



Canadian
Cancer Clinical
Trials Network

3CTN Y5 Performance Report

April 1, 2018 – March 31, 2019

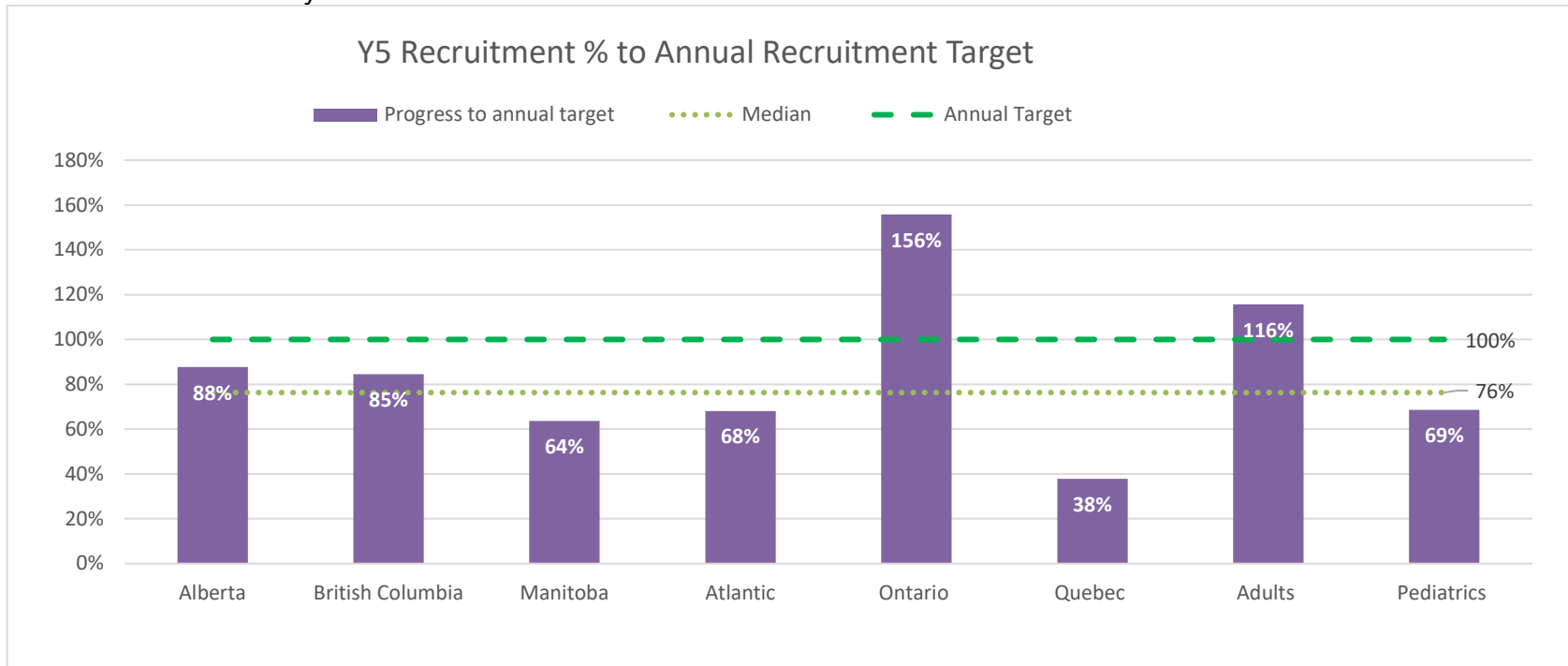
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Section A: Patient access and recruitment to the 3CTN Portfolio Trials

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:

- 4172 patients were recruited to Portfolio trials in Y5, 2018/19.
- Although the Q1-Q4 accrual of 4172 patients surpassed annual target of 3708 patients (i.e. 155% of pre-3CTN baseline recruitment) 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 883 patients to Ontario's total recruitment during this period and accounted for 21% of the entire Network total.
- Data for individual provinces excludes pediatric patients (shown separately)

