



Canadian
Cancer Clinical
Trials Network

Canadian Cancer Clinical Trials Network

Quarter Performance Report

Quarter 3, FY 2018/19 (Year 5): October 1 – December 31, 2018

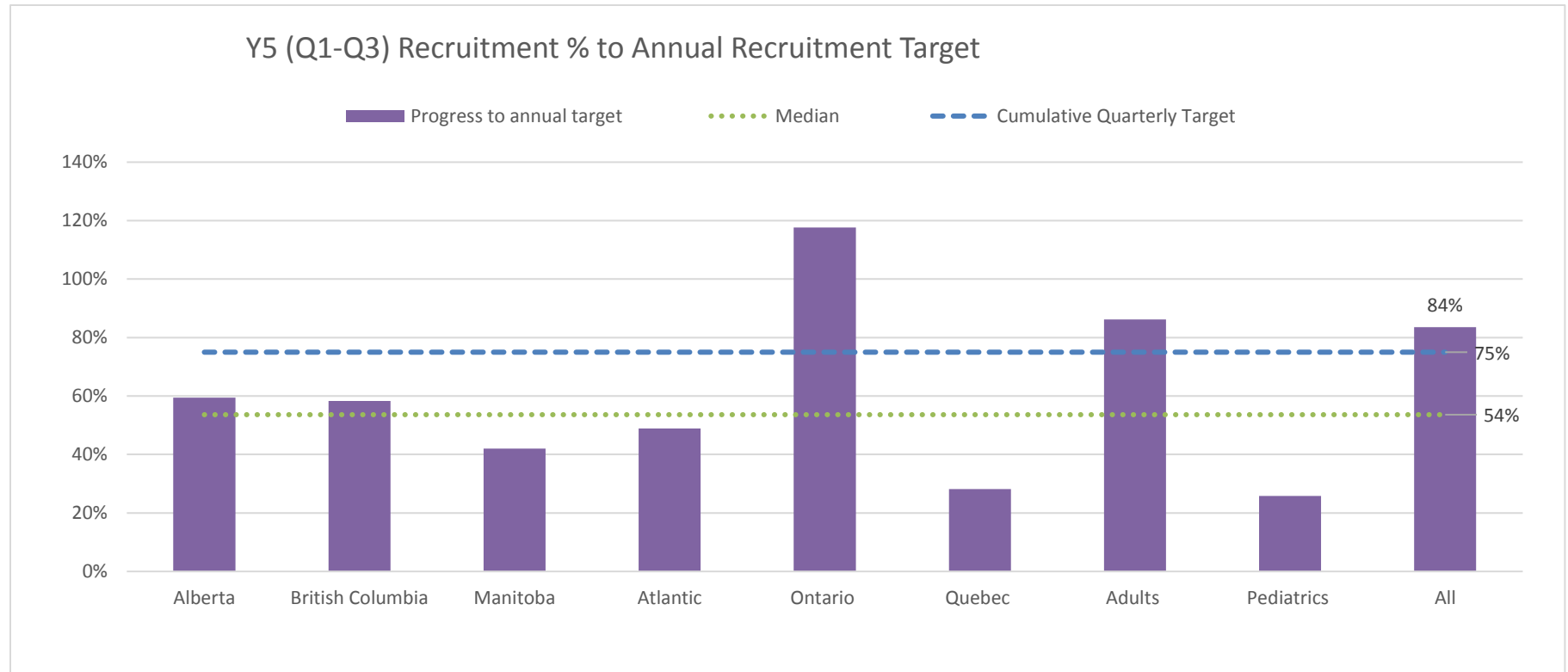
Table of Contents

Section A: Patient access and recruitment to the 3CTN Portfolio Trials.....	2
Patient Recruitment at All Network Sites	2
Number of patients recruited and number of Portfolio trials per Network site (by fiscal year).....	3
Patient recruited to 3CTN Portfolio trials, FY2019/20 (Y5) – BC, Alberta and Manitoba.....	3
Number of active recruiting 3CTN Portfolio trials – BC, Alberta and Manitoba.....	4
Patients recruited to 3CTN Portfolio trials, FY2019/20 (Y5) – Ontario	5
Number of active recruiting 3CTN Portfolio trials – Ontario	6
Patients recruited to 3CTN Portfolio trials, FY2018/19 (Y5) – Atlantic Region and Quebec.....	7
Number of Active Recruiting 3CTN Portfolio Trials – Atlantic Region and Quebec.....	8
Section B: 3CTN Portfolio Metrics.....	9
Active Recruiting Portfolio trials by disease site and phase.....	9
Active Recruiting Portfolio trials by study type and noted features.....	10
Overall Portfolio Complexity Breakdown, (Jan – Dec 2018)	10
Portfolio Impact Assessment.....	11
Overview of Portfolio applications.....	14
Appendix: Additional Notes	16
Table 1: Site Efficiency definitions	16
Table 2: Study Impact Criteria Definitions.....	17
Table 3. Reporting periods and dates Q4 2014/15 – Q4 2018/19	18

