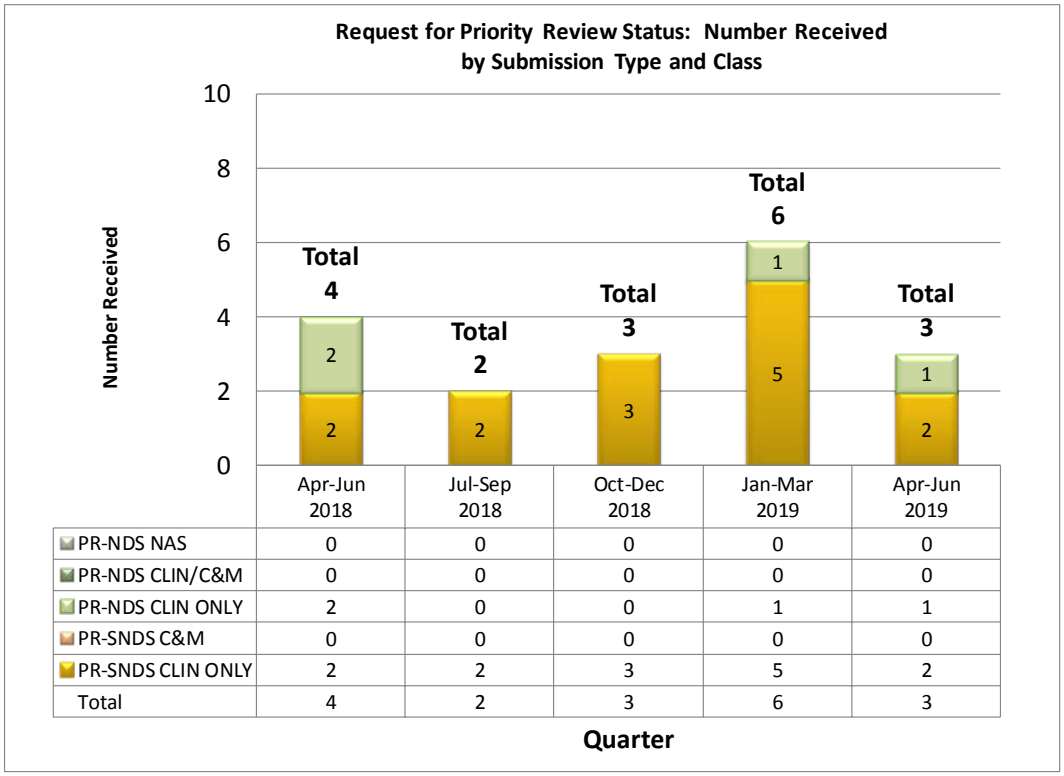


SNDS: Screening Cycle Completions



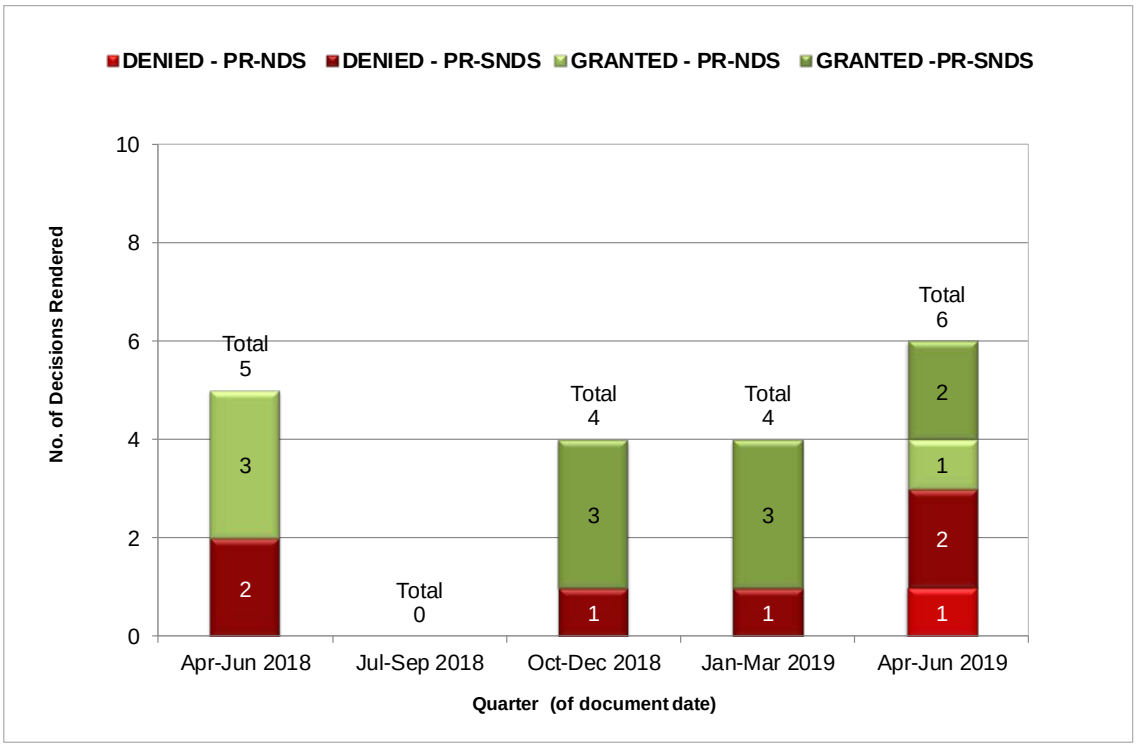
REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS)

Request for Priority Review Status: Number Received

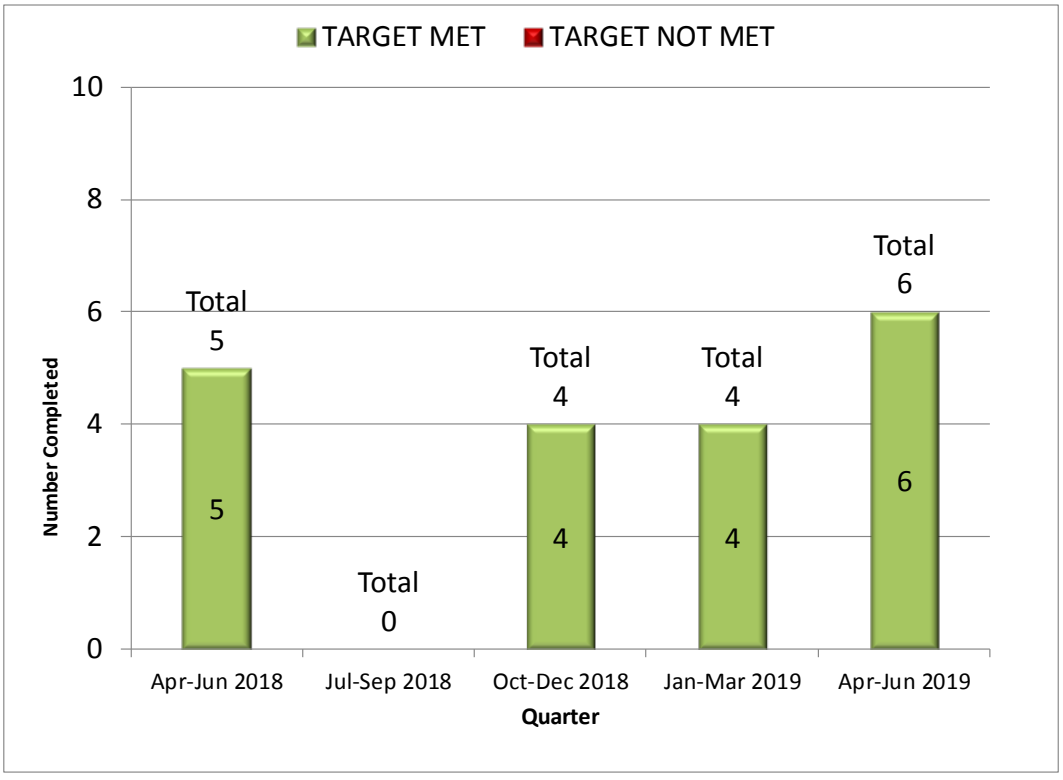


	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
PR-NDS NAS	0	0	0	0	0
PR-NDS CLIN/C&M	0	0	0	0	0
PR-NDS CLIN ONLY	2	0	0	1	1
PR-SNDS C&M	0	0	0	0	0
PR-SNDS CLIN ONLY	2	2	3	5	2
Total	4	2	3	6	3

