Santé Canada Health Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Quarterly Report

January – March

2019

Canada

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Direction des produits biologiques et des thérapies génétiques – Rapport trimestriel du rendement des présentations de drogue – janvier – mars 2019

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Publication date: June 2019

Cat H2-2E-PDF
ISSN 2561-5572
Pub 190071

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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 January – March 2018 to January – March 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 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 Review1 and 90 days for Review2. 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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[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

CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINB	-	Application for a Drug Identification Number - Biological Product
MP-NDS		Pre- New Drug Submission Meeting
MP-SNDS		Pre- Supplemental New Drug Submission Meeting
NDS	-	New Drug Submission
NC	-	Notifiable Change (Level II) – New Drug
PDC	-	Post Din Changes
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SNDS	-	Supplemental New Drug Submission
SNDS-C	-	Supplemental New Drug Submission – CONFIRMATORY
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 (Rx to OTC)
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	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.

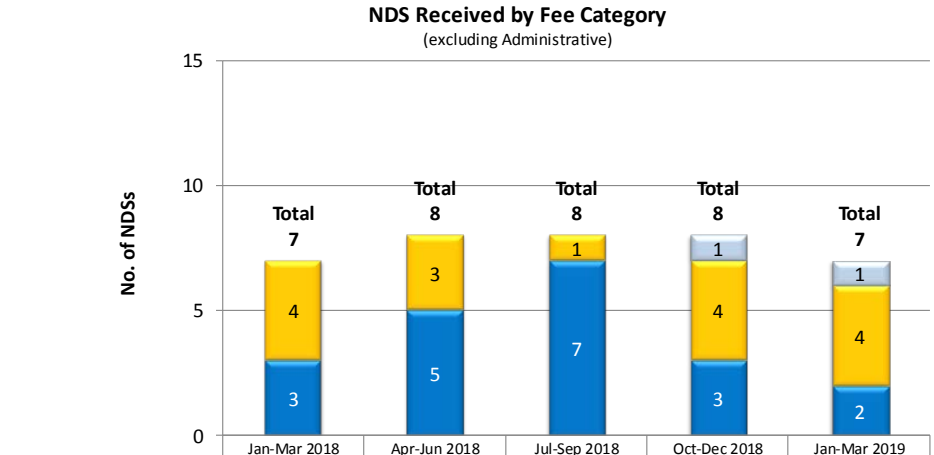
New Drug Submissions (NDS)

&

Supplemental New Drug Submissions (SNDS)

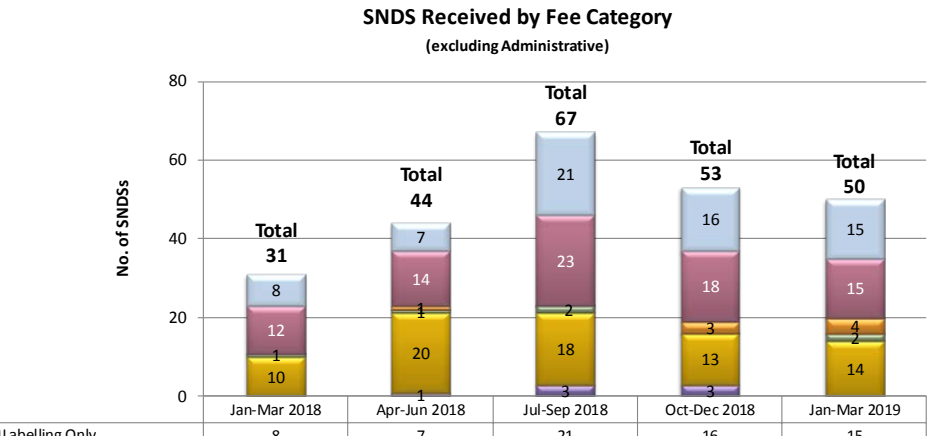
SUBMISSIONS RECEIVED[8, 9]

New Drug Submissions (NDS) Received by Fee Category



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

Supplemental New Drug Submissions (SNDS) Received by Fee Category



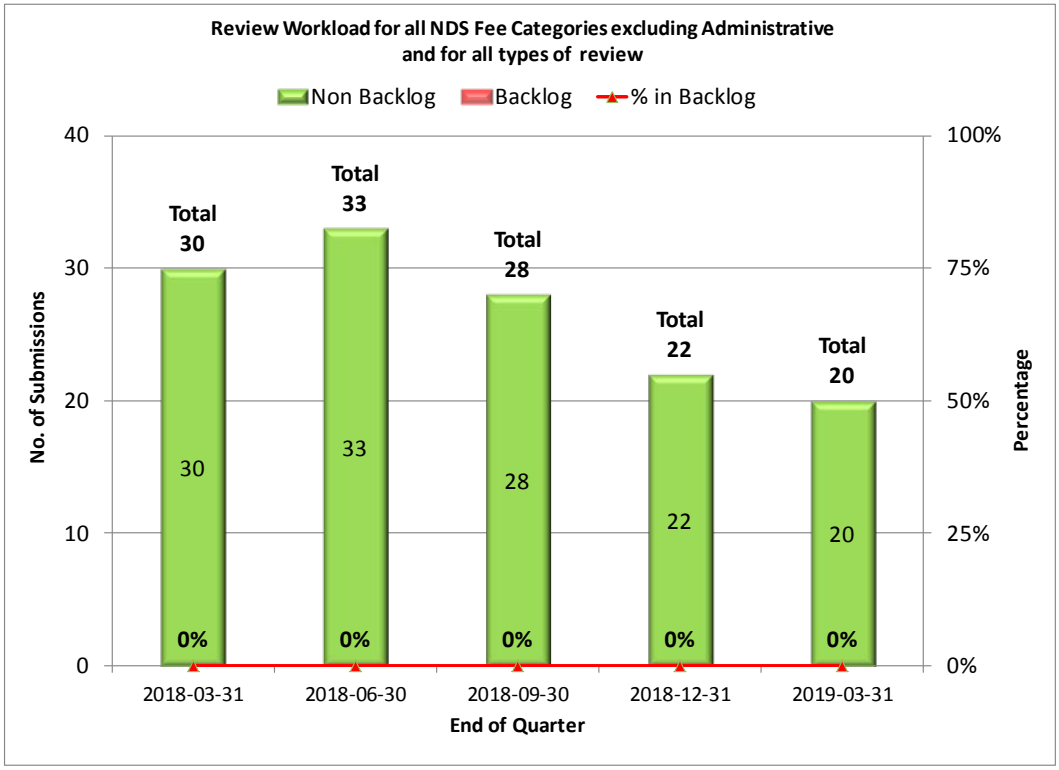
	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	8	7	21	16	15
Chemistry & Manufacturing	12	14	23	18	15
Clinical or Non-Clin and C&M	0	1	0	3	4
Published Data Only	1	1	2	0	2
Clinical or Non-Clin Only	10	20	18	13	14
Comparative Studies	0	1	3	3	0
Total	31	44	67	53	50
Priority Class	1	0	0	1	4
NOC-C Class	1	0	1	0	1
SNDS Confirmatory	1	2	2	1	0
Biosimilar	2	2	6	2	3

[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.

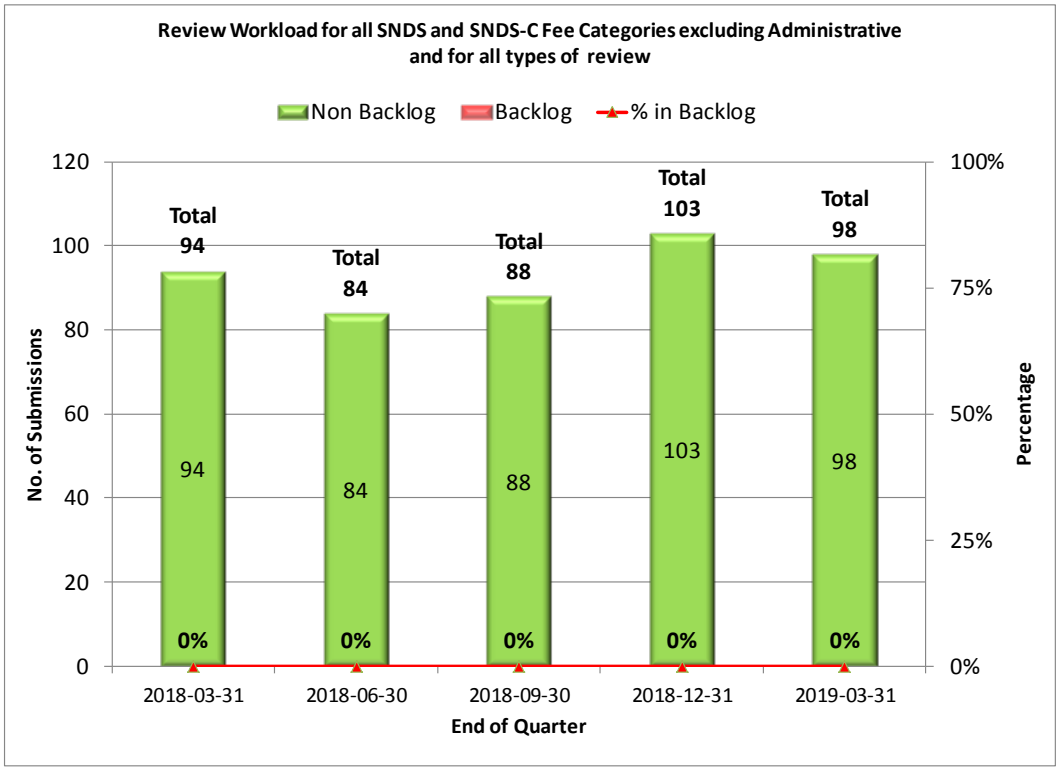
[9] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy , the Notice of Compliance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

WORKLOAD

New Drug Submission (NDS) Review Workload / Backlog



Supplemental New Drug Submission (SNDS) Review Workload / Backlog



WORKLOAD

New Drug Submission (NDS) Review Workload by Fee Category

BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Clinical or Non-Clin and C&M	**21**	**21**	**14**	**9**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**9**	**12**	**14**	**12**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**30**	**33**	**28**	**22**	**20**
Non Backlog	**30**	**33**	**28**	**22**	**20**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**5**	**7**	**5**	**3**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*

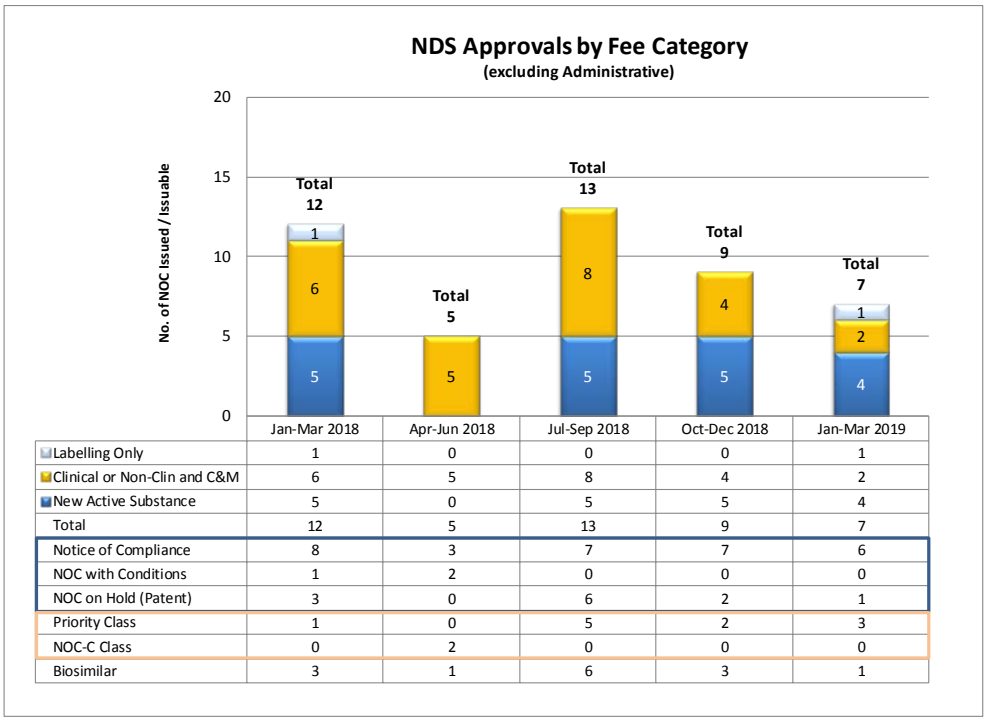
Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

BGTD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Comparative Studies	**1**	**1**	**3**	**6**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**26**	**26**	**22**	**29**	**26**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**54**	**48**	**48**	**48**	**49**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**4**	**4**	**2**	**4**	**6**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**2**	**2**	**1**	**3**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**7**	**3**	**12**	**13**	**10**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**94**	**84**	**88**	**103**	**98**
Non Backlog	**94**	**84**	**88**	**103**	**98**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**2**	**2**	**0**	**1**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**5**	**2**	**6**	**6**	**5**
Backlog	*0*	*0*	*0*	*0*	*0*