Section A: Patient access and recruitment to the 3CTN Portfolio Trials

Patient Recruitment at All Network Sites

Objective: To improve patient access to academic clinical trials and improve patient recruitment by greater than 75% within four years



Notes:

- 978 patients were recruited to Portfolio trials in Quarter 3, 2018/19. Y5 target is to achieve 55% above pre-3CTN baseline.
- Although the Q1-Q3 YTD accrual of 3098 patients surpassed the cumulative quarterly target of 2781 patients for the Network overall, Ontario was the only region currently on track to meet annual recruitment targets.
- The TMIST trial being conducted by 2 Ontario Cancer Centers contributed 651 patients to Ontario's total recruitment during this period and accounted for 21% of the entire Network total.

Number of patients recruited and number of Portfolio trials per Network site (by fiscal year)

Objectives: to improve patient access to academic clinical trials and improve patient recruitment by greater than 75% within four years;

Patient recruited to 3CTN Portfolio trials, FY2019/20 (Y5) – BC, Alberta and Manitoba

Network Site	Pre-3CTN Baseline	Q1	Q2	Q3	Y5 (YTD) Total	% of Baseline	% to Y5 Target
CancerCare Manitoba	99	18	25	31	74	75%	48%
Prairie Mountain Health	1	0	0	0	0	0%	0%
CancerCare Manitoba - Pediatrics	18	2	1	0	3	17%	11%
CancerCare Manitoba Total	118	20	26	31	77	65%	42%
BC Cancer Agency - Vancouver Centre	106	31	23	15	69	65%	42%
Abbotsford Centre	16	5	4	3	12	75%	48%
Centre for the North, Prince George	1	1	4	3	8	800%	516%
Sindi Ahluwalia Hawkins Centre for the Southern Interior	38	5	14	6	25	66%	42%
Vancouver Island Centre	26	18	18	19	55	212%	136%
British Columbia Cancer Agency Total	187	60	63	46	169	90%	58%
Alberta Health Services, Cross Cancer Institute	102	42	24	17	83	81%	52%
Alberta Health Services, Tom Baker Cancer Centre	76	24	34	23	81	107%	69%
Alberta Health Services Total	178	66	58	40	164	92%	59%
Western Region Total	483	146	147	117	410	85%	55%

Number of active recruiting 3CTN Portfolio trials – BC, Alberta and Manitoba

Network Site	Q1 2018-19	Q2 2018-19	Q3 2018-19
CancerCare Manitoba	28	27	29
Prairie Mountain Health	0	0	1
CancerCare Manitoba - Pediatrics	17	17	15
BC Cancer Agency - Vancouver Centre	25	25	27
Abbotsford Centre	4	4	4
Centre for the North, Prince George	3	3	3
Sindi Ahluwalia Hawkins Centre for the Southern Interior	9	10	6
Vancouver Island Centre	5	6	5
Alberta Health Services, Cross Cancer Institute	32	33	35
Alberta Health Services, Tom Baker Cancer Centre	34	30	28

Patients recruited to 3CTN Portfolio trials, FY2019/20 (Y5) – Ontario

Network Site	Pre-3CTN Baseline	Q1	Q2	Q3	Y5 (YTD) Total	% of Baseline	% to Y5 Target	% to Y5 Target w/o TMIST
London Health Sciences Centre	186	63	57	54	174	94%	60%	60%
Grand River Regional Cancer Centre	20	8	9	10	27	135%	87%	87%
Windsor Regional Cancer Centre	14	6	5	2	13	93%	60%	60%
Hamilton Health Sciences, Juravinski Cancer Centre	181	132	77	65	274	151%	98%	98%
Cambridge Memorial Hospital	11	1	0	0	1	9%	6%	6%
St. Joseph's Healthcare Hamilton	21	14	13	6	33	157%	101%	101%
Walker Family Cancer Centre, Niagara Health System	17	8	4	10	22	129%	83%	83%
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	141	138	183	183	504	357%	231%	93%
Humber River Hospital	1	2	2	2	6	600%	387%	387%
Michael Garron Hospital (Toronto East General)	2	2	0	0	2	100%	65%	65%
Princess Margaret Cancer Centre	396	199	150	208	557	141%	91%	91%
Markham Stouffville Hospital	1	0	0	0	0	0%	0%	0%
Mount Sinai Hospital	21	2	3	2	7	33%	22%	22%
Northeast Cancer Centre - Health Sciences North	24	7	6	4	17	71%	46%	46%
North York General Hospital	1	2	1	2	5	500%	323%	323%
Royal Victoria Regional Health Centre	8	4	3	2	9	113%	73%	73%
Southlake Regional Health Centre	10	19	16	16	51	510%	329%	329%
St. Michael's Hospital	19	0	1	0	1	5%	3%	3%
Thunder Bay Regional Health Sciences Centre	26	18	3	3	24	92%	60%	60%
Trillium Health Partners	27	4	3	2	9	33%	22%	22%
William Osler Health System	1	0	0	0	0	0%	0%	0%
The Ottawa Hospital Cancer Centre	132	183	218	204	605	458%	296%	124%
Cancer Centre of Southeastern Ontario at Kingston General Hospital	41	31	21	11	63	154%	99%	99%
Lakeridge Health, RSM Durham Regional Cancer Centre	22	4	2	3	9	41%	26%	26%
Ontario Total	1,323	847	777	789	2413	182%	118%	86%