Request for Priority Review Status: Decisions Rendered



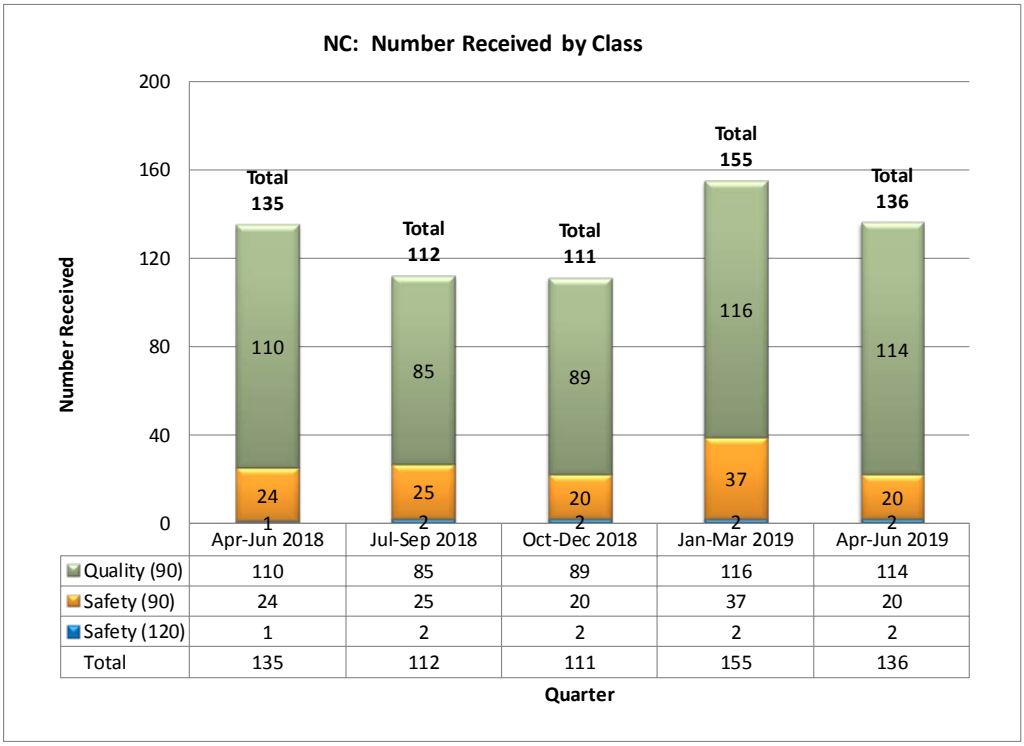
Request for Priority Review Status: Performance



NC: NOTIFIABLE CHANGE

NC: NOTIFIABLE CHANGE

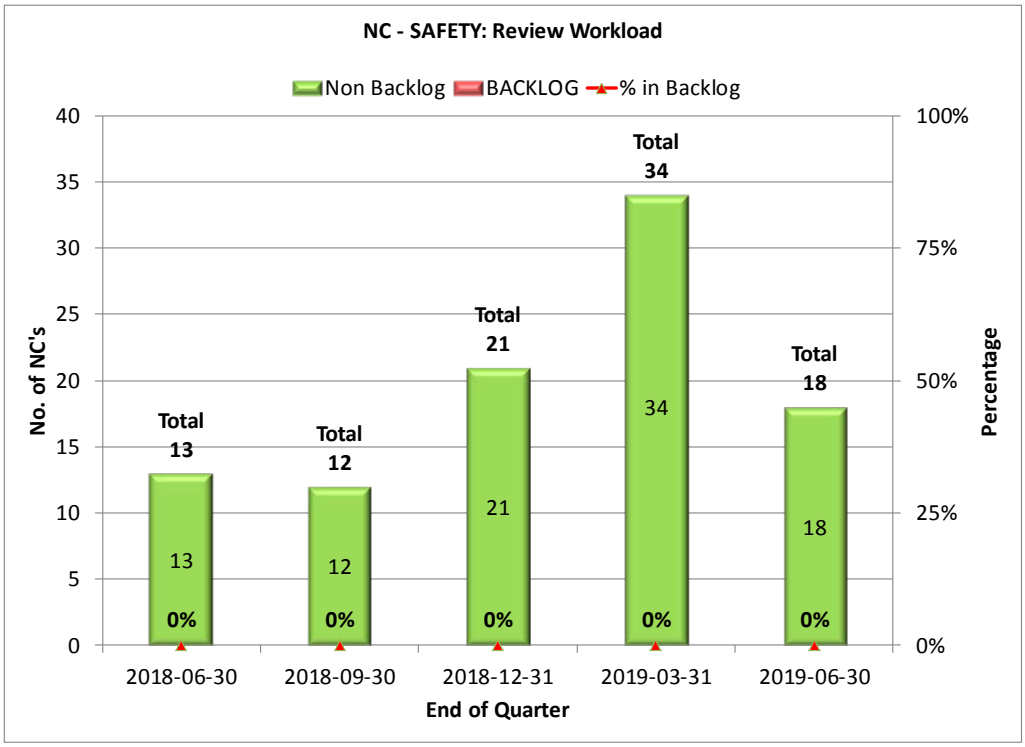
NC: Number Received by Class



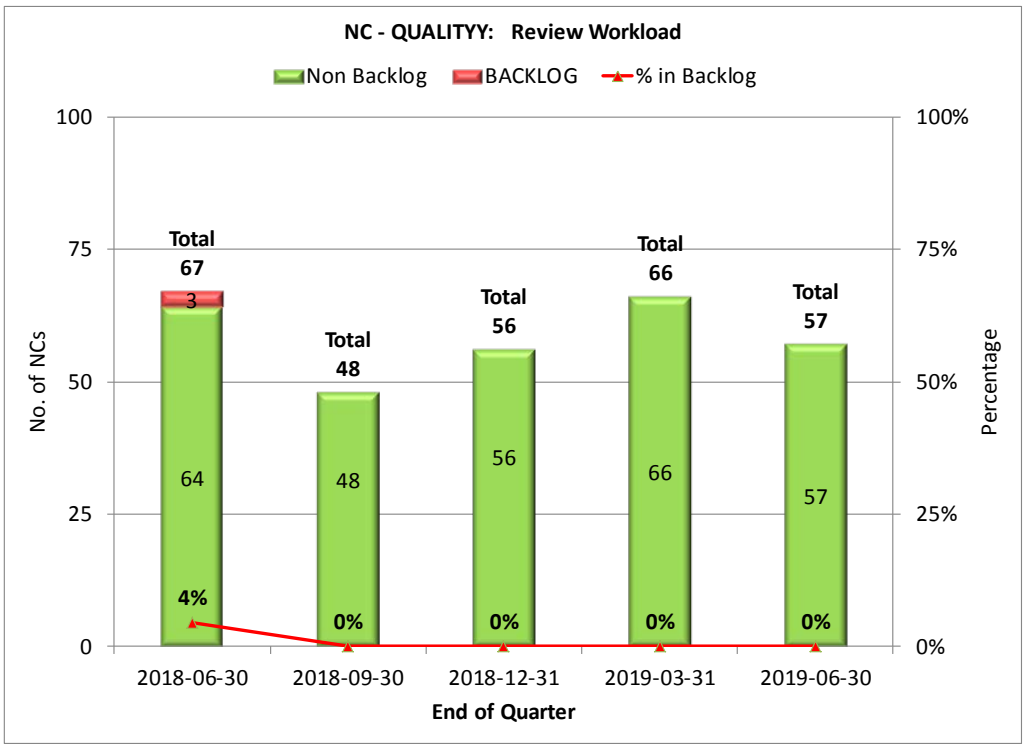
	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Quality (90)	110	85	89	116	114
Safety (90)	24	25	20	37	20
Safety (120)	1	2	2	2	2
Total	135	112	111	155	136