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

Overall summary of patient recruitment from Y1~Y5 by province/population

Network Region/Population	Pre-3CTN Baseline	Y1 (Q3, Q4)	Y2	Y3	Y4	Y5	Y5 % of Baseline	Y5 Target Achieved? (155% of pre-3CTN Baseline)
AB	178	90	252	262	253	242	136%	NO
BC	187	115	235	269	249	245	131%	NO
MB*	100	39	72	102	90	99	99%	NO
NL*	15	2	4	12	8	15	100%	NO
NS	39	5	40	52	45	42	108%	NO
ON	1,323	593	1,500	2,507	2,368	3,196	242%	YES
QC*	445	0	112	396	537	261	59%	NO
Pediatrics	105	40	86	83	98	72	69%	NO
Adults	2287	844	2215	3600	3550	4100	179%	YES
Overall (adults & peds)	2392	884	2301	3683	3648	4172	174%	YES

*data for individual provinces excludes pediatric patients (shown separately)

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

Network Sites	Pre-3CTN Baseline	Y1 (Q3,Q4)	Y2	Y3	Y4	Y5	% of Baseline	% to Y5 Target
CancerCare Manitoba - Adults	99	39	72	102	90	98	99%	64%
Prairie Mountain Health	1	0	0	0	0	1	100%	65%
CancerCare Manitoba - Pediatrics	18	5	20	14	17	4	22%	14%
Cancer Care Manitoba	118	44	92	116	107	103	87%	56%
BC Cancer Agency - Vancouver Centre	106	67	117	152	127	107	101%	65%
Abbotsford Centre	16	10	28	14	22	22	138%	89%
Centre for the North, Prince George	1	2	6	4	8	9	900%	581%
Sindi Ahluwalia Hawkins Centre for the Southern Interior	38	27	40	30	28	38	100%	65%
Vancouver Island Centre	26	9	44	69	64	69	265%	171%
BC Cancer Agency	187	115	235	269	249	245	131%	85%
Alberta Health Services, Cross Cancer Institute	102	50	112	137	99	103	101%	65%
Alberta Health Services, Tom Baker Cancer Centre	76	40	140	125	154	139	183%	118%
Alberta Health Services	178	90	252	262	253	242	136%	88%
Western Region	483	249	579	647	609	590	122%	79%

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

Network Sites	Pre-3CTN Baseline	Y1	Y2	Y3	Y4	Y5
CancerCare Manitoba	37	40	44	44	39	43
Prairie Mountain Health	0	0	0	0	0	1
CancerCare Manitoba - Pediatrics	19	23	28	24	24	28
BC Cancer Agency - Vancouver Centre	50	54	55	55	55	47
Abbotsford Centre	6	8	9	5	5	7
Centre for the North, Prince George	2	3	4	8	10	6
Sindi Ahluwalia Hawkins Centre for the Southern Interior	23	23	19	17	15	12
Vancouver Island Centre	12	13	13	12	10	12
Alberta Health Services, Cross Cancer Institute	29	44	53	49	41	45
Alberta Health Services, Tom Baker Cancer Centre	20	43	44	39	34	34