Number of active recruiting 3CTN Portfolio trials – Ontario

Network Site	Q1 2018-19	Q2 2018-19	Q3 2018-19
London Health Sciences Centre	45	46	46
Grand River Regional Cancer Centre	7	7	8
Windsor Regional Cancer Centre	4	4	5
Hamilton Health Sciences, Juravinski Cancer Centre	29	27	30
Cambridge Memorial Hospital	2	2	3
St. Joseph's Healthcare Hamilton	3	2	2
Walker Family Cancer Centre, Niagara Health System	8	7	8
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	32	34	34
Humber River Hospital	3	3	2
Michael Garron Hospital (Toronto East General Hospital)	2	2	2
Princess Margaret Cancer Centre	71	74	81
Markham Stouffville Hospital	0	0	1
Mount Sinai Hospital	4	4	4
Northeast Cancer Centre - Health Sciences North	6	7	7
North York General Hospital	3	4	3
Royal Victoria Regional Health Centre	8	6	6
Southlake Regional Health Centre	9	10	10
St. Michael's Hospital	1	1	1
Thunder Bay Regional Health Sciences Centre	5	5	5
Trillium Health Partners	3	3	3
William Osler Health System	1	1	2
The Ottawa Hospital Cancer Centre	38	37	41
Cancer Centre of Southeastern Ontario at Kingston General Hospital	26	25	25
Lakeridge Health, RSM Durham Regional Cancer Centre	3	4	3

Patients recruited to 3CTN Portfolio trials, FY2018/19 (Y5) – Atlantic Region and Quebec

Network Site	Pre-3CTN Baseline	Q1	Q2	Q3	Y5 (YTD) Total	% of Baseline	% to Y5 Target
Nova Scotia Health Authority	39	12	7	14	33	85%	55%
Eastern Regional Health Authority	15	4	1	6	11	73%	47%
Janeway Child Health Centre	4	0	0	0	0	0%	0%
Atlantic Region Total	58	16	8	20	44	76%	49%
CISSS de l'Outaouais	3	0	0	0	0	0%	0%
CHU de Québec – Université Laval	180	38	21	15	74	41%	27%
CIUSSS de l'Estrie – Centre Hospitalier Universitaire de Sherbrooke (CHUS)	46	6	4	4	14	30%	20%
Centre Hospitalier de l'Université de Montréal (CHUM)	153	34	27	23	84	55%	35%
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	3	0	3	0	3	100%	65%
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	60	9	5	3	17	28%	18%
CHU de Quebec - Pediatrics	17	7	3	2	12	71%	46%
Centre Hospitalier Universitaire de Sainte-Justine	42	10	9	4	23	55%	35%
Montreal Children's Hospital	24	2	1	1	4	17%	11%
Consortium de recherche en oncologie clinique du Québec (Q-CROC) Total	528	106	73	52	231	44%	28%
Eastern Region Total	586	122	81	72	275	47%	30%