WORKLOAD

NC-SAFETY: Review Workload



NC-QUALITY: Review Workload



WORKLOAD

NC-SAFETY: Review Workload by Class

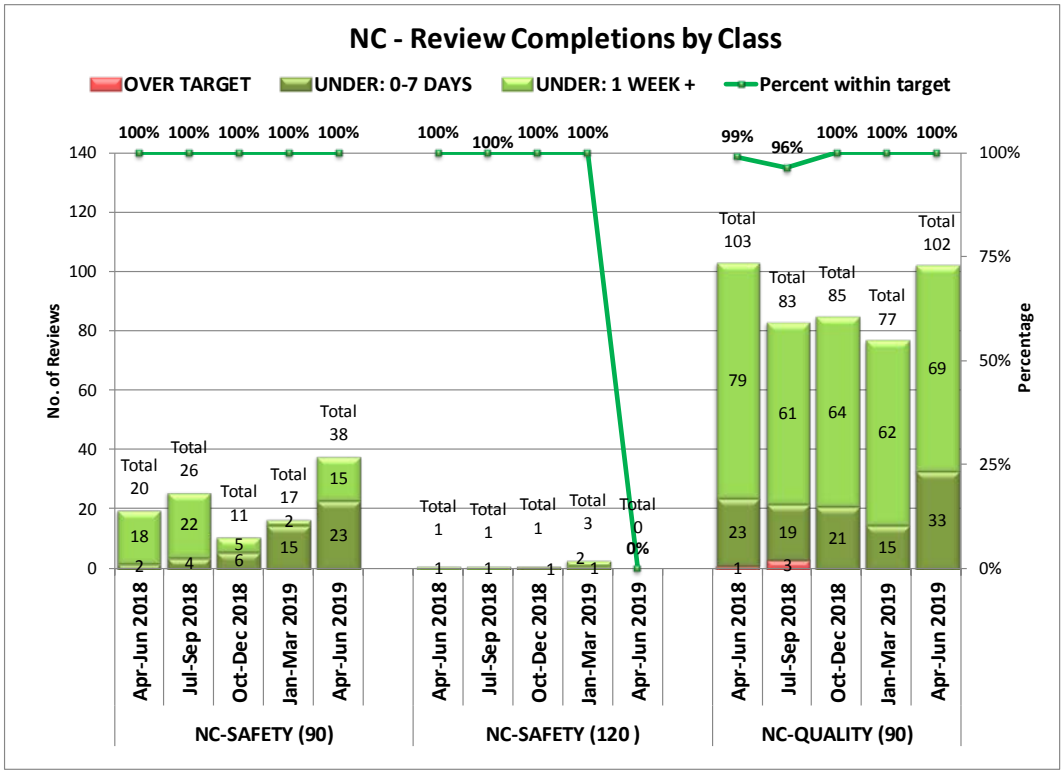
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2018-06-30	2018-09-30	2018-12-31	2019-03-31	2019-06-30
SAFETY - 90 day	11	10	18	34	15
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	2	2	3	0	3
Backlog	*0*	*0*	*0*	*0*	*0*
Total	13	12	21	34	18
Non Backlog	13	12	21	34	18
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC-QUALITY: Review Workload by Class

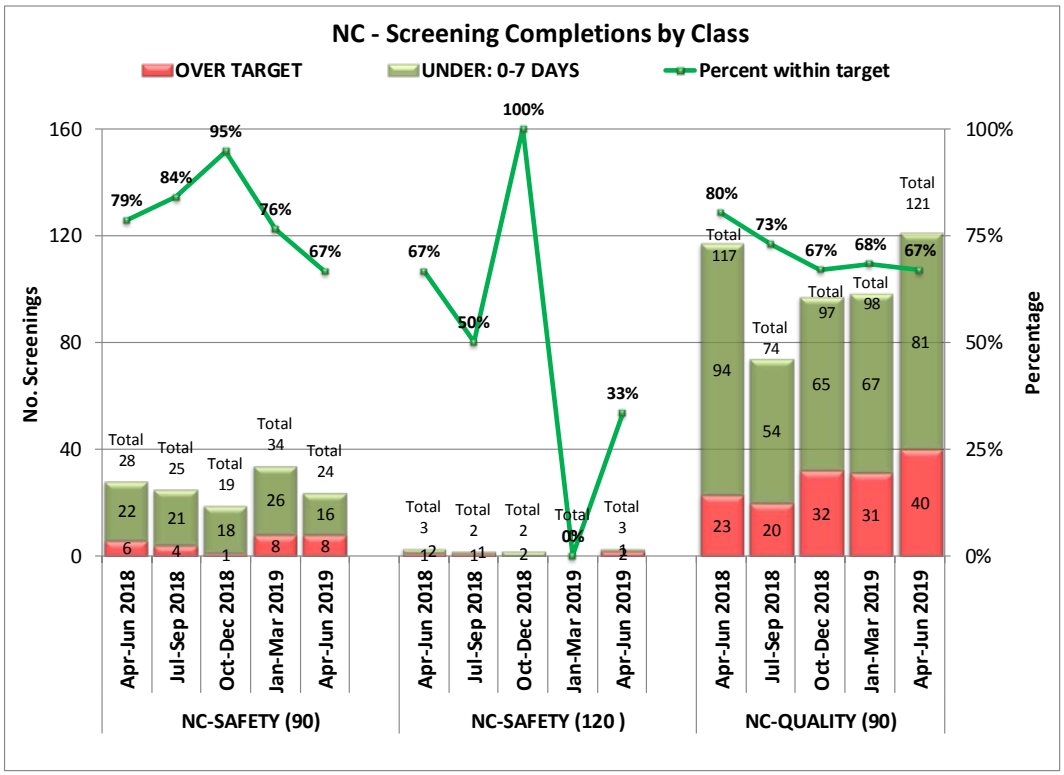
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2018-06-30	2018-09-30	2018-12-31	2019-03-31	2019-06-30
QUALITY - 90 day	67	48	56	66	57
Backlog	*3*	*0*	*0*	*0*	*0*
Total	67	48	56	66	57
Non Backlog	64	48	56	66	57
BACKLOG	3	0	0	0	0
% in Backlog	4%	0%	0%	0%	0%

PERFORMANCE

NC: Review Completions by Class



NC: Screening Completions by Class



NC: Decision Documents by Class

NC - SAFETY (90)					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	25	26	11	16	39
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	2	0	2	1	4
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

NC - QUALITY (90)					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	116	86	79	77	126
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	2	4	1	9	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	4	4	6	2	5
NC - HOLD (PATENT)	0	0	2	1	1

NC - SAFETY (120)					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	1	1	1	3	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	1	1	0	0	0

NC - ADMINISTRATIVE					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	3	0	1	1	0
CANCELLED BY COMPANY	0	0	0	0	0

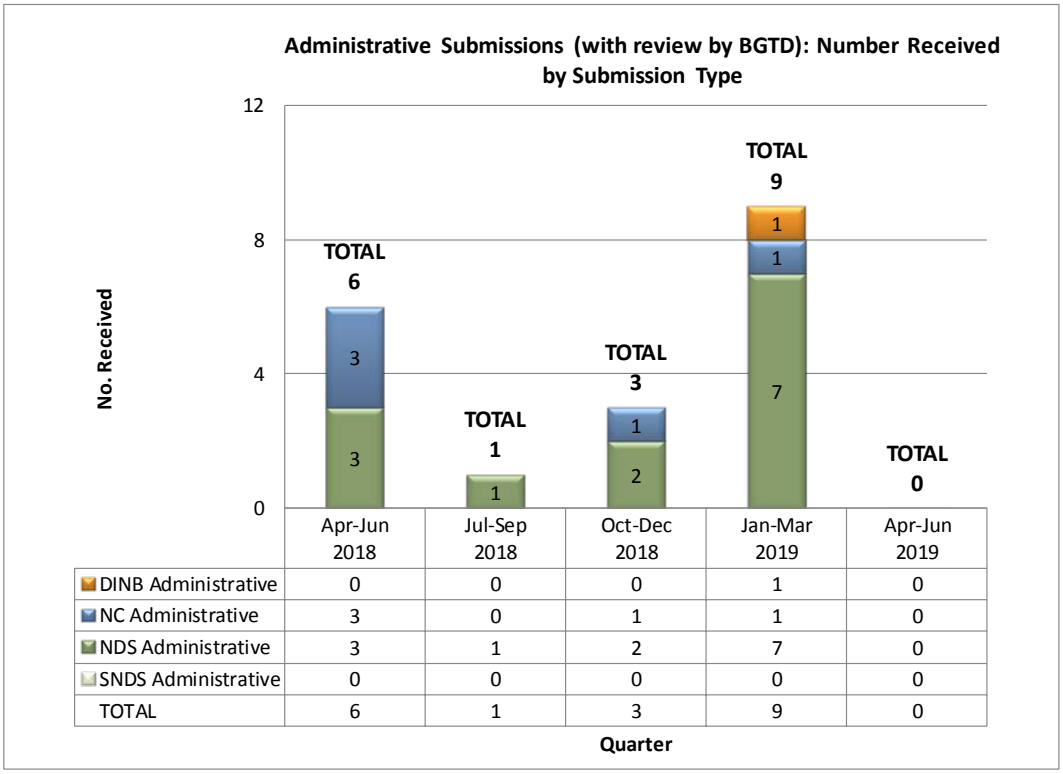
ADMINISTRATIVE SUBMISSIONS

Submissions in support of a manufacturer or product name change

ADMINISTRATIVE SUBMISSIONS (Processed by BGTD)