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

Network Sites	Pre-3CTN Baseline	Y1 (Q3, Q4)	Y2	Y3	Y4	Y5 Total	% of Baseline	% to Y5 Target	% to Y5 Target (w/o TMIST)
London Health Sciences Centre	186	72	172	187	169	248	133%	86%	86%
Grand River Regional Cancer Centre	20	12	13	43	32	32	160%	103%	103%
Windsor Regional Cancer Centre	14	8	17	63	32	16	114%	74%	74%
Hamilton Health Sciences, Juravinski Cancer Centre	181	110	231	247	454	345	191%	123%	123%
Cambridge Memorial Hospital	11	2	2	5	4	5	45%	29%	29%
St. Joseph's Healthcare Hamilton	21	0	30	54	74	40	190%	123%	123%
Walker Family Cancer Centre, Niagara Health System	17	5	22	13	23	37	218%	140%	140%
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	141	113	229	398	363	651	462%	298%	111%
Humber River Hospital	1	0	2	1	9	7	700%	452%	452%
Michael Garron Hospital (Toronto East General Hospital)	2	0	2	1	7	2	100%	65%	65%
Princess Margaret Cancer Centre	396	157	384	533	473	720	182%	117%	117%
Markham Stouffville Hospital	1	0	0	28	9	2	200%	129%	129%
Mount Sinai Hospital	21	0	12	40	7	12	57%	37%	37%
Northeast Cancer Centre - Health Sciences North	24	2	17	12	9	18	75%	48%	48%
North York General Hospital	1	3	4	8	11	9	900%	581%	581%
Royal Victoria Regional Health Centre	8	8	18	58	23	9	113%	73%	73%
Southlake Regional Health Centre	10	1	15	75	26	68	680%	439%	439%
St. Michael's Hospital	19	4	0	27	2	1	5%	3%	3%
Thunder Bay Regional Health Sciences Centre	26	2	3	46	16	25	96%	62%	62%
Trillium Health Partners	27	5	5	51	10	12	44%	29%	29%
William Osler Health System	1	0	0	29	13	0	0%	0%	0%
The Ottawa Hospital Cancer Centre	132	59	238	396	500	850	644%	415%	184%
Cancer Centre of Southeastern Ontario at Kingston General Hospital	41	24	58	122	84	72	176%	113%	113%
Lakeridge Health, RSM Durham Regional Cancer Centre	22	6	26	70	18	15	68%	44%	44%
Ontario Totals	1,323	593	1,500	2,507	2,368	3196	242%	156%	113%

Number of active recruiting 3CTN Portfolio trials – Ontario

Network Sites	Pre-3CTN Baseline	Y1 (Q3, Q4)	Y2	Y3	Y4	Y5
London Health Sciences Centre	79	77	77	81	77	83
Grand River Regional Cancer Centre	11	13	10	15	11	11
Windsor Regional Cancer Centre	4	6	5	11	8	7
Hamilton Health Sciences, Juravinski Cancer Centre	51	55	50	57	48	77
Cambridge Memorial Hospital	5	5	6	6	7	3
St. Joseph's Healthcare Hamilton	2	3	3	3	3	4
Walker Family Cancer Centre, Niagara Health System	10	9	8	8	10	12
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	10	43	47	59	56	55
Humber River Hospital	0	0	1	0	1	3
Michael Garron Hospital (Toronto East General Hospital)	3	3	3	0	0	3
Princess Margaret Cancer Centre	91	81	97	106	93	103
Markham Stouffville Hospital	0	0	0	2	2	2
Mount Sinai Hospital	6	7	10	9	9	5
Northeast Cancer Centre - Health Sciences North	10	9	8	5	4	11
North York General Hospital	0	1	1	1	2	5
Royal Victoria Regional Health Centre	5	10	11	14	13	9
Southlake Regional Health Centre	3	4	7	9	10	11
St. Michael's Hospital	4	4	5	6	5	4
Thunder Bay Regional Health Sciences Centre	8	9	8	7	9	6
Trillium Health Partners	9	7	5	5	5	6
William Osler Health System	0	0	1	2	2	3
The Ottawa Hospital Cancer Centre	56	53	53	67	62	76
Cancer Centre of Southeastern Ontario at Kingston General Hospital	18	19	23	29	27	30
Lakeridge Health, RSM Durham Regional Cancer Centre	13	14	18	15	15	11
Ontario Totals	117	125	142	156	152	155