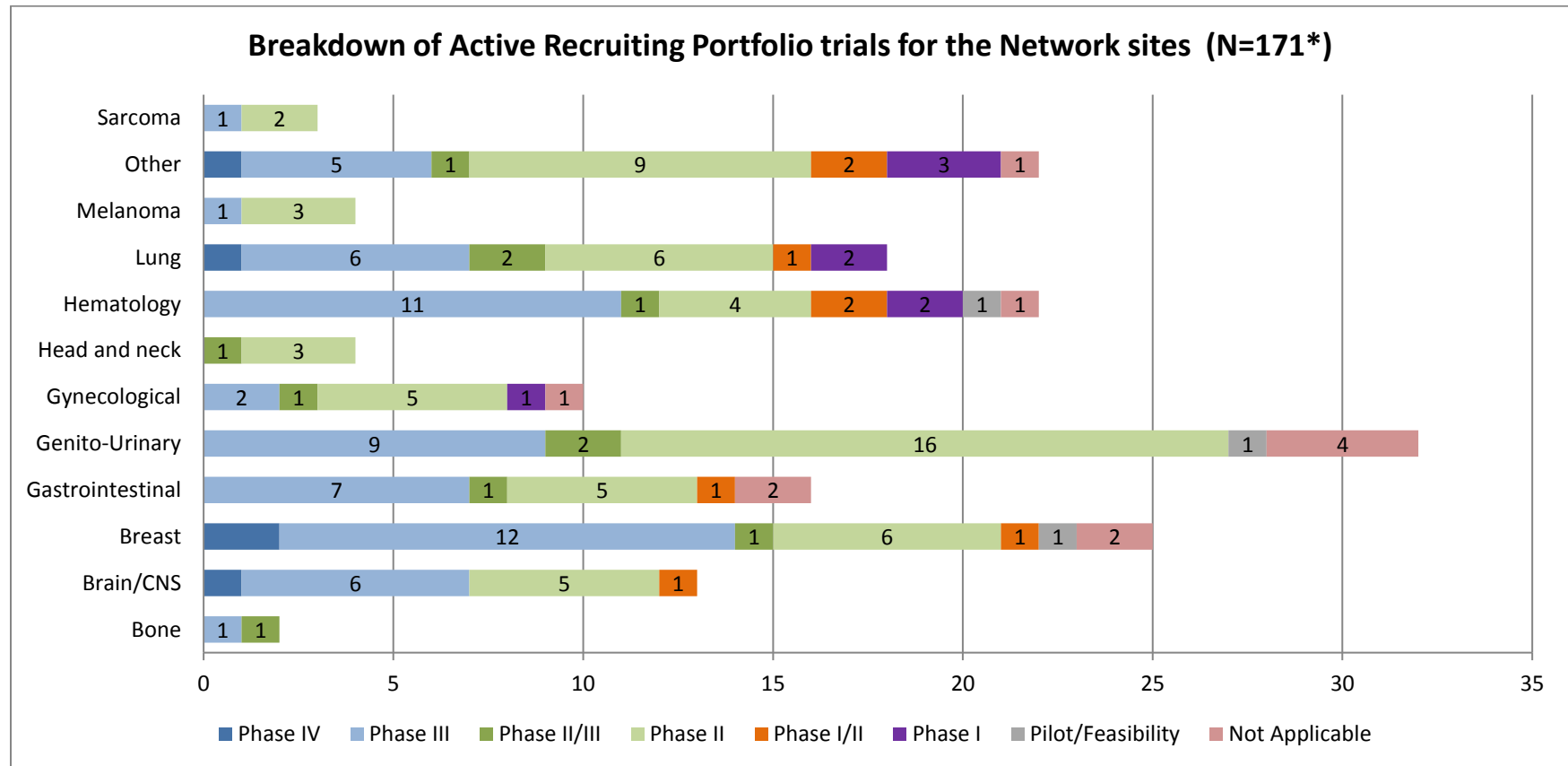
Number of Active Recruiting 3CTN Portfolio Trials – Atlantic Region and Quebec

Network Site	Q1 2018-19	Q2 2018-19	Q3 2018-19
Nova Scotia Health Authority	12	16	17
Eastern Regional Health Authority	4	6	5
Janeway Child Health Centre	11	9	9
CISSS de l'Outaouais	1	1	1
CHU de Québec – Université Laval	19	20	26
CIUSSS de l'Estrie – Centre Hospitalier Universitaire de Sherbrooke (CHUS)	13	11	13
Centre Hospitalier de l'Université de Montréal (CHUM)	32	34	37
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	2	2	2
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	12	13	11
CHU de Quebec - Pediatrics	13	16	17
Centre Hospitalier Universitaire de Sainte-Justine	30	22	22
Montreal Children's Hospital	25	25	20

Section B: 3CTN Portfolio Metrics

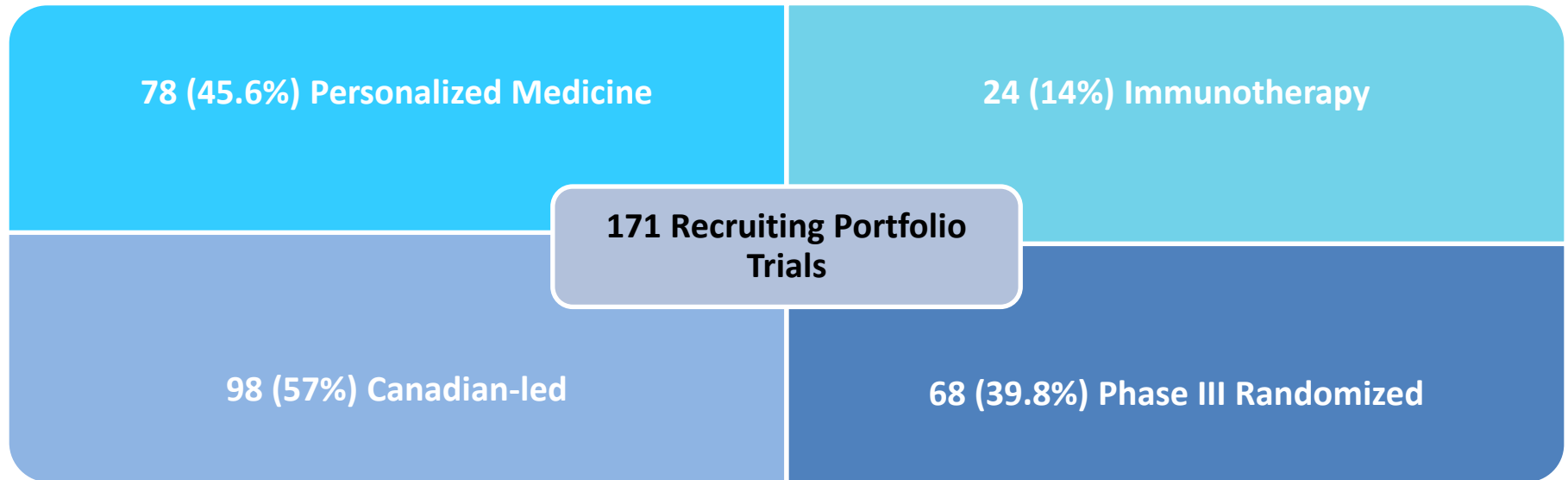
Active Recruiting Portfolio trials by disease site and phase