(e.g. product name changes that require a drug name review)

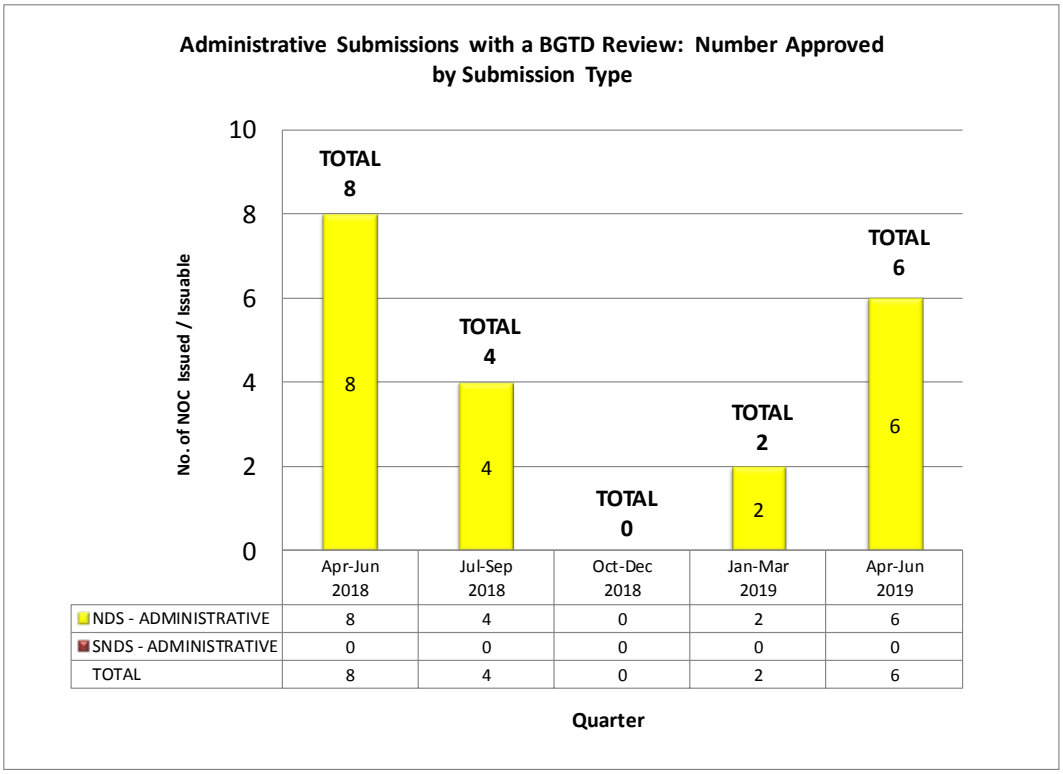
Administrative Submissions (with BGTD Review): Number Received



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
DINB Administrative	0	0	0	1	0
NC Administrative	3	0	1	1	0
NDS Administrative	3	1	2	7	0
SNDS Administrative	0	0	0	0	0
TOTAL	6	1	3	9	0

Quarter

Administrative Submissions (with BGTD Review): Number Approved



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
NDS - ADMINISTRATIVE	8	4	0	2	6
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	8	4	0	2	6

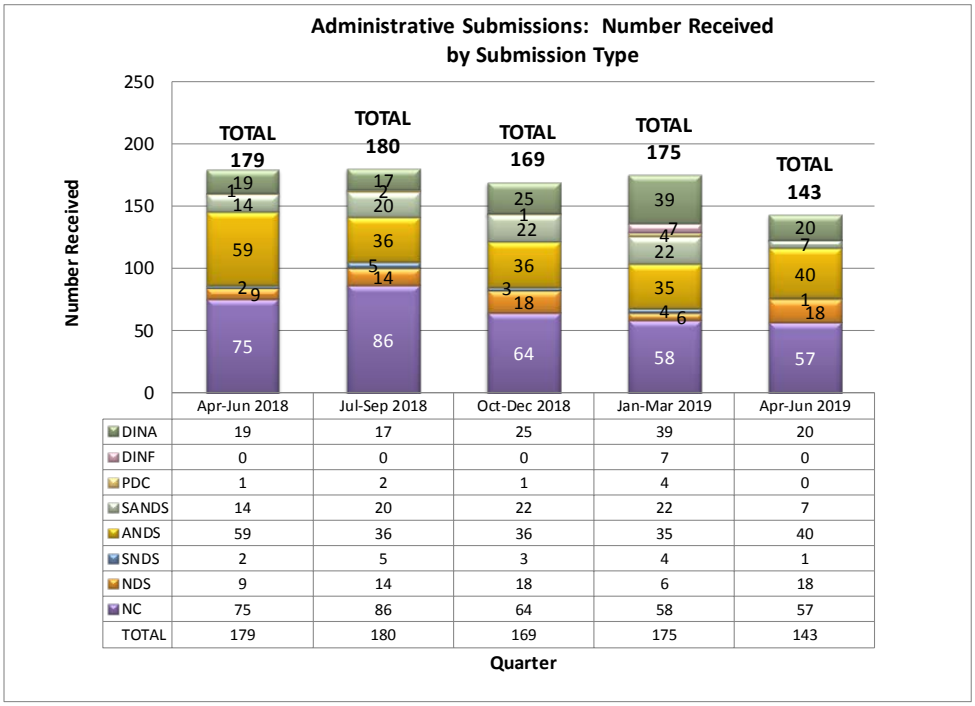
Quarter

ADMINISTRATIVE SUBMISSIONS (Processed by TPD)

(Manufacturer and/or Product Name Changes) [12]

RECEIVED

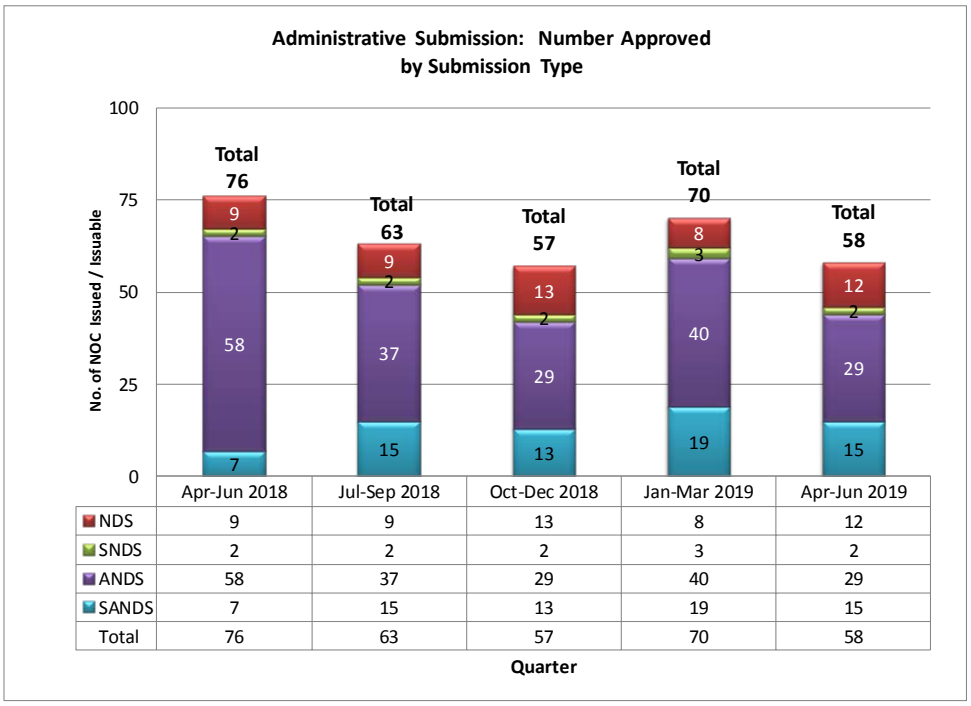
Administrative Submissions: Number Received



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
DINA	19	17	25	39	20
DINF	0	0	0	7	0
PDC	1	2	1	4	0
SANDS	14	20	22	22	7
ANDS	59	36	36	35	40
SNDS	2	5	3	4	1
NDS	9	14	18	6	18
NC	75	86	64	58	57
TOTAL	179	180	169	175	143

APPROVALS

Administrative Submissions: Number Approved



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
NDS	9	9	13	8	12
SNDS	2	2	2	3	2
ANDS	58	37	29	40	29
SANDS	7	15	13	19	15
Total	76	63	57	70	58

[12] 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.

