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# Biologics and Genetic Therapies Directorate

Drug Submission Performance Quarterly  
Report

July - September  
2019



**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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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 July – September 2018 to July – September 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<sup>1</sup> 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**<sup>2</sup> 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.

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<sup>1</sup> For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#)

<sup>2</sup> 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**<sup>3</sup> 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](#)<sup>4</sup> 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”<sup>5</sup> submissions.

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

Office of Submissions and Intellectual Property, Resource Management and Operations  
Directorate  
Finance Building, A.L. # 0202A1  
101 Tunney’s Pasture Driveway, Tunney’s Pasture  
Ottawa, Ontario, K1A 0K9

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Email: [hc.osip-bppi.sc@canada.ca](mailto:hc.osip-bppi.sc@canada.ca)

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<sup>3</sup> 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.

<sup>4</sup> 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).

<sup>5</sup> 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
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
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
<b>New Active Substance (NAS)</b>	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.
<b>Clinical or Non-Clinical Data and Chemistry and Manufacturing data</b>	Submissions based on clinical or non-clinical data <b>and</b> chemistry and manufacturing data for a drug that does not include a NAS.
<b>Clinical or Non-Clinical Data Only</b>	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
<b>Comparative Studies</b>	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.
<b>Chemistry and Manufacturing Data Only</b>	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
<b>Published Data Only</b>	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
<b>Switch from Prescription to Nonprescription Status</b>	Submissions based only on data that support the modification or removal of a medicinal ingredient on the <a href="#">Prescription Drug List</a> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
<b>Labelling Only<sup>6</sup></b>	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
<b>Administrative Submission</b>	Submissions in support of a manufacturer or product name change.
<b>Disinfectants<sup>7</sup></b>	Submissions and applications that include data in support of a disinfectant.
<b>Drug Identification Number (DIN) - Labelling Standards</b>	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](#)

<sup>6</sup> For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

<sup>7</sup> The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from the Therapeutic Products Directorate (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.

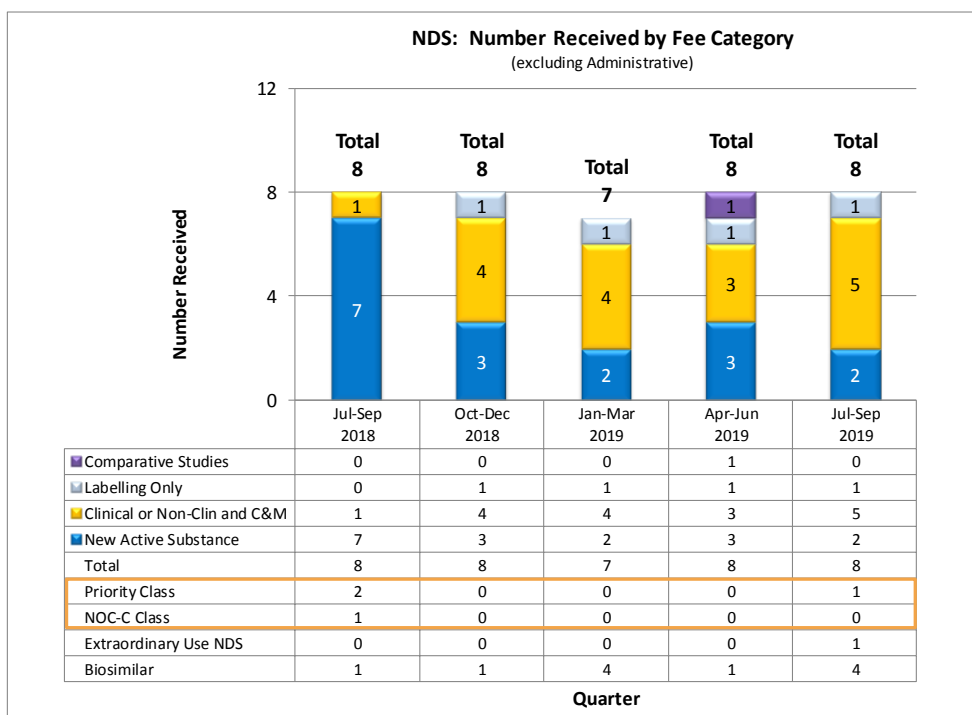
**New Drug Submissions  
(NDS)**

**&**

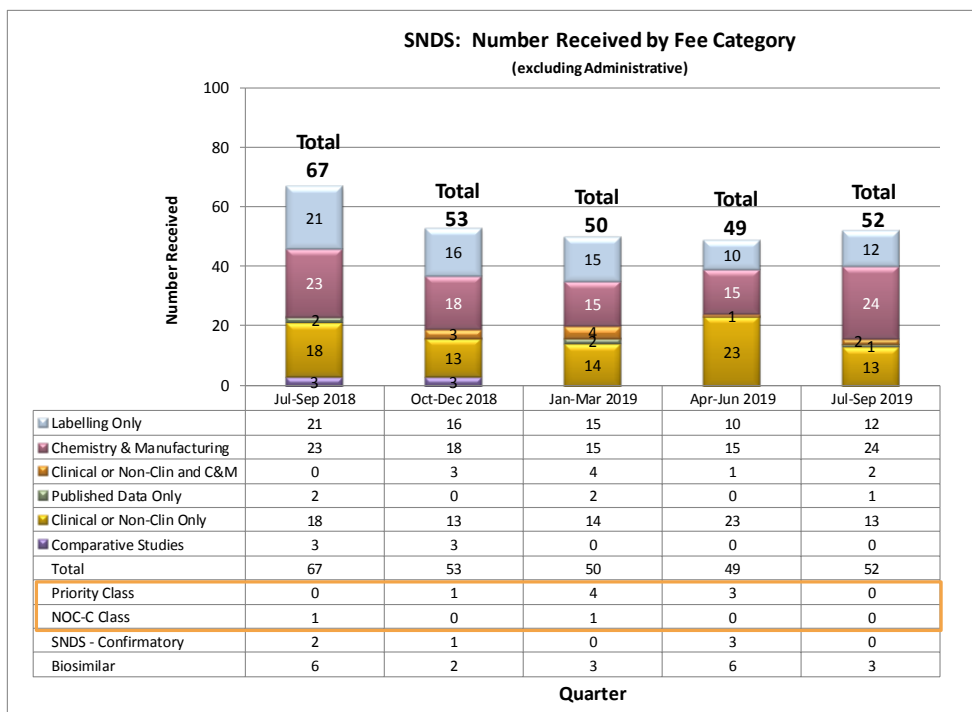
**Supplemental New Drug Submissions  
(SNDS)**

## SUBMISSIONS RECEIVED<sup>8,9</sup>

### NDS: Received by Fee Category



### SNDS: Received by Fee Category

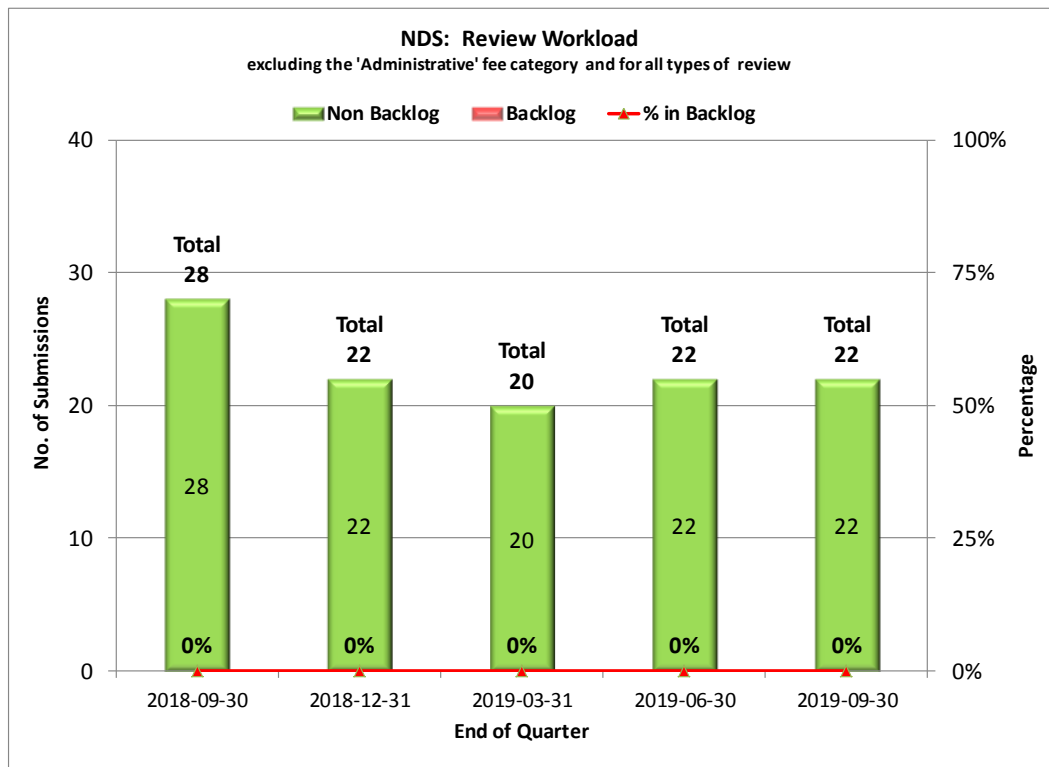


<sup>8</sup> **Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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

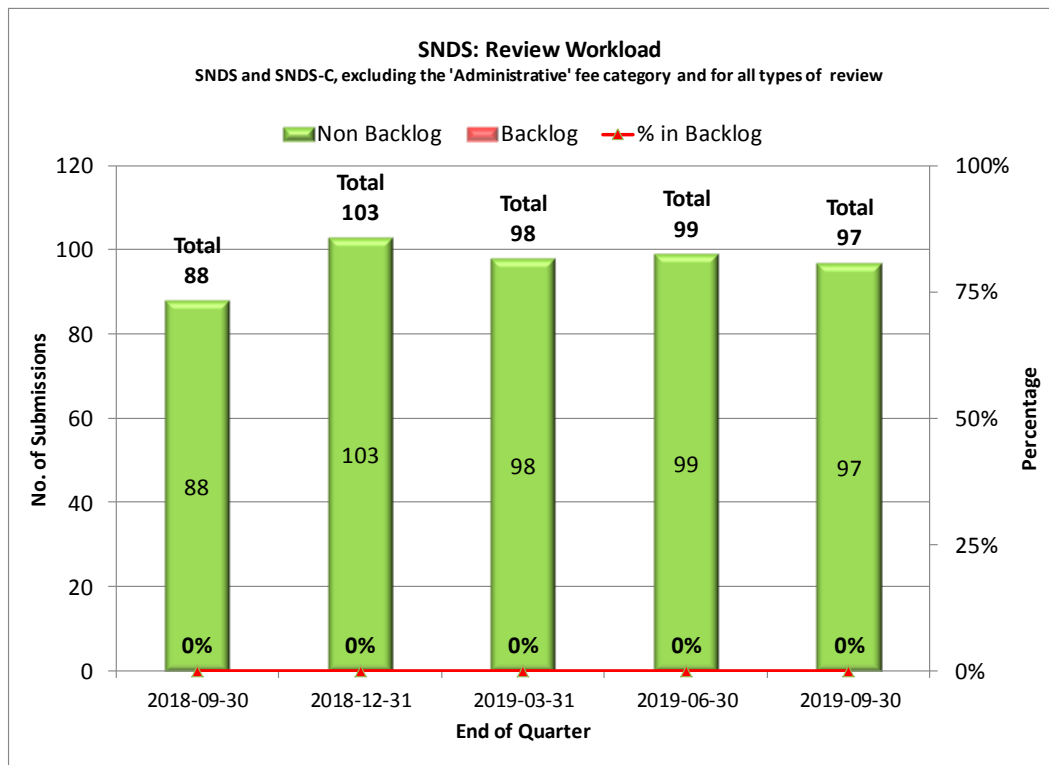
<sup>9</sup> Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the [Priority Review of Drug Submissions Policy](#), the [Notice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