APPROVALS

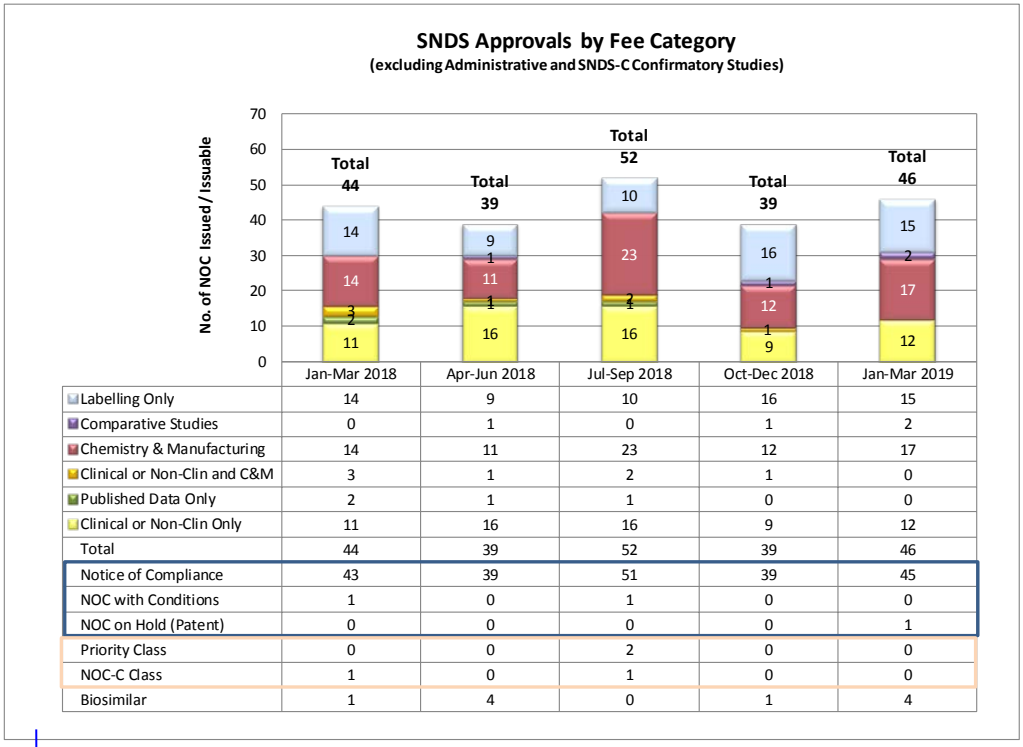
[10], [11]

New Drug Submission (NDS) Approvals by Fee Category and NOC Type



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	1	0	0	0	1
Clinical or Non-Clin and C&M	6	5	8	4	2
New Active Substance	5	0	5	5	4
Total	12	5	13	9	7
Notice of Compliance	8	3	7	7	6
NOC with Conditions	1	2	0	0	0
NOC on Hold (Patent)	3	0	6	2	1
Priority Class	1	0	5	2	3
NOC-C Class	0	2	0	0	0
Biosimilar	3	1	6	3	1

Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	14	9	10	16	15
Comparative Studies	0	1	0	1	2
Chemistry & Manufacturing	14	11	23	12	17
Clinical or Non-Clin and C&M	3	1	2	1	0
Published Data Only	2	1	1	0	0
Clinical or Non-Clin Only	11	16	16	9	12
Total	44	39	52	39	46
Notice of Compliance	43	39	51	39	45
NOC with Conditions	1	0	1	0	0
NOC on Hold (Patent)	0	0	0	0	1
Priority Class	0	0	2	0	0
NOC-C Class	1	0	1	0	0
Biosimilar	1	4	0	1	4

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

*revised Apr 2019

Biosimilars: List of NDS & SNDS issued an NOC – FY 2018-19 by Quarter

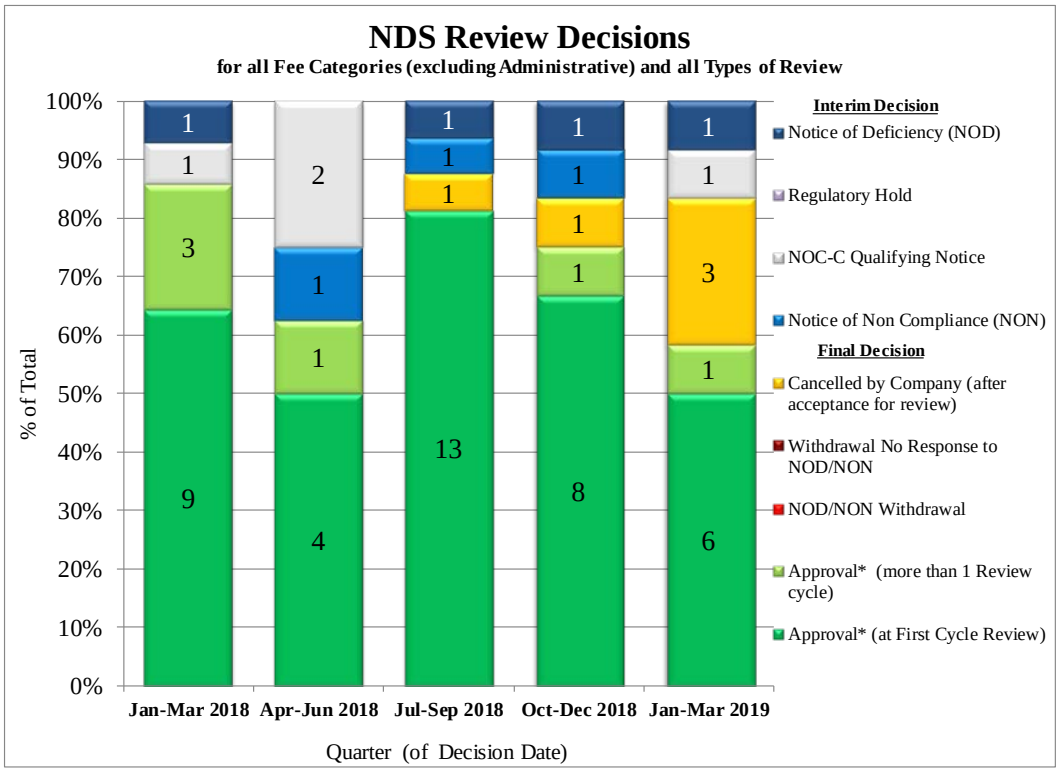
Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2018-19	Notice of Compliance (NOC) Date
NDS	FULPHILA	CLIN/C&M	BGP PHARMA ULC	PEGFILGRASTIM	Q3	2018-Dec-24
	HADLIMA, HADLIMA PUSHTOUCH	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q1	2018-May-08
	HADLIMA, HADLIMA PUSHTOUCH	CLIN/C&M	SAMSUNG BIOEPIS CO., LTD	ADALIMUMAB	Q1	2018-May-08
	LAPELGA	CLIN/C&M	APOTEX INC.	PEGFILGRASTIM	Q1	2018-Apr-05
	MVASI	CLIN/C&M	AMGEN CANADA INC	BEVACIZUMAB	Q1	2018-Apr-30
New Drug Submission Total						**5**
SNDS	ADMELOG	LABELLING ONLY	SANOFI-AVENTIS CANADA INC	INSULIN LISPRO	Q1	2018-Apr-30
	BASAGLAR	C&M ONLY	ELI LILLY CANADA INC	INSULIN GLARGINE	Q1	2018-May-10
	BRENZYS	LABELLING ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q1	2018-Jun-18
	BRENZYS (PFP), BRENZYS (PFS)	CLIN ONLY	SAMSUNG BIOEPIS CO., LTD	ETANERCEPT	Q1	2018-Jun-14
	ERELZI	CLIN ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Jan-17
	ERELZI (SENSOREADY PEN), ERELZI (PREFILLED SYRINGE)	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Feb-11
	ERELZI (SYRINGE), ERELZI (PEN)	C&M ONLY	SANDOZ CANADA INCORPORATED	ETANERCEPT	Q4	2019-Feb-27
	RENFLEXIS	COMP/C&M	SAMSUNG BIOEPIS CO., LTD	INFLIXIMAB	Q3	2018-Nov-06
Supplemental New Drug Submission Total						**8**

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

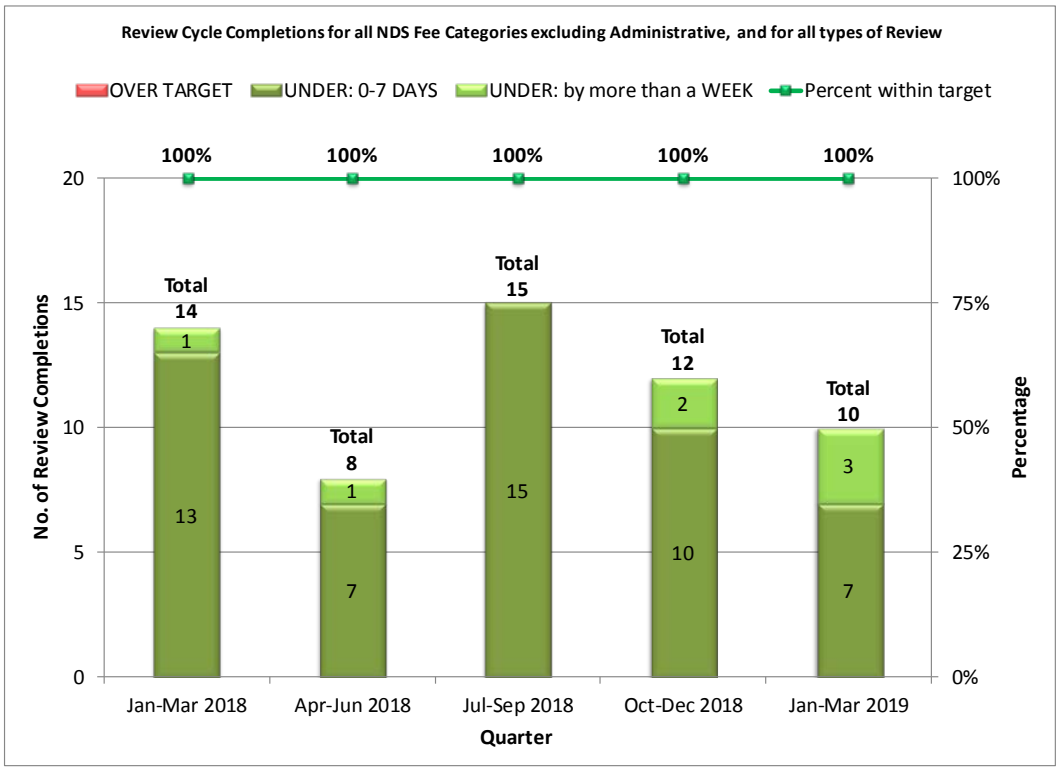
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity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