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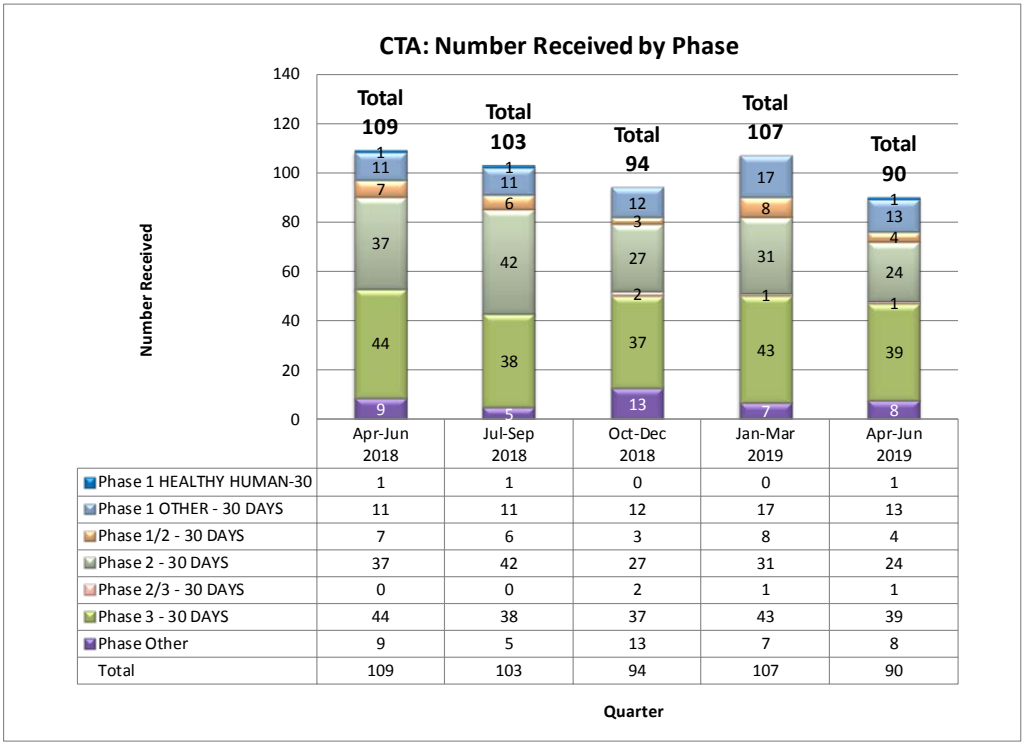
CLINICAL TRIAL APPLICATIONS AND AMENDMENTS

(CTA & CTA-A)

CLINICAL TRIAL APPLICATIONS (CTA)

CTA: Number Received by Phase

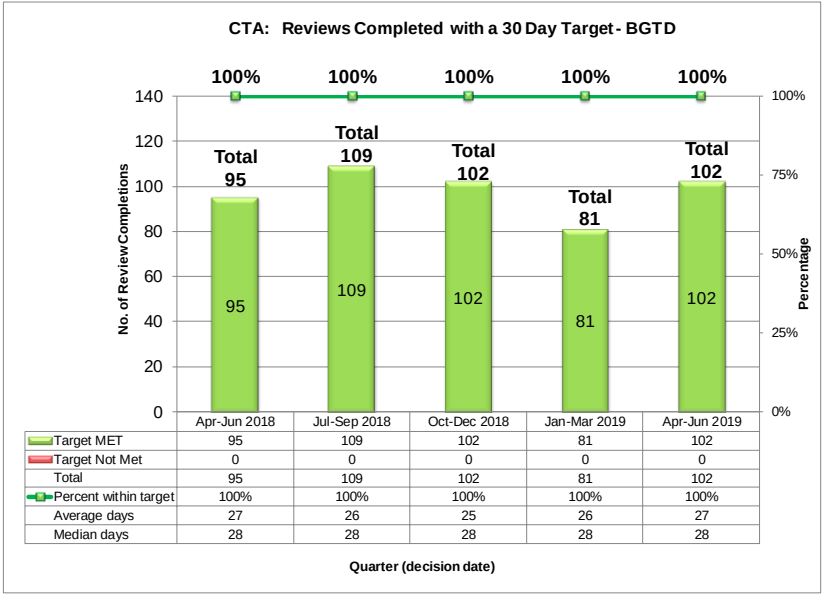


	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Phase 1 HEALTHY HUMAN-30	1	1	0	0	1
Phase 1 OTHER - 30 DAYS	11	11	12	17	13
Phase 1/2 - 30 DAYS	7	6	3	8	4
Phase 2 - 30 DAYS	37	42	27	31	24
Phase 2/3 - 30 DAYS	0	0	2	1	1
Phase 3 - 30 DAYS	44	38	37	43	39
Phase Other	9	5	13	7	8
Total	109	103	94	107	90

CTA: Number of Decisions by Document Type

CTA					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	92	108	100	80	97
CANCELLED BY COMPANY DURING REVIEW	3	1	2	1	5
CANCELLED BY COMPANY AT PROCESSING	0	4	2	0	2
REJECTION LETTER (SCR)	0	1	0	1	2
NOT SATISFACTORY NOTICE	0	0	0	1	0

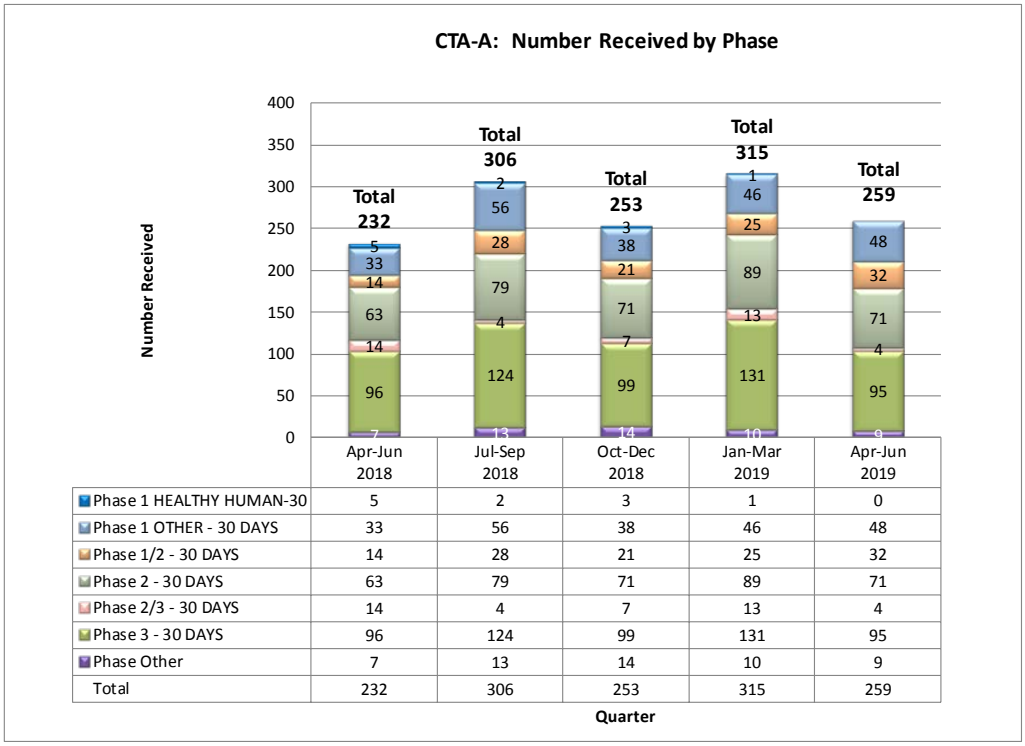
CTA: Review Completed with a 30 Day Target



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Target MET	95	109	102	81	102
Target Not Met	0	0	0	0	0
Total	95	109	102	81	102
Percent within target	100%	100%	100%	100%	100%
Average days	27	26	25	26	27
Median days	28	28	28	28	28

CLINICAL TRIAL APPLICATION- AMENDMENTS (CTA-A)