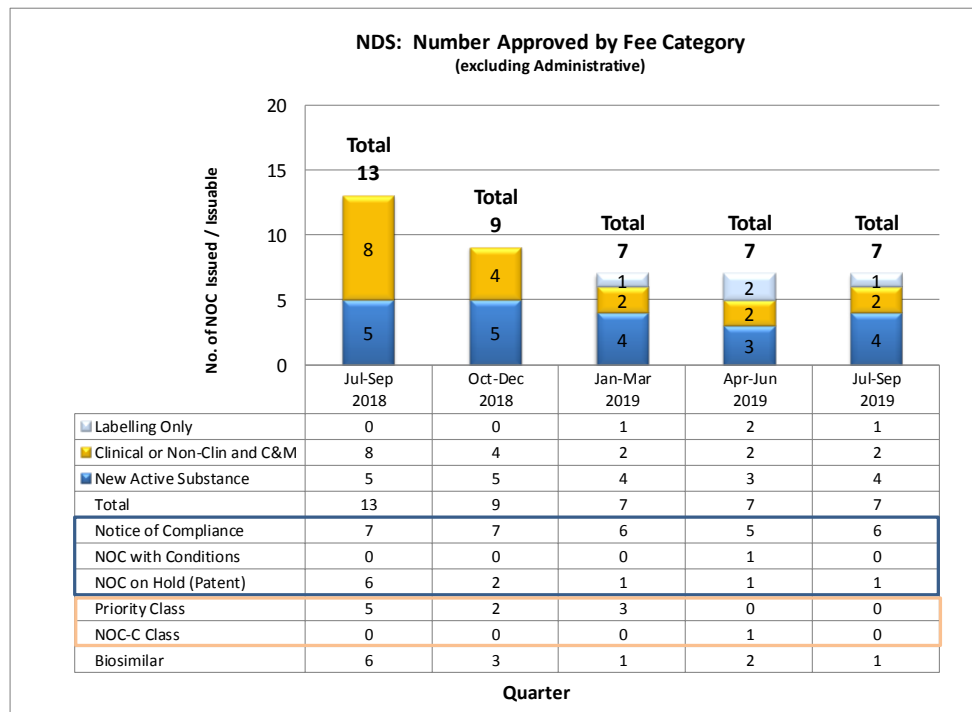
NDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Clinical or Non-Clin and C&M	14	9	10	12	14
Backlog	0	0	0	0	0
New Active Substance	14	12	10	9	7
Backlog	0	0	0	0	0
<b>Total</b>	<b>28</b>	<b>22</b>	<b>20</b>	<b>22</b>	<b>22</b>
Non Backlog	28	22	20	22	22
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	5	3	0	0	1
Backlog	0	0	0	0	0

### SNDS: Review Workload by Fee Category

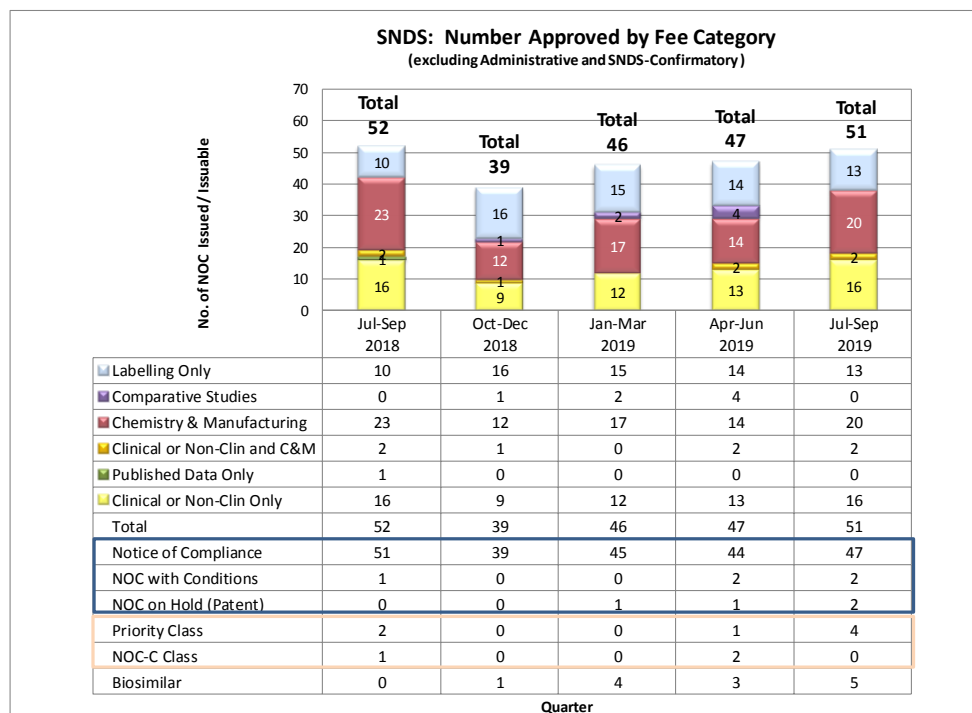
SNDS: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Comparative Studies	3	6	4	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	22	29	26	25	25
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	48	48	49	54	55
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	2	4	6	7	6
Backlog	0	0	0	0	0
Published Data	1	3	3	4	4
Backlog	0	0	0	0	0
Labelling Only	12	13	10	9	7
Backlog	0	0	0	0	0
<b>Total</b>	<b>88</b>	<b>103</b>	<b>98</b>	<b>99</b>	<b>97</b>
Non Backlog	88	103	98	99	97
Backlog	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%
Priority (subset)	0	1	4	7	3
Backlog	0	0	0	0	0
SNDS-C (Confirmatory)	6	6	5	4	4
Backlog	0	0	0	0	0

## APPROVALS<sup>10 11</sup>

### NDS: Number Approved by Fee Category and NOC Type



### SNDS: Number Approved by Fee Category and NOC Type



<sup>10</sup> 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](#).

<sup>11</sup> **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 Market Authorization for NDS & SNDS by Quarter

Submission Type	Class	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NDS	CLIN/C&M	0	1	0	3	2
<b>NDS Total</b>		<b>0</b>	<b>1</b>	<b>0</b>	<b>3</b>	<b>2</b>
SNDS	C&M ONLY	0	0	2	1	1
	C&M/LABELLING	0	0	0	0	0
	CLIN ONLY	0	0	1	1	1
	CLIN/C&M	0	0	0	0	0
	COMP/C&M	0	1	0	0	0
	LABELLING ONLY	0	0	0	0	3
<b>SNDS Total</b>		<b>0</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>5</b>

### Biosimilars: NDS & SNDS Market Authorizations in Q1-Q2 FY 2019-20

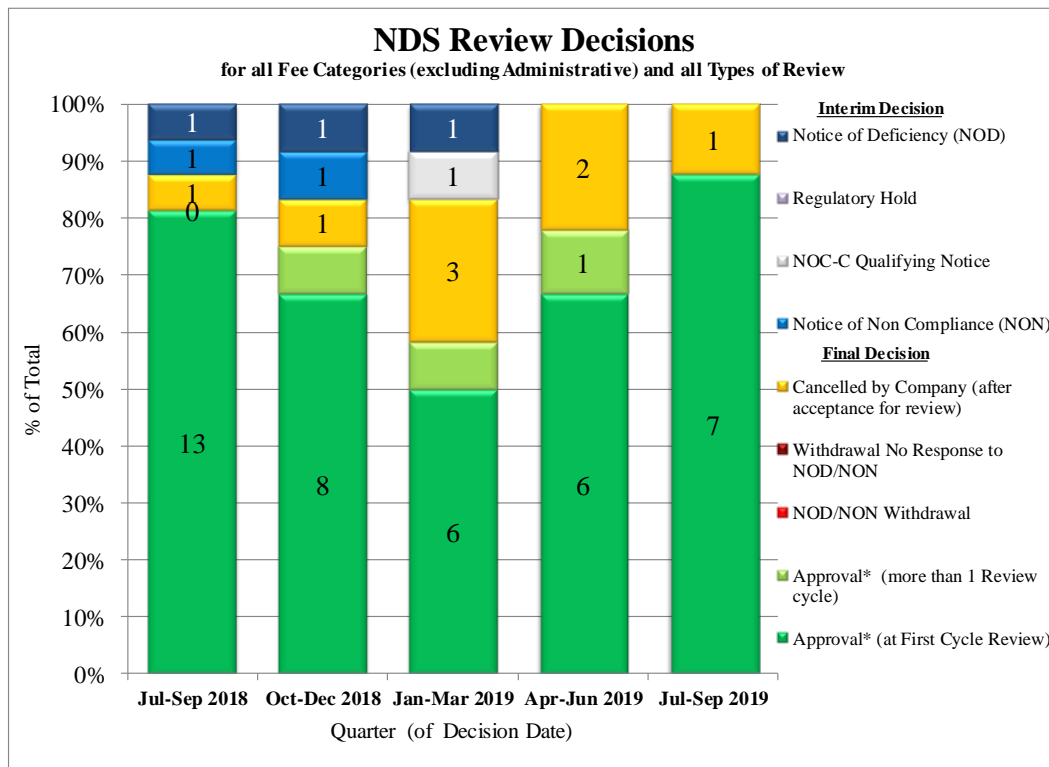
Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2019-20	Notice of Compliance (NOC) Date
NDS	HERZUMA	CLIN/C&M	CELLTRION HEALTHCARE CO LTD	TRASTUZUMAB	Q2	2019-Sep-03
	OGIVRI	CLIN/C&M	BGP PHARMA ULC	TRASTUZUMAB	Q1	2019-May-03
	TRAZIMERA	CLIN/C&M	PFIZER CANADA ULC	TRASTUZUMAB	Q2	2019-Aug-15
	TRUXIMA	CLIN/C&M	CELLTRION HEALTHCARE CO LTD	RITUXIMAB	Q1	2019-Apr-04
	ZIRABEV	CLIN/C&M	PFIZER CANADA ULC	BEVACIZUMAB	Q1	2019-Jun-14
<b>New Drug Submission Total</b>						<b>5</b>
SNDS	HERZUMA	LABELLING ONLY	CELLTRION HEALTHCARE CO LTD	TRASTUZUMAB	Q2	2019-09-03
	INFLECTRA	CLIN ONLY	CELLTRION HEALTHCARE CO LTD	INFLIXIMAB	Q2	2019-Aug-28
	INFLECTRA	C&M ONLY	CELLTRION HEALTHCARE CO LTD	INFLIXIMAB	Q2	2019-Jul-18
	MVASI	C&M ONLY	AMGEN CANADA INC.	BEVACIZUMAB	Q1	2019-Apr-02
	MVASI	CLIN ONLY	AMGEN CANADA INC.	BEVACIZUMAB	Q1	2019-Jun-05
	TRAZIMERA	LABELLING ONLY	PFIZER CANADA ULC	TRASTUZUMAB	Q2	2019-Aug-15
	TRUXIMA	LABELLING ONLY	CELLTRION HEALTHCARE CO LTD	RITUXIMAB	Q2	2019-Sep-22
<b>Supplemental New Drug Submission Total</b>						<b>7</b>

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

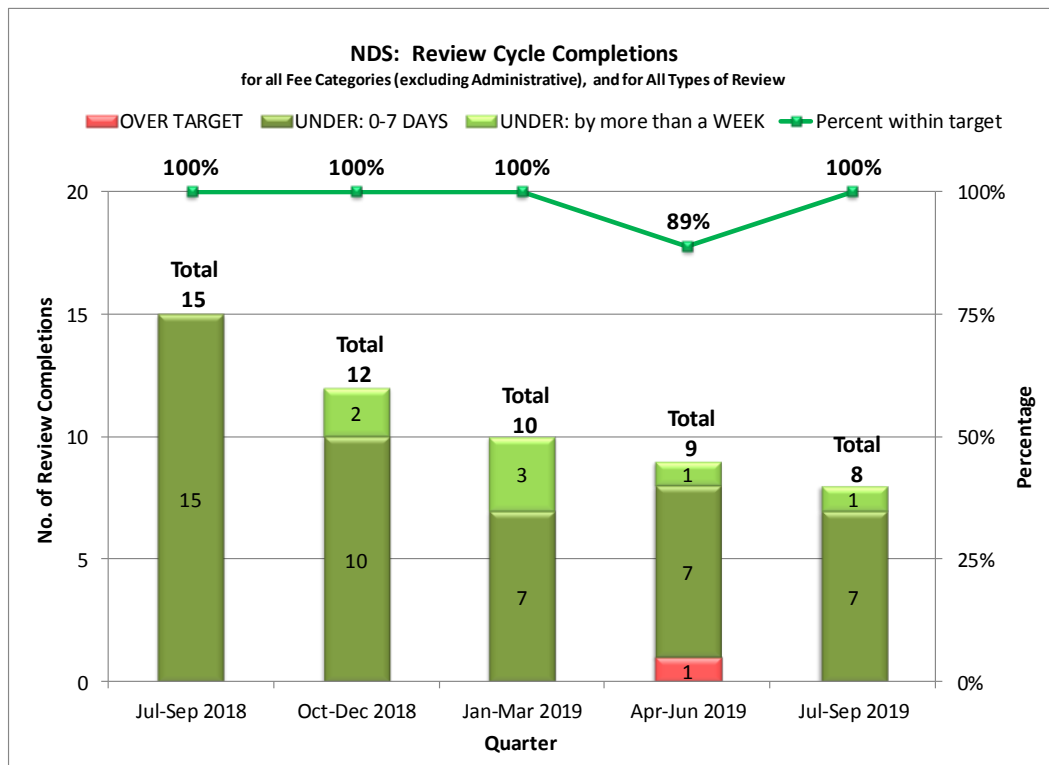
**Biosimilar:** A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration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