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

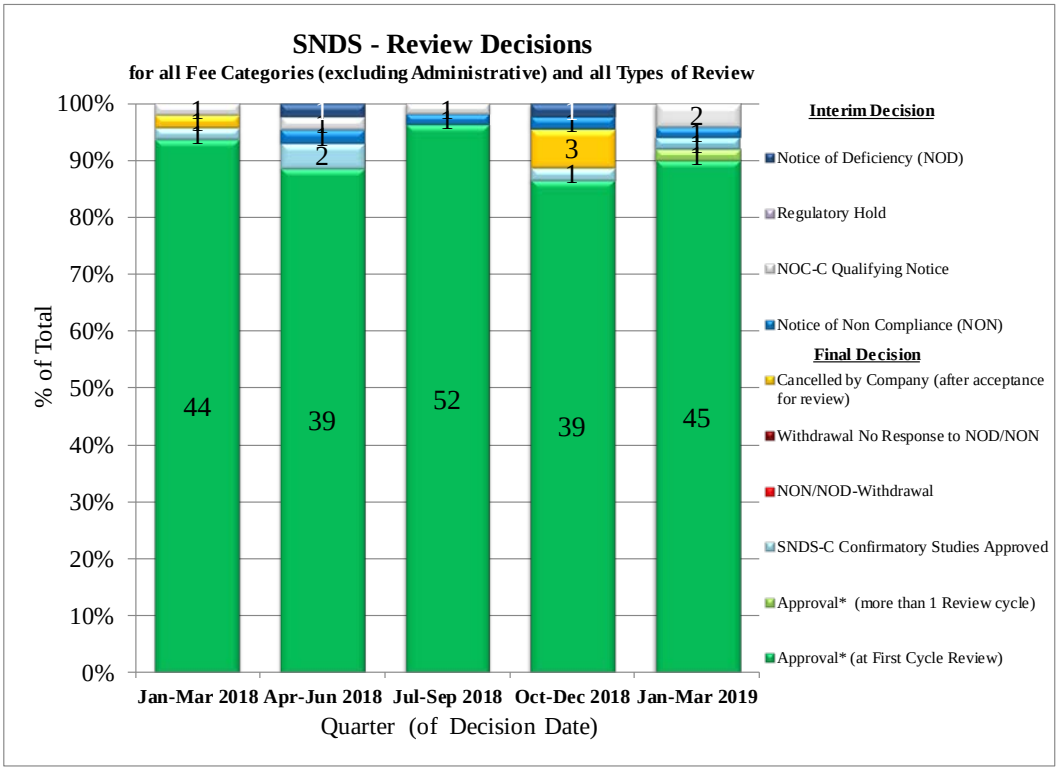


NDS - Review Cycle Completions Showing Percentage Within Target

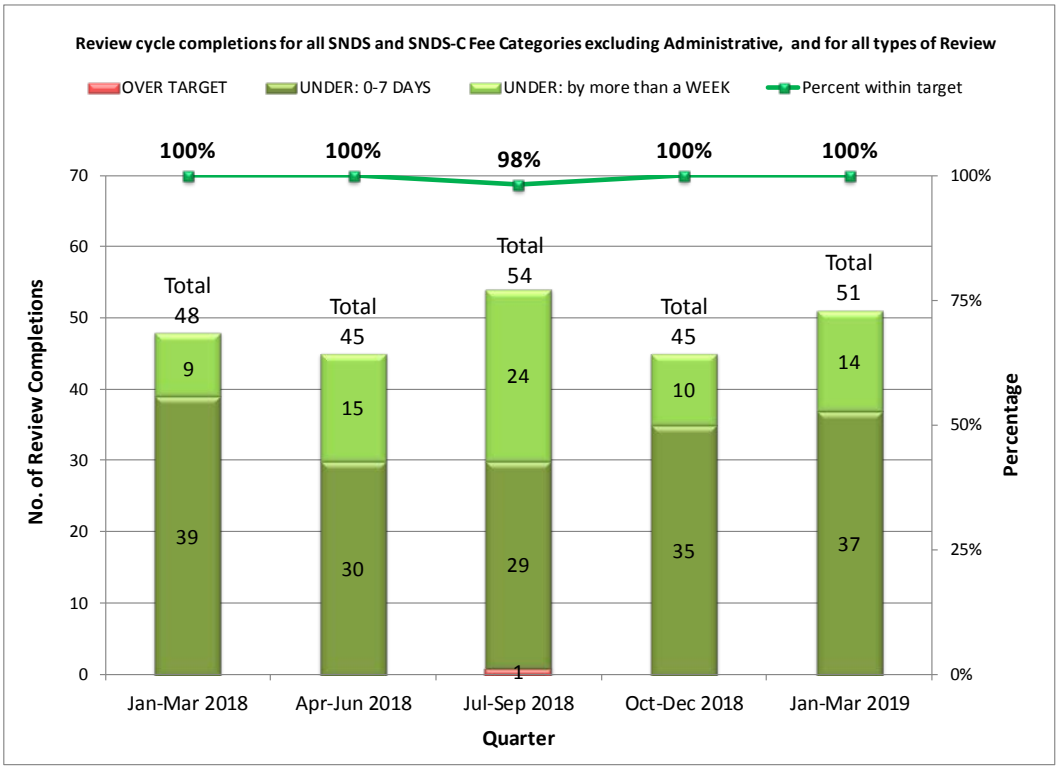


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

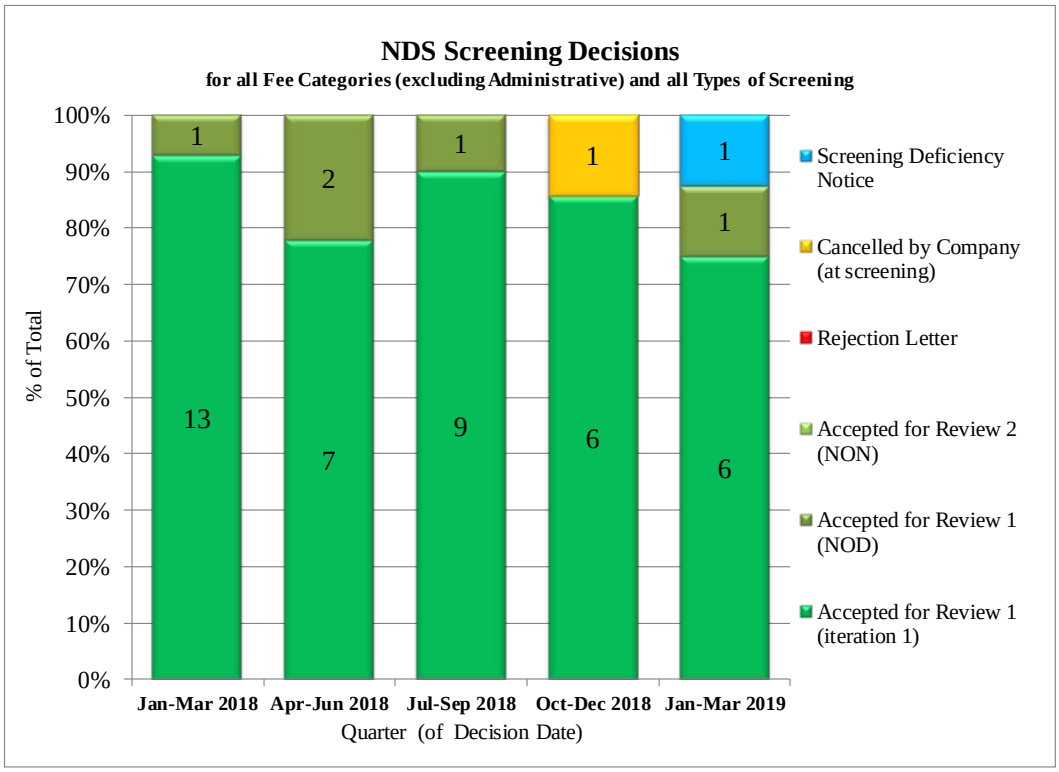


SNDS - Review Cycle Completions Showing Percentage Within Target

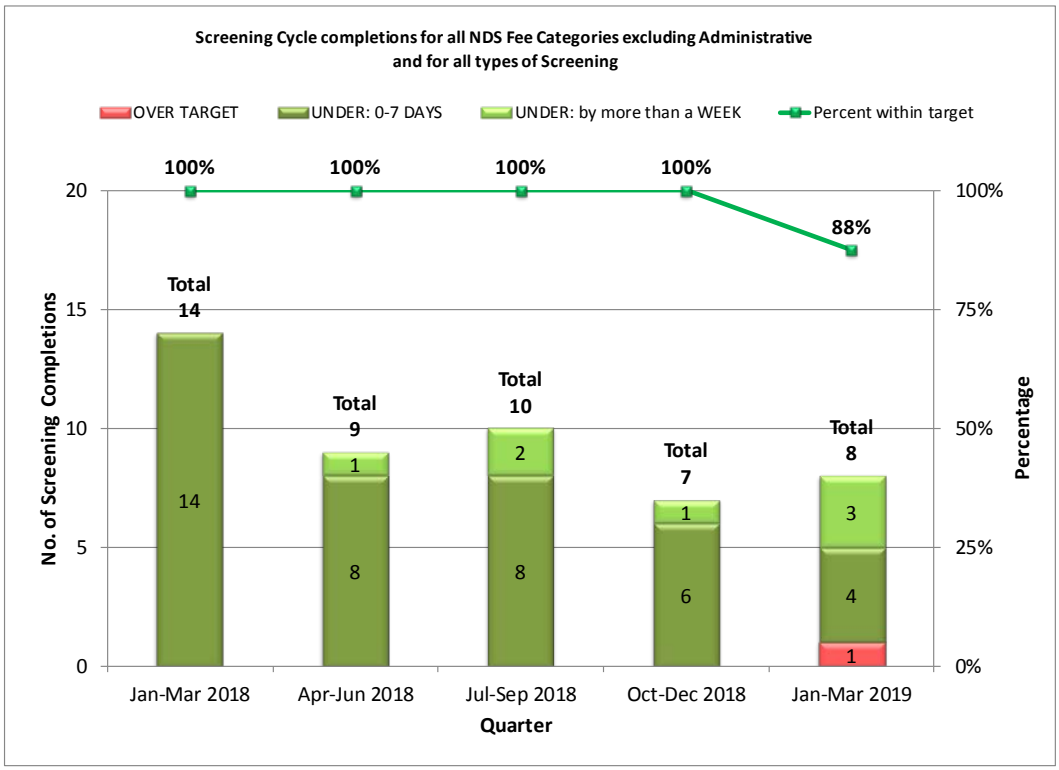


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

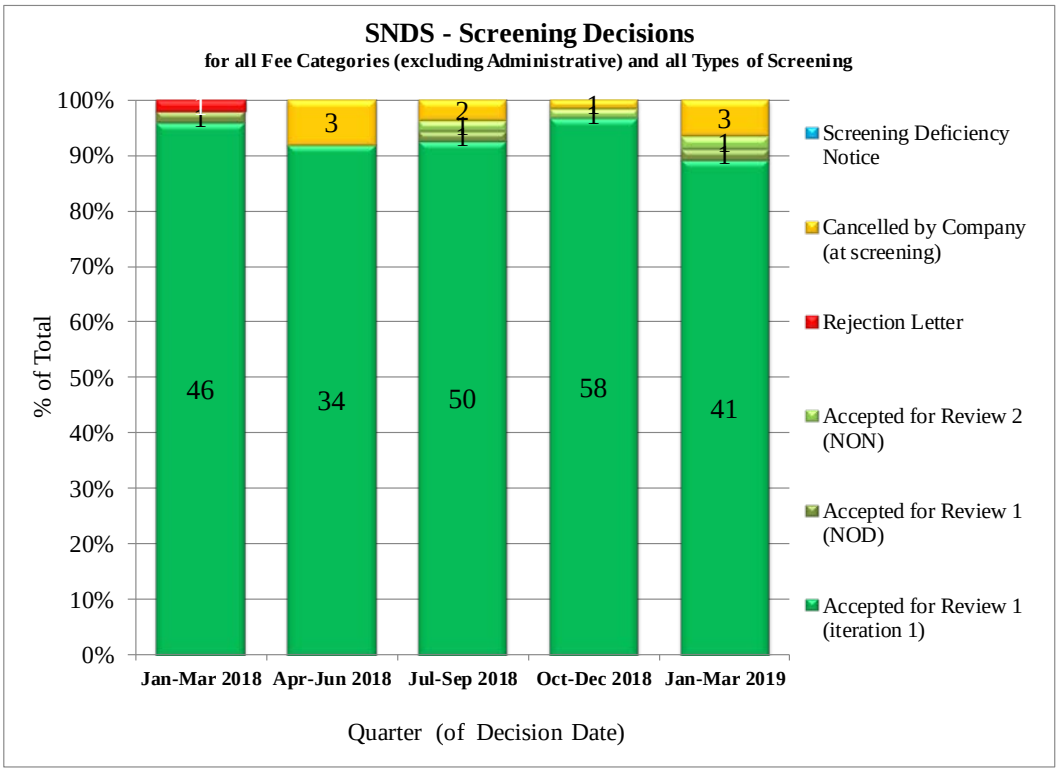


NDS - Screening Cycle Completions Showing Percentage Within Target

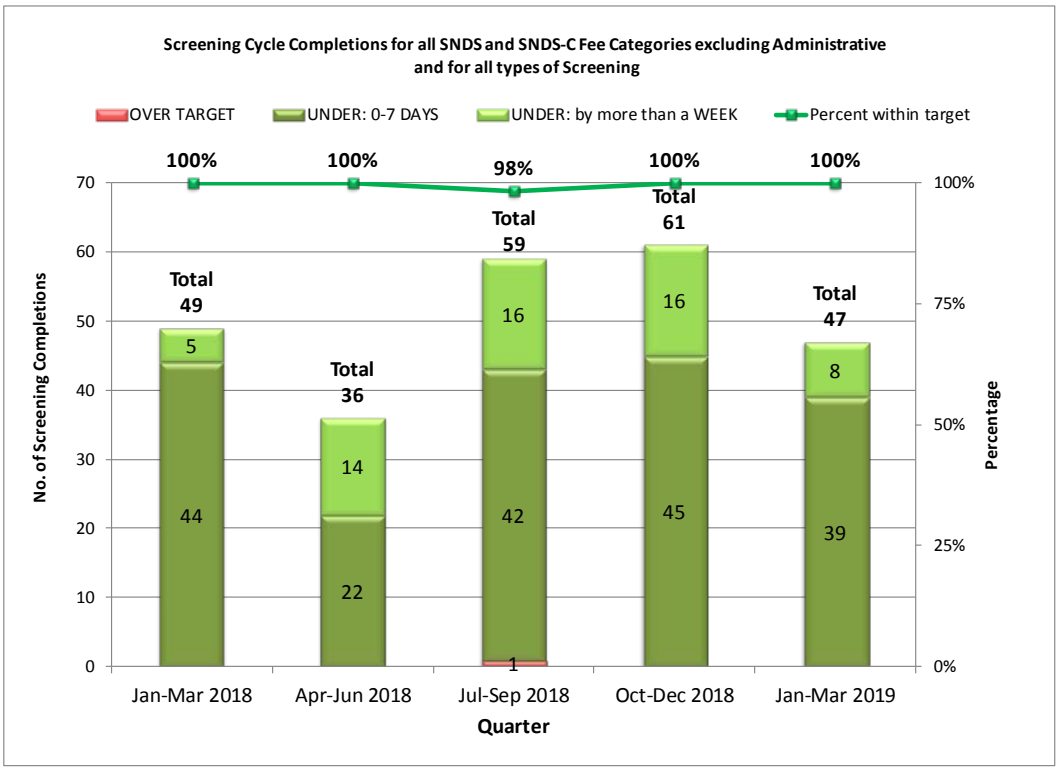


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions

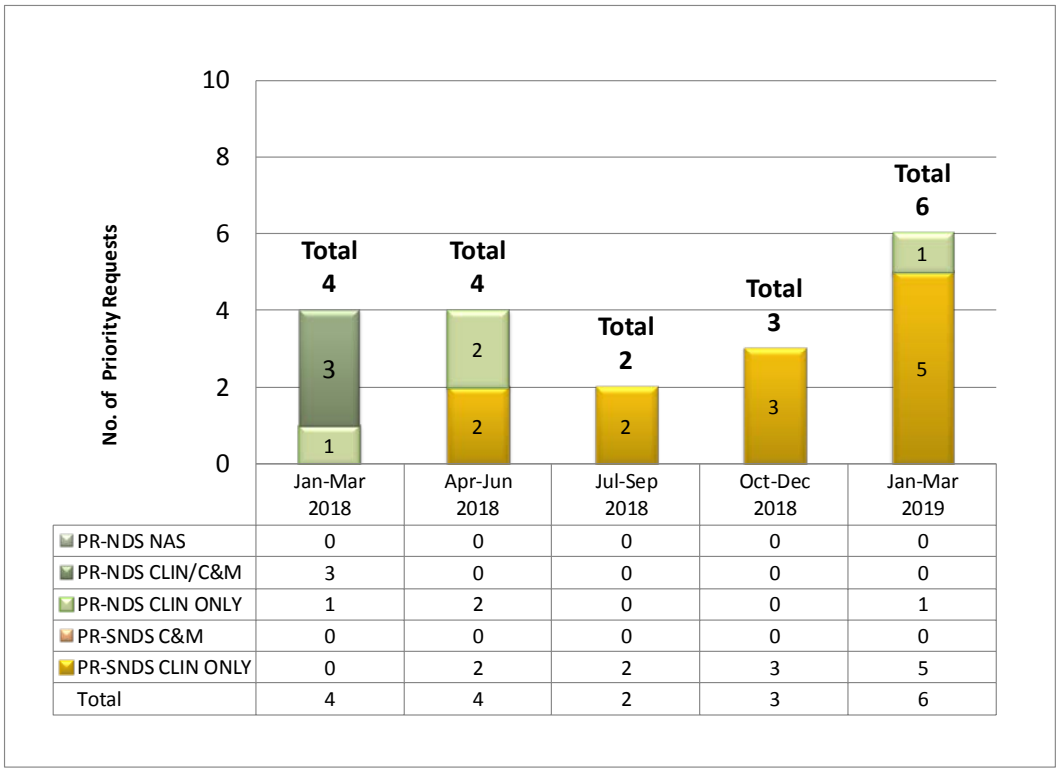


SNDS - Screening Cycle Completions Showing Percentage Within Target



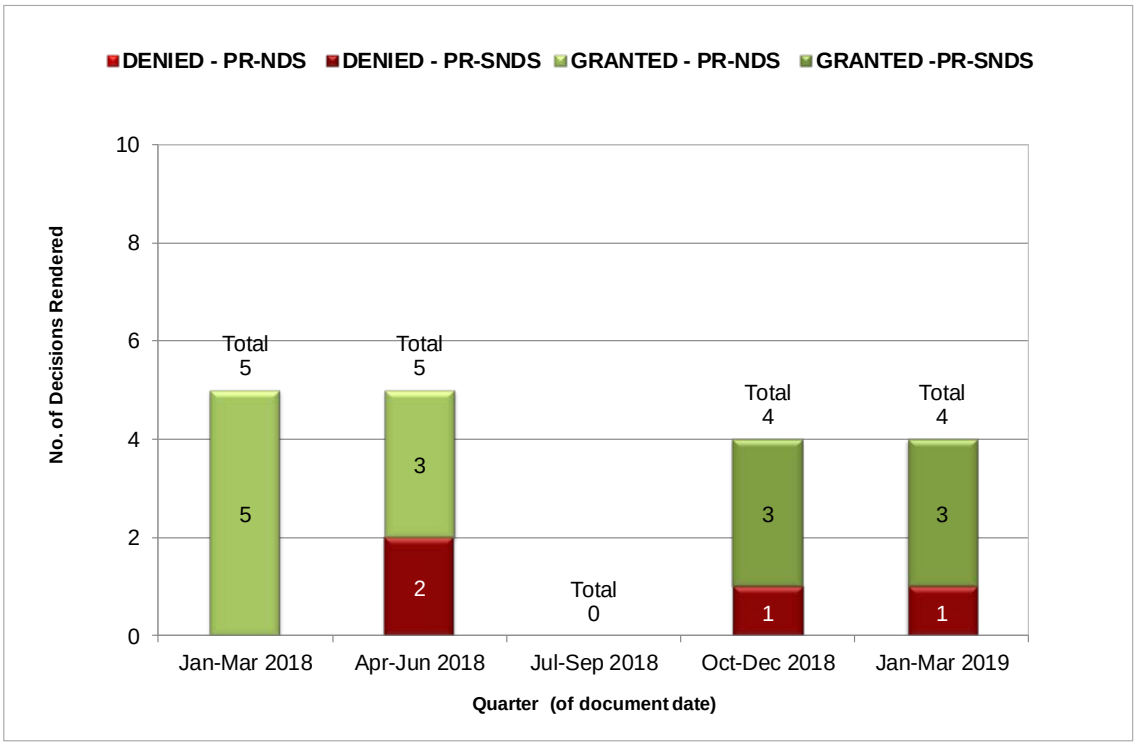
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

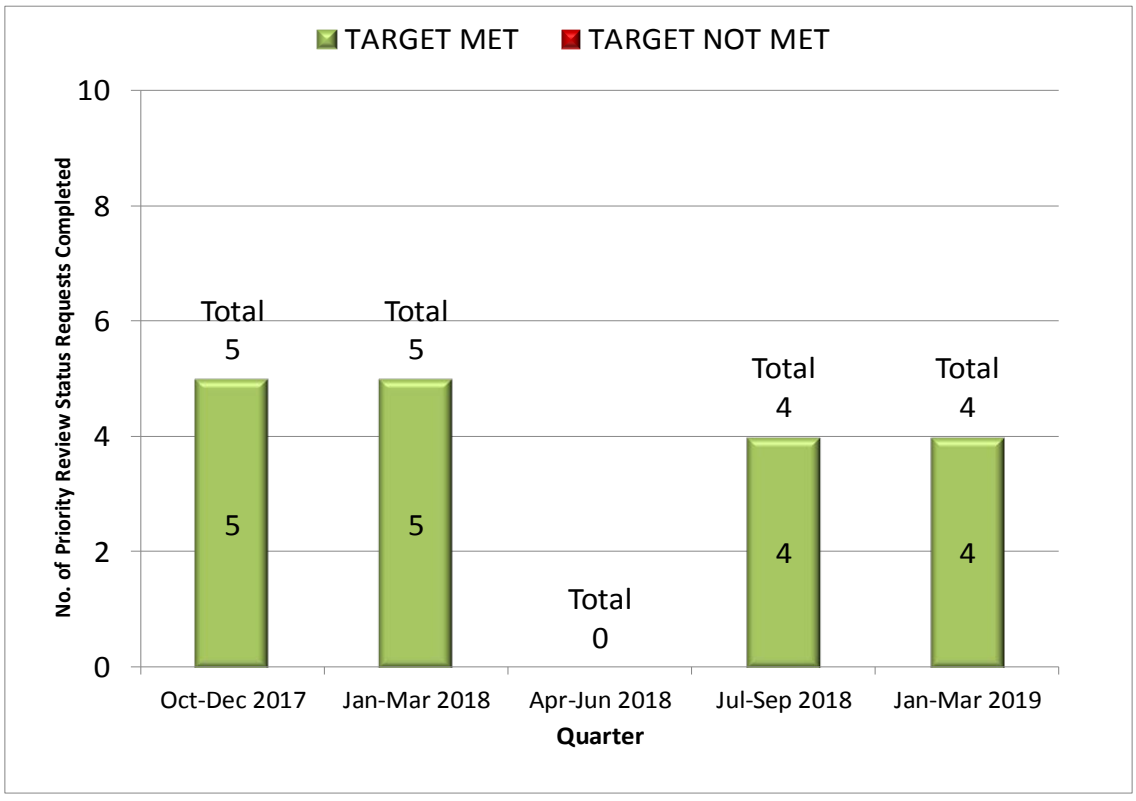


