Biologics and Genetic Therapies Directorate
Drug Submission Performance Quarterly Report

July - September
2012

Canada

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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 2011 to July - September 2012. Statistics are provided by Submission Type and show the number received, the number in workload, the number of decisions and the number of approvals.

What's New

- Average and Median Days were added to CTA and CTA-A performance graphs which are now based on the date of review decision (rather than the target date).
- The new Cost Recovery Fee Categories[1] introduced on April 1st 2011 have been incorporated into the reports.
- 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[2].
- 'Labelling Only' are now reported along with the other Fee Categories. The Fee Category "Administrative Submission" is reported in a separate section of the report.
- Final results from confirmatory trials submitted in the form of an SNDS-C[3] are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures.
- 'Requests for Reconsideration of Final Decision' figures will continue to be reported on an annual basis but have been removed from the quarterly reports.

General Information

There are several steps involved in the drug submission review[4] 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.

[1] For further clarification refer to the Fees in Respect of Human Drugs and Medical Devices at http://www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php

[2] This is not to be confused with the 'UF Review 1(iteration 1)' performance standards that will be employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR)

[3] For further Clarification refer to the Guidance Document: Notice of Compliance with Conditions (NOC/c). http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.php#a3.3

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

Workload is the number of submissions "under active review" on a given day. **"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 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 Patent regulations or due to de-scheduling (from prescription to Over the Counter).

A **review cycle completion**[5]. 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[2] 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"[6] submissions.

Any questions or comments on this report should be forwarded to:
Office of Submissions and Intellectual Property (OSIP) (formerly SIPD)
Finance Building (#2), A.L. # 0201A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 1B9
Tel: (613) 957-3123 Fax: (613) 941-0825
Email: SIPDMAIL@hc-sc.gc.ca

[5] 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.

[6] For further clarification refer to the Guidance for Industry: Management of Drug Submissions http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php#a5.7

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
YPBR	-	Yearly Biologic Product Report

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patent Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to De-Scheduling
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)* *This new NAS definition came into effect on April 1 2011*	Submissions 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 ingredient such as a salt, ester, enantiomer, solvate or polymorph.
Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.
Clinical or non-clinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.
Comparative studies	Submissions based on comparative studies (e.g. clinical or non-clinical data, bioavailability, pharmacokinetic and pharmacodynamic data) with or without chemistry and manufacturing data for a drug that does not include a new active substance.
Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.
Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.
Switch from prescription to nonprescription status	Submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the *Food and Drug Regulations* (i.e. identical claim for existing drug).
Labelling only	Submissions of labelling material (i.e. does 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	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number application - labelling standards	Applications attesting to compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications **http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/fee_frais_guide-eng.php#app1**

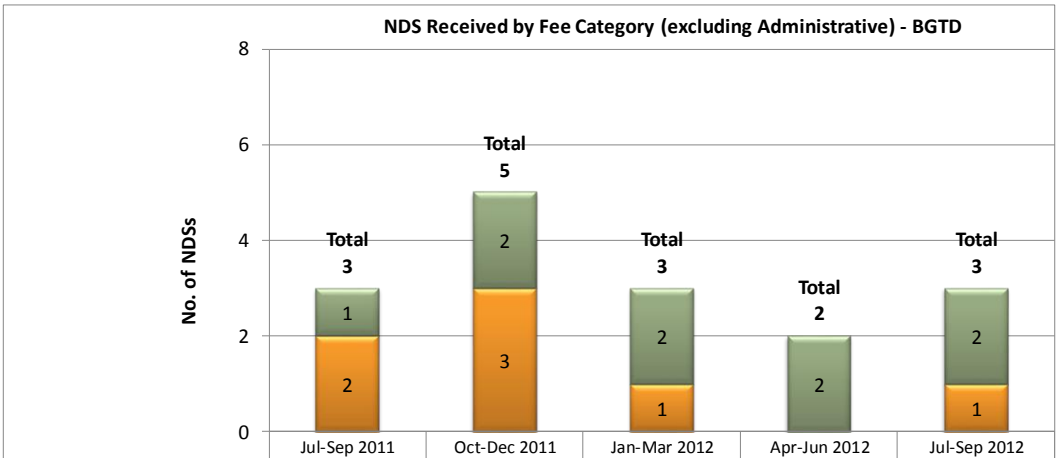
New Drug Submissions (NDS)

&

Supplemental New Drug Submissions (SNDS)

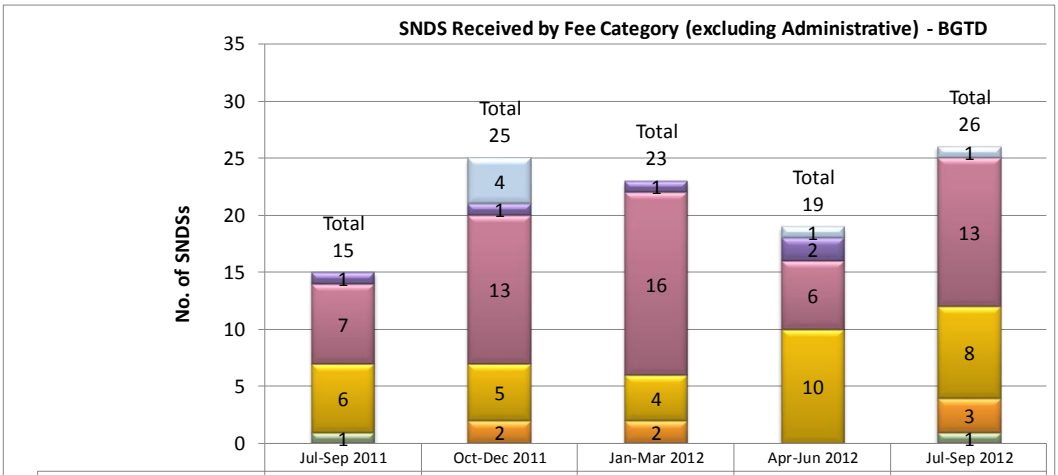
SUBMISSIONS RECEIVED

New Drug Submissions (NDS) Received by Fee Category



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
New Active Substance*	1	2	2	2	2
Clinical or Non-Clin and C&M	2	3	1		1
Labelling Only					
Disinfectants					
Comparative Studies					
Chemistry & Manufacturing					
Clinical or Non-Clin Only					
Total	3	5	3	2	3
Priority (subset)	0	1	1	0	1
Emergency Use NDS	0	0	0	0	0

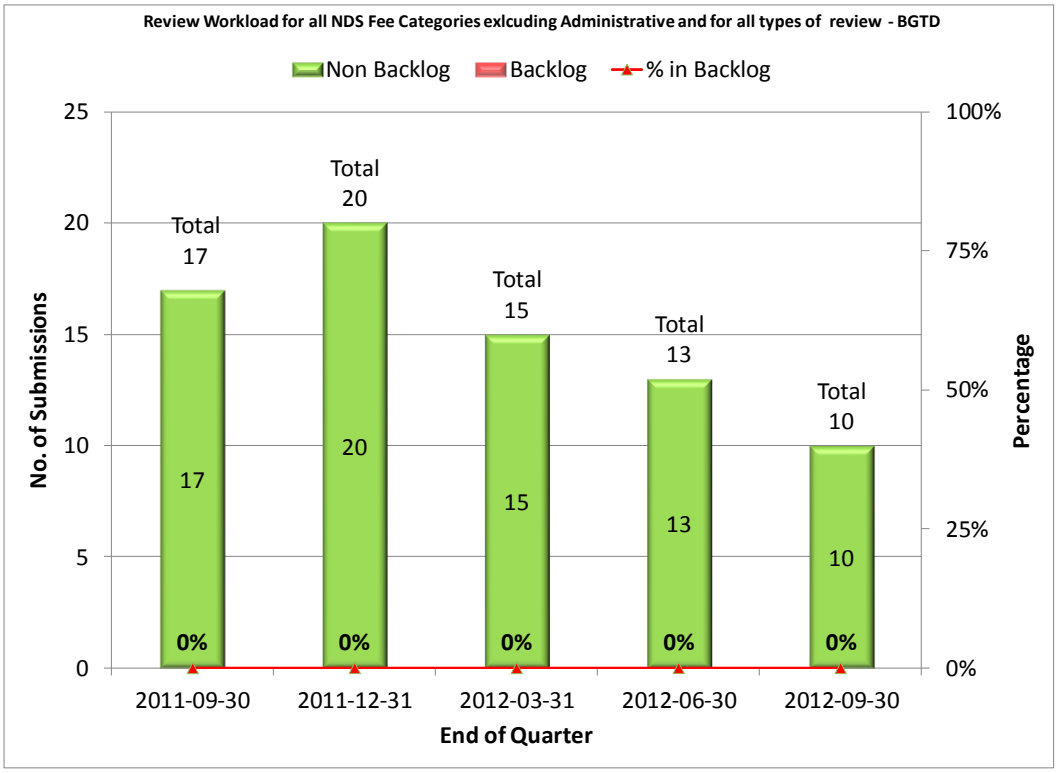
Supplemental New Drug Submissions (SNDS) Received by Fee Category



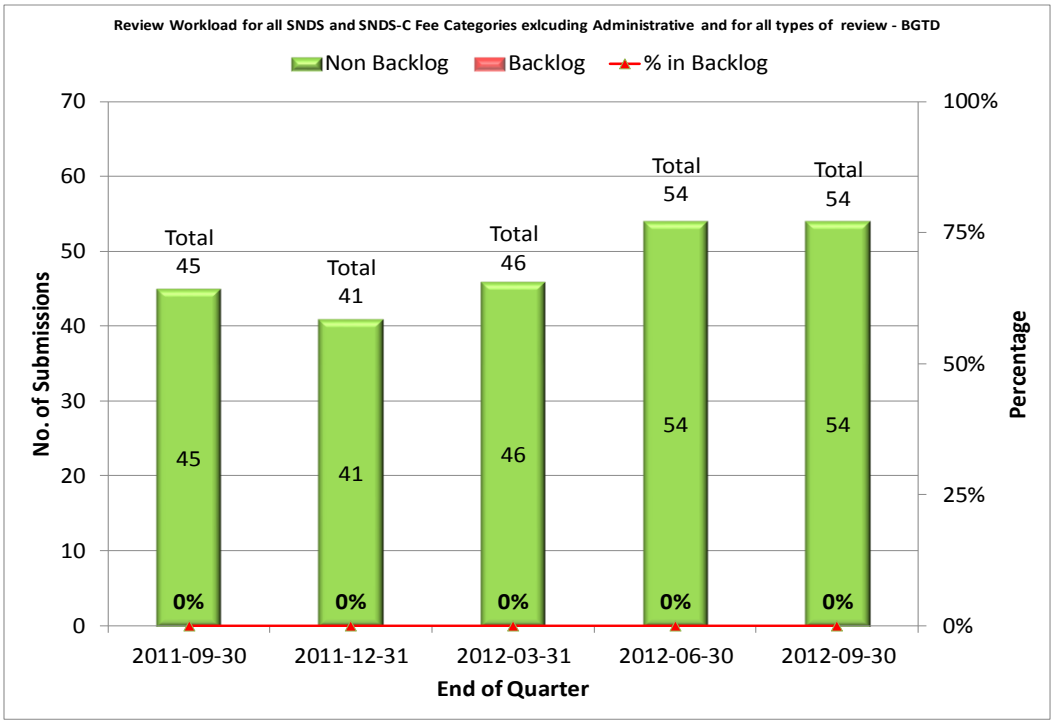
	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Labelling Only		4		1	1
Comparative Studies	1	1	1	2	
Chemistry & Manufacturing	7	13	16	6	13
Clinical or Non-Clin Only*	6	5	4	10	8
Clinical or Non-Clin and C&M		2	2		3
Published Data Only	1				1
Switch from Rx to OTC					
Total	15	25	23	19	26
Priority (subset)	1	0	0	0	0
*SNDS Confirmatory	0	0	0	0	1