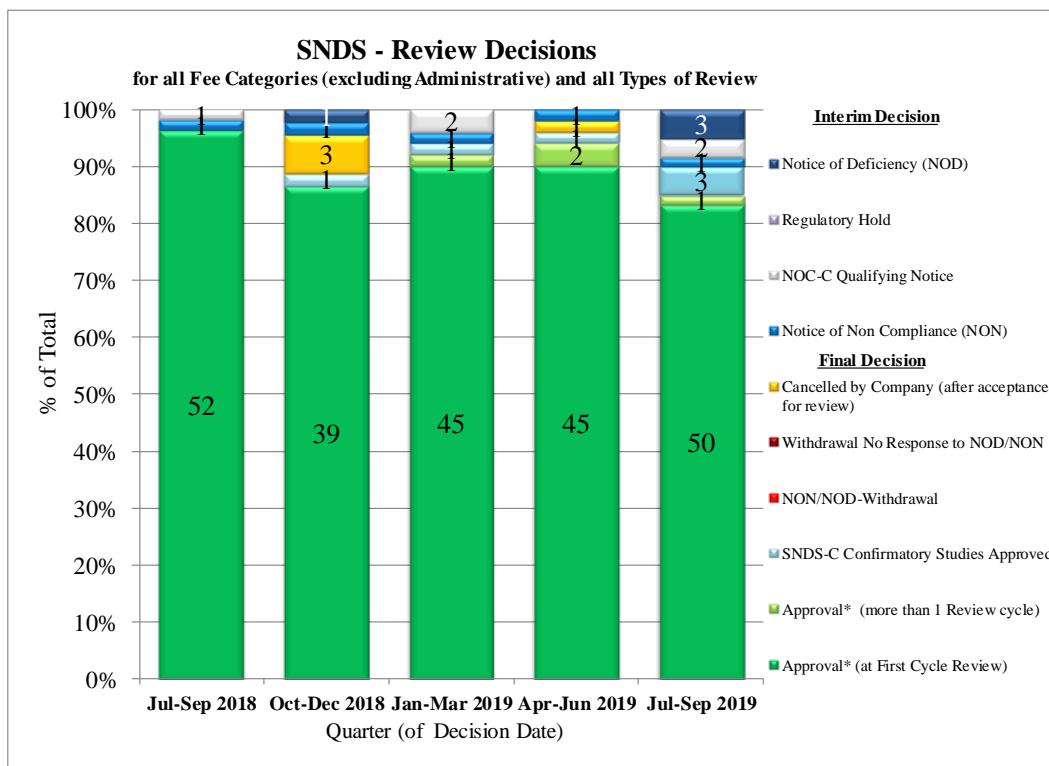


### NDS: Review Cycle Completions

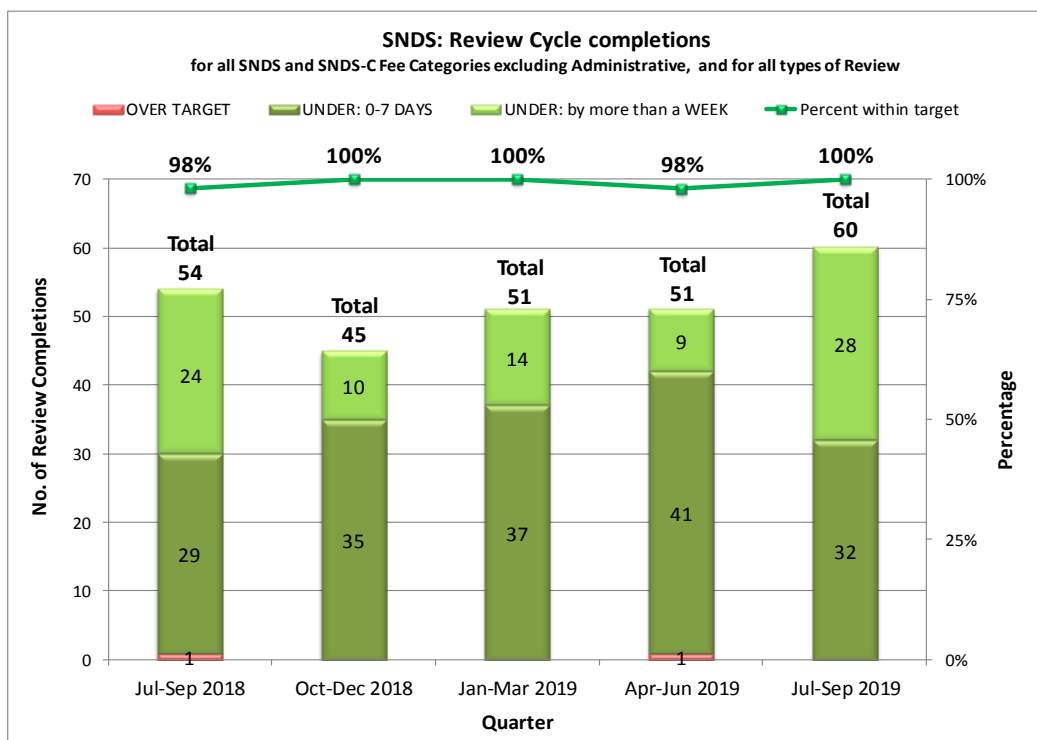


## REVIEW PERFORMANCE

### SNDS: Review Decisions by Type

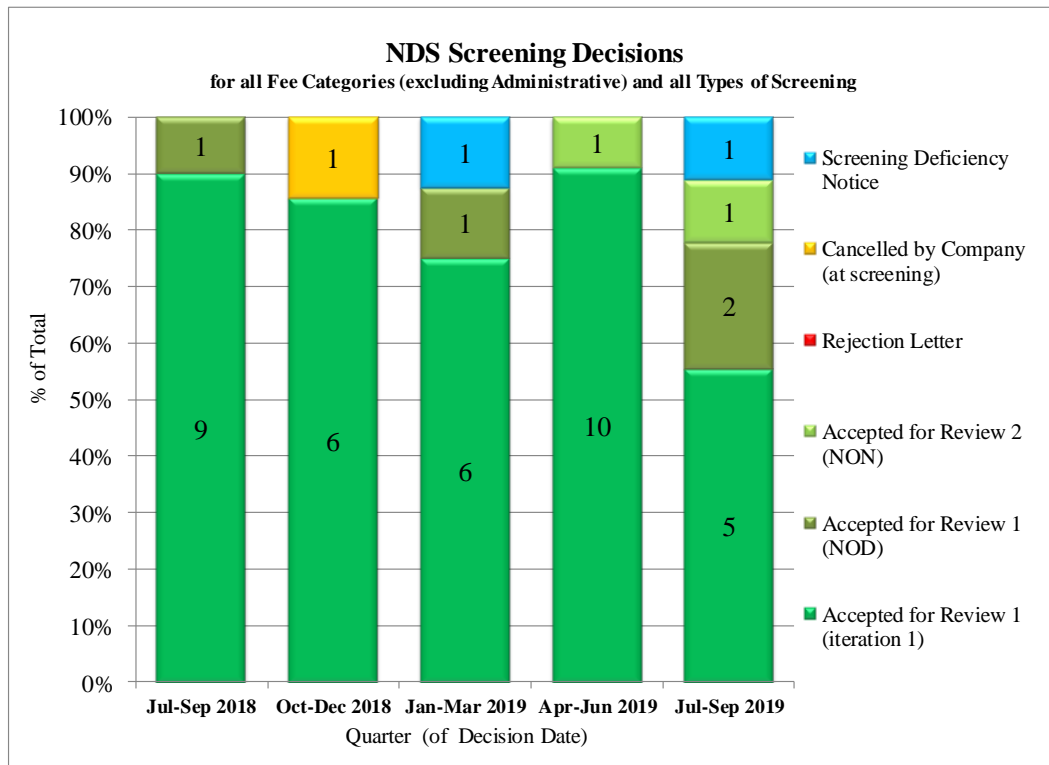


### SNDS: Review Cycle Completions

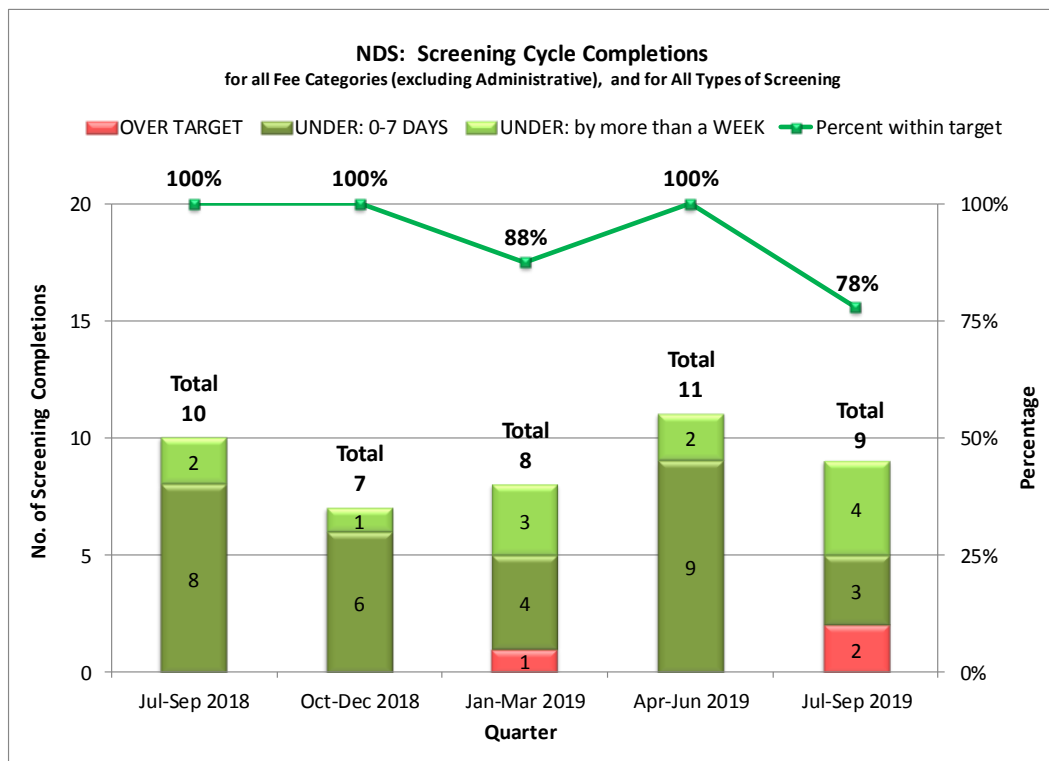


## SCREENING PERFORMANCE

### NDS: Screening Decisions by Type

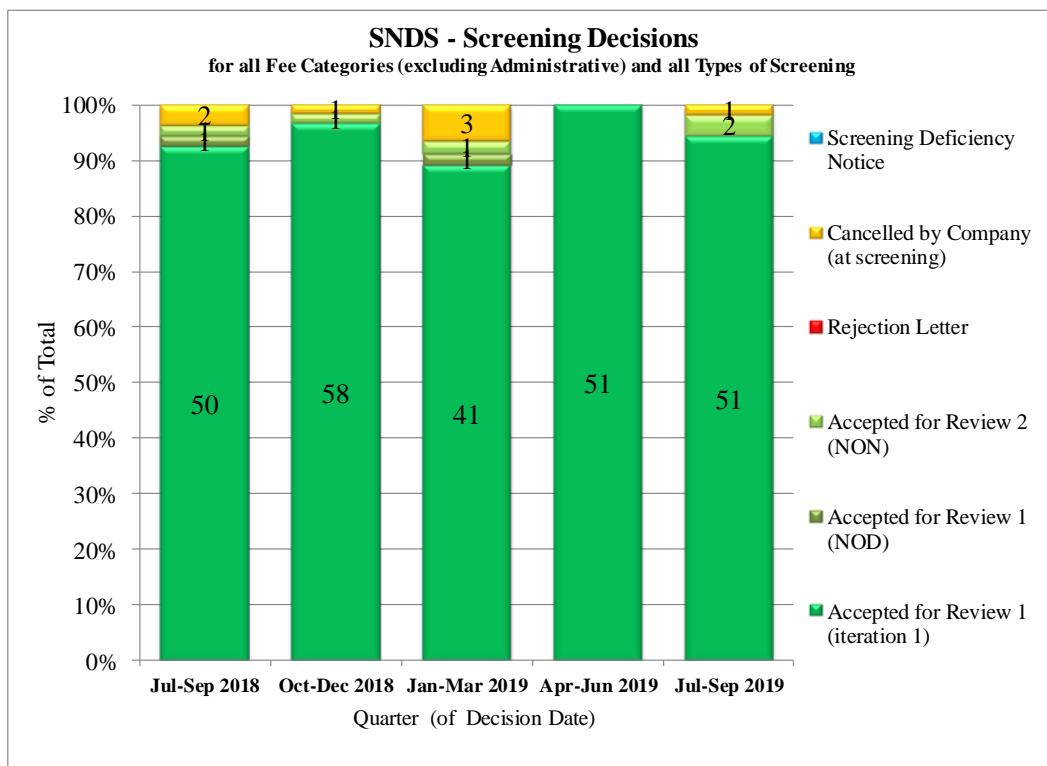