CTA-A: Number Received by Phase

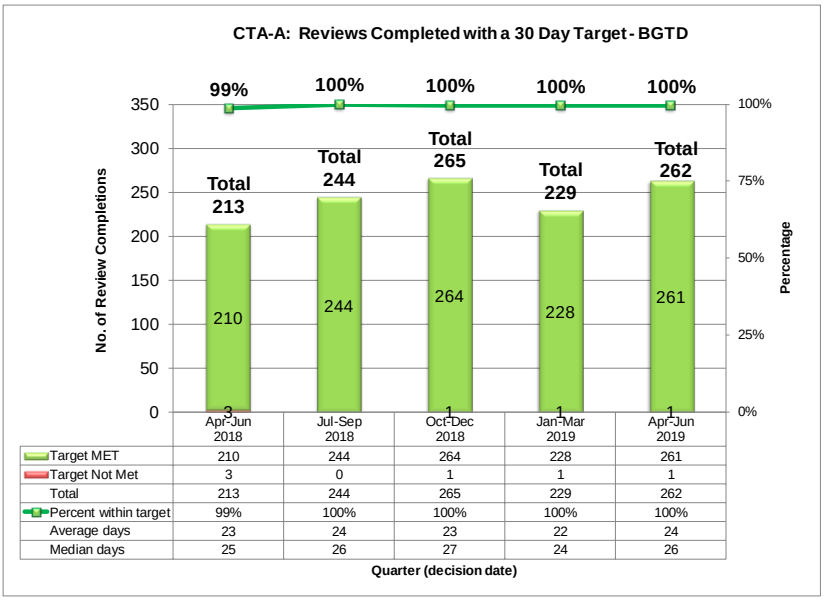


	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Phase 1 HEALTHY HUMAN-30	5	2	3	1	0
Phase 1 OTHER - 30 DAYS	33	56	38	46	48
Phase 1/2 - 30 DAYS	14	28	21	25	32
Phase 2 - 30 DAYS	63	79	71	89	71
Phase 2/3 - 30 DAYS	14	4	7	13	4
Phase 3 - 30 DAYS	96	124	99	131	95
Phase Other	7	13	14	10	9
Total	232	306	253	315	259

CTA-A: Decisions by Type

CTA-A					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	228	297	279	244	272
REJECTION LETTER (SCR)	7	4	2	7	6
CANCELLED BY COMPANY DURING REVIEW	1	2	0	1	2
CANCELLED BY COMPANY AT PROCESSING	0	2	6	1	1

CTA-A: Reviews Completed with a 30 Day Target



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Target MET	210	244	264	228	261
Target Not Met	3	0	1	1	1
Total	213	244	265	229	262
Percent within target	99%	100%	100%	100%	100%
Average days	23	24	23	22	24
Median days	25	26	27	24	26

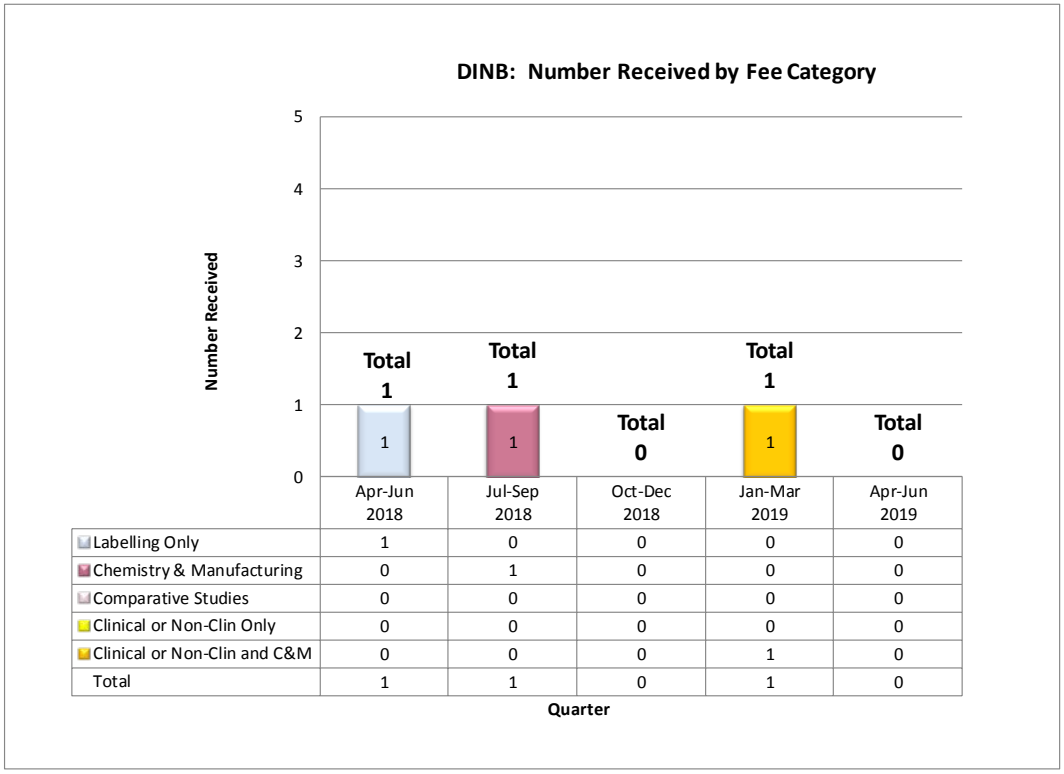
DINB

Application for a Drug Identification Number

Biological Product

DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER – BIOLOGICAL PRODUCT

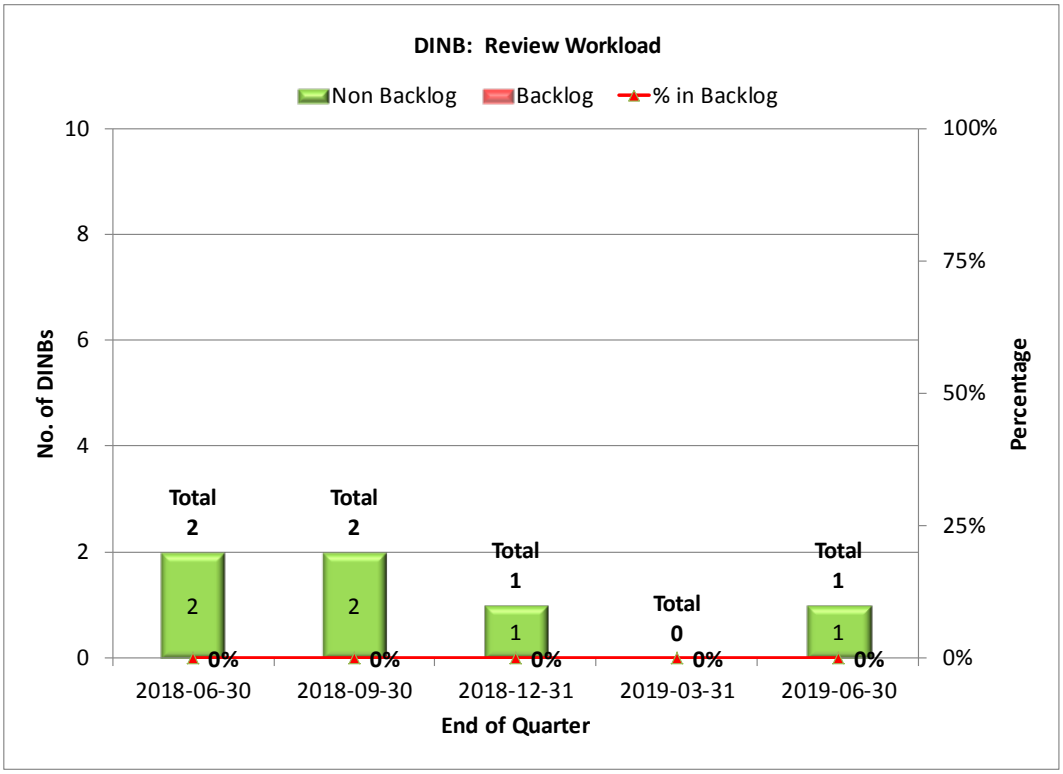
DINB: Number Received by Fee Category



	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Labelling Only	1	0	0	0	0
Chemistry & Manufacturing	0	1	0	0	0
Comparative Studies	0	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	0	1	0
Total	1	1	0	1	0