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

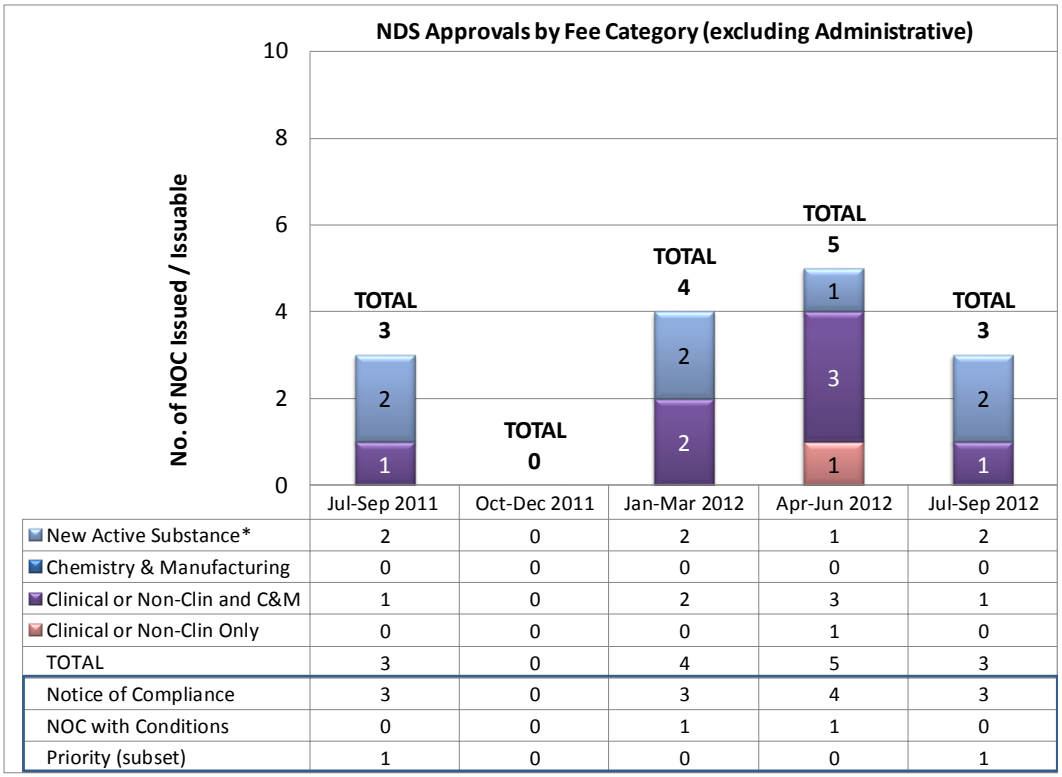
BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
Clinical or Non-Clin Only	1	1	1	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	11	12	9	6	5
Backlog	0	0	0	0	0
New Active Substance	5	7	5	7	5
Backlog	0	0	0	0	0
Total	**17**	**20**	**15**	**13**	**10**
Non Backlog	**17**	**20**	**15**	**13**	**10**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	1	1	1	2	0
Non Backlog	1	1	1	2	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					
	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
Comparative Studies	1	1	1	4	3
Backlog	0	0	0	0	0
Chemistry & Manufacturing	13	16	24	26	21
Backlog	0	0	0	0	0
Clinical or Non-Clin Only	26	20	18	17	22
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	4	2	3	6	6
Backlog	0	0	0	0	0
Published Data	1	1	0	0	2
Backlog	0	0	0	0	0
Labelling Only	0	1	0	1	0
Backlog	0	0	0	0	0
Total	**45**	**41**	**46**	**54**	**54**
Non Backlog	**45**	**41**	**46**	**54**	**54**
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	3	2	0	0	1
Non Backlog	3	2	0	0	1
Backlog	0	0	0	0	0

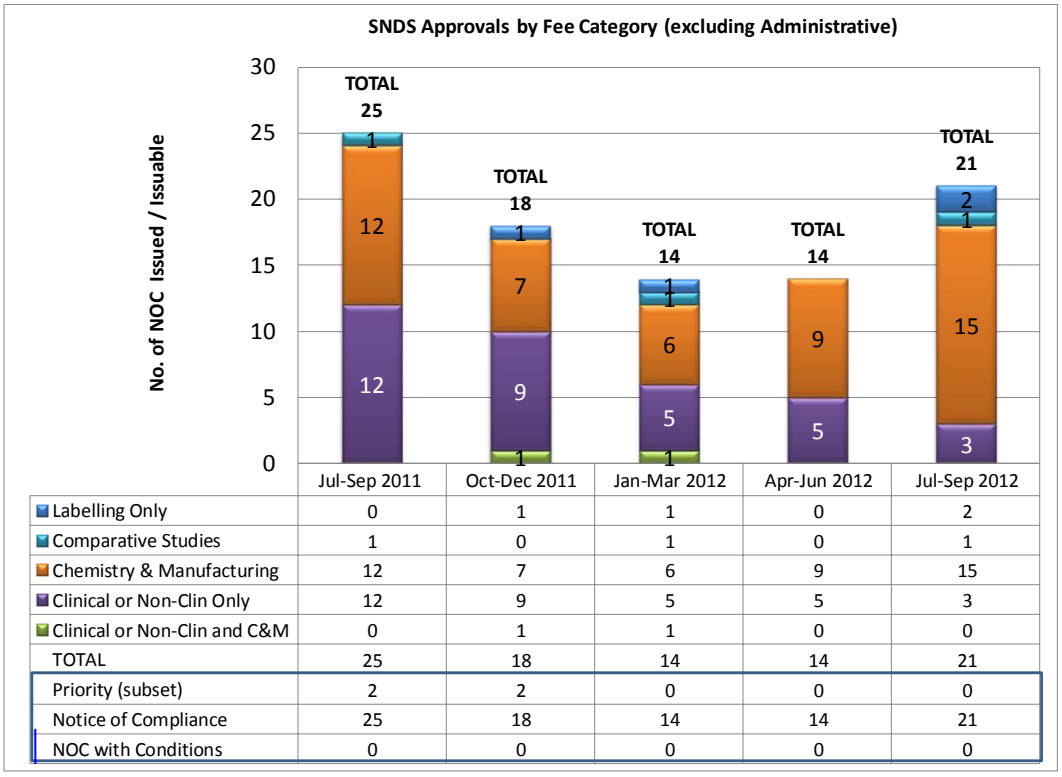
APPROVALS

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



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
New Active Substance*	2	0	2	1	2
Chemistry & Manufacturing	0	0	0	0	0
Clinical or Non-Clin and C&M	1	0	2	3	1
Clinical or Non-Clin Only	0	0	0	1	0
TOTAL	3	0	4	5	3
Notice of Compliance	3	0	3	4	3
NOC with Conditions	0	0	1	1	0
Priority (subset)	1	0	0	0	1

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



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Labelling Only	0	1	1	0	2
Comparative Studies	1	0	1	0	1
Chemistry & Manufacturing	12	7	6	9	15
Clinical or Non-Clin Only	12	9	5	5	3
Clinical or Non-Clin and C&M	0	1	1	0	0
TOTAL	25	18	14	14	21
Priority (subset)	2	2	0	0	0
Notice of Compliance	25	18	14	14	21
NOC with Conditions	0	0	0	0	0

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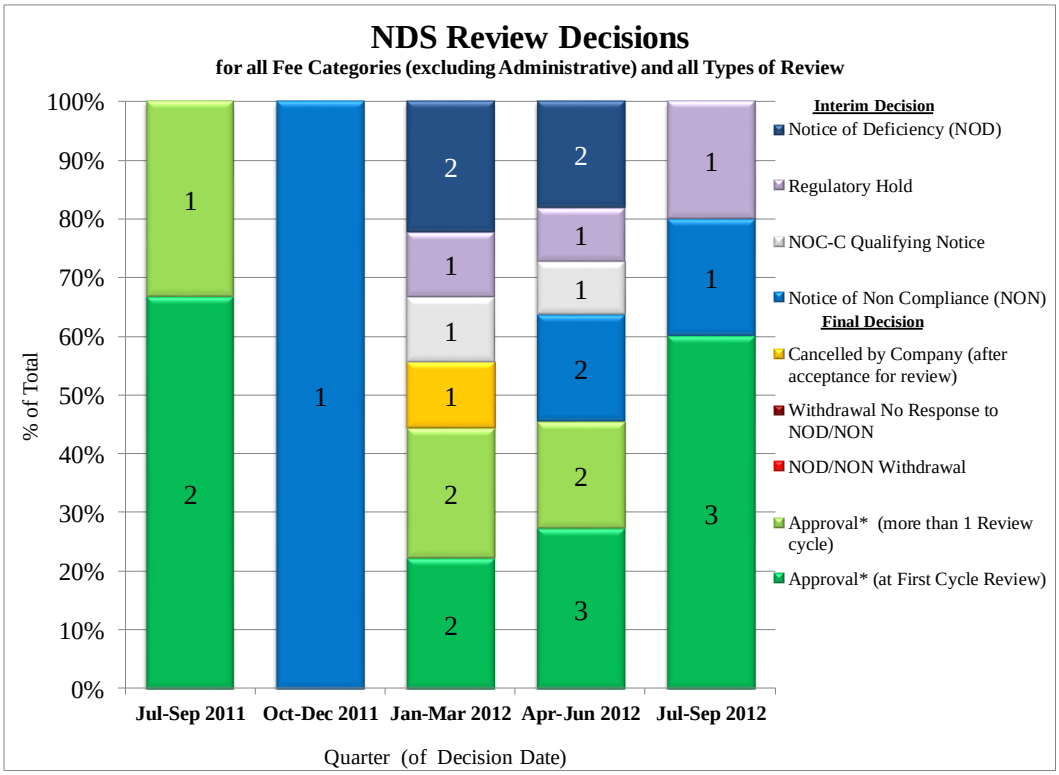
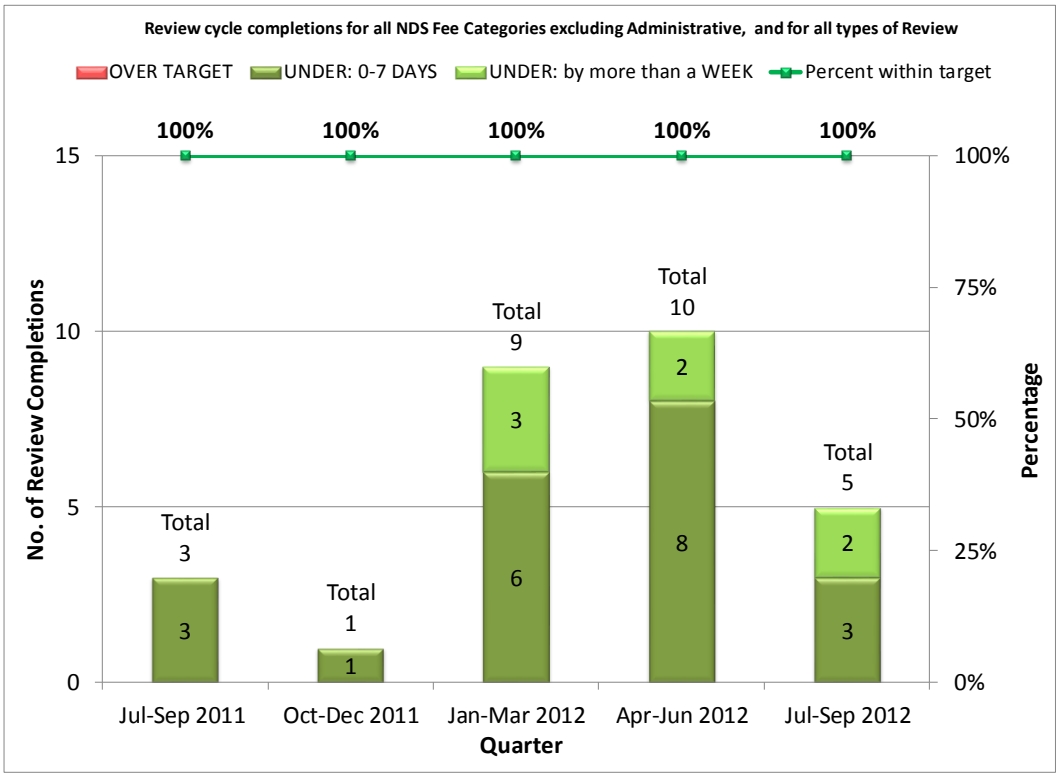
REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