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
PR-NDS NAS	0	0	0	0	0
PR-NDS CLIN/C&M	3	0	0	0	0
PR-NDS CLIN ONLY	1	2	0	0	1
PR-SNDS C&M	0	0	0	0	0
PR-SNDS CLIN ONLY	0	2	2	3	5
Total	4	4	2	3	6

Priority Review Status Requests: Decisions Rendered



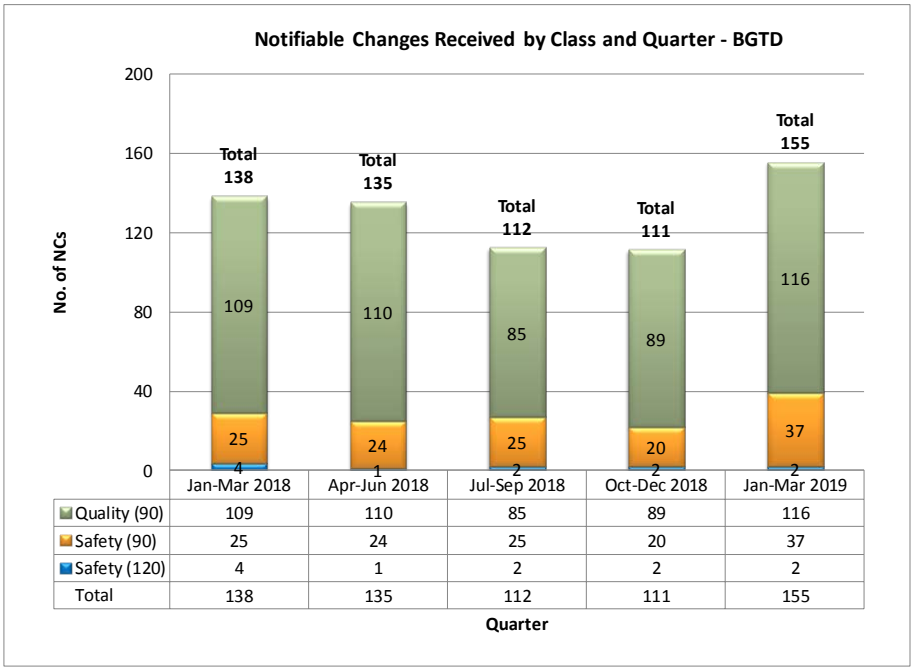
Priority Review Status Request: Performance



Notifiable Changes (NC)

NOTIFIABLE CHANGE

Submissions Received - Notifiable Change (NC)



Decision Documents by Class - Notifiable Change (NC)

NC - SAFETY (90)					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	22	25	26	11	16
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	1	2	0	2	1
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

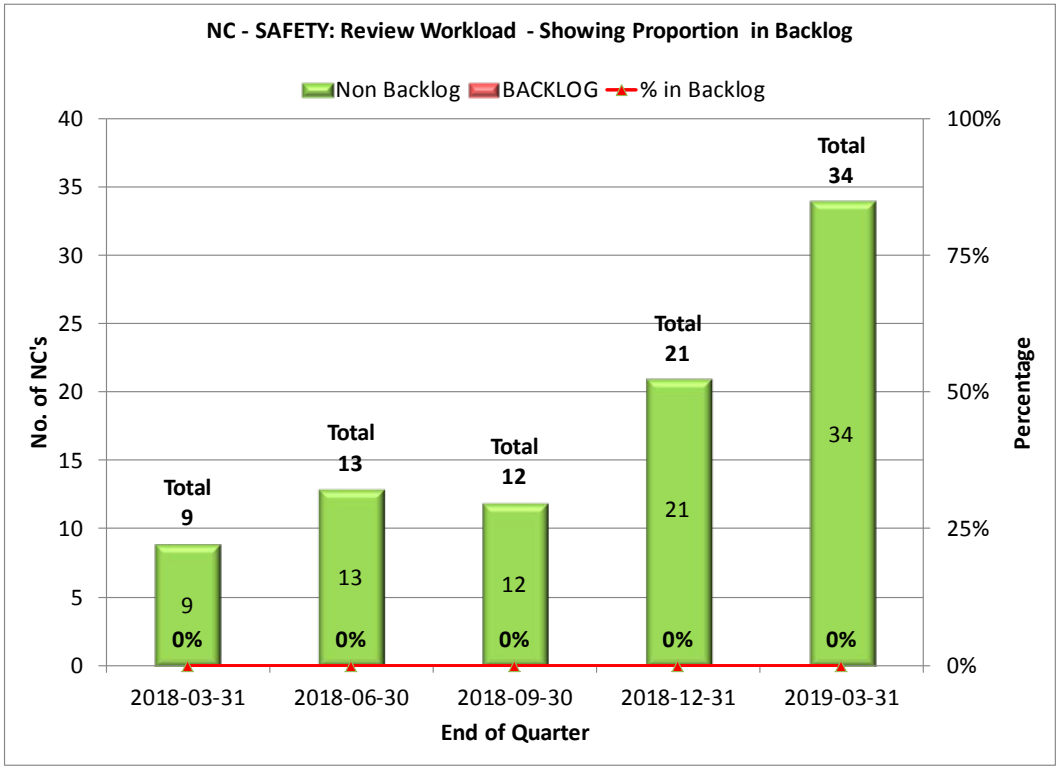
NC - QUALITY (90)					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	85	116	86	79	77
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	11	2	4	1	9
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	4	4	6	2
NC - HOLD (PATENT)	0	0	0	2	1