### NDS: Screening Cycle Completions

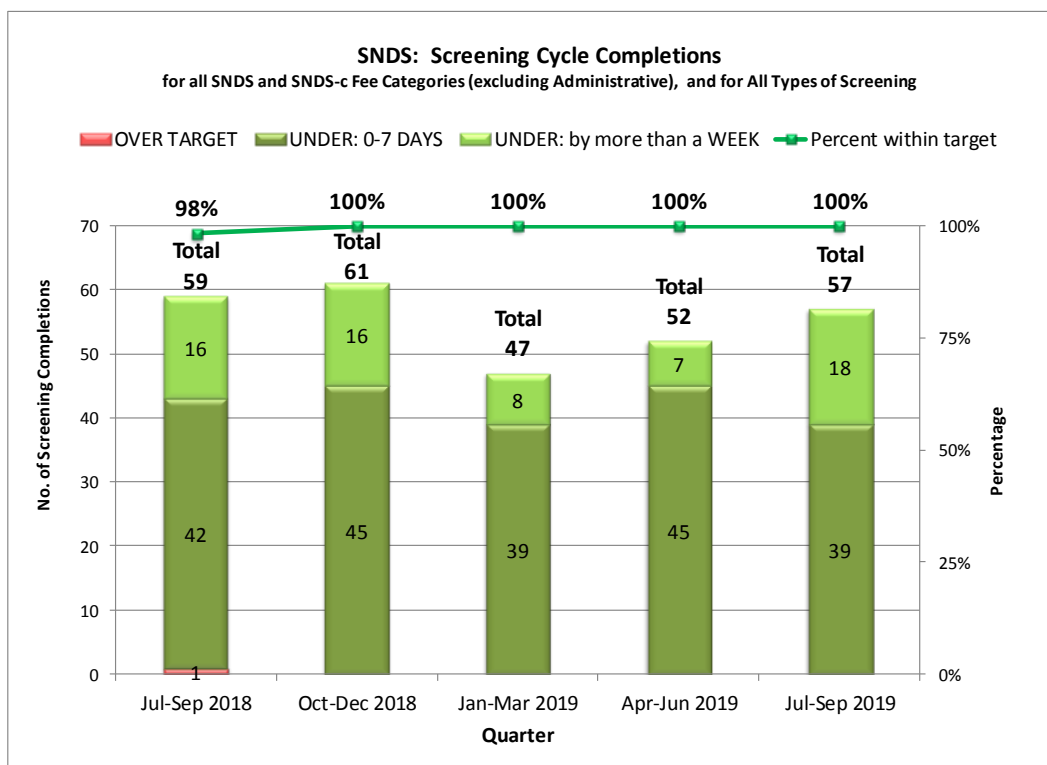


## SCREENING PERFORMANCE

### SNDS: Screening Decisions by Type

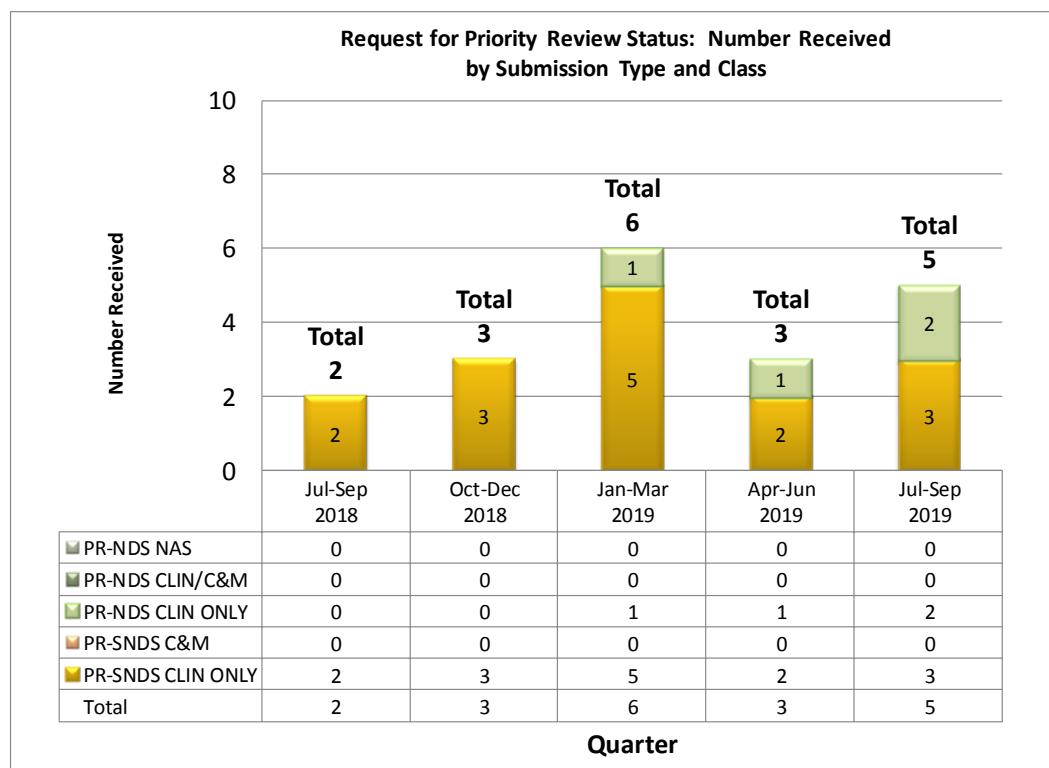


### SNDS: Screening Cycle Completions

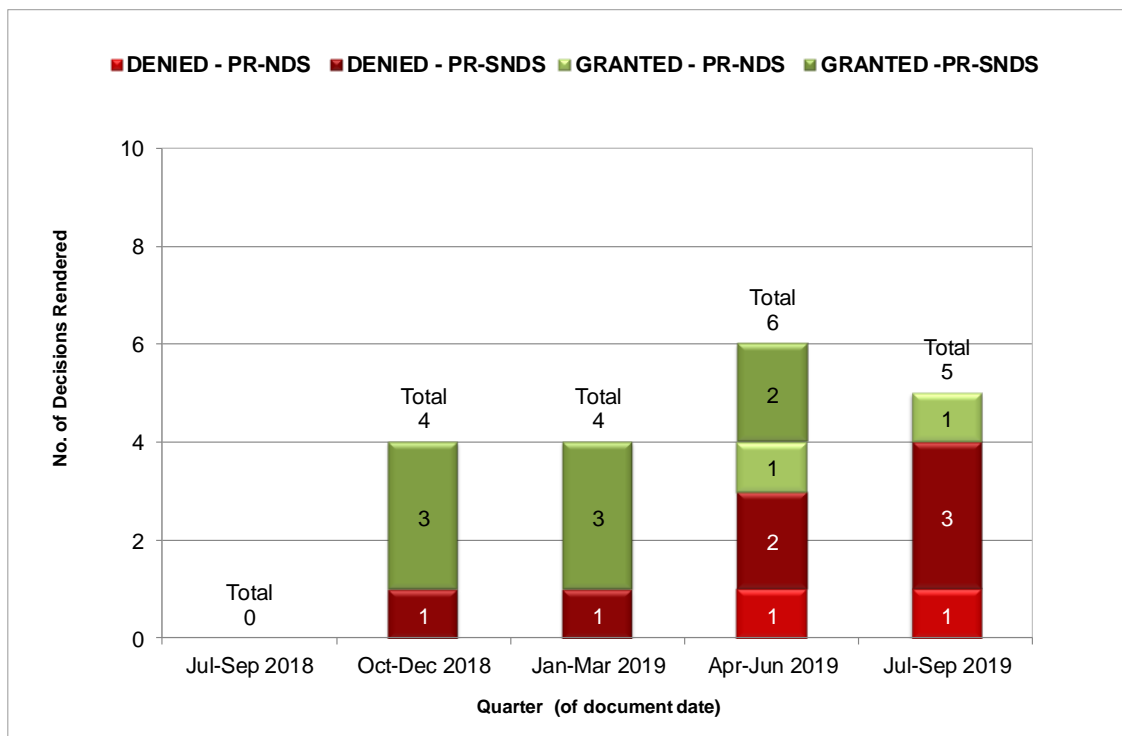


# REQUEST FOR PRIORITY REVIEW STATUS (NDS & SNDS)

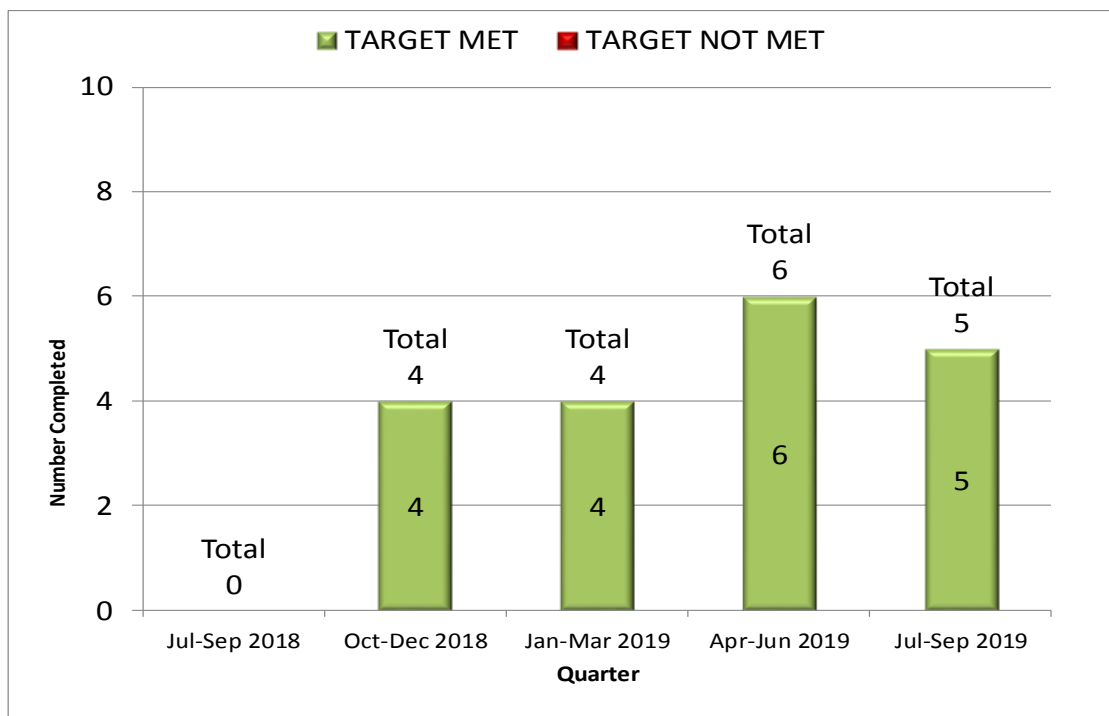
## Request for Priority Review Status: Number Received