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

Network Sites	Pre-3CTN Baseline	Y1 (Q3, Q4)	Y2	Y3	Y4	Y5	% of Baseline	% to Y5 Target
Nova Scotia Health Authority	39	5	40	52	45	42	108%	69%
Eastern Regional Health Authority	15	2	4	12	8	15	100%	65%
Janeway Child Health Centre	4	1	3	4	4	0	0%	0%
Atlantic Canada Totals	58	8	47	68	57	57	98%	63%
CISSS de l'Outaouais	3	0	0	4	32	1	33%	22%
CHU de Québec – Université Laval, adults	180	0	25	144	236	99	55%	35%
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke, adults (CIUSSS-Estrie-CHUS)	46	0	16	70	55	18	39%	25%
Centre Hospitalier de l'Université de Montréal (CHUM)	153	0	59	123	149	112	73%	47%
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	3	0	0	4	16	8	267%	172%
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	60	0	12	51	49	23	38%	25%
CHU de Quebec - Pediatrics	17	7	14	7	17	22	129%	83%
Centre hospitalier universitaire de Sainte-Justine	42	18	26	44	40	37	88%	57%
Montreal Children's Hospital	24	9	23	14	20	8	33%	22%
Quebec Clinical Research Organization in Cancer (Q-CROC) Totals	528	34	175	461	614	328	62%	40%
Eastern Region Totals	586	42	222	529	671	385	66%	42%

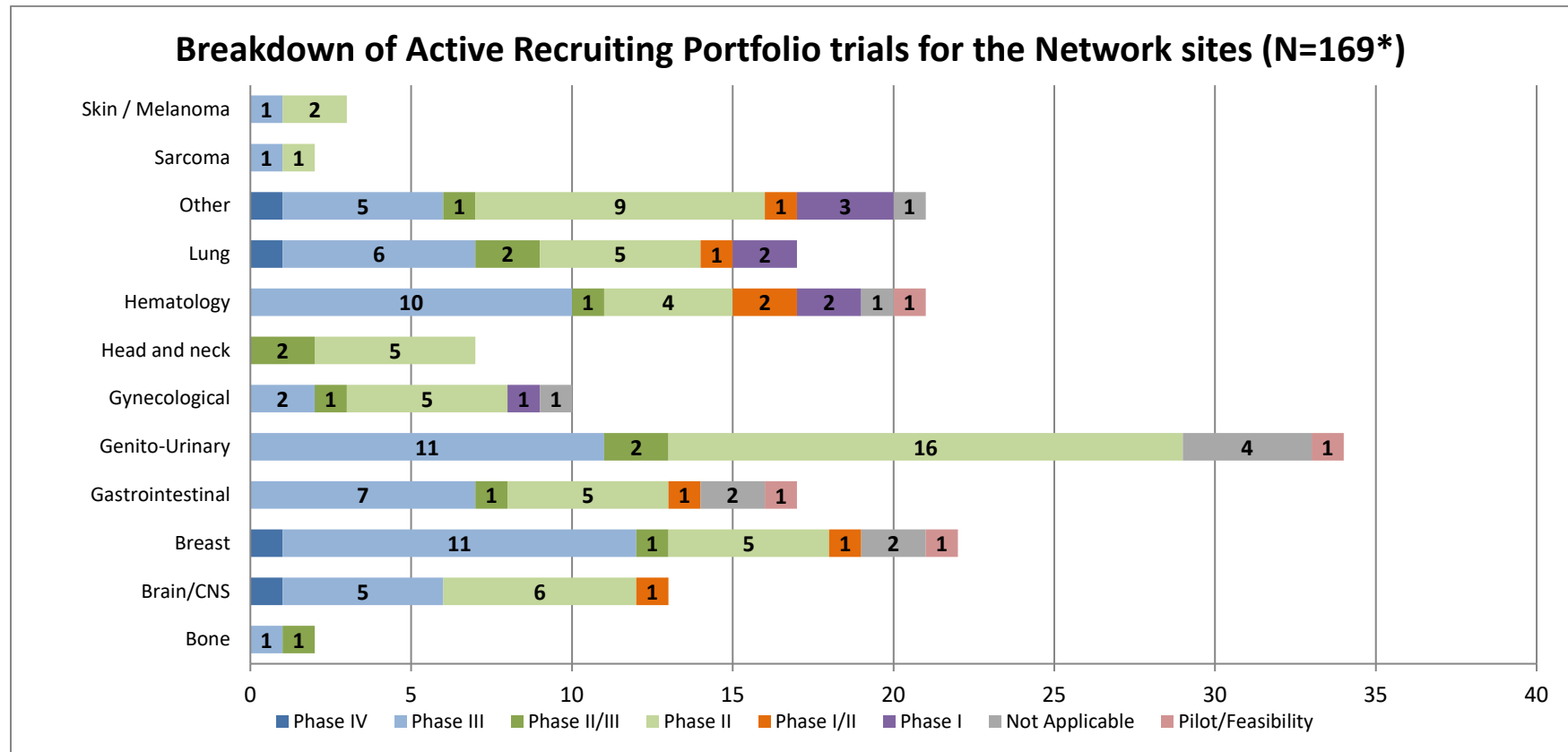
Number of Active Recruiting 3CTN Portfolio Trials – Atlantic Region and Quebec