NC - SAFETY (120)					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	2	1	1	1	3
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	0	1	1	0	0

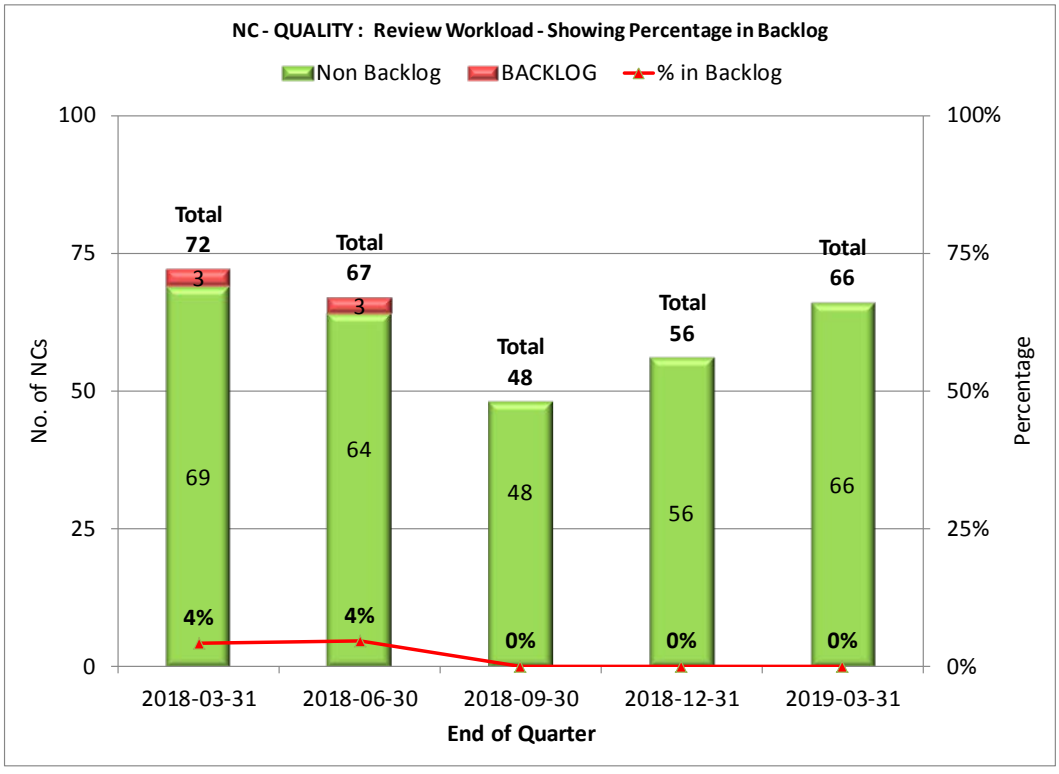
NC - ADMINISTRATIVE					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	4	3	0	1	1
CANCELLED BY COMPANY	0	0	0	0	0

WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload / Backlog



Notifiable Change (NC) QUALITY - Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload by Class

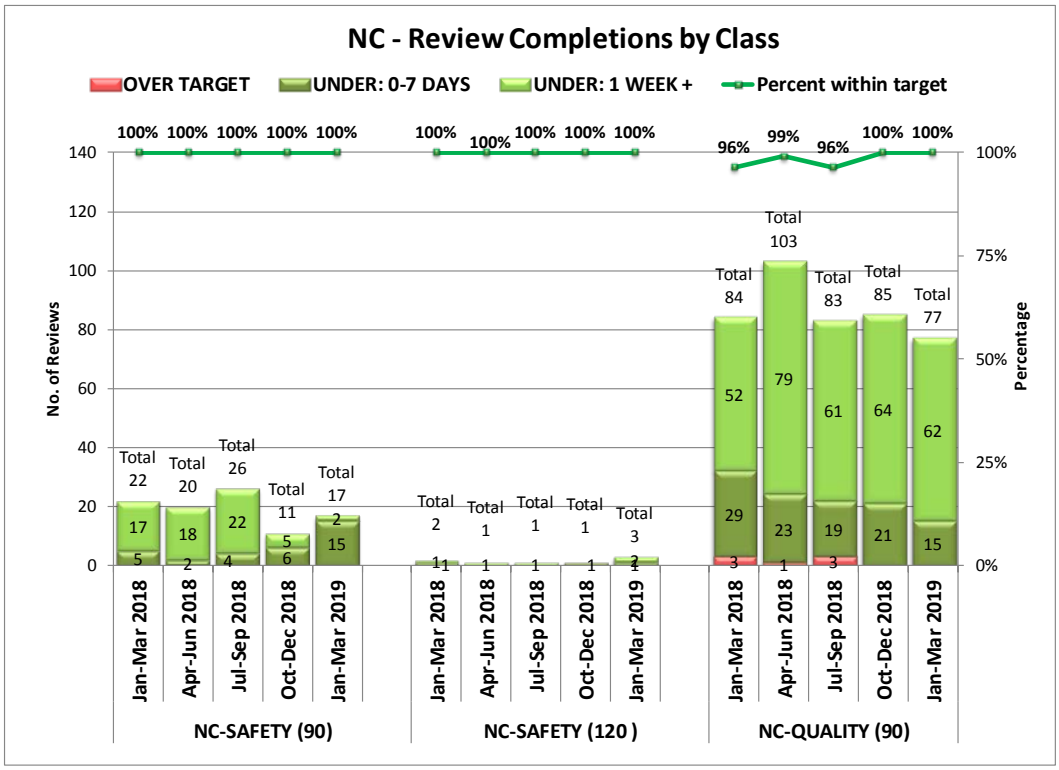
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
SAFETY - 90 day	8	11	10	18	34
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	1	2	2	3	0
Backlog	*0*	*0*	*0*	*0*	*0*
Total	9	13	12	21	34
Non Backlog	9	13	12	21	34
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY - Review Workload by Class

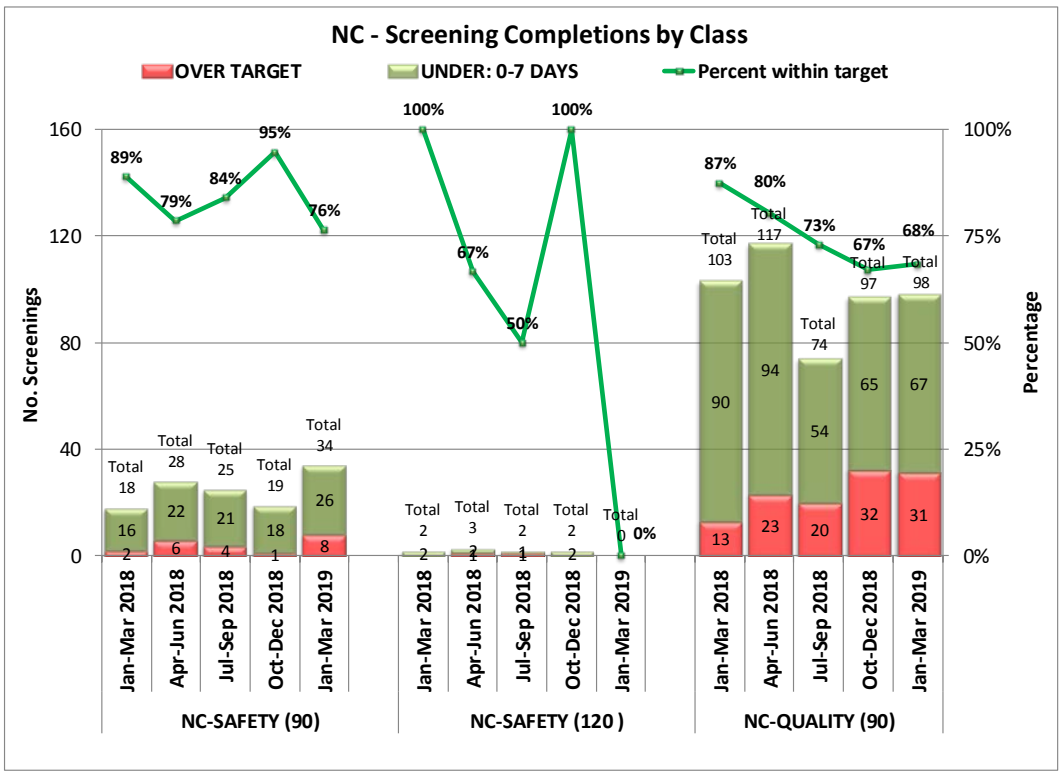
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
QUALITY - 90 day	72	67	48	56	66
Backlog	*3*	*3*	*0*	*0*	*0*
Total	72	67	48	56	66
Non Backlog	69	64	48	56	66
BACKLOG	3	3	0	0	0
% in Backlog	4%	4%	0%	0%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Change (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



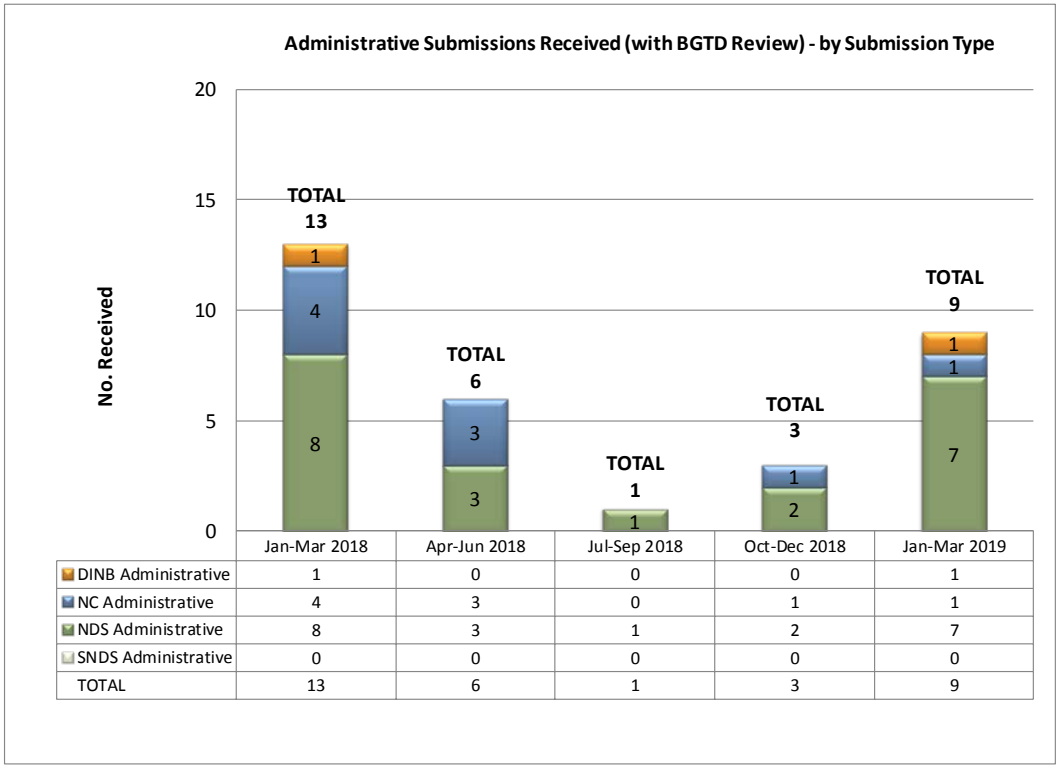
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS (BGTD)

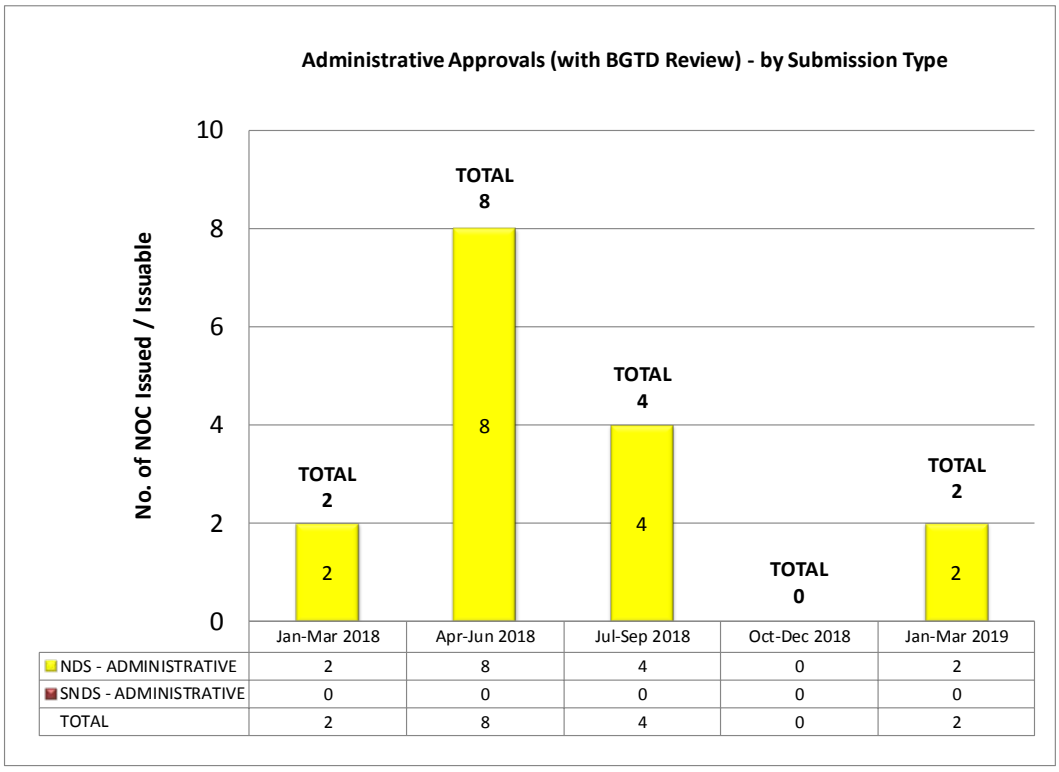
(e.g. product name changes that require a drug name review)