REVIEW WORKLOAD

DINB: Review Workload

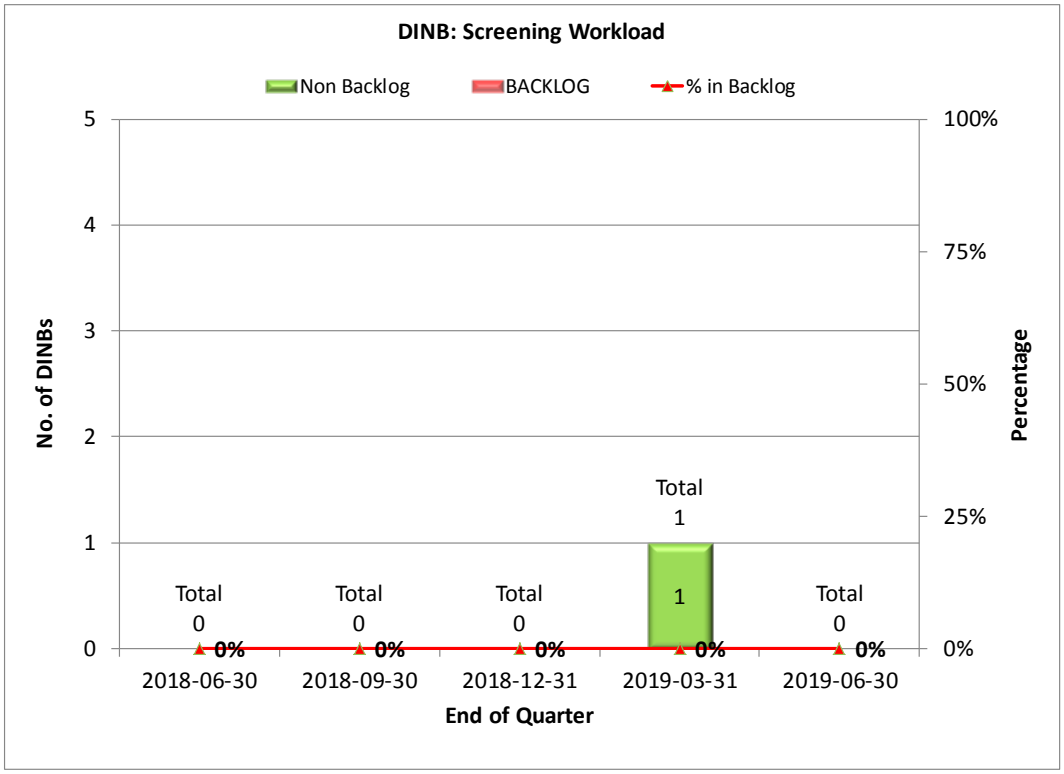


DINB: Review Workload by Fee Category

BGTD DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
	2018-06-30	2018-09-30	2018-12-31	2019-03-31	2019-06-30
Labelling Only	1	0	0	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	1	2	1	0	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	2	2	1	0	1
Non Backlog	2	2	1	0	1
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

SCREENING WORKLOAD

DINB: Screening Workload



DINB: Screening Workload by Fee Category

BGTD DINB: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
	2018-06-30	2018-09-30	2018-12-31	2019-03-31	2019-06-30
Labelling Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**0**	**0**	**0**	**1**	**0**
Non Backlog	**0**	**0**	**0**	**1**	*0*
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISIONS

DINB: Number of Decisions by Fee Category

DINB - Labelling Only					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

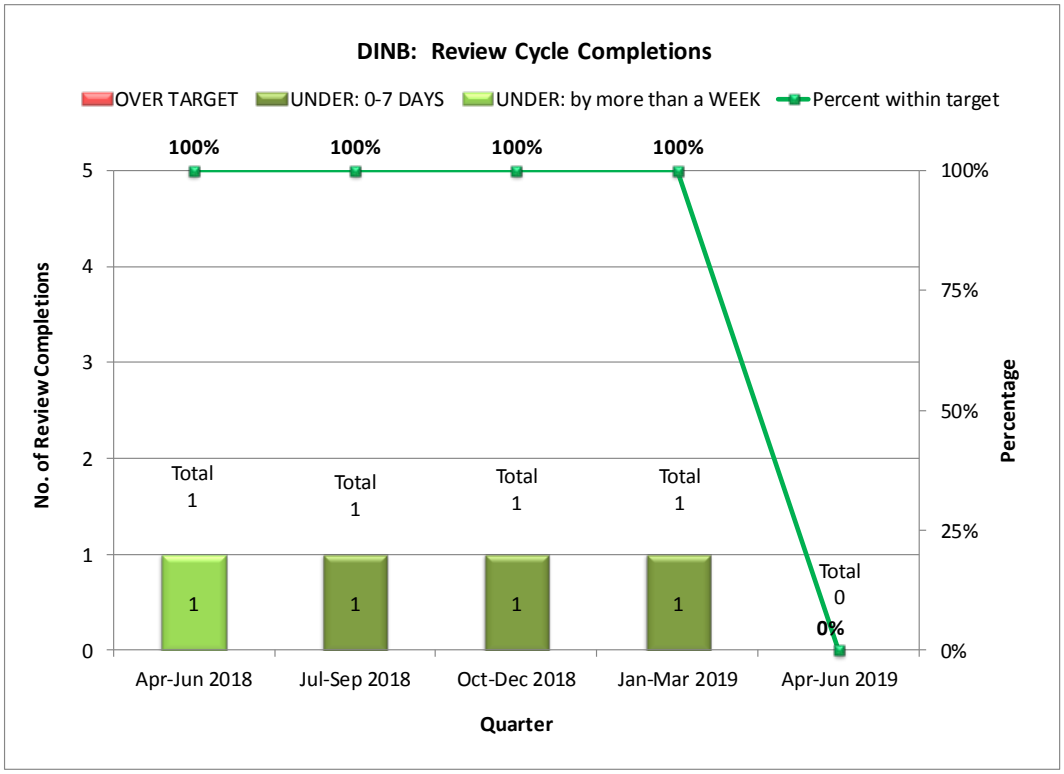
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

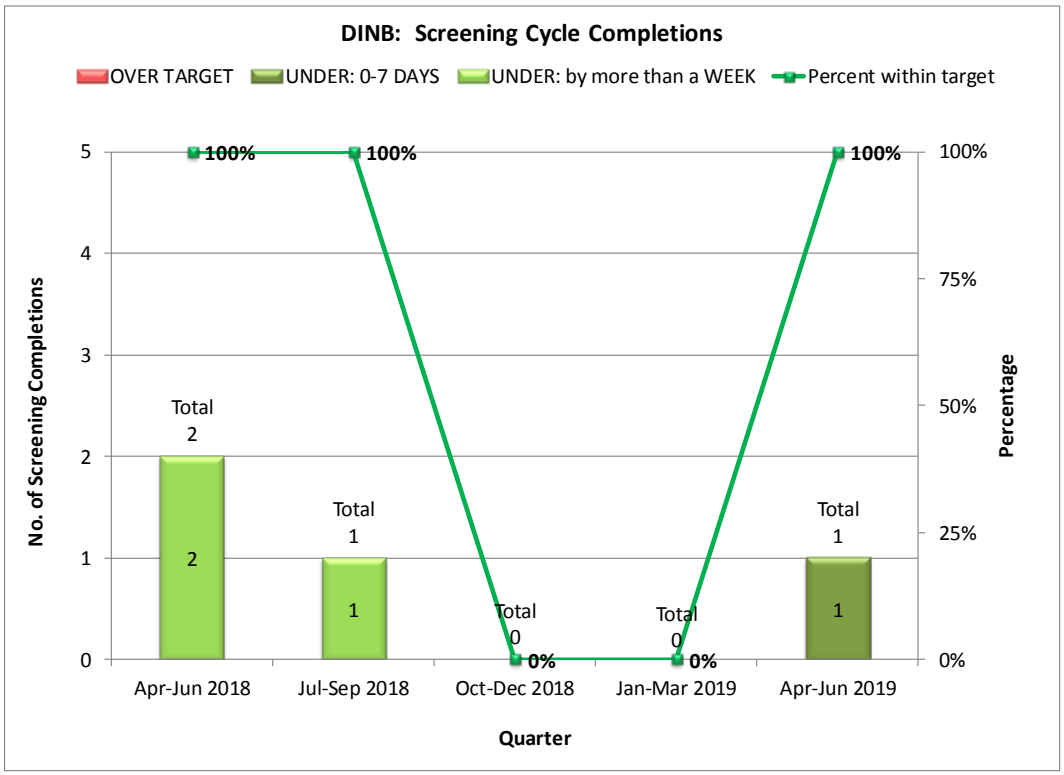
DINB - Administrative					
DOCUMENT TYPE	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**	**Apr-Jun 2019**
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