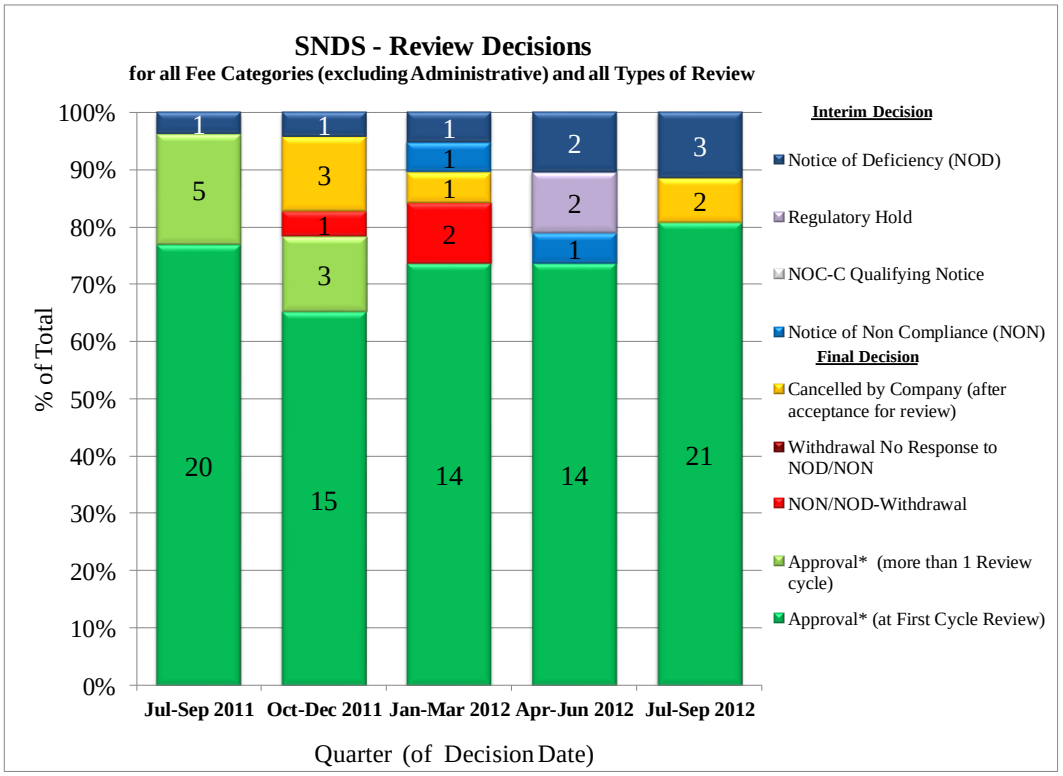


NDS - Review Cycle Completions Showing Percentage Within Target

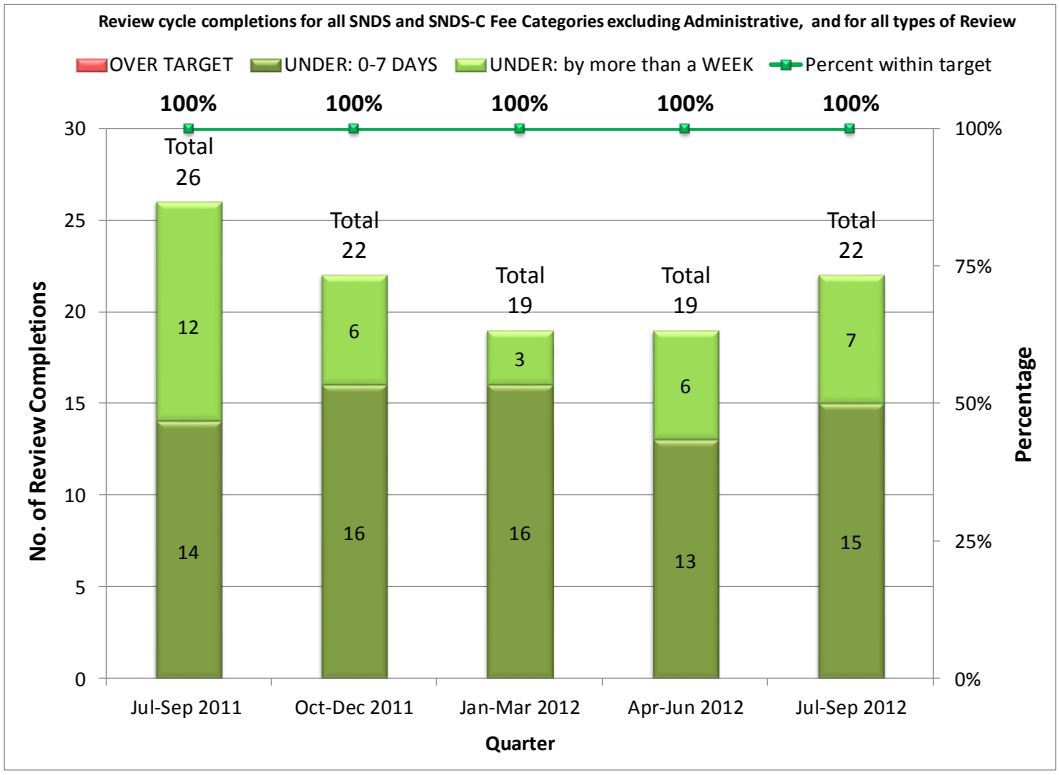


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

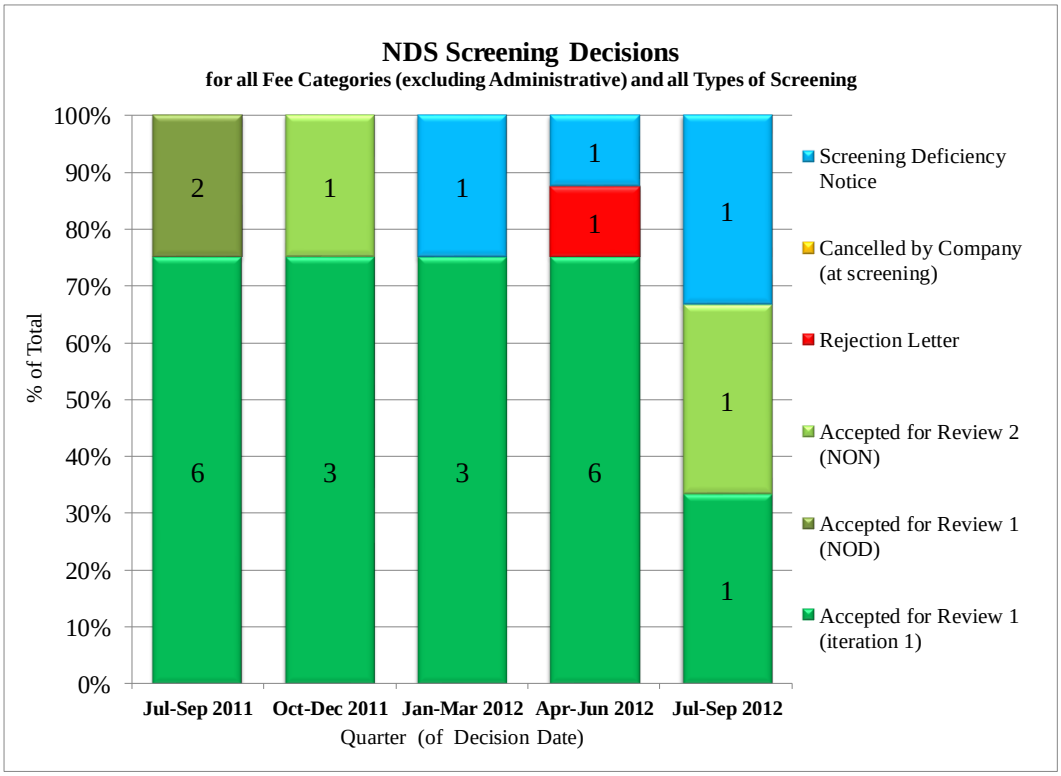


SNDS - Review Cycle Completions Showing Percentage Within Target

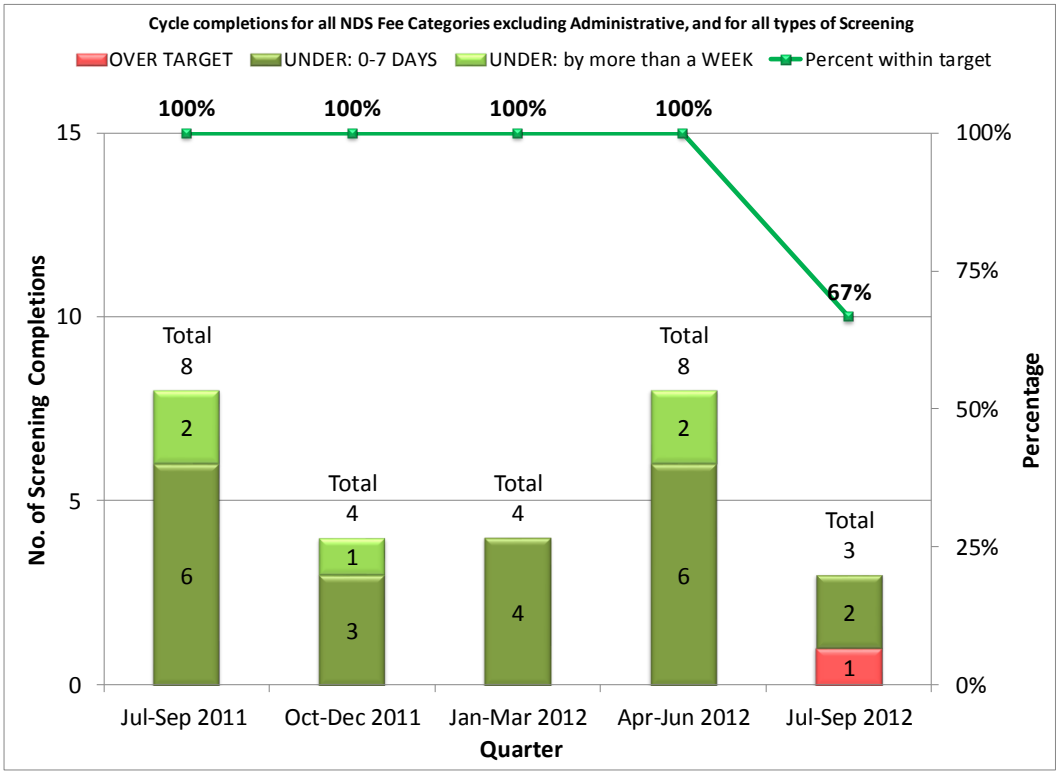


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

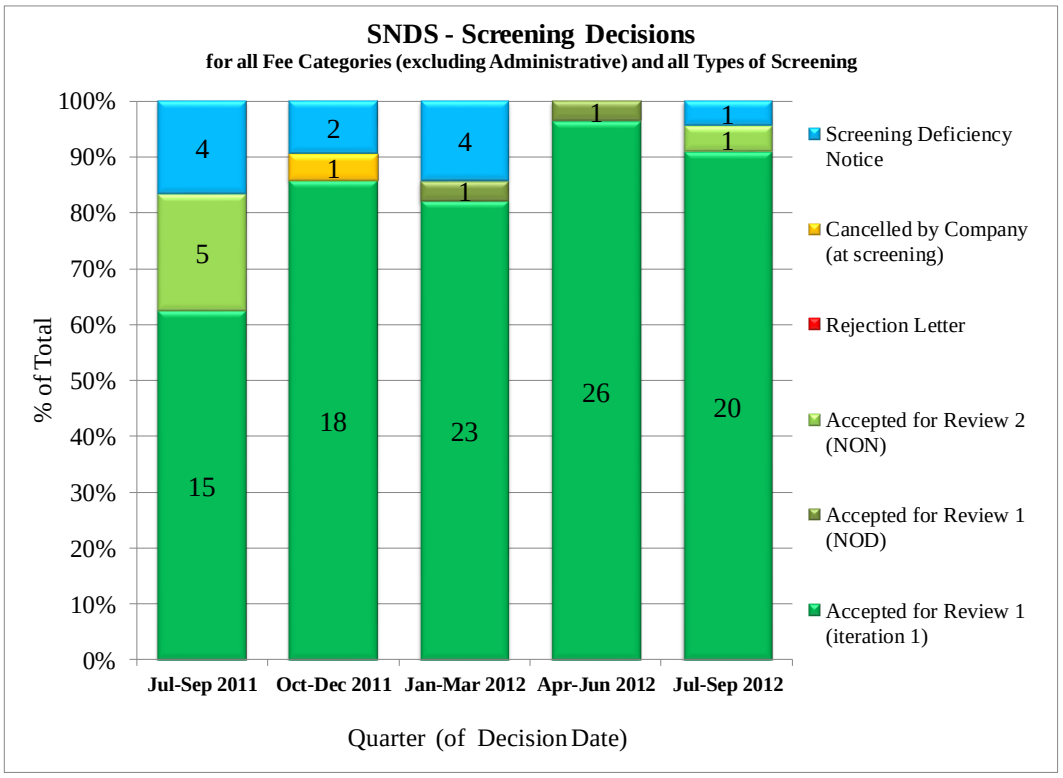


NDS - Screening Cycle Completions Showing Percentage Within Target

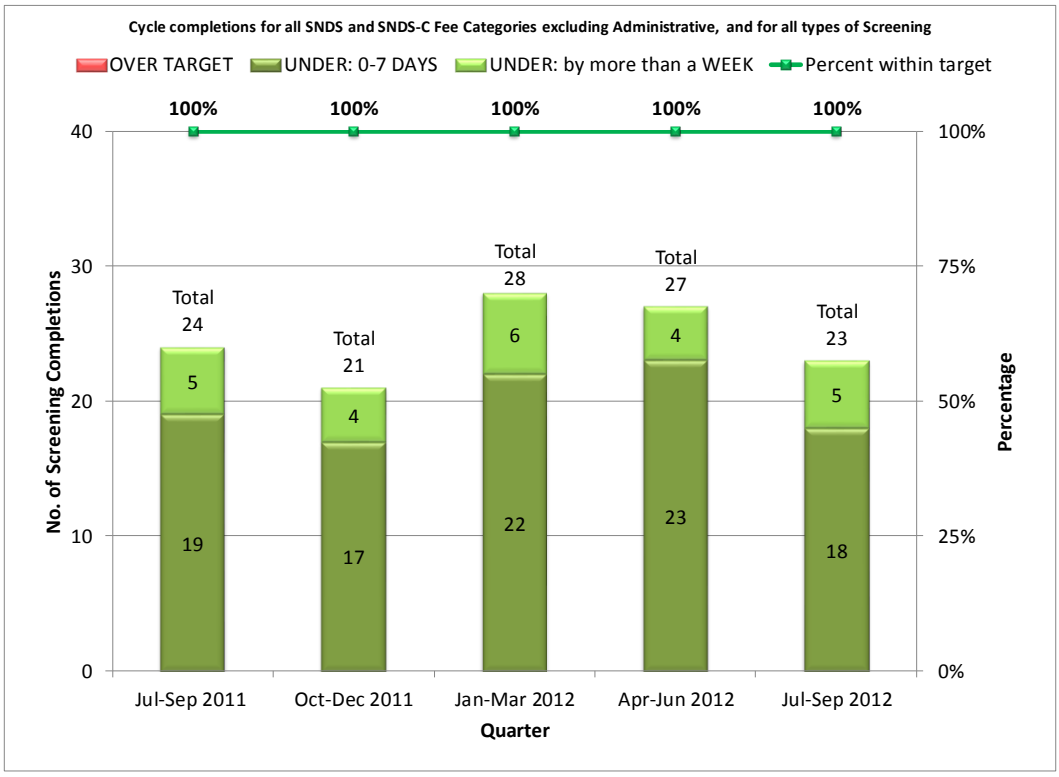


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions

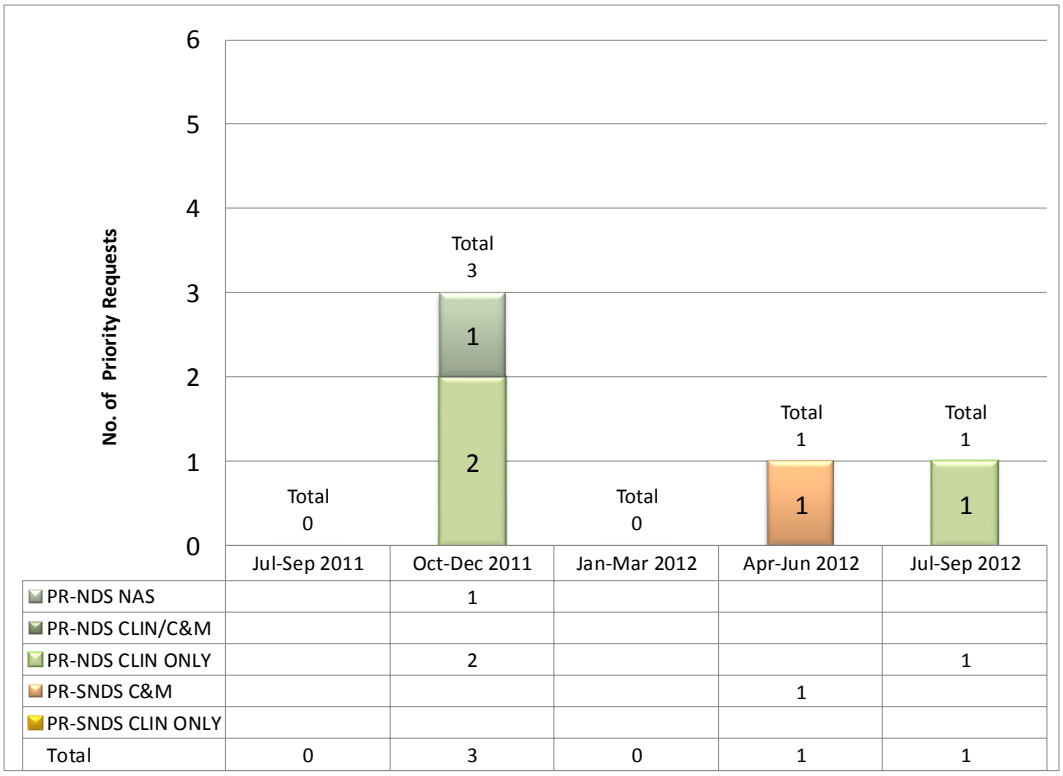


SNDS - Screening Cycle Completions Showing Percentage Within Target



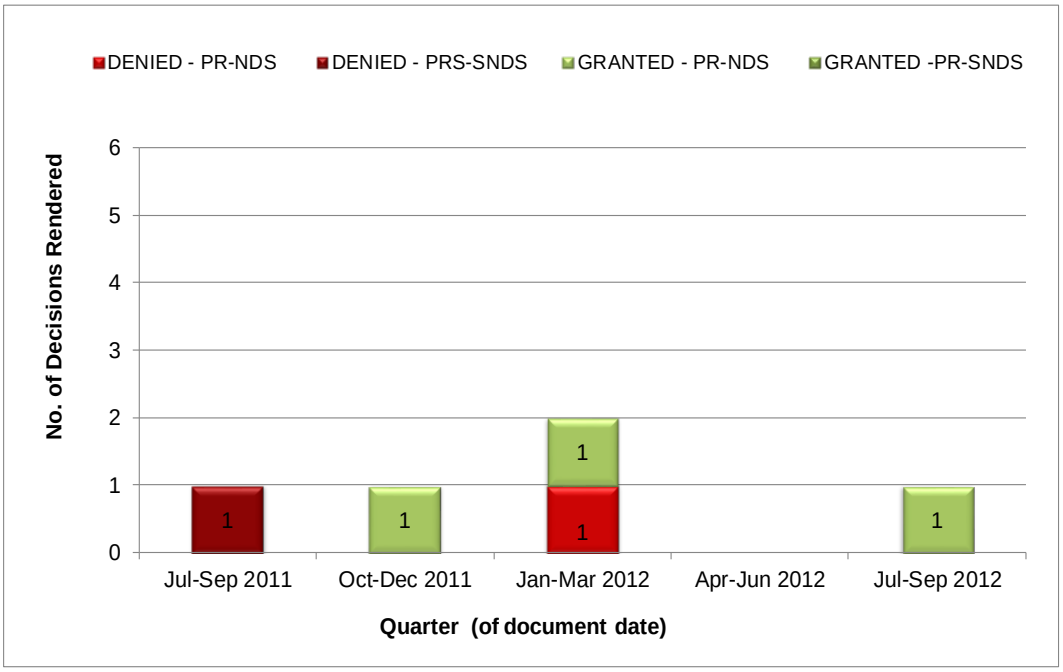
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

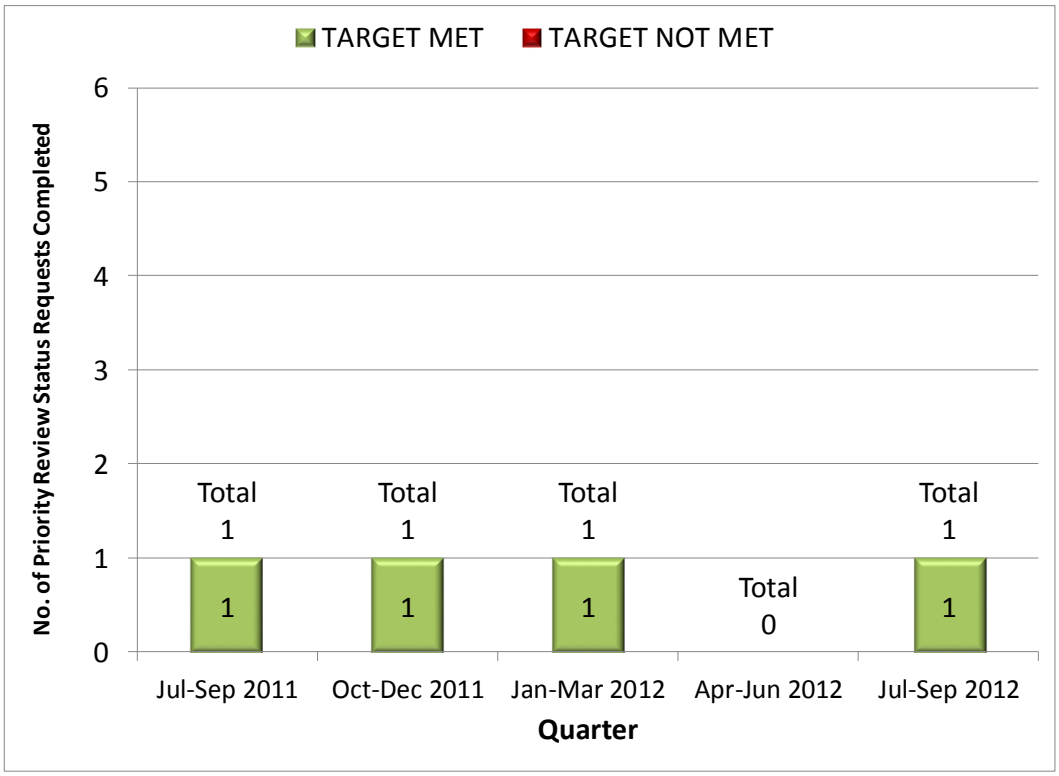


	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
PR-NDS NAS		1			
PR-NDS CLIN/C&M					
PR-NDS CLIN ONLY		2			1
PR-SNDS C&M				1	
PR-SNDS CLIN ONLY					