## Request for Priority Review Status: Decisions Rendered



## Request for Priority Review Status: Performance

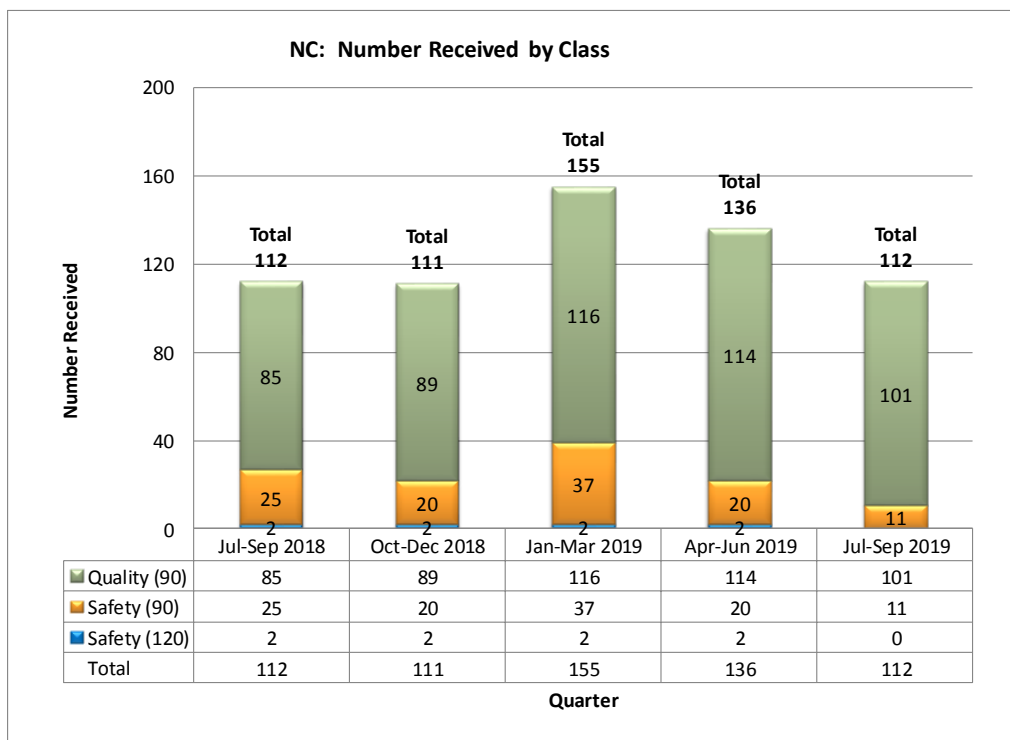


**NC: NOTIFIABLE CHANGE**



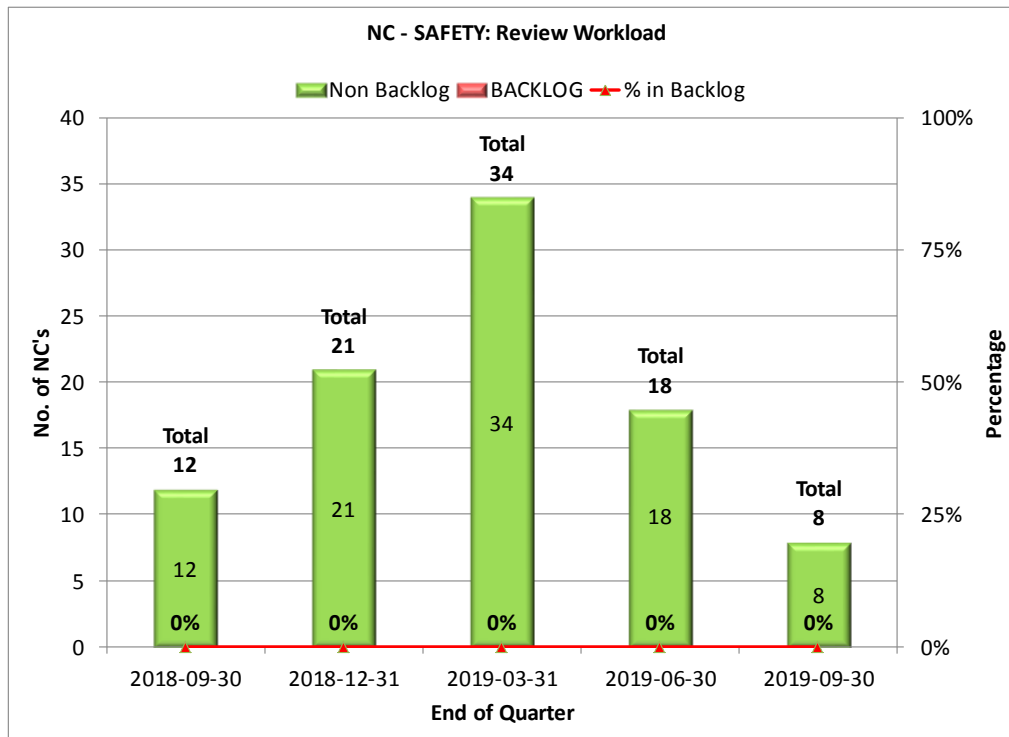
## NC: NOTIFIABLE CHANGE

### NC: Number Received by Class

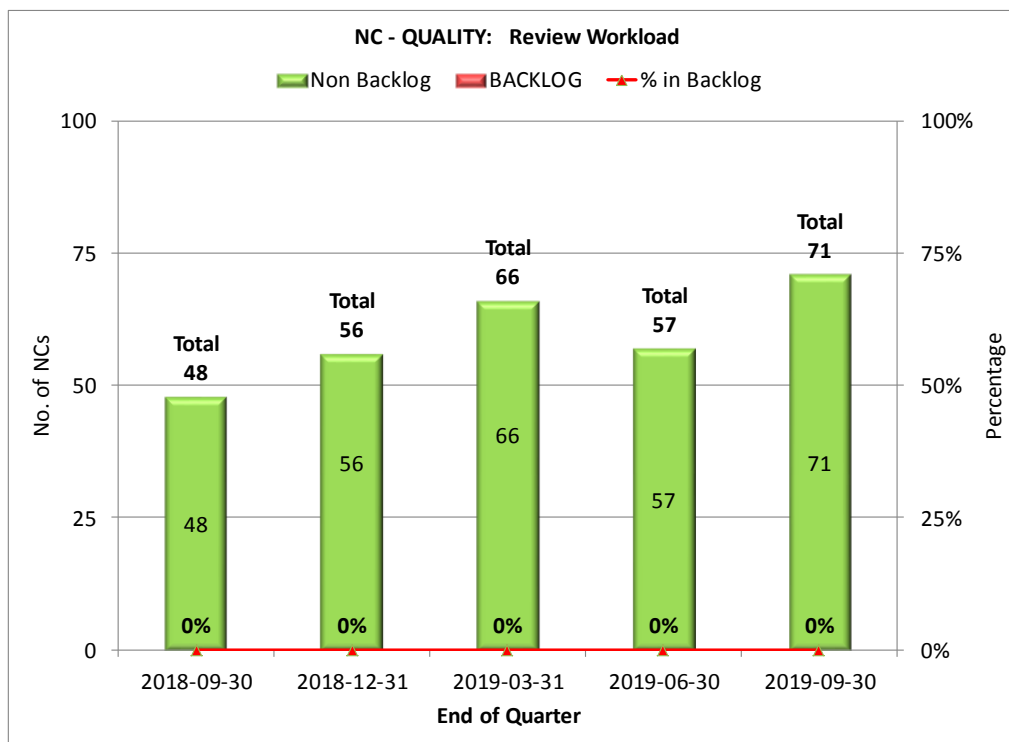


## WORKLOAD

### NC-SAFETY: Review Workload



### NC-QUALITY: Review Workload



## WORKLOAD

### NC-SAFETY: Review Workload by Class

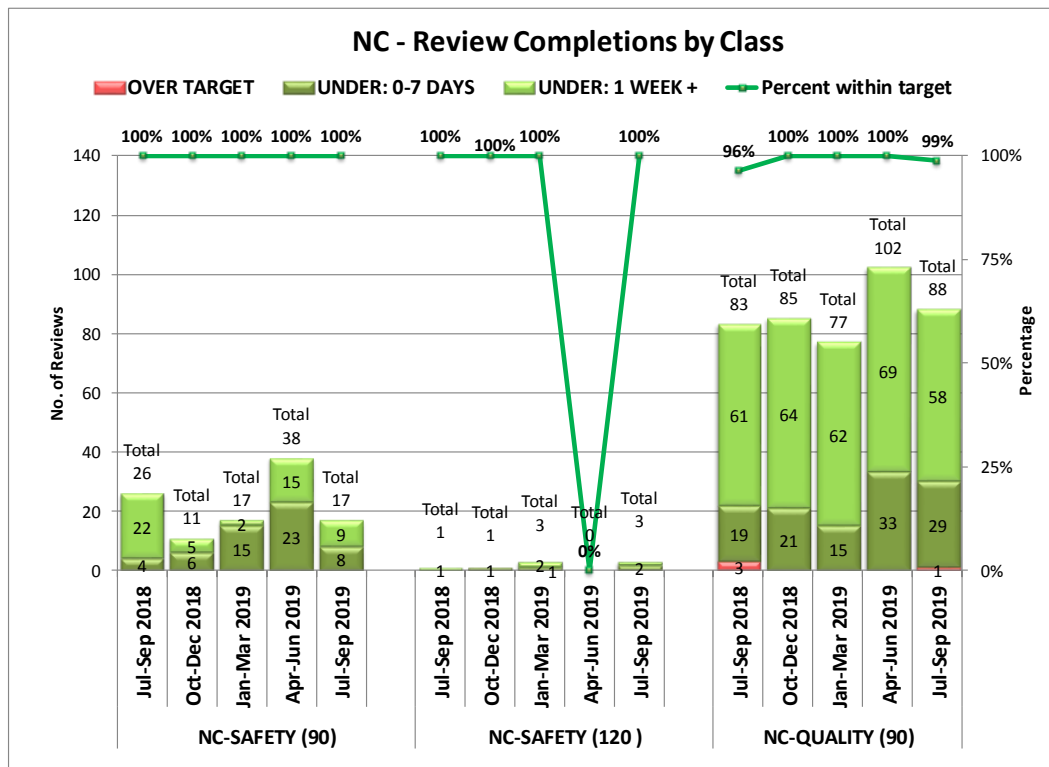
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
Class	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
<b>SAFETY - 90 day</b>	<b>10</b>	<b>18</b>	<b>34</b>	<b>15</b>	<b>7</b>
Backlog	0	0	0	0	0
<b>SAFETY - 120 day</b>	<b>2</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>1</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>12</b>	<b>21</b>	<b>34</b>	<b>18</b>	<b>8</b>
<b>Non Backlog</b>	<b>12</b>	<b>21</b>	<b>34</b>	<b>18</b>	<b>8</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

### NC-QUALITY: Review Workload by Class

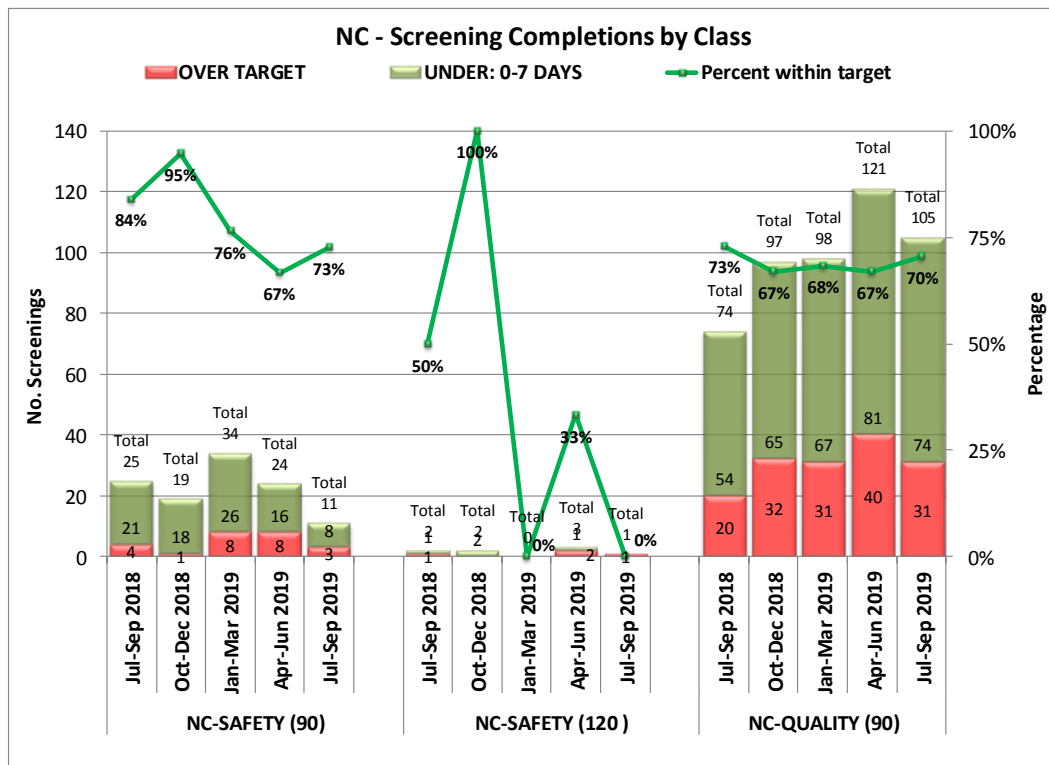
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
<b>QUALITY - 90 day</b>	<b>48</b>	<b>56</b>	<b>66</b>	<b>57</b>	<b>71</b>
Backlog	0	0	0	0	0
<b>Total</b>	<b>48</b>	<b>56</b>	<b>66</b>	<b>57</b>	<b>71</b>
<b>Non Backlog</b>	<b>48</b>	<b>56</b>	<b>66</b>	<b>57</b>	<b>71</b>
<b>BACKLOG</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>% in Backlog</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

## PERFORMANCE

### NC: Review Completions by Class



### NC: Screening Completions by Class



## NC: Decision Documents by Class

NC - SAFETY (90)					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	26	11	16	39	18
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	0	2	1	4	0
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	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	86	79	77	126	89
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	4	1	9	1	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	4	6	2	5	5
NC - HOLD (PATENT)	0	2	1	1	0

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

NC - ADMINISTRATIVE					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	0	1	1	0	2
CANCELLED BY COMPANY	0	0	0	0	0