Objective: To monitor and optimize the portfolio in order to create opportunities for new trials and demonstrate 3CTN's impact.



*as of Feb. 28, 2019

Active Recruiting Portfolio trials by study type and noted features



Overall Portfolio Complexity Breakdown, (Jan – Dec 2018)

Complexity mix by number of total portfolio trials (N=219 excluding TMIST trial), as of December 31.

Patient Scope	Low		Standard		High	
	# of trials	Recruited (total)	# of trials	Recruited (total)	# of trials	Recruited (total)
Overall	26%	45%	58%	50%	16%	5%
Adults	26%	45%	59%	50%	15%	5%
Peds	14%	15%	51%	76%	35%	9%

Portfolio Impact Assessment

Objective: To provide a more specific and translatable impact description of 3CTN Portfolio trials for existing and future stakeholders.

As part of the continuing plan for implementing the 3CTN Portfolio Impact Assessment Criteria (see Appendix Table 2), an initial review of 248 closed to recruitment/completed trials was conducted and results reported in the table will be reviewed by the Portfolio Committee.

An assessment of all remaining Portfolio trials, those currently open to accrual, is expected to be completed by the end of March 2019.

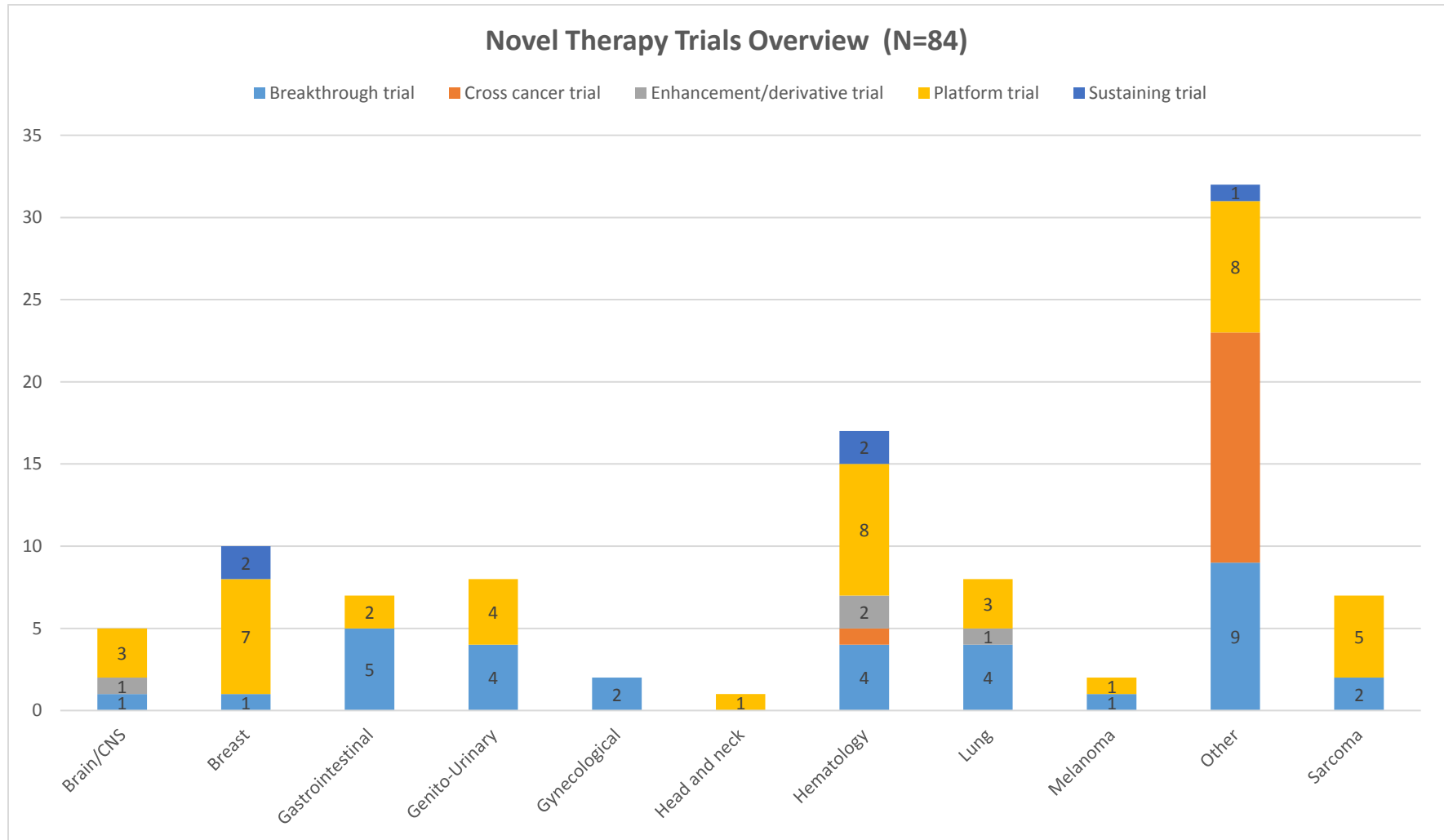
Thereafter, all new trials will be assessed upon inclusion into the Portfolio and results updated quarterly.