Administrative Submissions Received (with BGTD Review)



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
DINB Administrative	1	0	0	0	1
NC Administrative	4	3	0	1	1
NDS Administrative	8	3	1	2	7
SNDS Administrative	0	0	0	0	0
TOTAL	13	6	1	3	9

Administrative Submission Approvals (with BGTD Review)

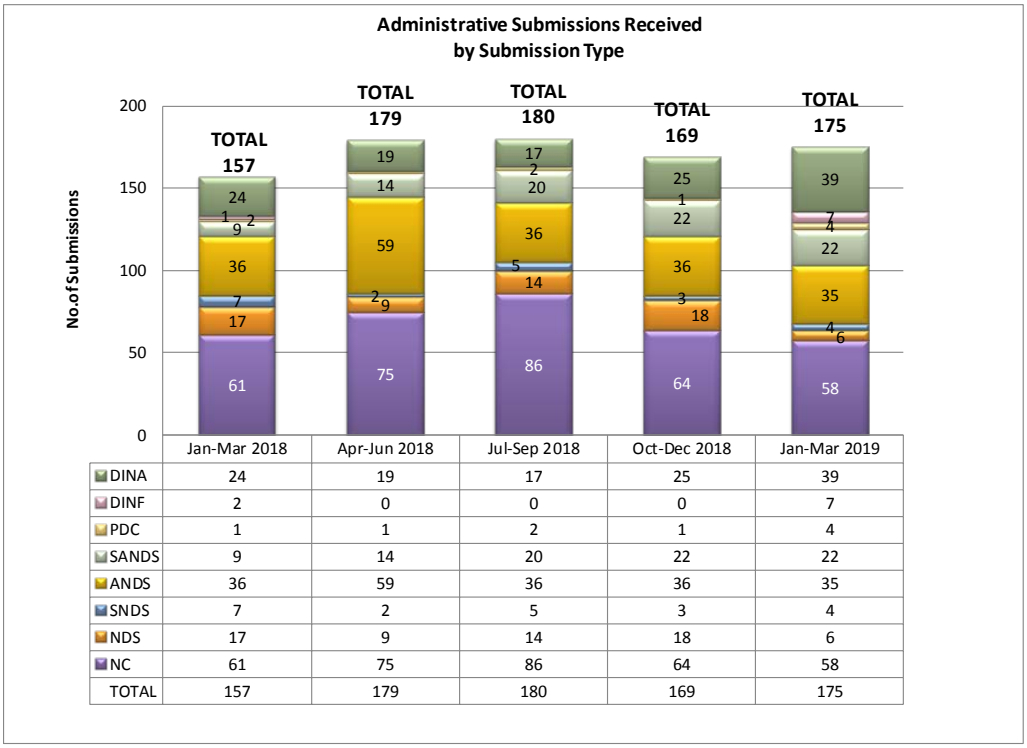


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
NDS - ADMINISTRATIVE	2	8	4	0	2
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	2	8	4	0	2

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

RECEIVED

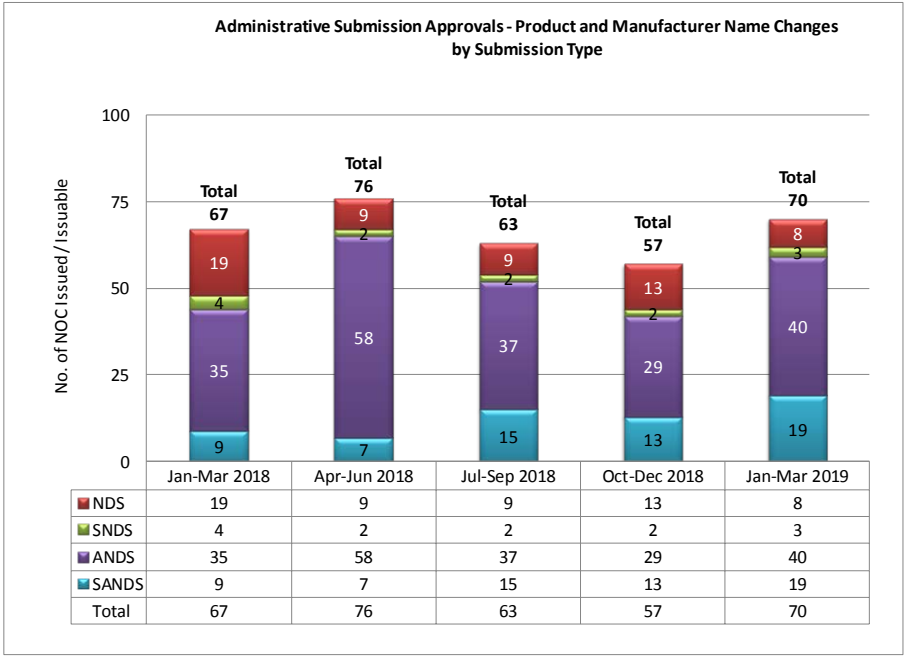
Administrative Submissions Received by Submission Type



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
DINA	24	19	17	25	39
DINF	2	0	0	0	7
PDC	1	1	2	1	4
SANDS	9	14	20	22	22
ANDS	36	59	36	36	35
SNDS	7	2	5	3	4
NDS	17	9	14	18	6
NC	61	75	86	64	58
TOTAL	157	179	180	169	175

APPROVALS

Administrative Submission Approvals * for NDS, SNDS, ANDS and SANDS



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
NDS	19	9	9	13	8
SNDS	4	2	2	2	3
ANDS	35	58	37	29	40
SANDS	9	7	15	13	19
Total	67	76	63	57	70

[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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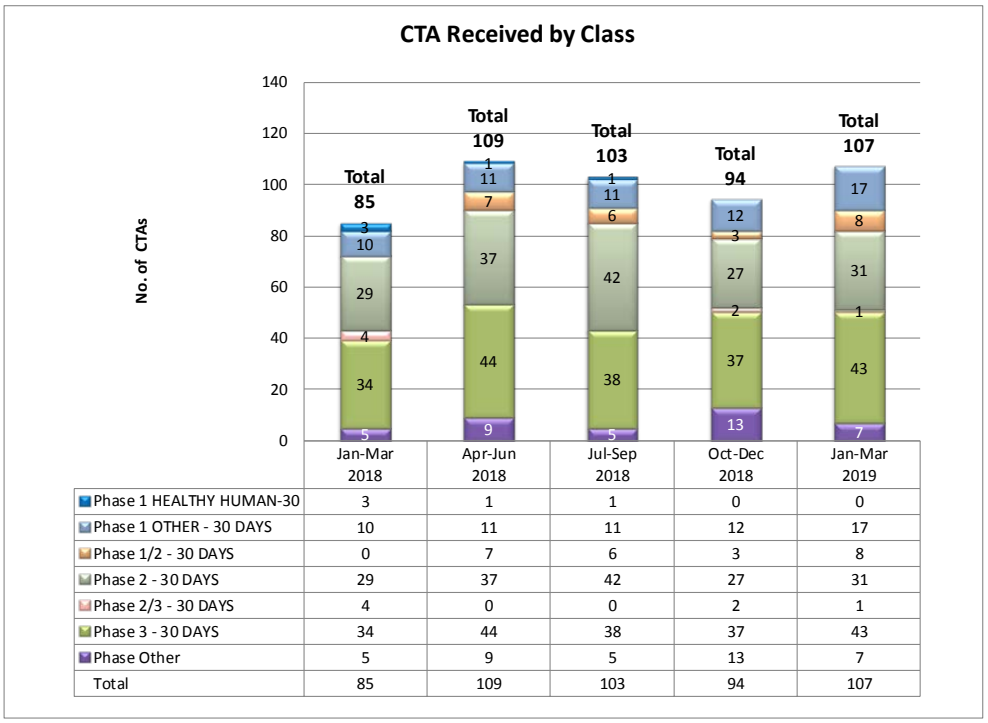
Clinical Trial Applications and Amendments

(CTA & CTA-A)

Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)

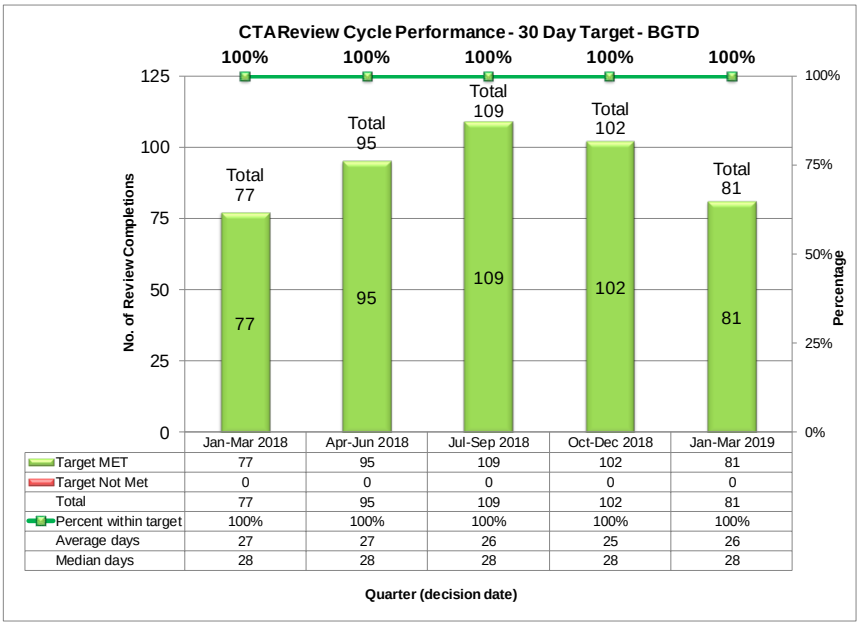


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Phase 1 HEALTHY HUMAN-30	3	1	1	0	0
Phase 1 OTHER - 30 DAYS	10	11	11	12	17
Phase 1/2 - 30 DAYS	0	7	6	3	8
Phase 2 - 30 DAYS	29	37	42	27	31
Phase 2/3 - 30 DAYS	4	0	0	2	1
Phase 3 - 30 DAYS	34	44	38	37	43
Phase Other	5	9	5	13	7
Total	85	109	103	94	107

Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	75	92	108	100	80
CANCELLED BY COMPANY DURING REVIEW	2	3	1	2	1
CANCELLED BY COMPANY AT PROCESSING	3	0	4	2	0
REJECTION LETTER (SCR)	0	0	1	0	1
NOT SATISFACTORY NOTICE	0	0	0	0	1

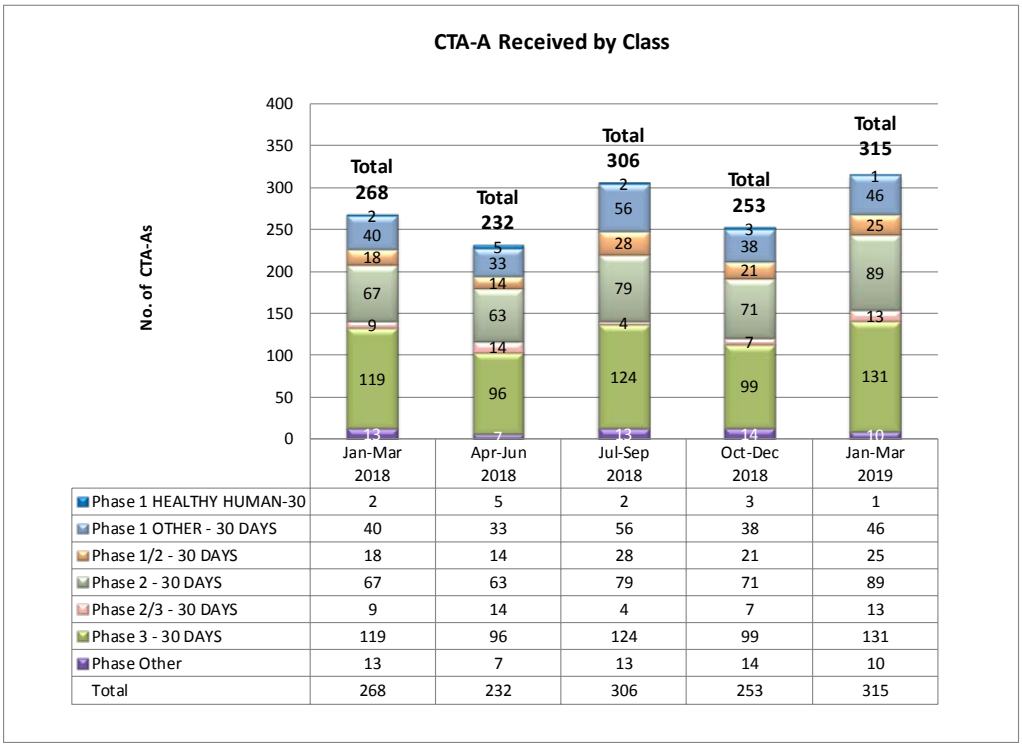
Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Target MET	77	95	109	102	81
Target Not Met	0	0	0	0	0
Total	77	95	109	102	81
Percent within target	100%	100%	100%	100%	100%
Average days	27	27	26	25	26
Median days	28	28	28	28	28