PERFORMANCE

DINB: Review Cycle Completions

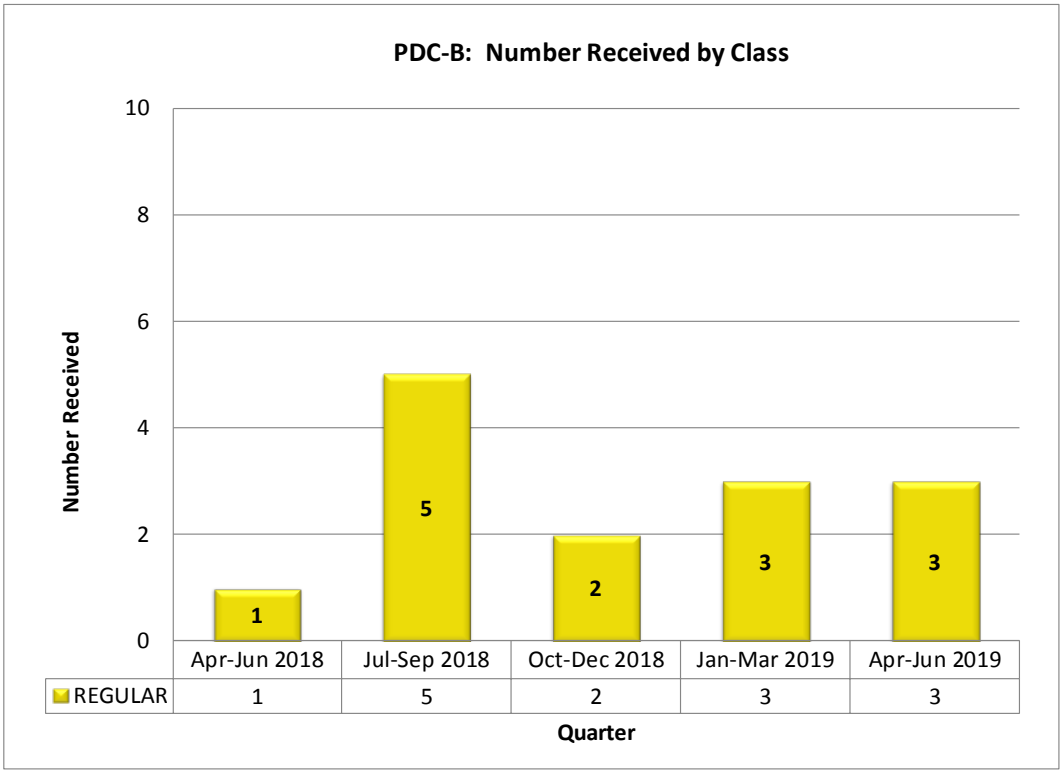


DINB: Screening Cycle Completions



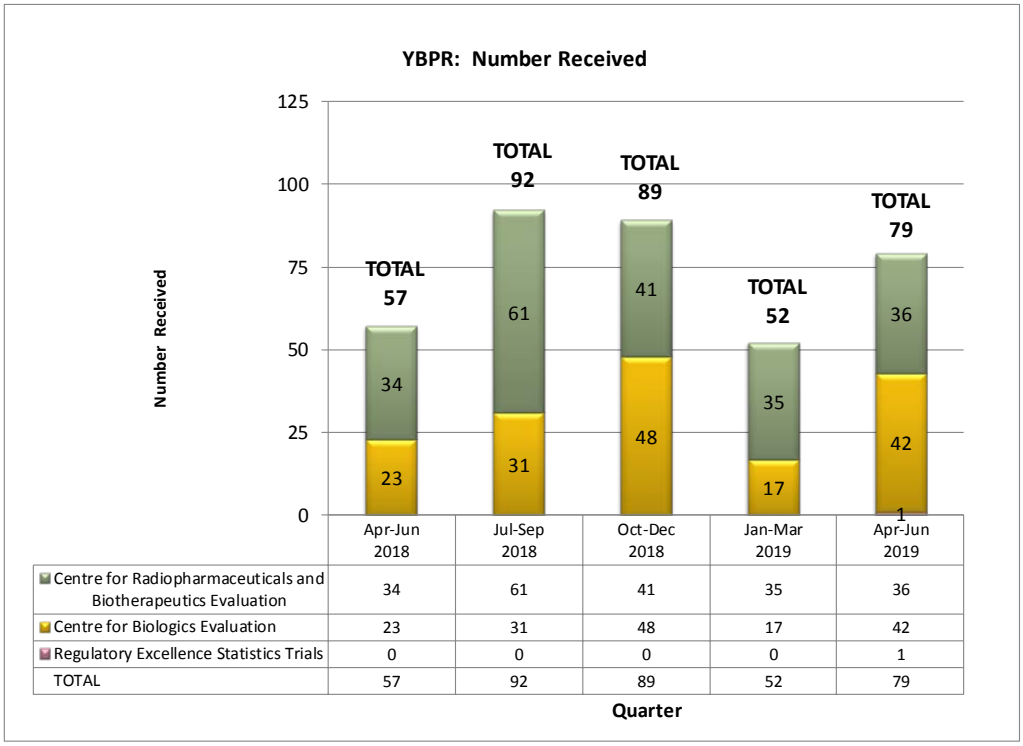
POST-AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT (PDC-B)

PDC-B: Number Received



YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) [13]

YBPR: Number Received

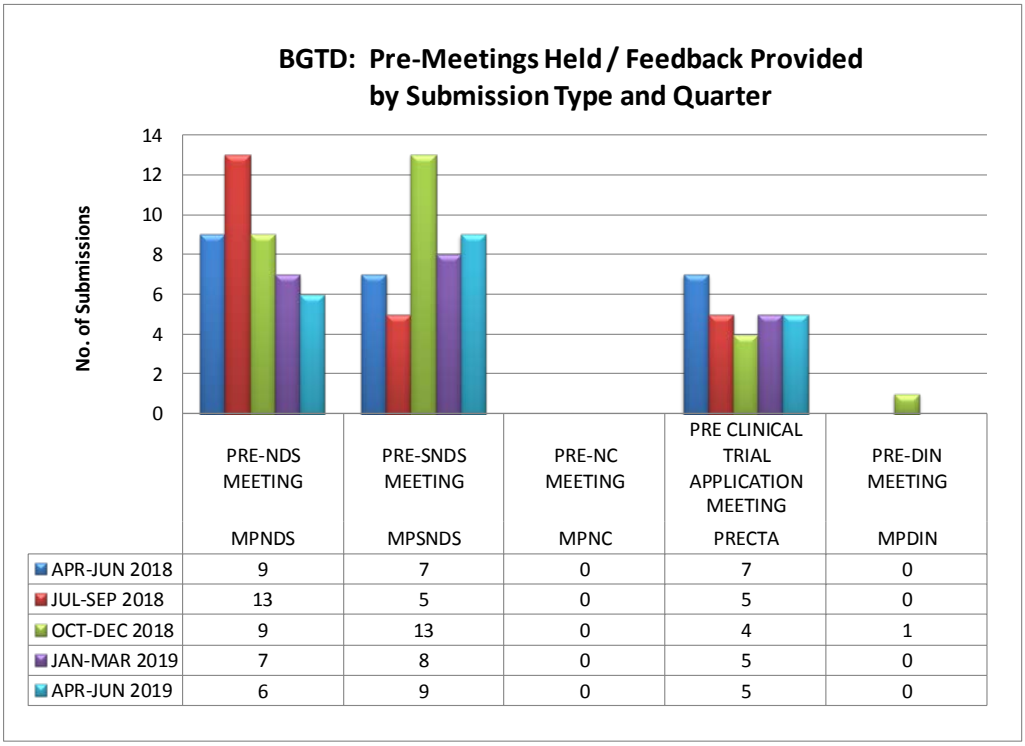


	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	34	61	41	35	36
Centre for Biologics Evaluation	23	31	48	17	42
Regulatory Excellence Statistics Trials	0	0	0	0	1
TOTAL	57	92	89	52	79

[13] Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

APPENDIX A: PRE-SUBMISSION MEETINGS [14]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING MPNDS	PRE-SNDS MEETING MPSNDS	PRE-NC MEETING MPNC	PRE CLINICAL TRIAL APPLICATION MEETING PRECTA	PRE-DIN MEETING MPDIN
APR-JUN 2018	9	7	0	7	0
JUL-SEP 2018	13	5	0	5	0
OCT-DEC 2018	9	13	0	4	1
JAN-MAR 2019	7	8	0	5	0
APR-JUN 2019	6	9	0	5	0

[14] 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 Guidance for Industry: Management of Drug Submissions