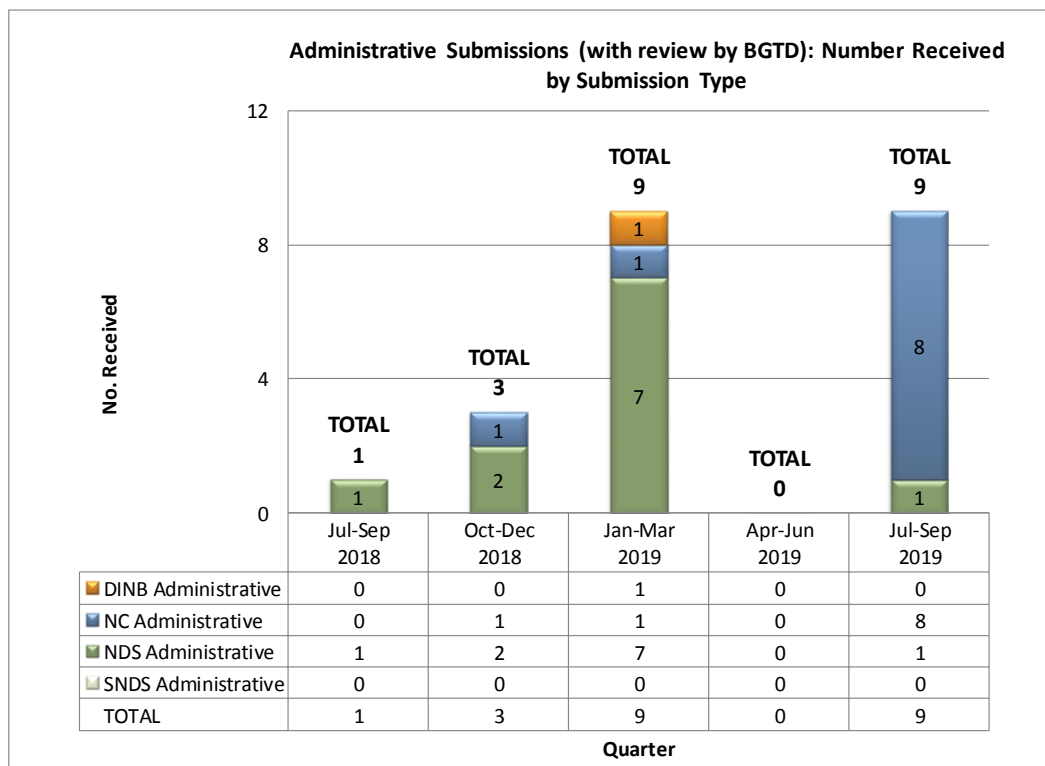
## **ADMINISTRATIVE SUBMISSIONS**

Submissions in support of a manufacturer or product name change

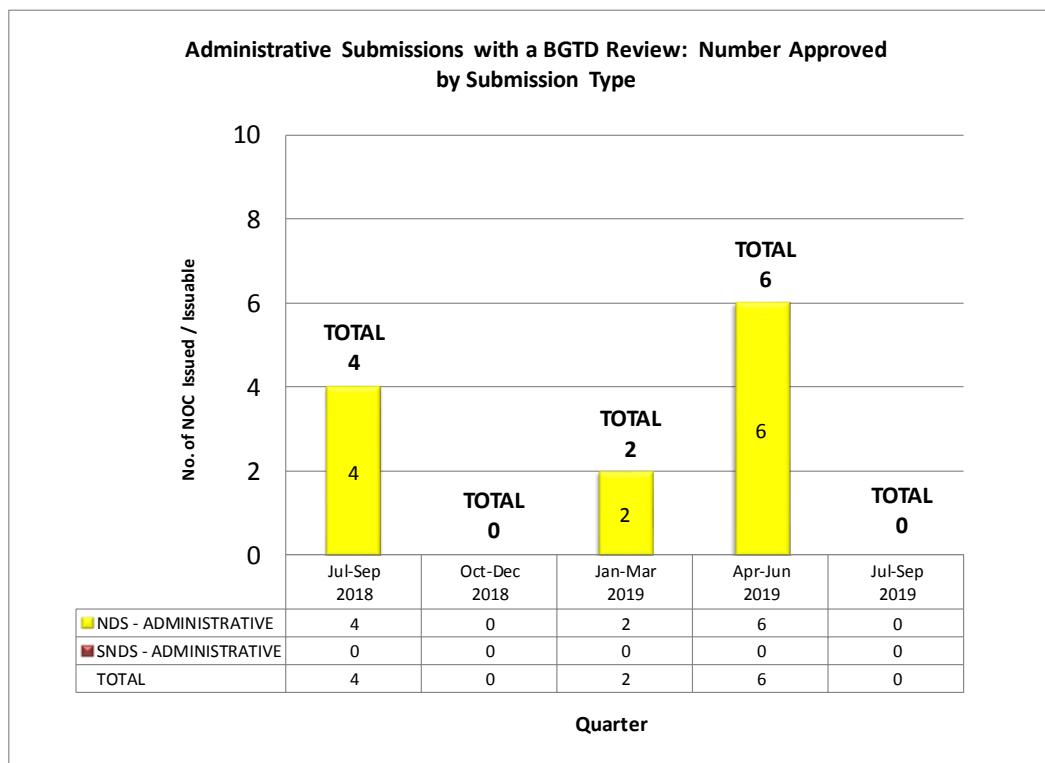
## ADMINISTRATIVE SUBMISSIONS (Processed by BGTD)

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

### Administrative Submissions (with BGTD Review): Number Received



### Administrative Submissions (with BGTD Review): Number Approved

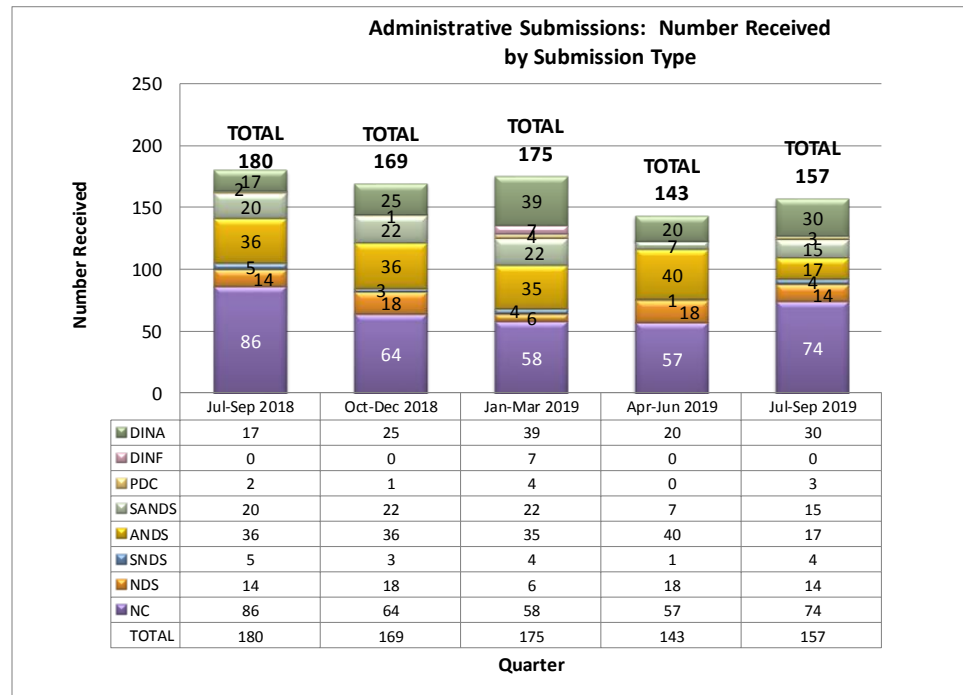


## ADMINISTRATIVE SUBMISSIONS (Processed by TPD)

(Manufacturer and/or Product Name Changes)<sup>12</sup>

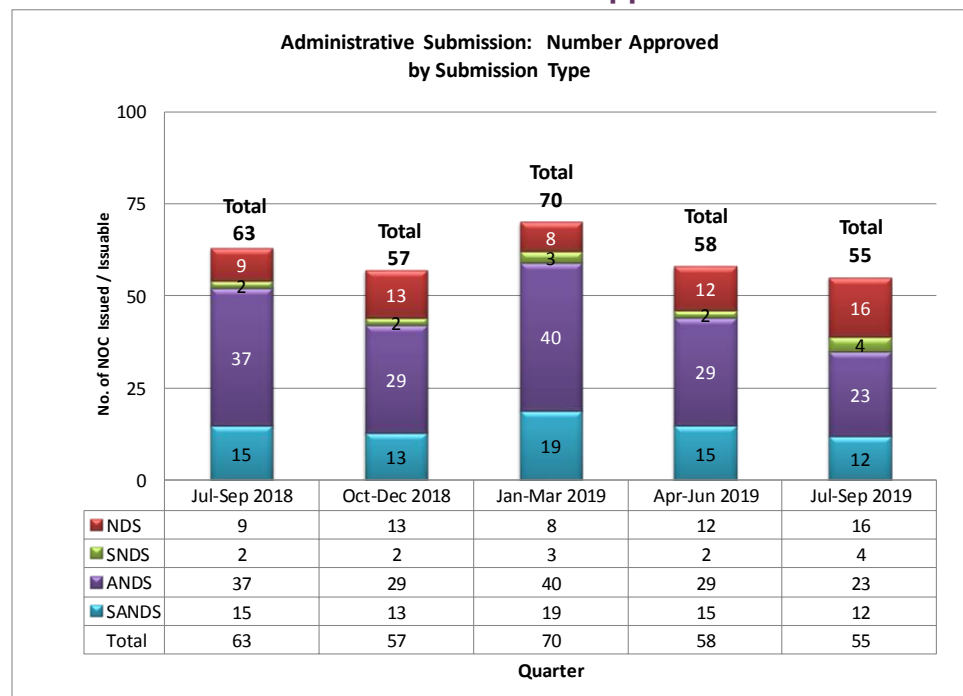
### RECEIVED

#### Administrative Submissions: Number Received



### APPROVALS

#### Administrative Submissions: Number Approved



<sup>12</sup> 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.

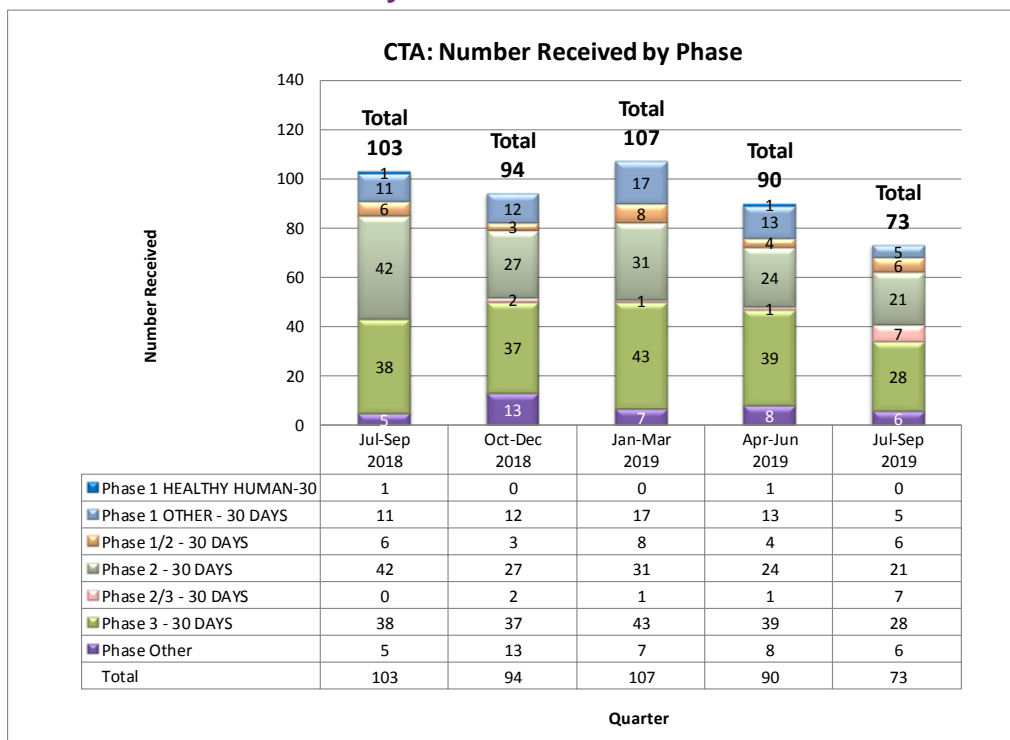


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# **CLINICAL TRIAL APPLICATIONS AND AMENDMENTS (CTA & CTA-A)**

## CLINICAL TRIAL APPLICATIONS (CTA)

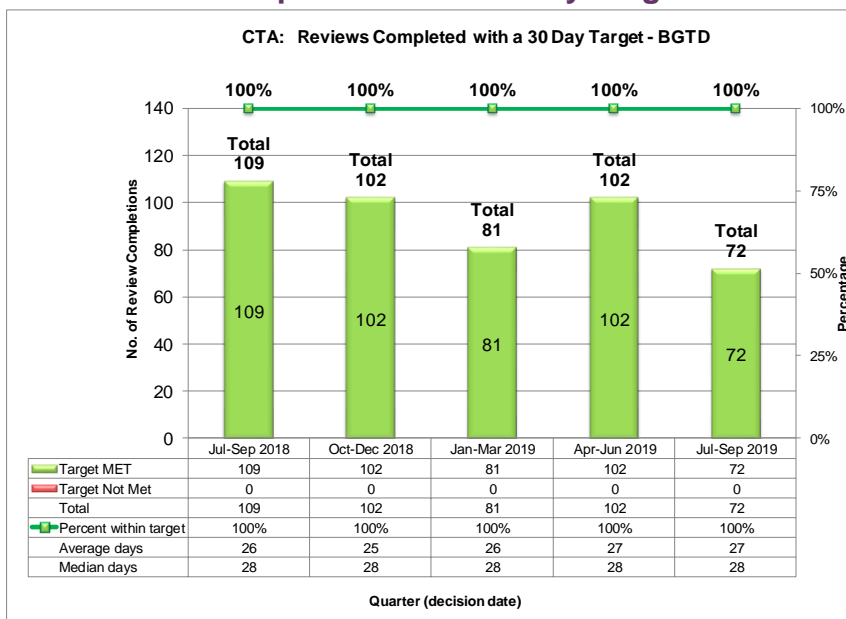
### CTA: Number Received by Phase



### CTA: Number of Decisions by Document Type

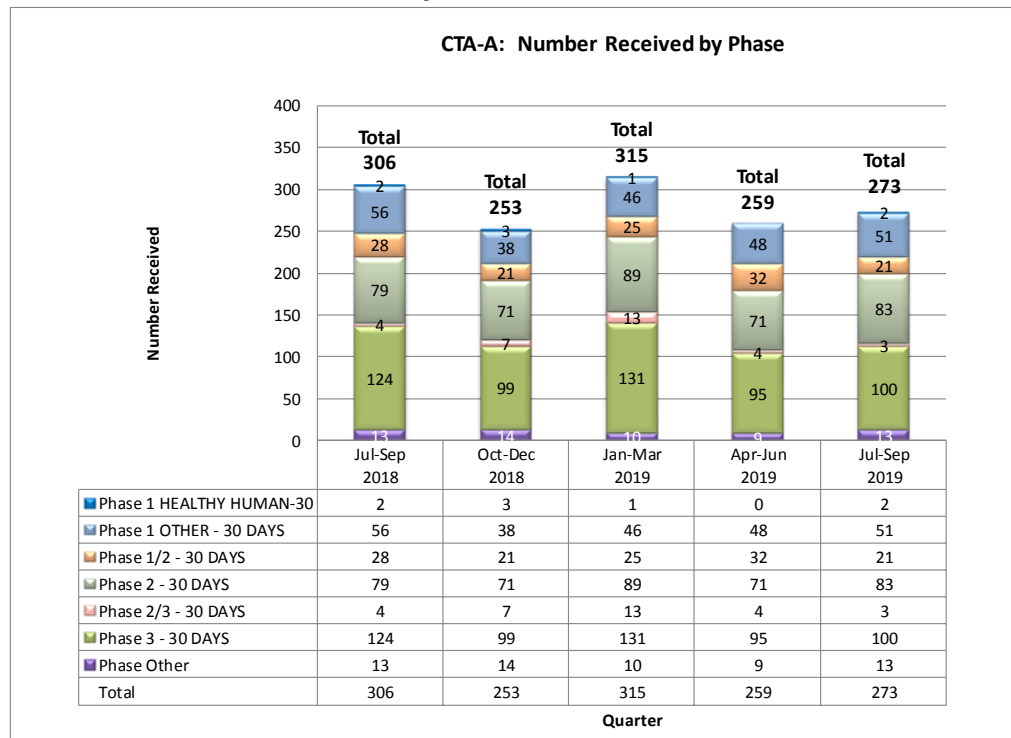
CTA					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	108	100	80	97	69
CANCELLED BY COMPANY DURING REVIEW	1	2	1	5	3
CANCELLED BY COMPANY AT PROCESSING	4	2	0	2	6
REJECTION LETTER (SCR)	1	0	1	2	3
NOT SATISFACTORY NOTICE	0	0	1	0	0