Network Sites	Pre-3CTN Baseline	Y1 (Q3, Q4)	Y2	Y3	Y4	Y5
Nova Scotia Health Authority	14	17	21	20	19	31
Eastern Regional Health Authority	6	5	6	4	3	13
Janeway Child Health Centre	5	5	8	8	5	15
CISSS de l'Outaouais	1	1	1	1	3	3
CHU de Québec – Université Laval, Adults	39	34	39	39	36	37
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke, adults (CIUSSS-Estrie-CHUS)	10	12	15	10	10	26
Centre Hospitalier de l'Université de Montréal (CHUM)	28	36	41	39	29	58
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	4	6	5	6	8	3
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	6	9	13	10	9	20
CHU de Quebec - Pediatrics	11	13	14	11	8	24
Centre hospitalier universitaire de Sainte-Justine	9	10	13	9	4	34
Montreal Children's Hospital	5	5	9	9	4	33

Section B: 3CTN Portfolio Metrics

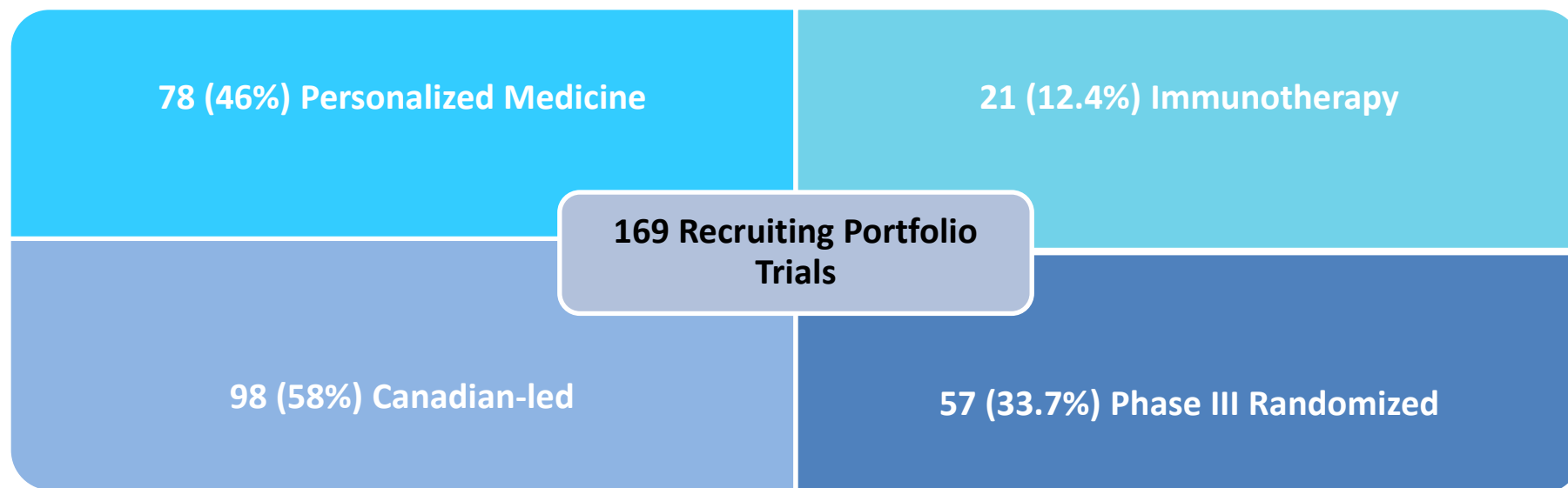
Active Recruiting Portfolio trials by disease site and phase