Total	0	3	0	1	1

Priority Review Status Requests: Decisions Rendered



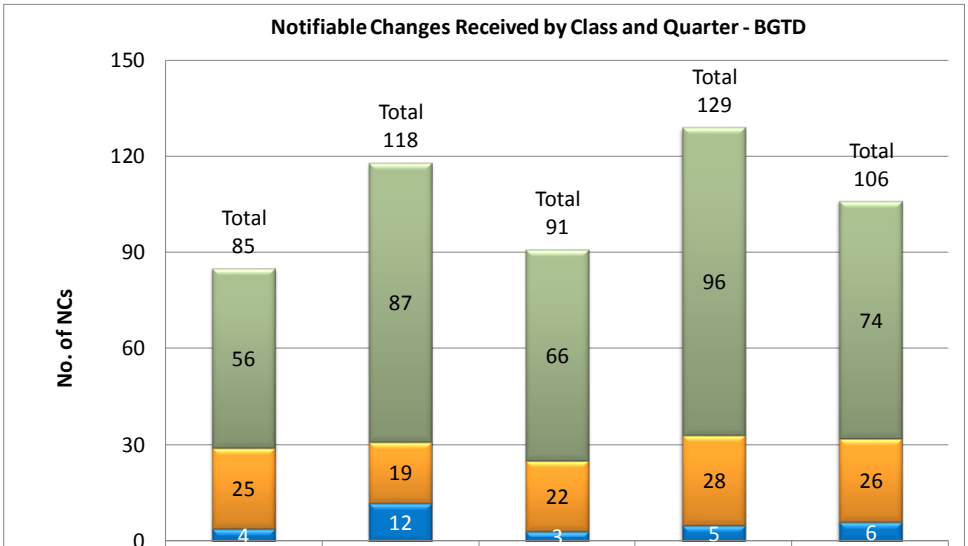
Priority Review Status Request: Performance



Notifiable Changes (NC)

NOTIFIABLE CHANGE[7, 8]

Submissions Received - Notifiable Change (NC)



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Quality (90)	56	87	66	96	74
Safety (90)	25	19	22	28	26
Safety (120)	4	12	3	5	6
Total	85	118	91	129	106

Decision Documents by Class - Notifiable Change (NC)

NC - SAFETY (90)					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	42	18	15	28	23
REJECTION LETTER (SCREENING)	2	3		3	1
CANCELLED BY COMPANY		3		1	1
NOT SATISFACTORY LETTER					1

NC - QUALITY (90)					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	72	54	85	35	97
NOT SATISFACTORY NOTICE	1	4			
REJECTION LETTER (SCREENING)	2	5	17	9	6
SCREENING DEFICIENCY NOTICE	2	2	2		1
CANCELLED BY COMPANY	3			5	1

NC - SAFETY (120)					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	4	2	10	4	6
REJECTION LETTER (SCREENING)		2			
SCREENING DEFICIENCY NOTICE		1			