### CTA: Review Completed with a 30 Day Target



# CLINICAL TRIAL APPLICATION- AMENDMENTS (CTA-A)

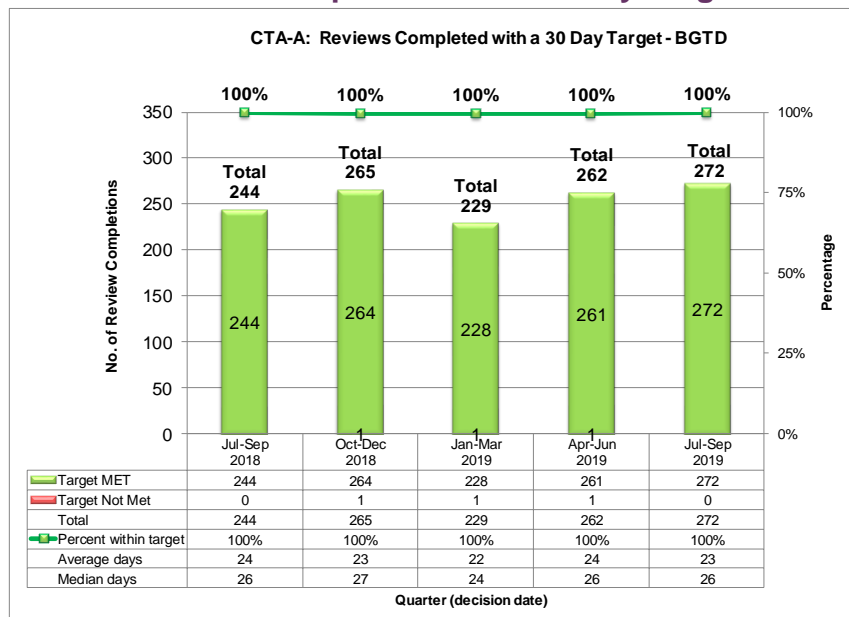
## CTA-A: Number Received by Phase



## CTA-A: Decisions by Type

CTA-A					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	297	279	244	272	272
REJECTION LETTER (SCR)	4	2	7	6	3
CANCELLED BY COMPANY DURING REVIEW	2	0	1	2	1
CANCELLED BY COMPANY AT PROCESSING	2	6	1	1	1

## CTA-A: Reviews Completed with a 30 Day Target



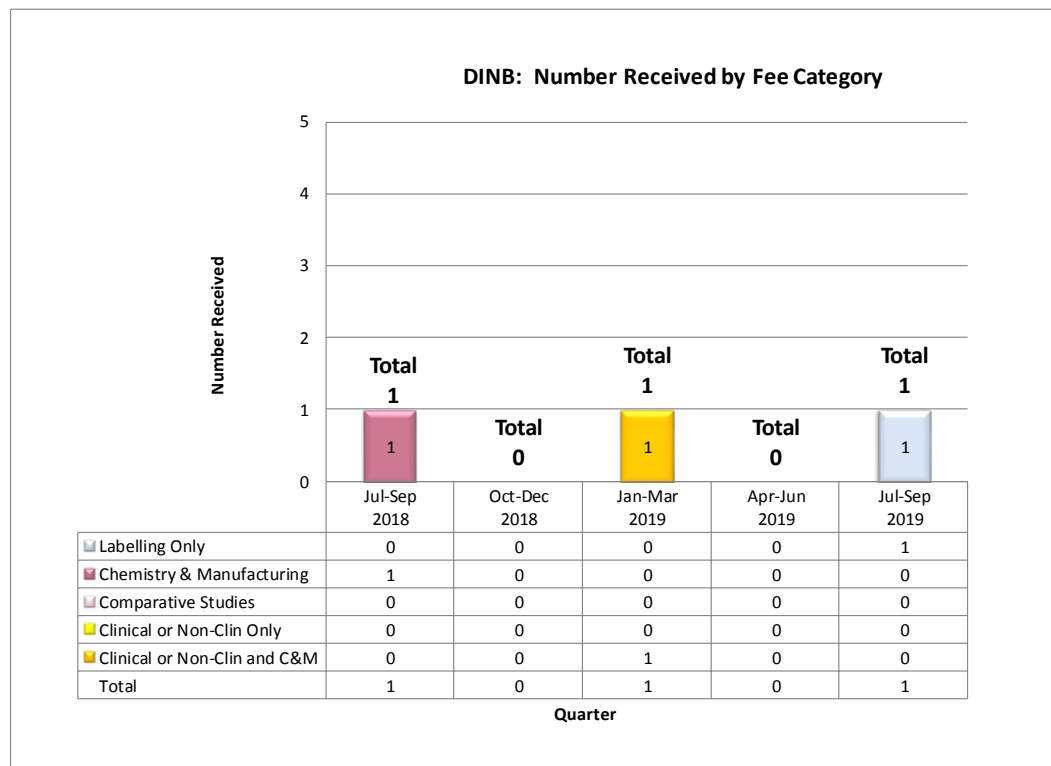
# **DINB**

## **Application for a Drug Identification Number**

### **Biological Product**

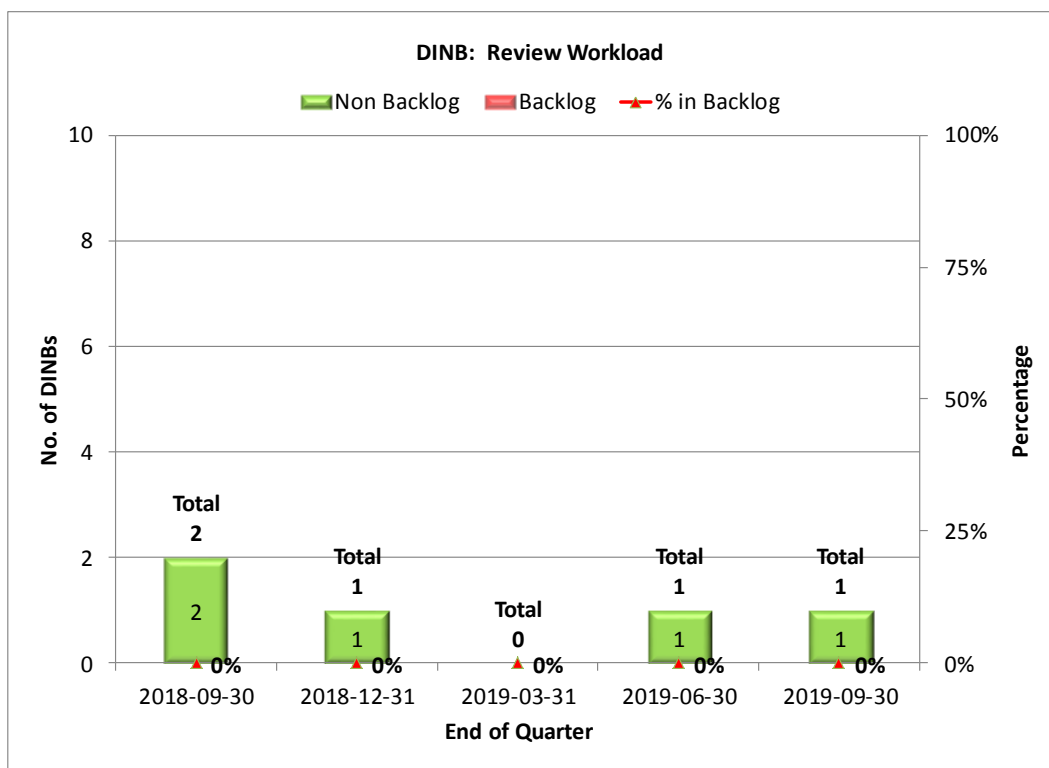
# DINB: APPLICATION FOR A DRUG IDENTIFICATION NUMBER - BIOLOGICAL PRODUCT

## DINB: Number Received by Fee Category



## REVIEW WORKLOAD

### DINB: Review Workload

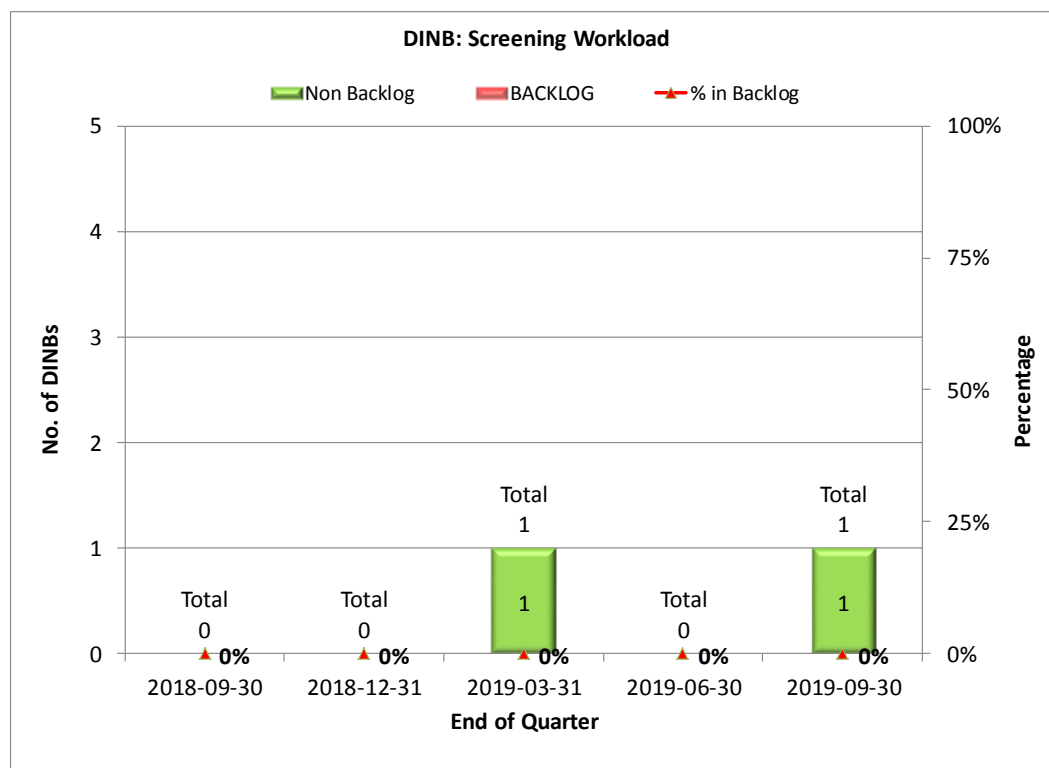


### DINB: Review Workload by Fee Category

DINB: REVIEW WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
<b>Labelling Only</b>	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Chemistry &amp; Manufacturing</b>	2	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
<b>Total</b>	2	1	0	1	1
<b>Non Backlog</b>	2	1	0	1	1
<b>Backlog</b>	0	0	0	0	0
<b>% in Backlog</b>	0%	0%	0%	0%	0%

## SCREENING WORKLOAD

### DINB: Screening Workload



### DINB: Screening Workload by Fee Category

DINB: SCREENING WORKLOAD BY FEE CATEGORY (excluding Administrative) and End of Quarter					
FEE Category	2018-09-30	2018-12-31	2019-03-31	2019-06-30	2019-09-30
Labelling Only	0	0	0	0	1
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	1	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
<b>Total</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
Non Backlog	0	0	1	0	1
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	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 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	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