Closed/Completed Portfolio trials with Publications

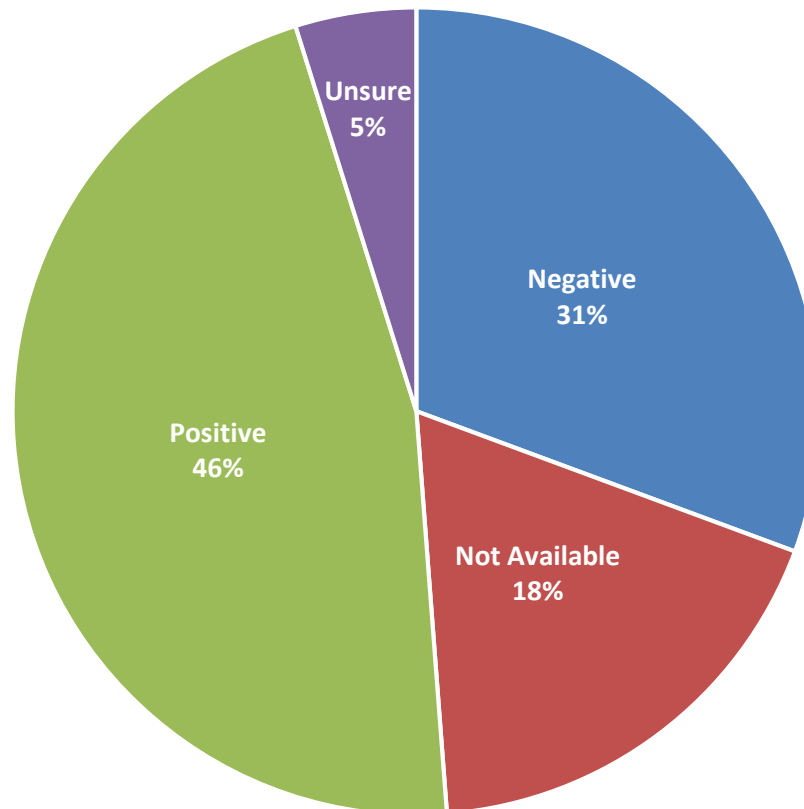
Trial Categories of Interest	Breakthrough Trial	Cross Cancer Trial	Enhancement /Derivative Trial	N/A	Platform Trial	Sustaining Trial	Total # of Trials per Study Criteria
Lifestyle Interventions					5	1	6
N/A					2		2
Novel therapy	33	15	4		42	5	84
Patient management		13	7	4	40	23	79
Precision medicine	20	13	10		84	10	122
Rare cancer setting	4	3	4		61	4	73
Vulnerable populations	6	7	6	1	54	7	73
Grand Total	34	29	15	4	152	39	248

Note: A trial may fit into more than one categories; N=248 refers to the unique count of the reviewed trials.

Breakdown of Novel Therapy Trials by Disease Site



Preliminary Assessment of Closed Portfolio Trials for Study Results (N=248)