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



*as of May 21, 2019

Active Recruiting Portfolio trials by study type and noted features



Overall Portfolio Complexity Breakdown, (April 2018 – March 2019)

Complexity mix by number of total portfolio trials (N=219 excluding TMIST trial), as of May 21.

Patient Scope	Low		Standard		High	
	% of trials	Recruited (total)	% of trials	Recruited (total)	% of trials	Recruited (total)
Overall	25%	43%	58%	52%	16%	5%
Adults	24%	42%	55%	52%	14%	5%
Peds	3%	1%	11%	3%	8%	1%

Portfolio Impact Assessment

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

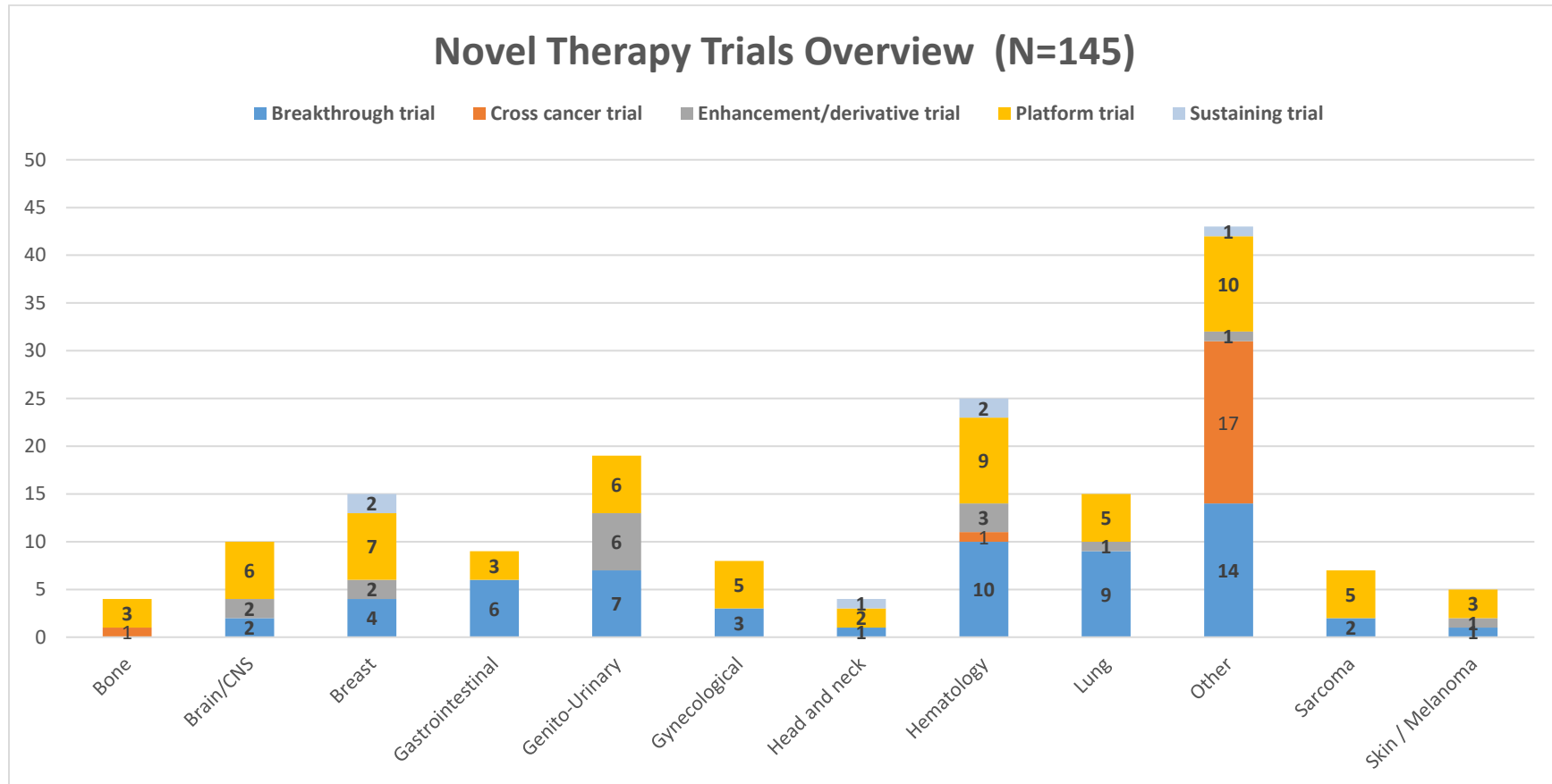
As part of the continuing plan for implementing the 3CTN Portfolio Impact Assessment Criteria (see Appendix Table 2), an initial review of 588 existing Portfolio trials was completed and pending review by the Portfolio Committee.