Clinical Trial Application- Amendments (CTA-A)

Number Received - Clinical Trial Application Amendments (CTA-A)

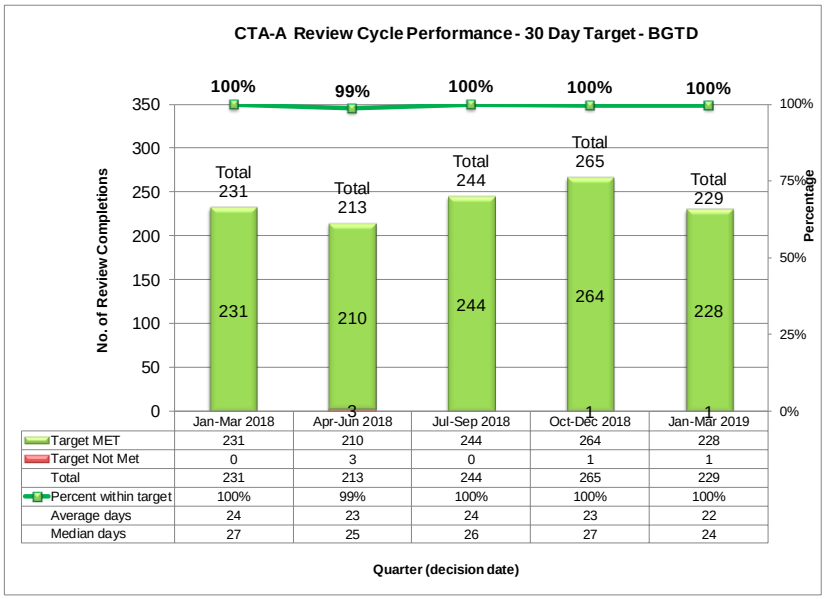


	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Phase 1 HEALTHY HUMAN-30	2	5	2	3	1
Phase 1 OTHER - 30 DAYS	40	33	56	38	46
Phase 1/2 - 30 DAYS	18	14	28	21	25
Phase 2 - 30 DAYS	67	63	79	71	89
Phase 2/3 - 30 DAYS	9	14	4	7	13
Phase 3 - 30 DAYS	119	96	124	99	131
Phase Other	13	7	13	14	10
Total	268	232	306	253	315

Decision Documents - Clinical Trial Application Amendments (CTA-A)

CTA-A					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	240	228	297	279	244
REJECTION LETTER (SCR)	4	7	4	2	7
CANCELLED BY COMPANY DURING REVIEW	2	1	2	0	1
CANCELLED BY COMPANY AT PROCESSING	3	0	2	6	1

Performance – CTA-A Reviews - 30 Day Target



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Target MET	231	210	244	264	228
Target Not Met	0	3	0	1	1
Total	231	213	244	265	229
Percent within target	100%	99%	100%	100%	100%
Average days	24	23	24	23	22
Median days	27	25	26	27	24

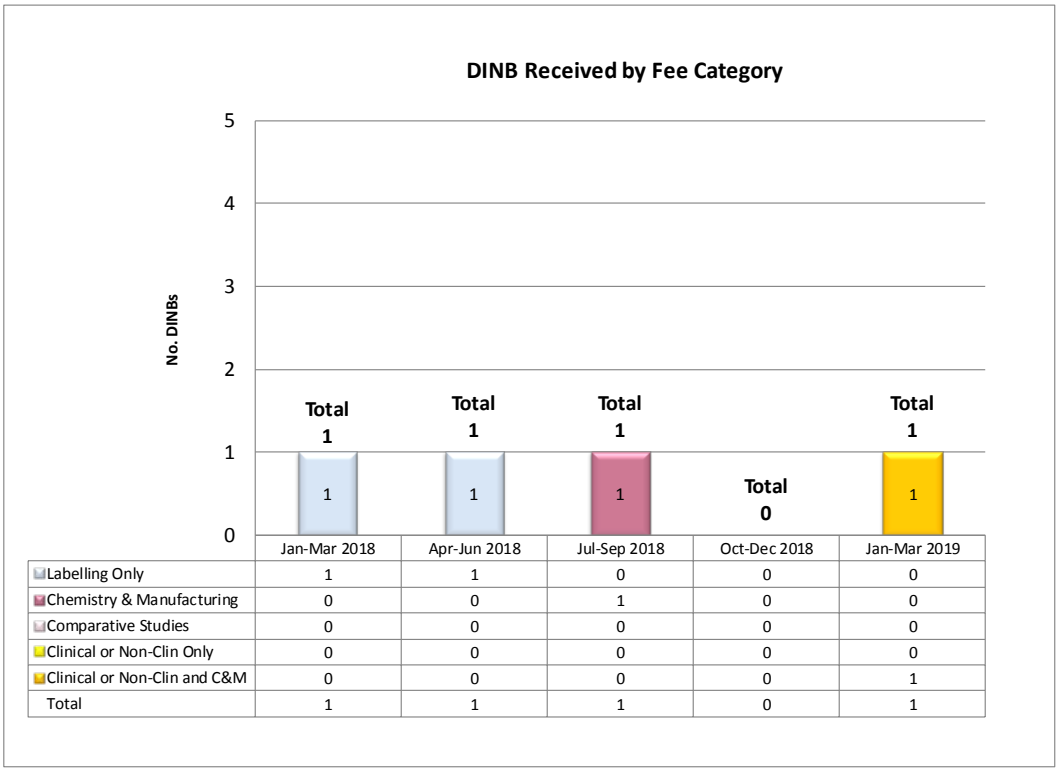
DINB

Application for a Drug Identification Number

Biological Product

DINB: Application for a Drug Identification Number – BIOLOGICAL PRODUCT

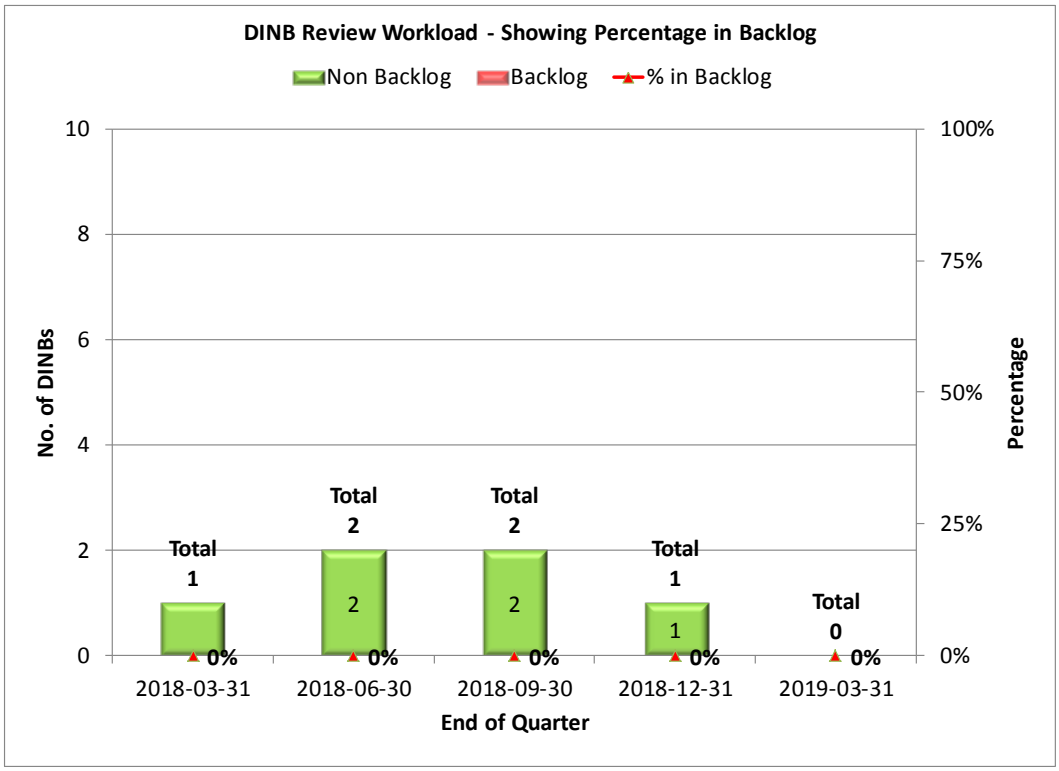
Number Received - DINB



	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Labelling Only	1	1	0	0	0
Chemistry & Manufacturing	0	0	1	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	0	1
Total	1	1	1	0	1

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DINB

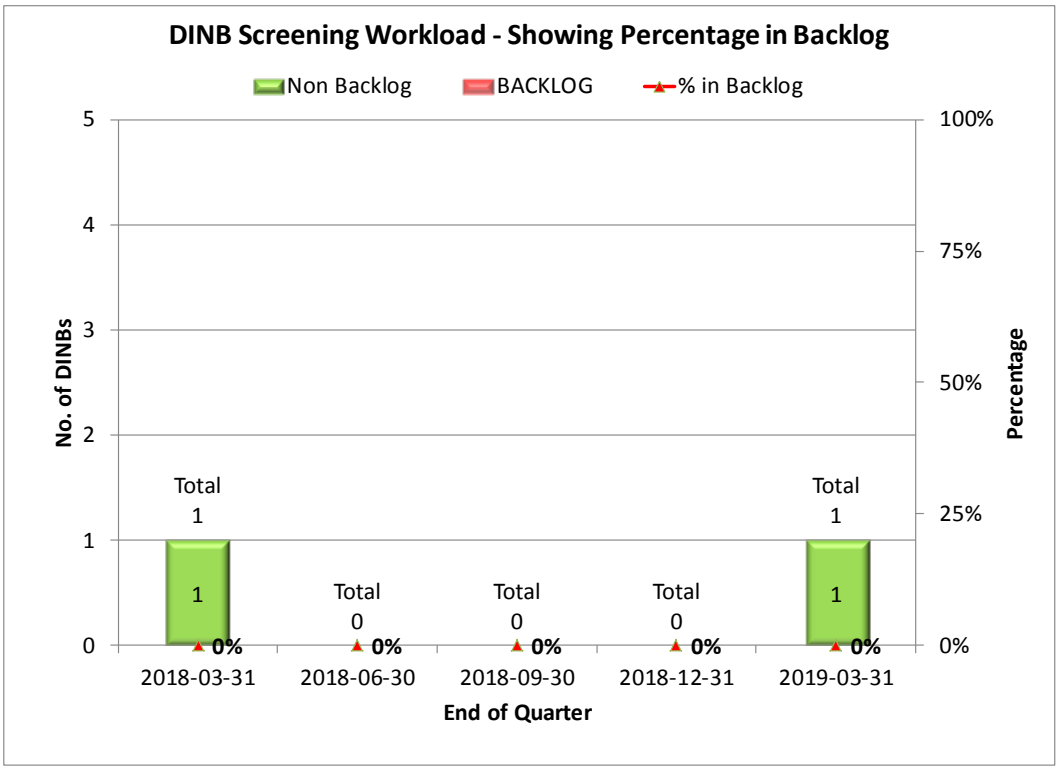


Review Workload by Class - DINB

BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**1**	**1**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**0**	**1**	**2**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**2**	**2**	**1**	**0**
Non Backlog	**1**	**2**	**2**	**1**	**0**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog - DINB



Screening Workload by Class - DINB

BGTD DINB All SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Only	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Form & Supporting Data	**0**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**0**	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**1**	**0**	**0**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**0**	**0**	**0**	**1**
Non Backlog	**1**	**0**	**0**	**0**	*1*
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINB by Class

DINB - Labelling Only					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 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	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