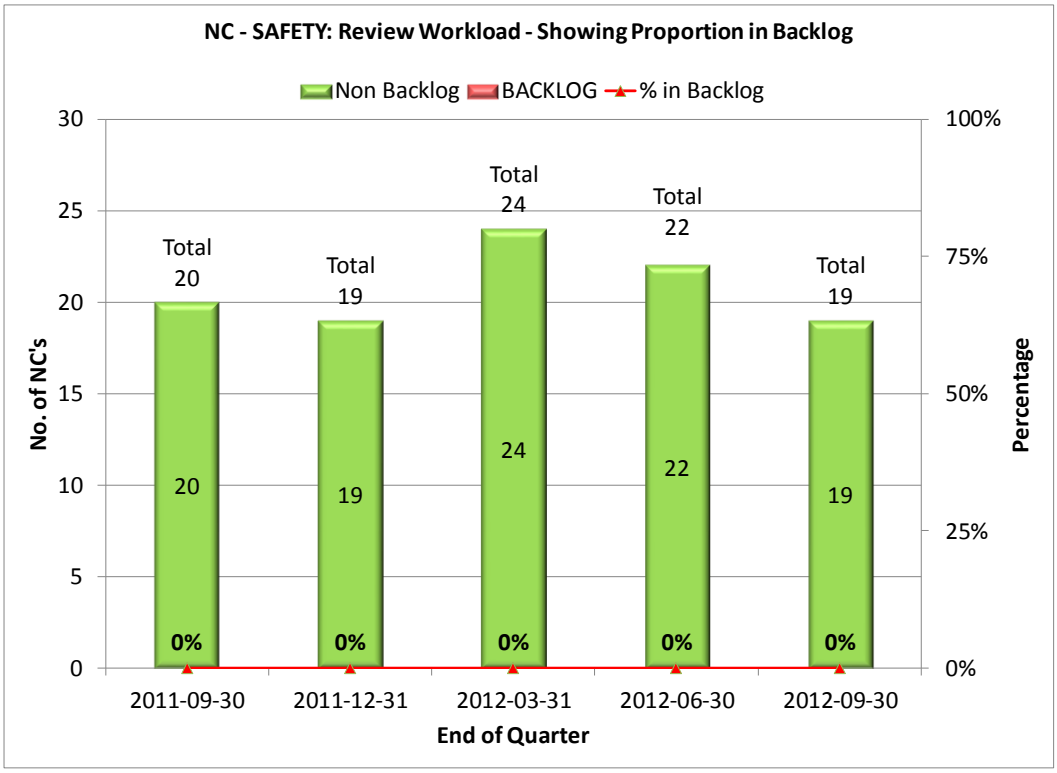
NC - ADMINISTRATIVE (QUALITY)					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	9	3	5	7	1
CANCELLED BY COMPANY			1		

[7] Post-Notice of Compliance (NOC) Changes Guidance Documents. were effective as of September 30, 2009 http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld-postnoc_change_apresac/noc_postnotice_ac_apresavis_change-eng.php

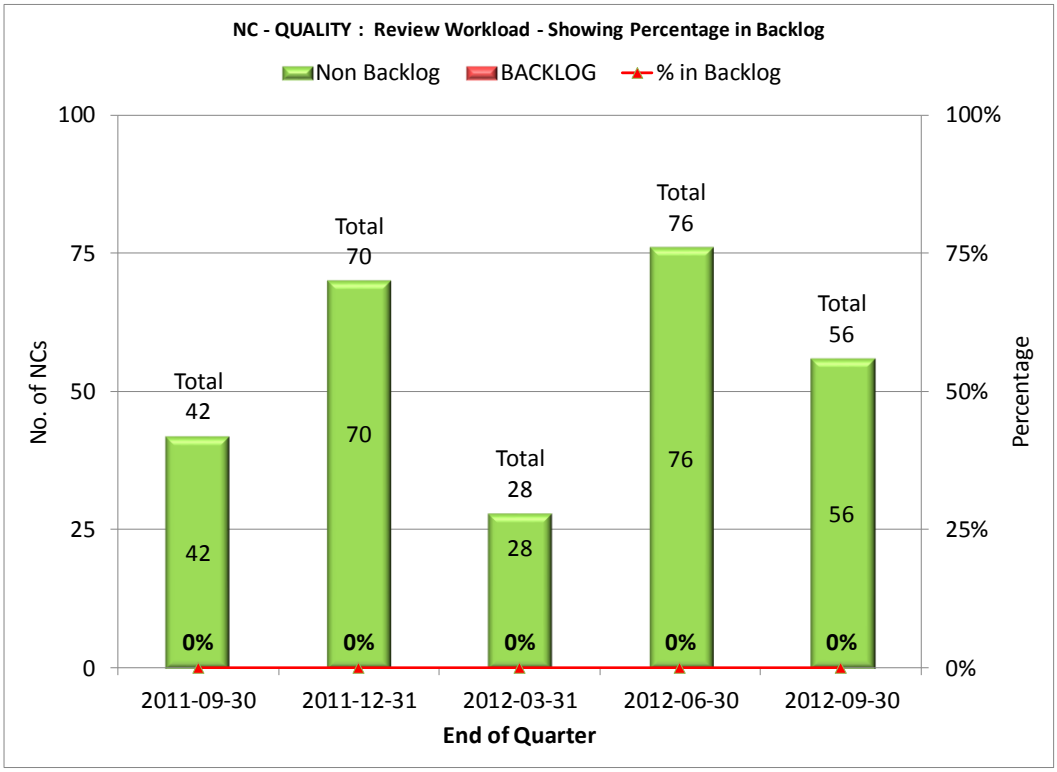
[8] Post-Notice of Compliance (NOC) Changes - Quality Guidance Appendix 1 for Human Pharmaceuticals became effective October 17, 2011.

WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload / Backlog



Notifiable Change (NC) QUALITY - Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload by Class

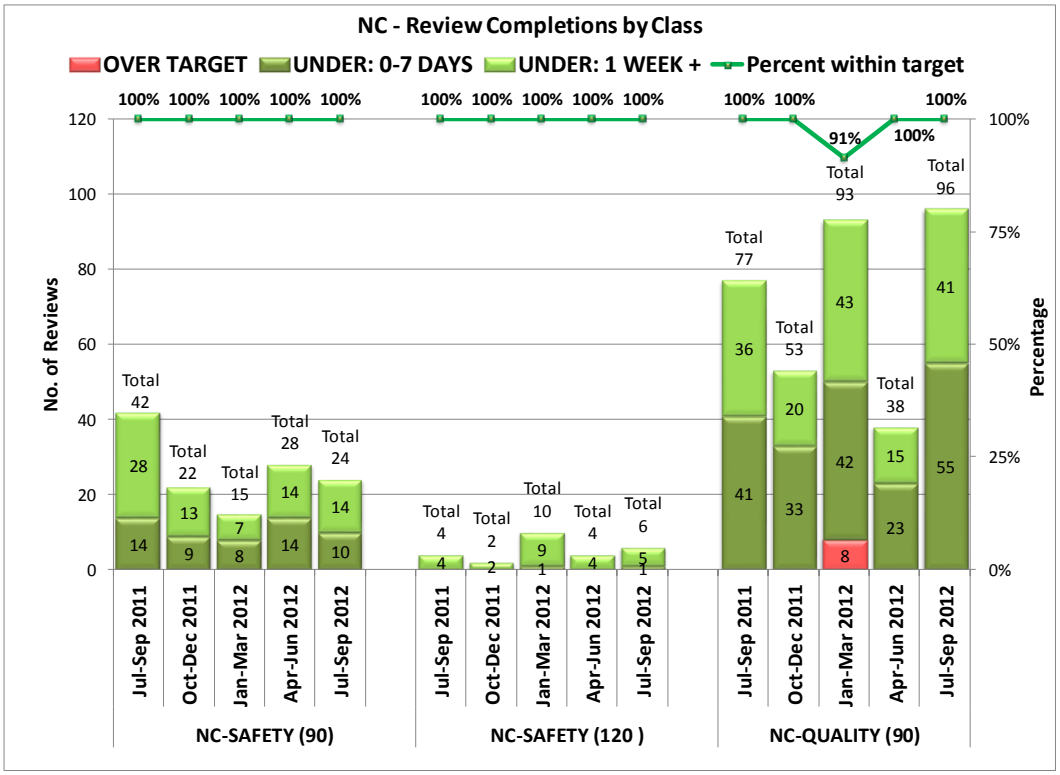
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
SAFETY - 90 day	19	10	22	20	16
Backlog	0	0	0	0	0
SAFETY - 120 day	1	9	2	2	3
	0	0	0	0	0
Total	20	19	24	22	19
Non Backlog	20	19	24	22	19
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

Notifiable Change (NC) QUALITY - Review Workload by Class

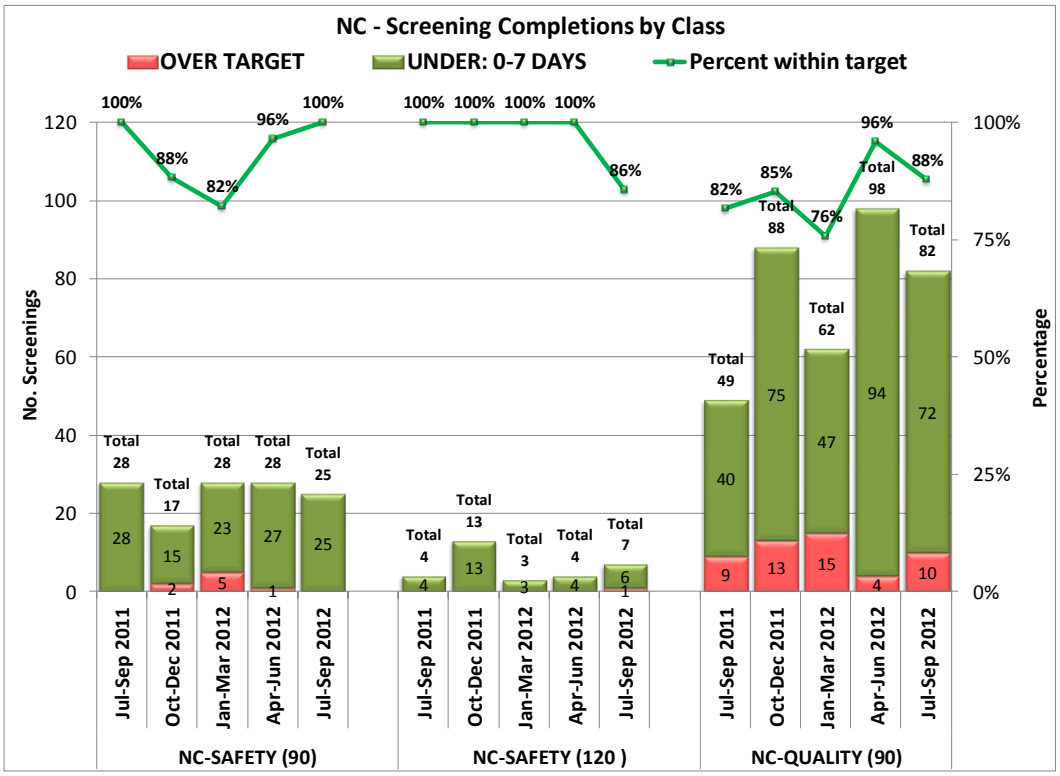
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
QUALITY - 90 day	42	70	28	76	56
Backlog	0	0	0	0	0
Total	42	70	28	76	56
Non Backlog	42	70	28	76	56
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

REVIEW Completions by Class - Notifiable Change (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



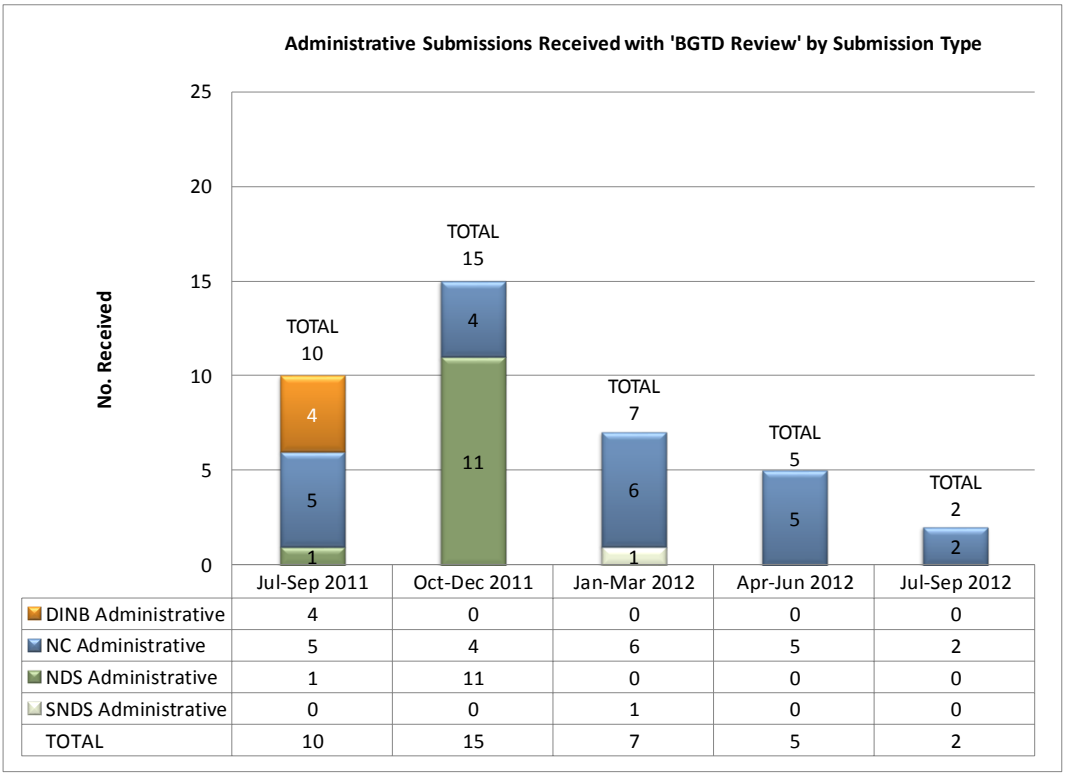
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS (with BGTD Review)