Thereafter, all new trials will be assessed upon inclusion into the Portfolio and results updated quarterly. As of June 3, 2019, 597 trials have been reviewed and preliminary summary is below

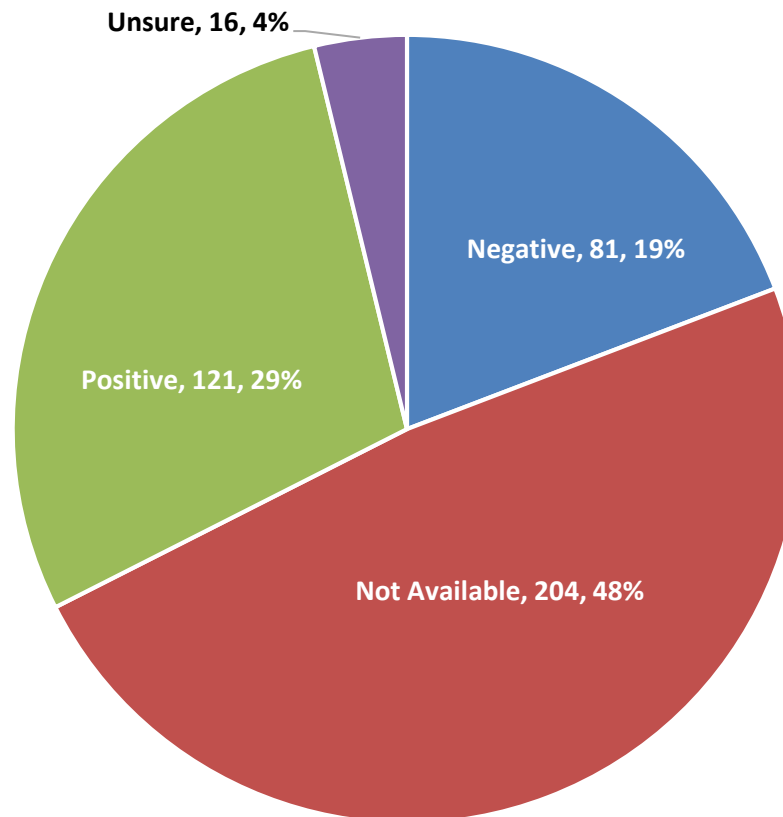
Trial Categories of Interest	Breakthrough Trial	Cross Cancer Trial	Enhancement /Derivative Trial	N/A	Platform Trial	Sustaining Trial	Total # of Trials per Study Criteria
Lifestyle Interventions					15	2	17
N/A					25	7	34
Novel therapy	59	19	16		64	6	145
Patient management	2	26	15	5	114	62	206
Precision medicine	39	19	41	1	164	19	263
Rare cancer setting	19	13	21	2	159	27	229
Vulnerable populations	12	11	15	1	110	19	157
Grand Total	61	50	56	5	370	97	597