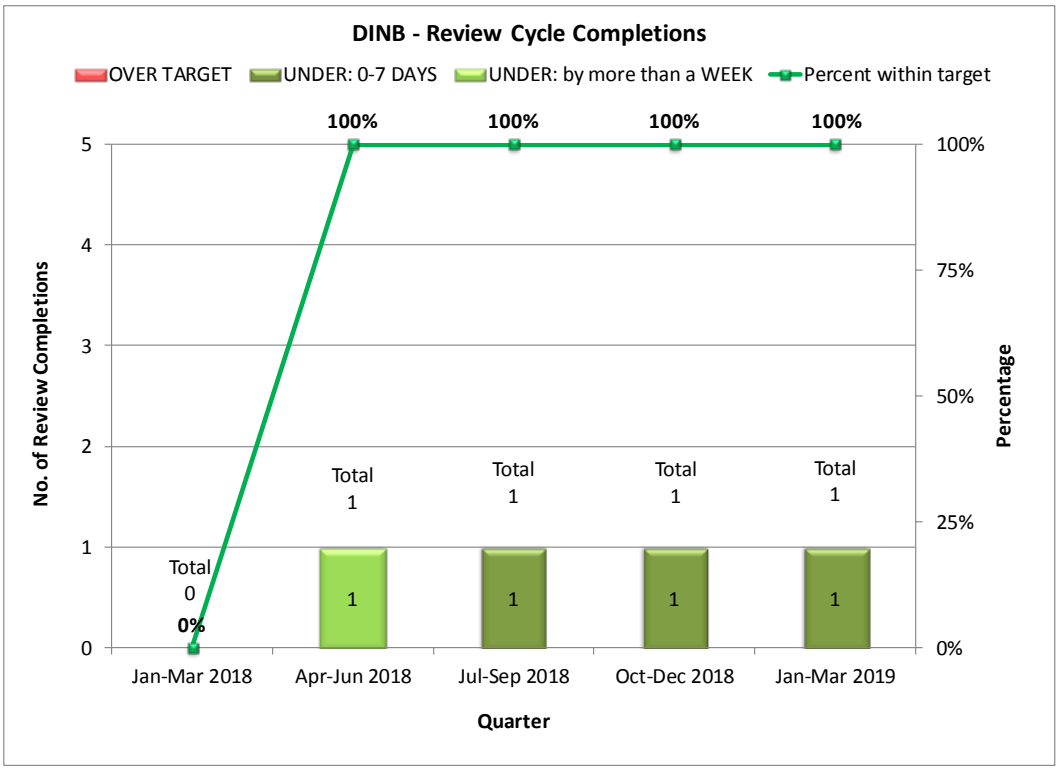
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

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

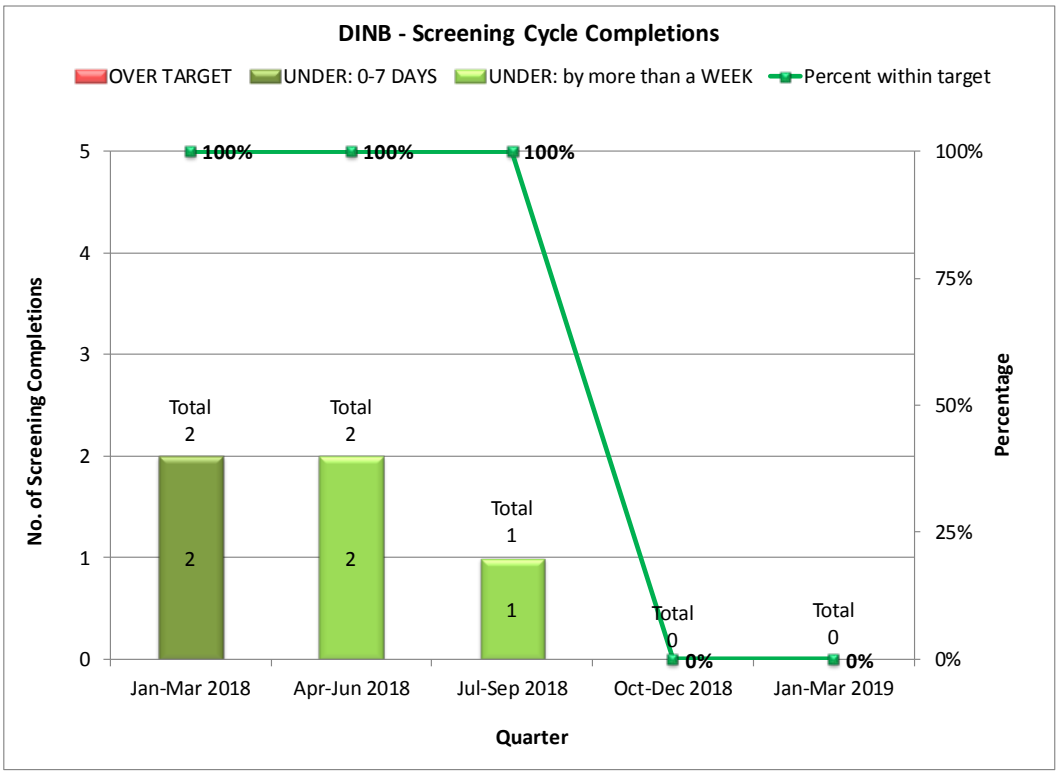
DINB - Administrative					
DOCUMENT TYPE	**Jan-Mar 2018**	**Apr-Jun 2018**	**Jul-Sep 2018**	**Oct-Dec 2018**	**Jan-Mar 2019**
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target - DINB

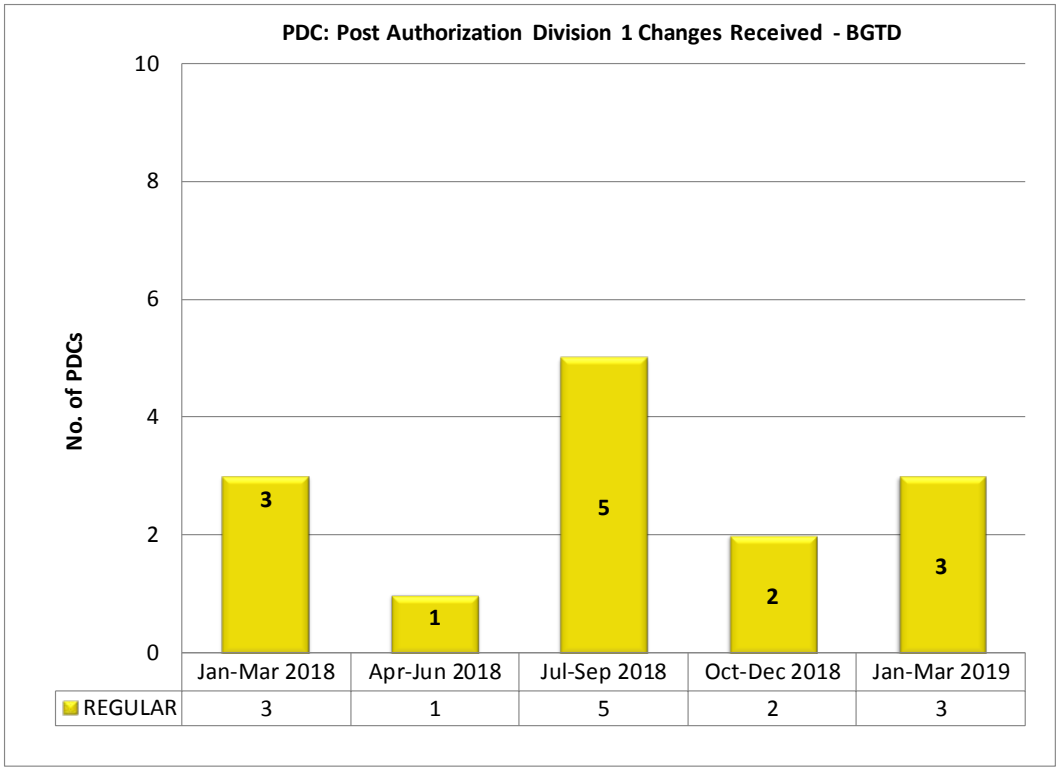


Performance Screening Cycle Completions Showing Percentage Within Target - DINB



Post –Authorization Division 1 Changes - Biologics (PDC-B)

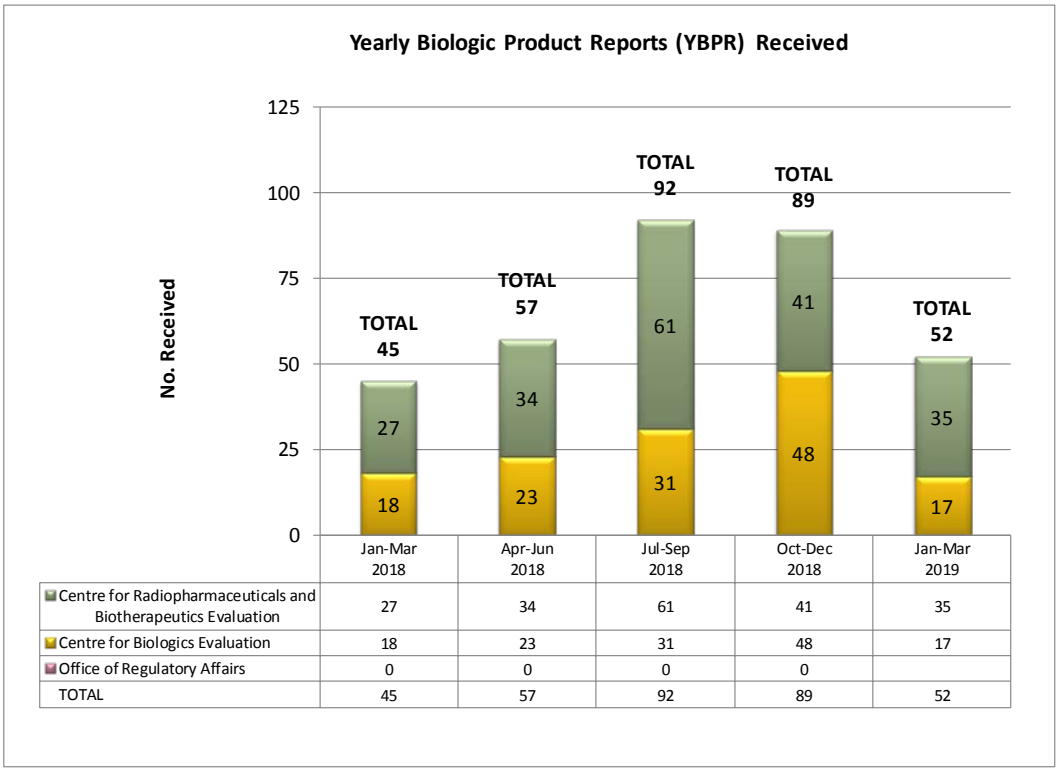
Post –Authorization Division 1 Changes - Biologics (PDC-B) Received



Yearly Biologic Product Reports (YBPR)

[13])

Yearly Biologic Product Report s (YBPR) Received



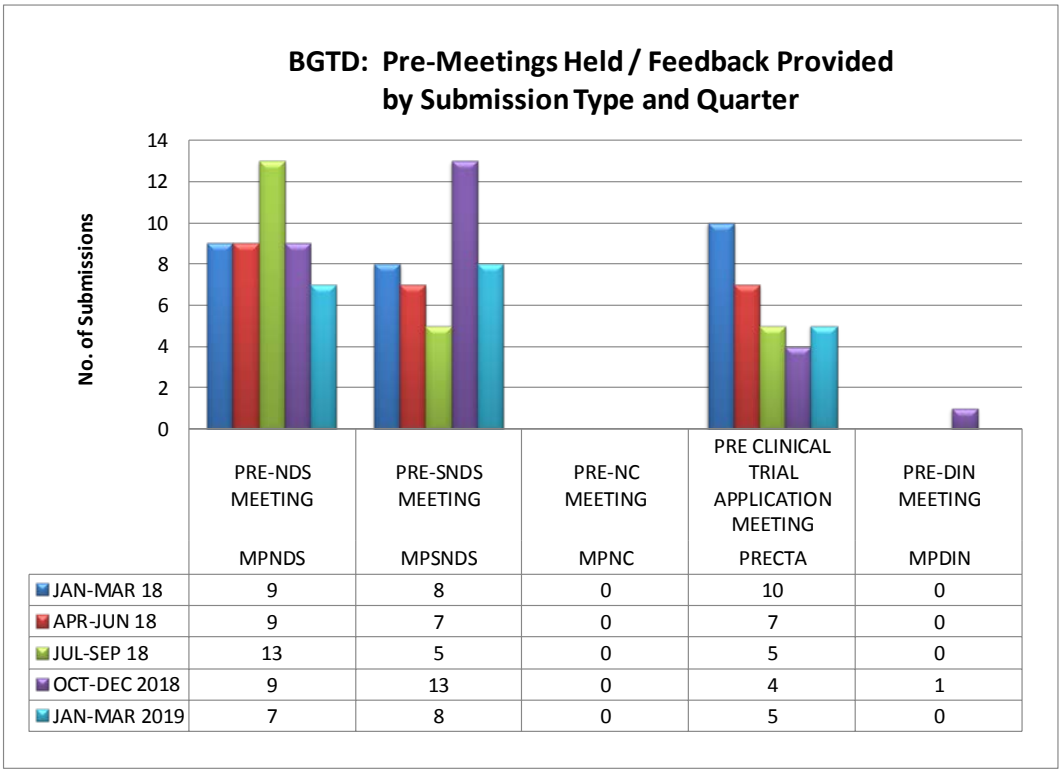
	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Centre for Radiopharmaceuticals and Biotherapeutics Evaluation	27	34	61	41	35
Centre for Biologics Evaluation	18	23	31	48	17
Office of Regulatory Affairs	0	0	0	0	
TOTAL	45	57	92	89	52

[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
JAN-MAR 18	9	8	0	10	0
APR-JUN 18	9	7	0	7	0
JUL-SEP 18	13	5	0	5	0
OCT-DEC 2018	9	13	0	4	1
JAN-MAR 2019	7	8	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