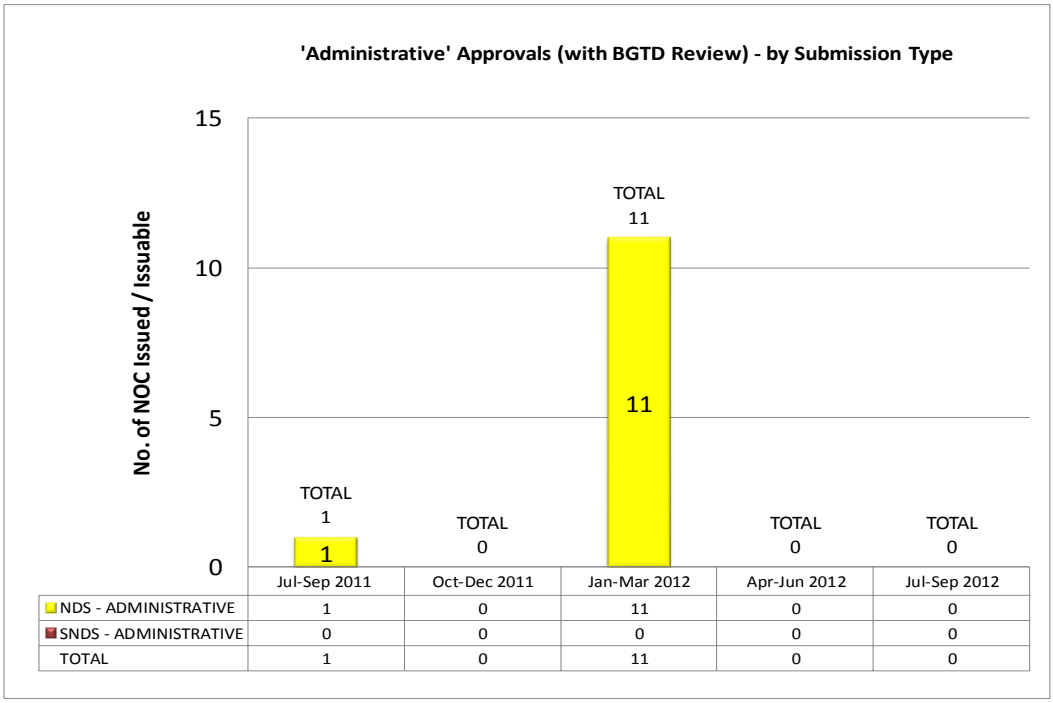
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD Review)



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
DINB Administrative	4	0	0	0	0
NC Administrative	5	4	6	5	2
NDS Administrative	1	11	0	0	0
SNDS Administrative	0	0	1	0	0
TOTAL	10	15	7	5	2

Administrative Submission Approvals (with BGTD Review)

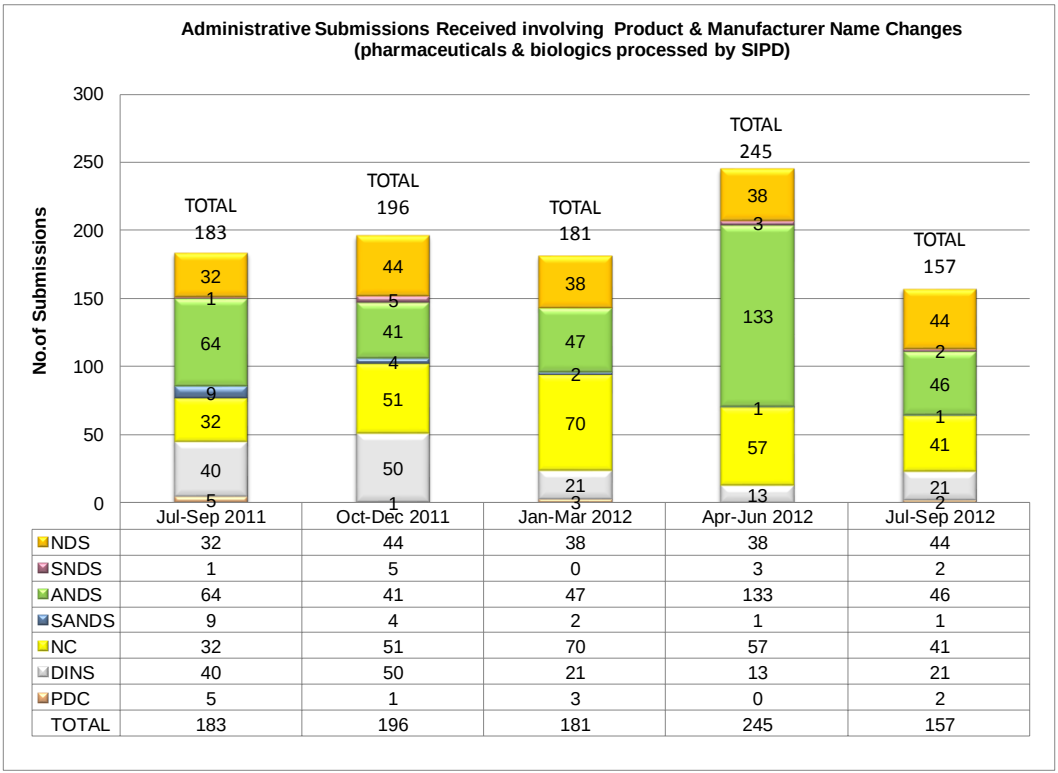


	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
NDS - ADMINISTRATIVE	1	0	11	0	0
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	1	0	11	0	0

ADMINISTRATIVE SUBMISSIONS (Processed by SIPD)

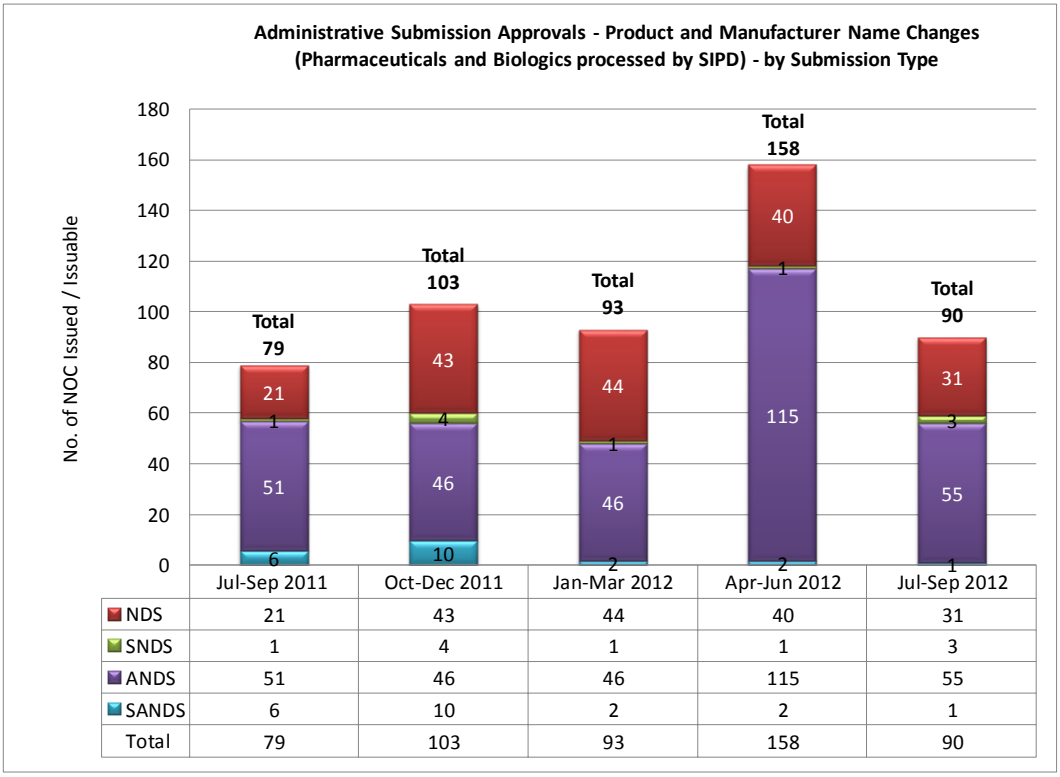
(Product & Manufacturer Name Changes)

Administrative Submissions Received by Submission Type (SIPD)



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
NDS	32	44	38	38	44
SNDS	1	5	0	3	2
ANDS	64	41	47	133	46
SANDS	9	4	2	1	1
NC	32	51	70	57	41
DINS	40	50	21	13	21
PDC	5	1	3	0	2
TOTAL	183	196	181	245	157

Administrative Submission Approvals (SIPD) - for NDS, SNDS, ANDS and SANDS



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
NDS	21	43	44	40	31
SNDS	1	4	1	1	3
ANDS	51	46	46	115	55
SANDS	6	10	2	2	1
Total	79	103	93	158	90

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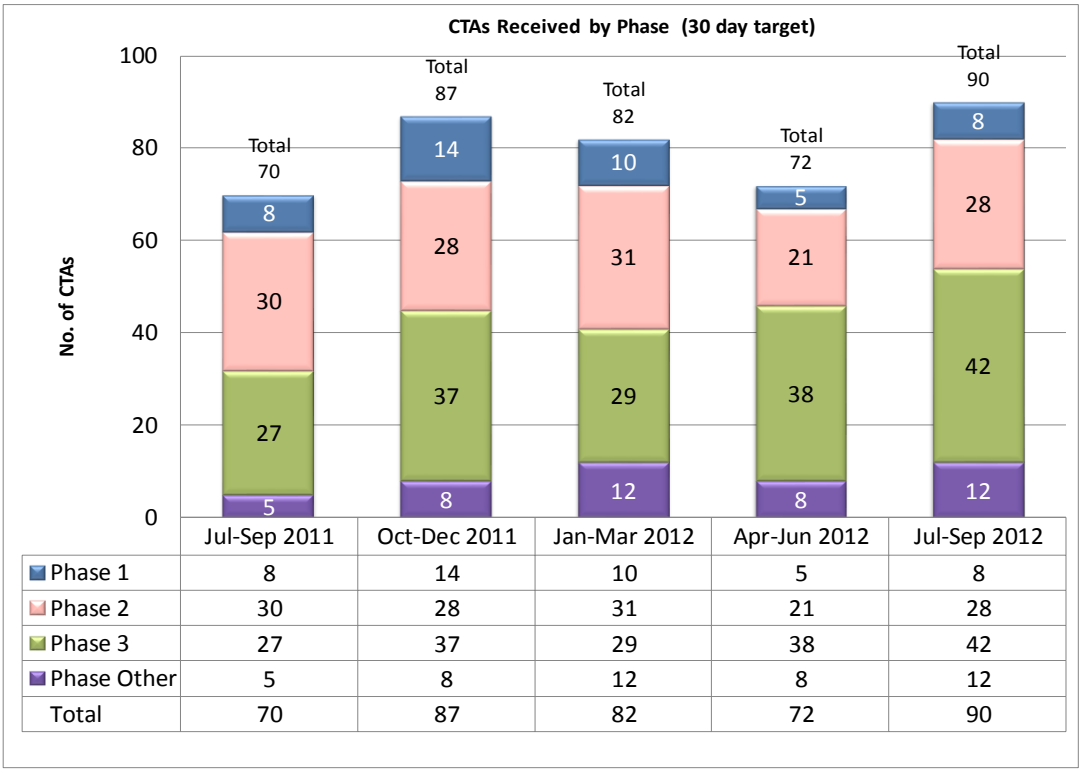
Clinical Trial Applications and Amendments

(CTA & CTA-A)

Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)

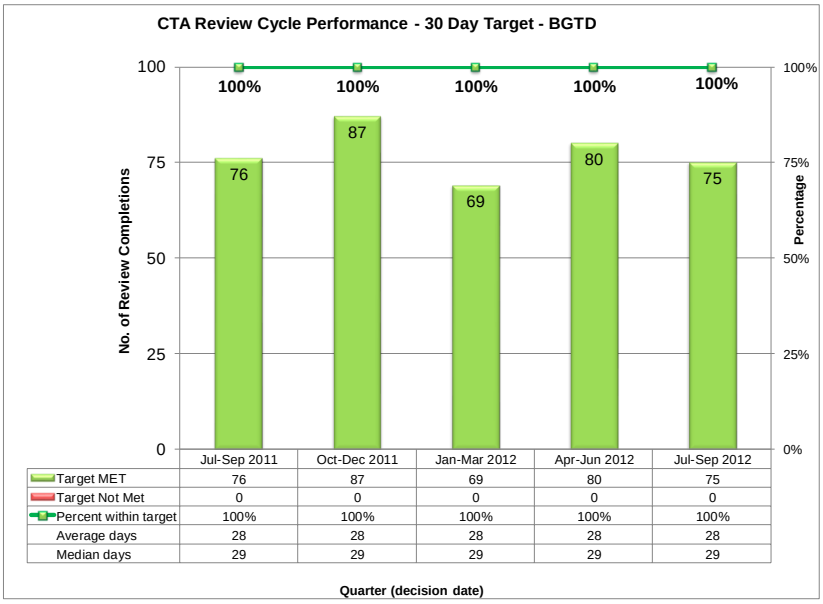


	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Phase 1	8	14	10	5	8
Phase 2	30	28	31	21	28
Phase 3	27	37	29	38	42
Phase Other	5	8	12	8	12
Total	70	87	82	72	90

Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	75	80	66	79	72
CANCELLED BY COMPANY	4	6	6	1	6
NOT SATISFACTORY NOTICE		1	1		1
REJECTION LETTER (SCREENING)			1	1	

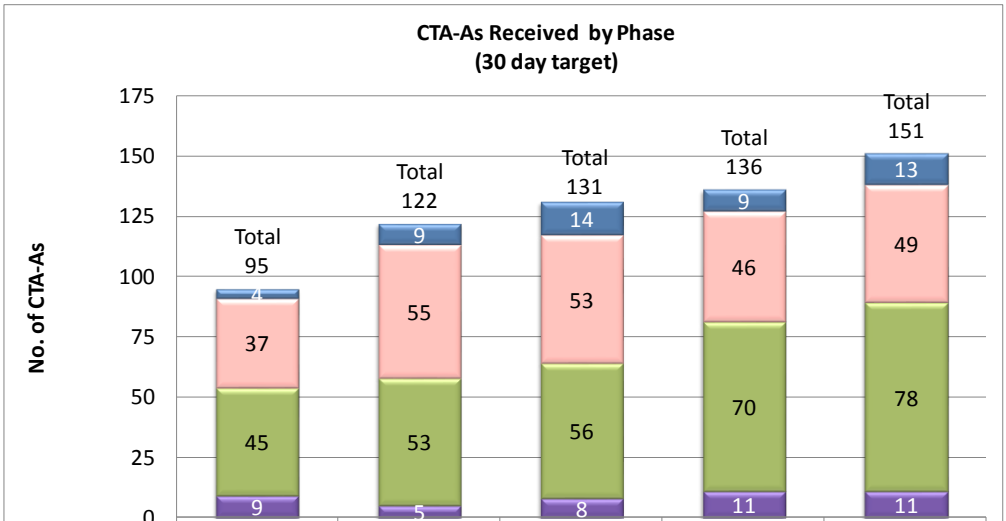
Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Target MET	76	87	69	80	75
Target Not Met	0	0	0	0	0
Percent within target	100%	100%	100%	100%	100%
Average days	28	28	28	28	28
Median days	29	29	29	29	29

Clinical Trial Application- Amendments (CTA-A)

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

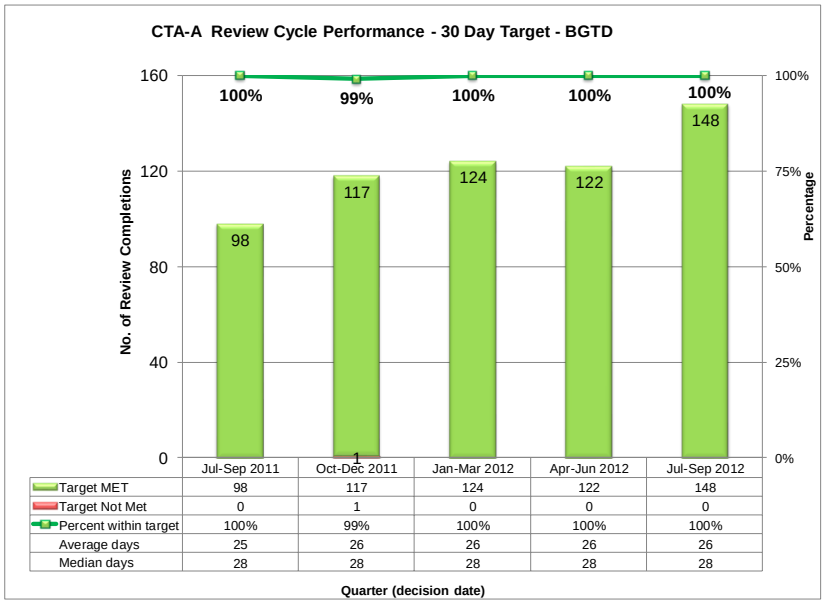


	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Phase 1	4	9	14	9	13
Phase 2	37	55	53	46	49
Phase 3	45	53	56	70	78
Phase Other	9	5	8	11	11
Total	95	122	131	136	151

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

CTA-A					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	100	118	124	123	143
REJECTION LETTER (SCREENING)				3	
CANCELLED BY COMPANY			2	2	5
NOT SATISFACTORY NOTICE			3		1

Performance – CTA-A Reviews - 30 Day Target



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Target MET	98	117	124	122	148
Target Not Met	0	1	0	0	0
Percent within target	100%	99%	100%	100%	100%
Average days	25	26	26	26	26
Median days	28	28	28	28	28

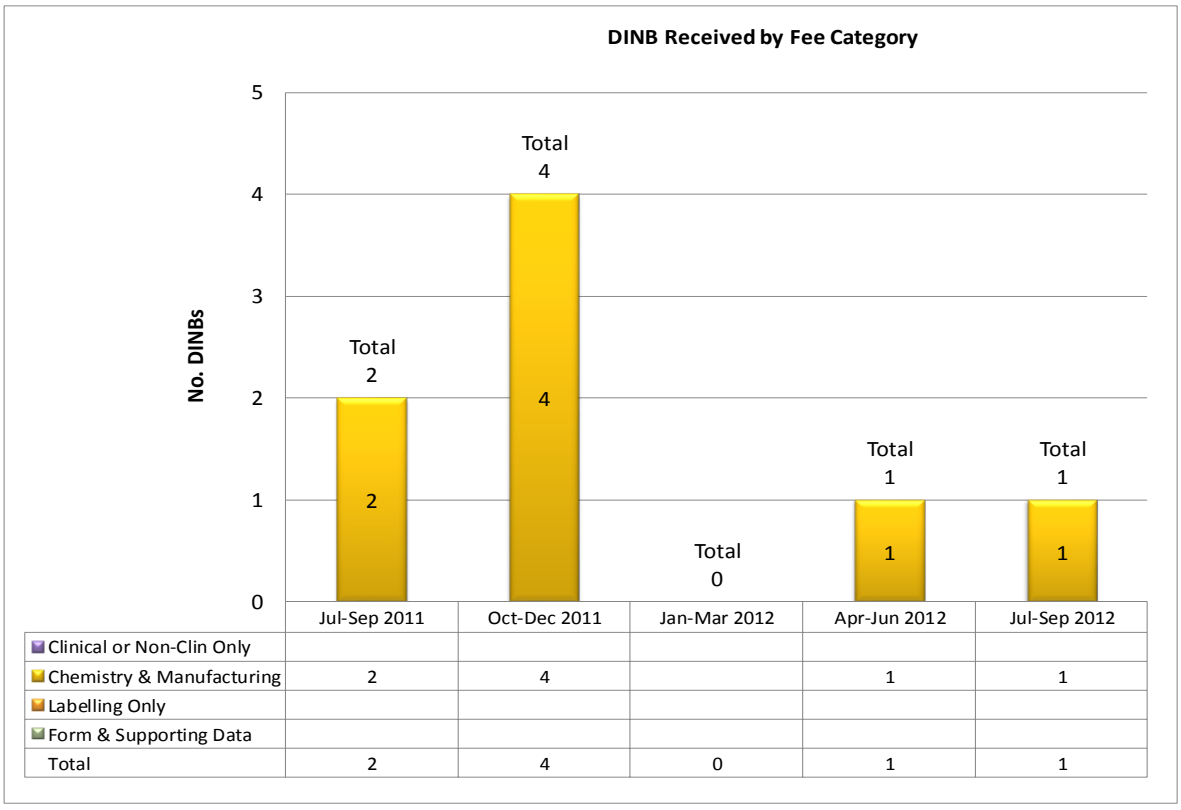
DINB

Application for a Drug Identification Number

Biological Product

DINB: Application for a Drug Identification Number – BIOLOGICAL PRODUCT

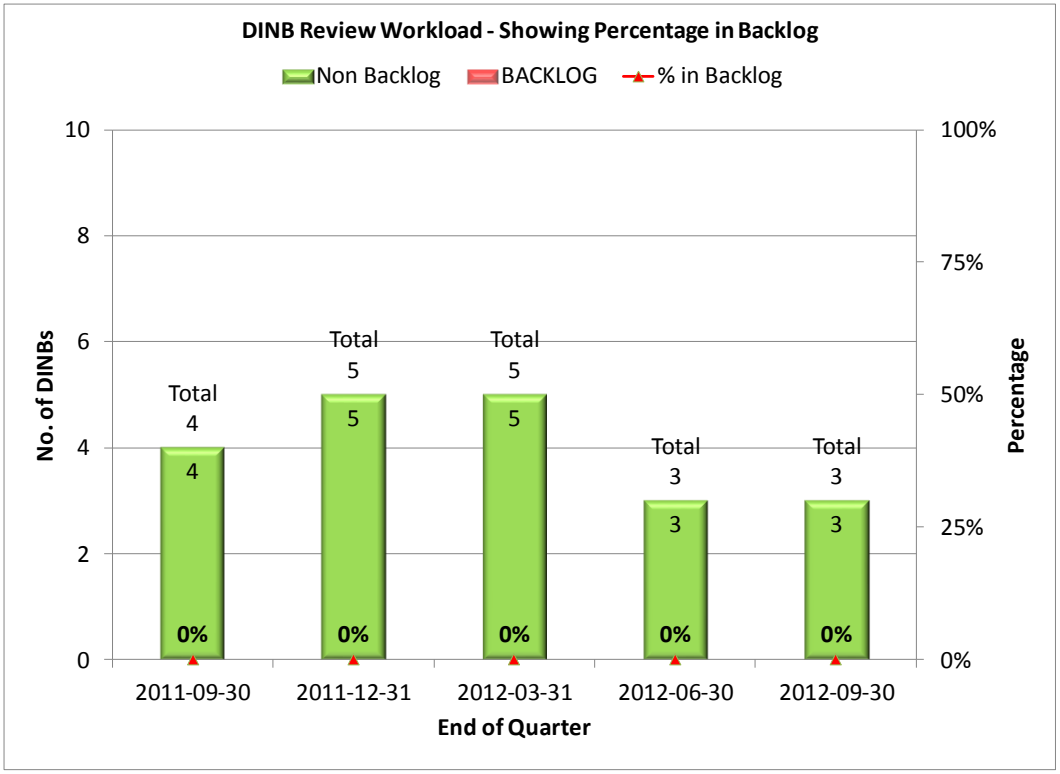
Number Received - DINB



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Clinical or Non-Clin Only					
Chemistry & Manufacturing	2	4		1	1
Labelling Only					
Form & Supporting Data					
Total	2	4	0	1	1