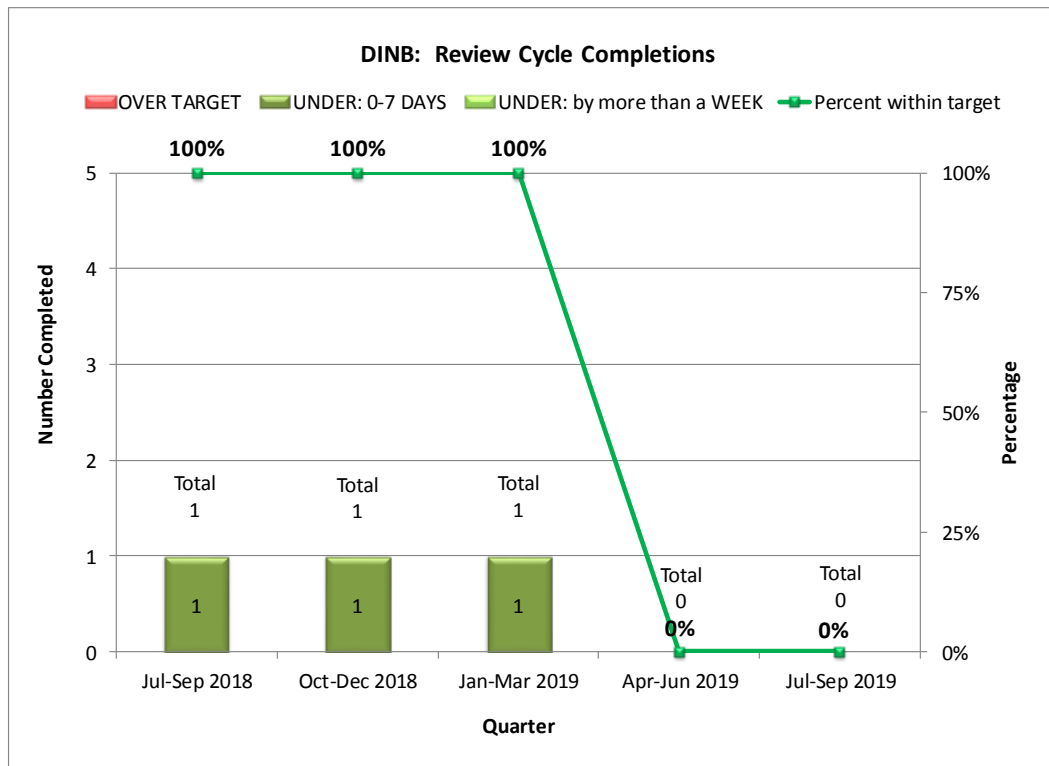
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

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

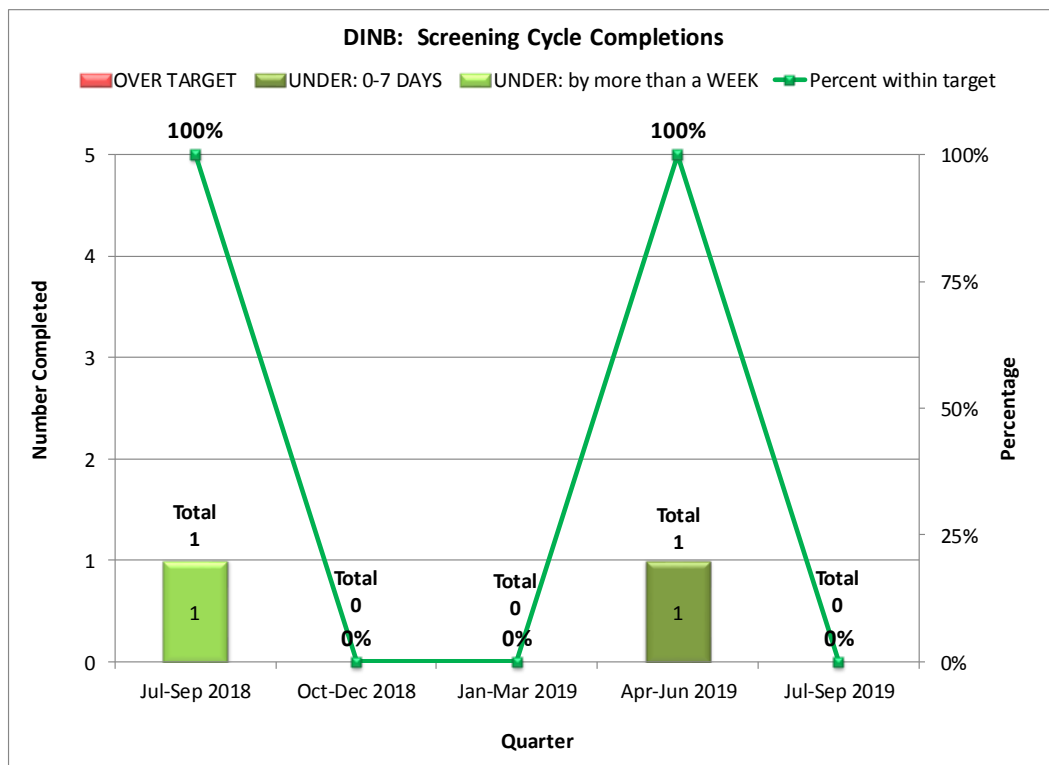
DINB - Administrative					
DOCUMENT TYPE	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Apr-Jun 2019	Jul-Sep 2019
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

## PERFORMANCE

### DINB: Review Cycle Completions

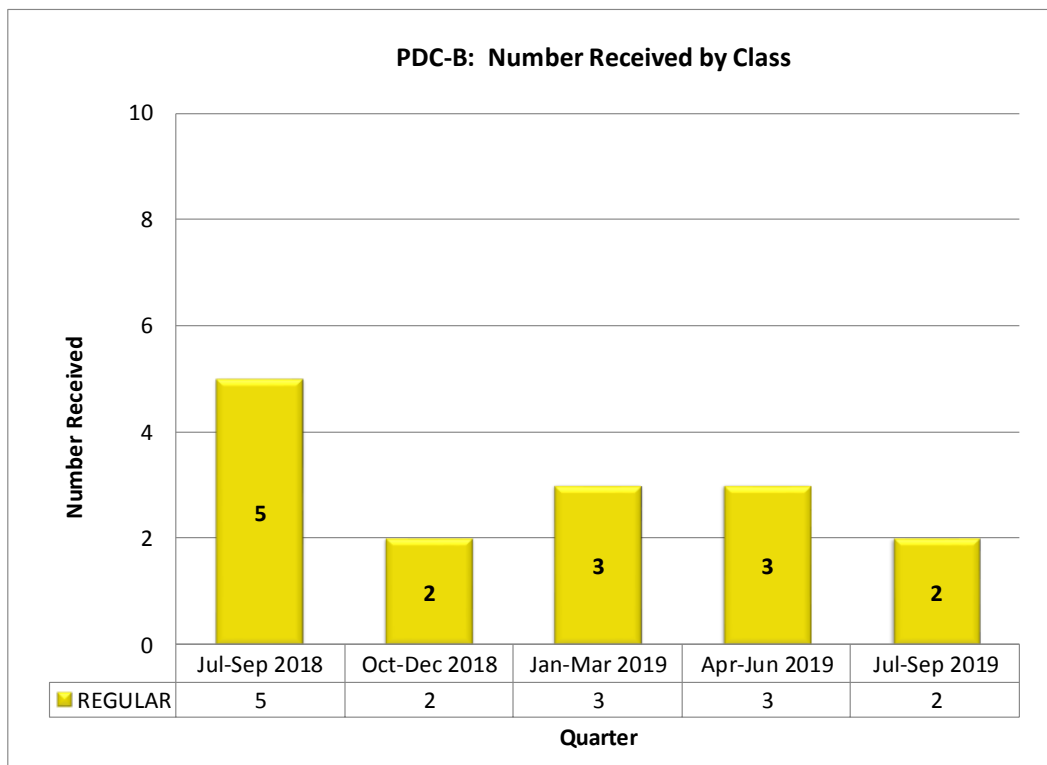


### DINB: Screening Cycle Completions



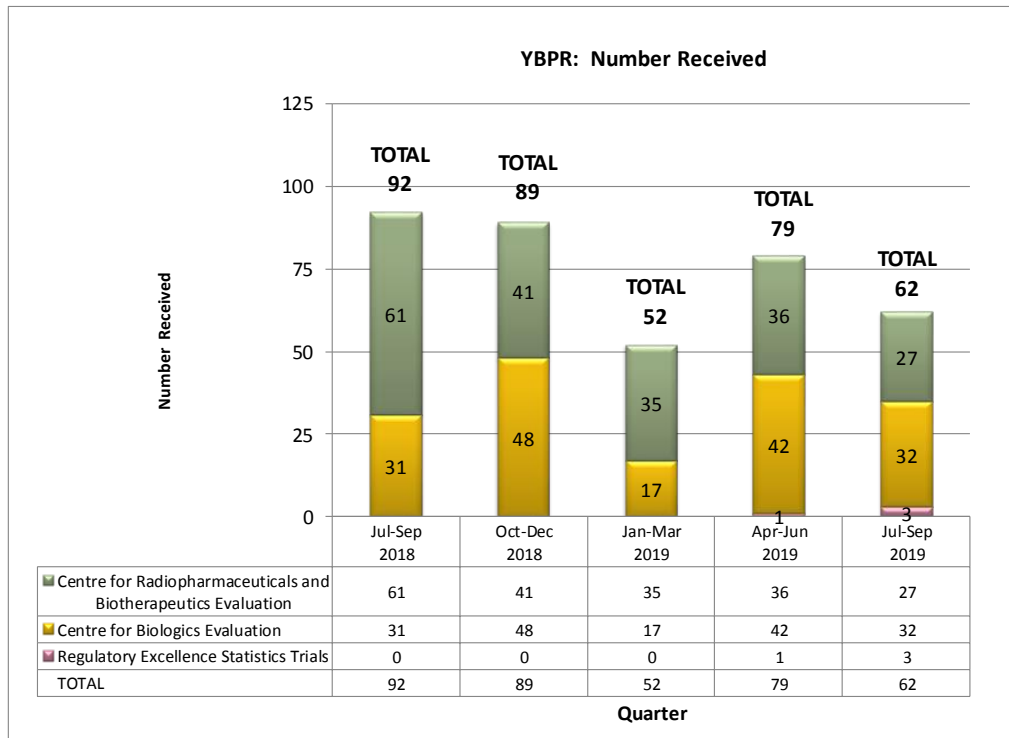
## POST-AUTHORIZATION DIVISION 1 CHANGE FOR A BIOLOGIC DRUG PRODUCT (PDC-B)

### PDC-B: Number Received



## YEARLY BIOLOGIC PRODUCT REPORTS (YBPR) <sup>13</sup>

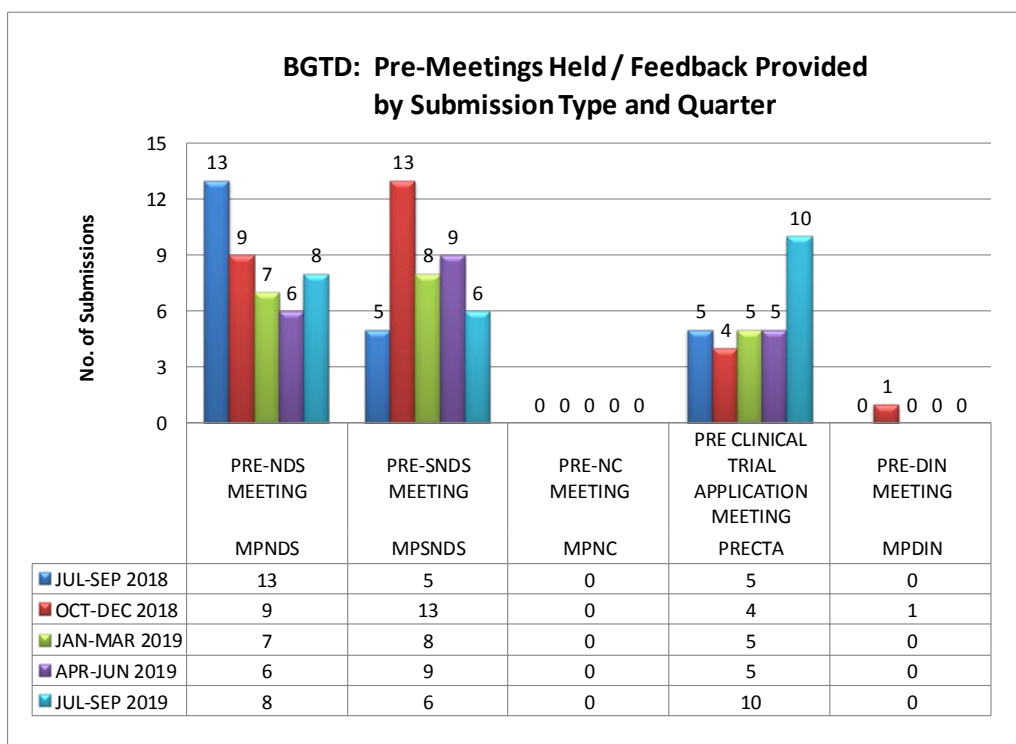
### YBPR: Number Received



<sup>13</sup> 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 <sup>14</sup>

## Pre-submission Meetings Held / Feedback Provided



<sup>14</sup> 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](#)