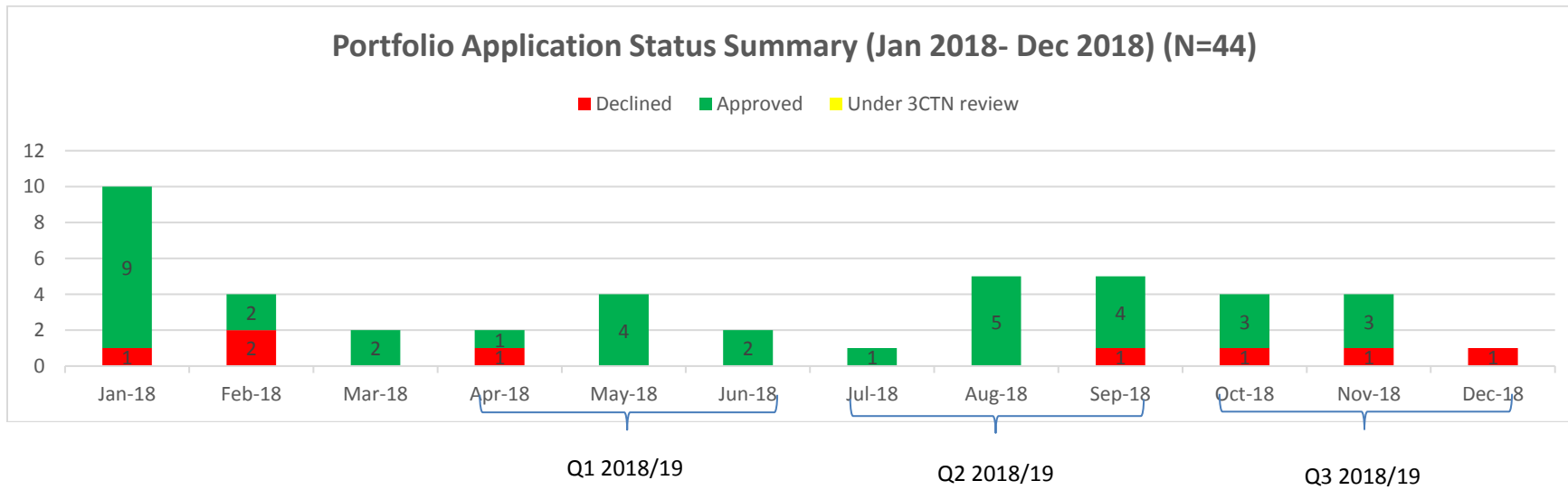
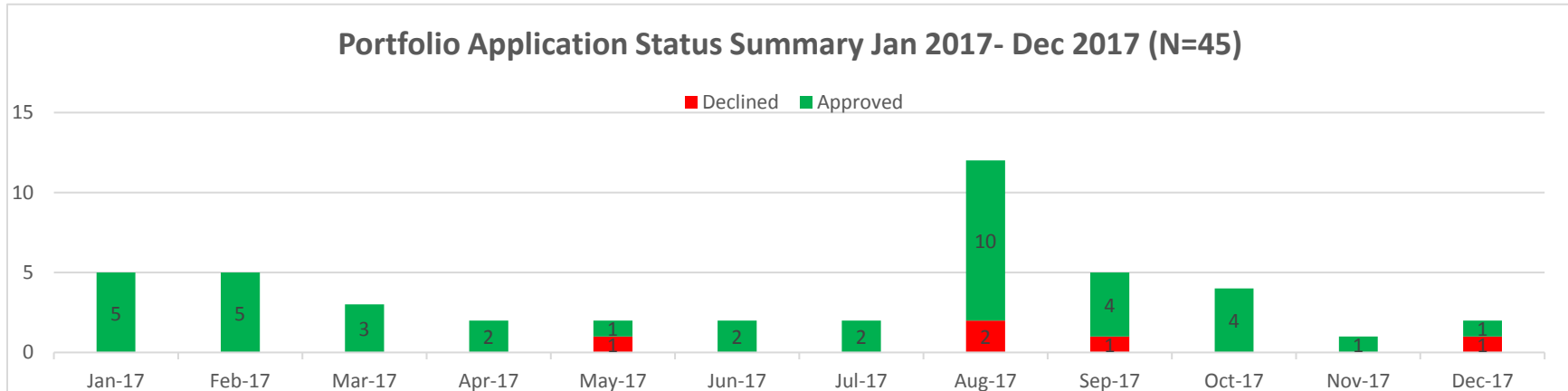


Note: assessments were based on primary end point results as reported from study publications.

Overview of Portfolio applications

Since Jan. 2015, there have been 246 applications received in total with an acceptance rate 82%.

As of December 31, 2018, received 44 applications were received for the year, which was comparable to total for 2017. The following graphs provide a monthly comparison of the last two years (updated March 10, 2019).



Portfolio application efficiency

Objective: To improve portfolio application processing time

Portfolio Approval Process Timeline

Calendar Year	# Application Completed	Average Application Processing Time (days)	Median Application Processing Time (Days)
2015	89	24	8
2016	70	24	6
2017	45	19	6
2018	46	21	6

Facilitated Peer Review (FPR) Process

Calendar Year	# Application Completed	Average FPR Time (days)	Median FPR Time (days)
2015	6	47	39
2016	10	98	79
2017	4	79	74
2018	10	84	78

Note: 1) from application received to approve/decline the application since Jan 13, 2015 to Dec. 2018; 2) from date site agreed to pursue peer review to date last reviewer submitted completed peer review package to 3CTN (approved as peer reviewed).