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DINB

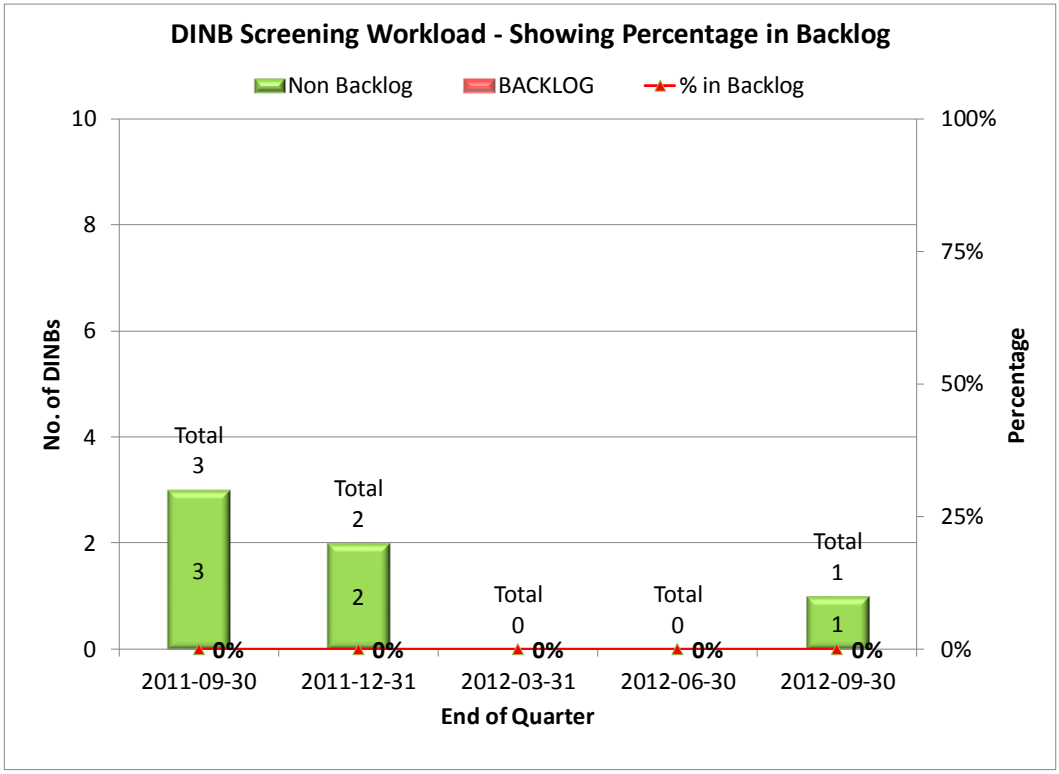


Review Workload by Class - DINB

BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
Labelling Only (Form)	0	0	0	0	0
Backlog	0	0	0	0	0
Form and Supporting Data	**2**	**1**	**1**	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**2**	**4**	**4**	**3**	**3**
Backlog	0	0	0	0	0
Total	**4**	**5**	**5**	**3**	**3**
Non Backlog	**4**	**5**	**5**	**3**	**3**
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					
	2011-09-30	2011-12-31	2012-03-31	2012-06-30	2012-09-30
Labelling Only (Form)	0	0	0	0	0
Backlog	0	0	0	0	0
Form & Supporting Data	**1**	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	0	0	0
Backlog	0	0	0	0	0
Chemistry & Manufacturing	**2**	**2**	0	0	**1**
Backlog	0	0	0	0	0
Total	**3**	**2**	0	0	**1**
Non Backlog	**3**	**2**	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 (Form)					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	4				

DINB - FORM AND SUPPORTING DATA					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	1				
NOTIFICATION FORM/DIN ISSUED		1			

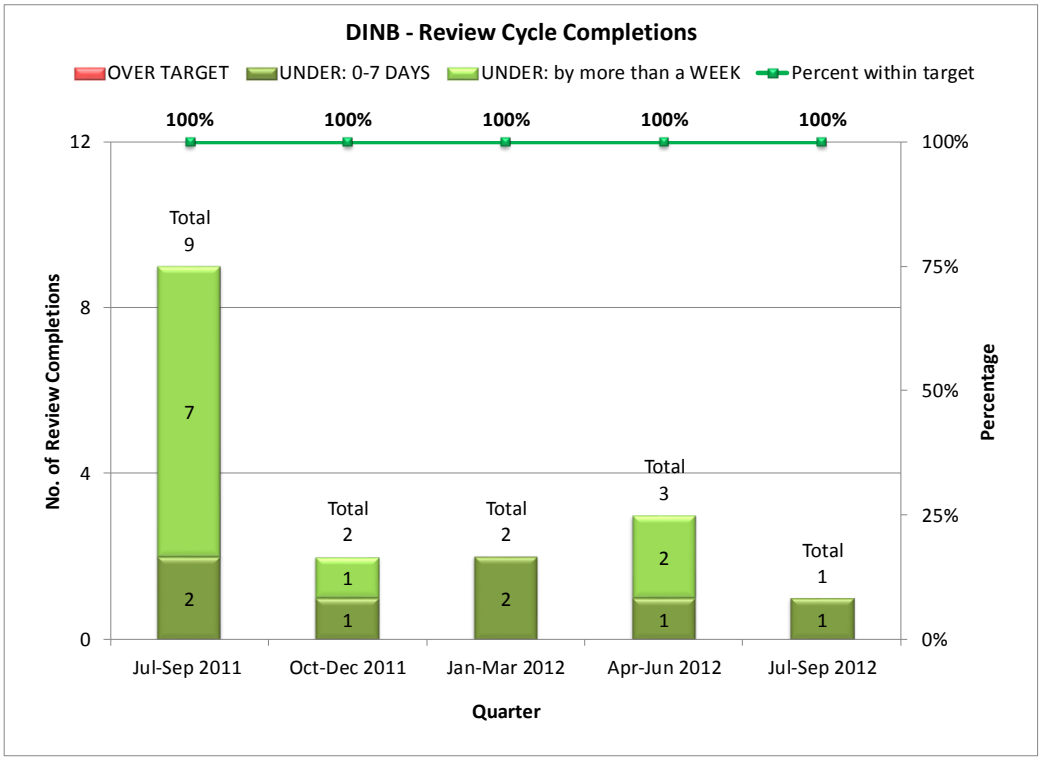
DINB - CLIN ONLY					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER					

DINB - C&M ONLY					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NO OBJECTION LETTER	2				
SCREENING DEFICIENCY NOTICE	1	3	2		
NOTICE OF DEFICIENCY			1		
CANCELLED BY COMPANY		2			

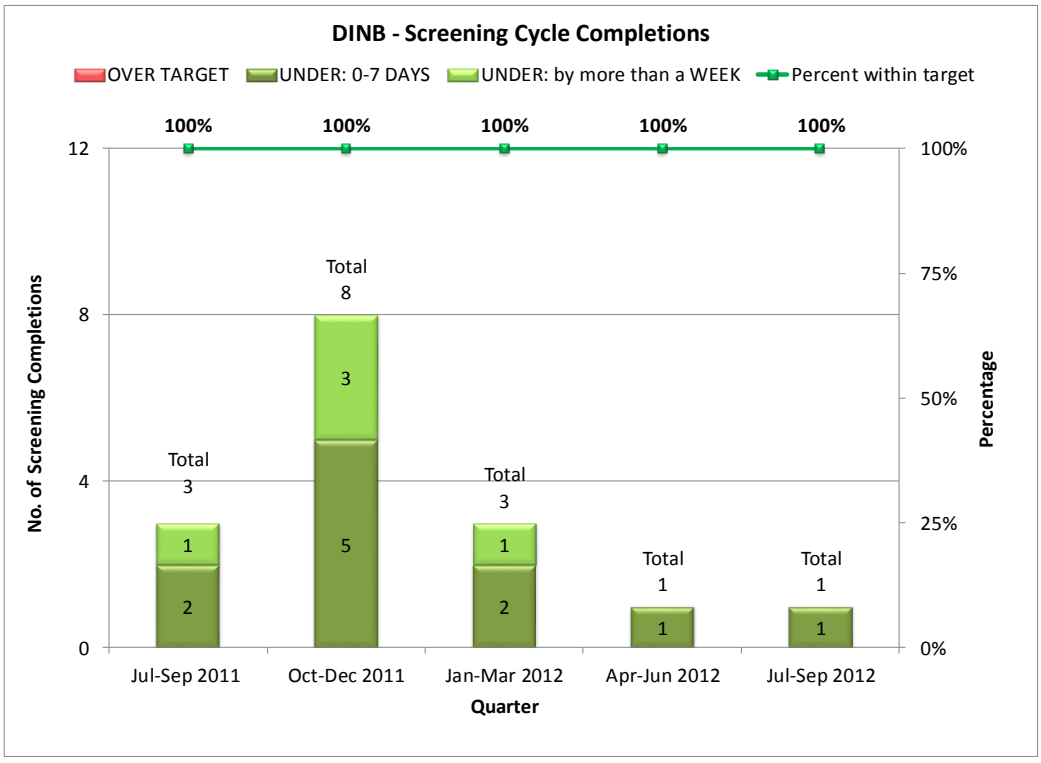
DINB - ADMINISTRATIVE					
DOCUMENT TYPE	**Jul-Sep 2011**	**Oct-Dec 2011**	**Jan-Mar 2012**	**Apr-Jun 2012**	**Jul-Sep 2012**
NOTIFICATION FORM/DIN ISSUED	4				5

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target - DINB

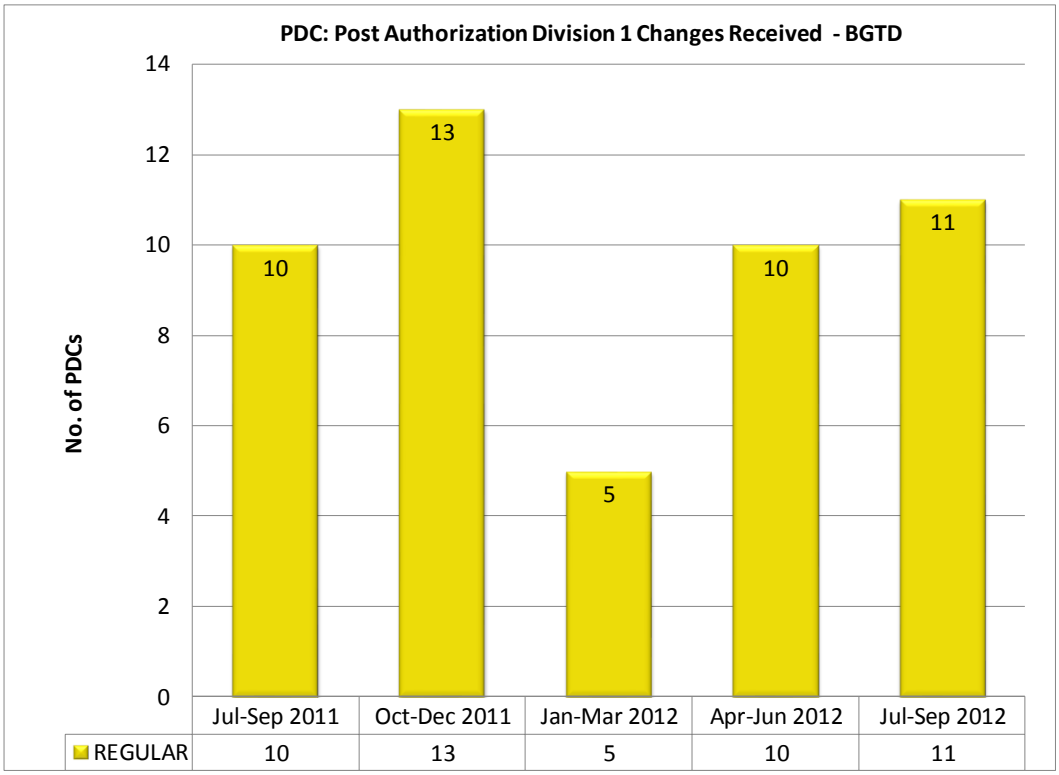


Performance Screening Cycle Completions Showing Percentage Within Target - DINB



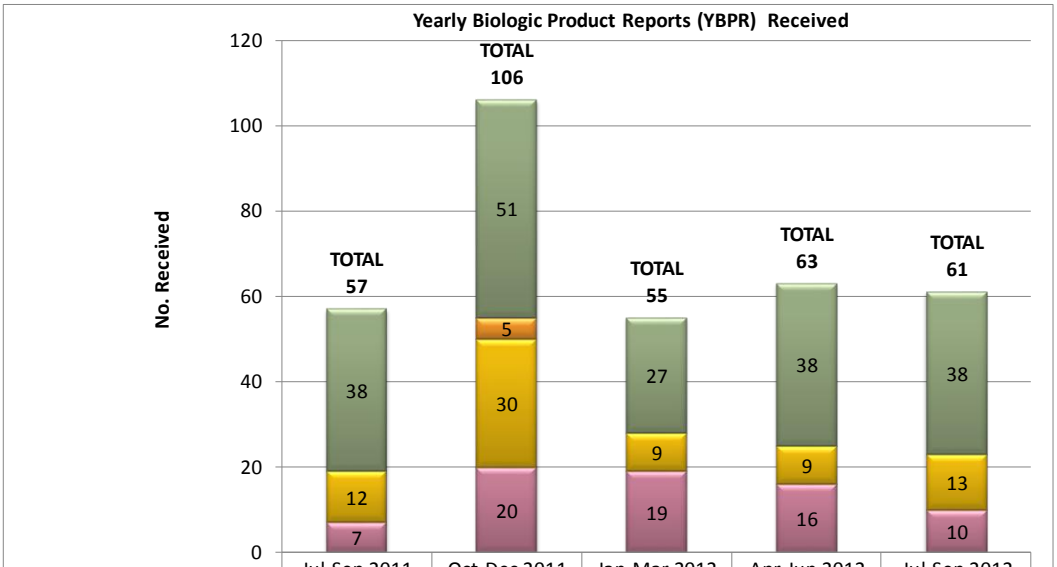
Post –Authorization Division 1 Changes (PDC)

Post –Authorization Division 1 Changes (PDC) Received



Yearly Biologic Product Reports (YBPR[9])

Yearly Biologic Product Report s (YBPR) Received



	Jul-Sep 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012	Jul-Sep 2012
Radiopharmaceuticals and Biotherapeutics	38	51	27	38	38
Biologics		5			
Blood and Tissues	12	30	9	9	13
Vaccines	7	20	19	16	10
TOTAL	57	106	55	63	61

[9] 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.

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