Appendix: Additional Notes

Table 1: Site Efficiency definitions

Metric	Definition/formula	2018-2022 Target	Source	Frequency Reported
Start date of site activation process to Site Open to Accrual (New for 2018-2022)	=site open to accrual – start date of site activation process Note: Start Date of Site Activation Process/Date Site Confirmed Participation= the date that the site has the critical decision and package to start the trial activation process (whichever date is later): 1) access to the protocol; 2) the site PIs has expressed interest in the trial; 3) the site has confirmed its participation as a site through a formal or informal review process	300 days (average)	Site	Quarterly
Centralized Site REB Processing Time (Lead applicant submission to approval)	=Centralized site REB approval date - Centralized site submission date	90 days (average)	Site/ethics board	Semi-annual
Local Site REB Processing Time (site submission to approval)	=local site REB approval date - local site submission date	90 days (average, if not using centralized process) 7 days (average, if the site is not a lead applicant and supplementary material submission is required)	Site	Quarterly
Local Site REB Approval to First Patient Recruited	=first patient recruited to the site - local site REB approval date	90 days (average)	Site	Quarterly
Site Open to Accrual to First Patient Recruited	=first patient recruited to the site - site open to accrual date	60 days (average)	Site	Quarterly
Recruiting Period (from open to closed to accrual)	= site closed to accrual date - site open to accrual date	300 days (average)	Site	Quarterly
Site Accrual vs. Site Target	= total accrual when closed/ site accrual set when the site open to accrual	Sites recruited to 60% of site target 40% of sites recruiting greater than 75% of site target	Site	Quarterly
SOPs	Sites to use regulatory compliant clinical trial operations standard operating procedures (SOPs)	100% of sites	Site	Annual
CTRNet	Number of sites who have registered with CTRNet	100% of sites	Site	Annual

Table 2: Study Impact Criteria Definitions

Impact Assessment	Impact Category	Proposed Definition
Trial categories of special interests	Novel Therapy	Trials involving newly developed intervention (e.g. drug, novel biomarker or diagnosis)
	Rare Cancer Setting	As defined by the National Cancer Institute Cancer Facts and Figures 2017, cancer that occurs in <15 out of 100,000 people each year (e.g. mesothelioma, nasopharynx, gallbladder, soft tissue)
	Patient Management	Patient education, awareness, self- assessment trials, symptom control, improving patient experience
	Vulnerable Populations	Pediatric, AYA, elderly, organ dysfunction
	Lifestyle Interventions	Trials focused on lifestyle changes that may prevent, decrease severity and/or delay disease progression and treatment side effects (e.g. exercise, diet)
	Precision Medicine	Biomarker, immunotherapy, diagnosis, and targeted therapies
Potential Impact on Patient Population	Breakthrough Trial	Trial involving a first in class, or novel intervention (drug, biologic, technology or technique) that could dramatically change how people with a particular type of cancer are treated
	Platform Trial	Using already available (e.g. FDA approved) interventions for new combination, new types, settings or stages of cancer
	Enhancement/ Derivative Trial	Using additional targeting biomarker screening to tailor treatment and investigate outcomes (question should this also include imaging enhanced treatment)
	Sustaining Trial	Calibrating/focusing on dosages, treatment cycles or schedule (e.g. colon cancer adjuvant 3 - 6 months)
	Cross Cancer Trial	Results applied to multiple disease sites or basket/umbrella trials
Innovativeness of Trials	Incremental	Potential for iterative changes/advancement (e.g. next in class drugs)
	Paradigm Shifting	Potential for radical improvements in cancers/policy changes within cancer, or across a cancer spectrum (e.g. first in class drugs in phase III trials; introduction of new previously unused intervention or approach; first trials of OncotypeDx in local breast cancer that transformed patient management; first immunotherapy trials)
Study Results	Positive/Negative	Bases on comparison of published results with the study primary outcome/end points

Table 3. Reporting periods and dates Q4 2014/15 – Q4 2018/19

Fiscal Year	Quarter	Period	Recruitment Database Lock
2014/15	Q3	October – December 2014	NA*
	Q4	January – March 2015	NA*
2015/16	Q1	April – June 2015	NA*
	Q2	July – September 2015	October 20, 2015
	Q3	October – December 2015	March 31, 2016
	Q4	January – March 2016	May 31, 2016
2016/17	Q1	April – June 2016	August 31, 2016
	Q2	July – September 2016	November 15, 2016
	Q3	October – December 2016	February 15, 2017
	Q4	January – March 2017	May 31, 2017
2017/18	Q1	April – June 2017	August 31, 2017
	Q2	July – September 2017	September 30, 2017
	Q3	October – December 2018	December 31, 2018
	Q4	January – March 2018	May 15, 2018
2018/19	Q1	April – June 2018	August 31, 2018
	Q2	July – September 2018	November 30, 2018
	Q3	October – December 2018	February 15, 2019
	Q4	January – March 2019	May 31, 2019
2019/20	Q1	April – June 2019	August 31, 2019
	Q2	July – September 2019	November 30, 2019
	Q3	October – December 2019	February 15, 2020
	Q4	January – March 2020	May 31, 2020

*Dates not available; database lock implemented in Q2 2015/16