Note: A trial may fit into more than one categories; N=597 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=422)

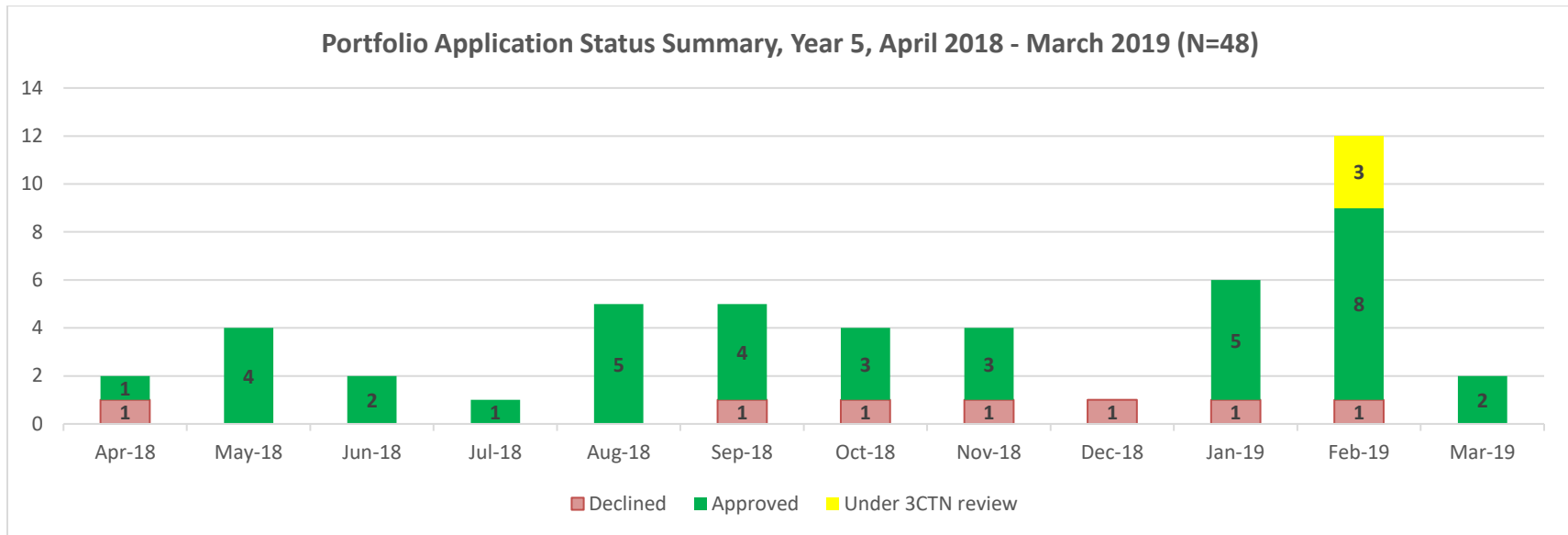
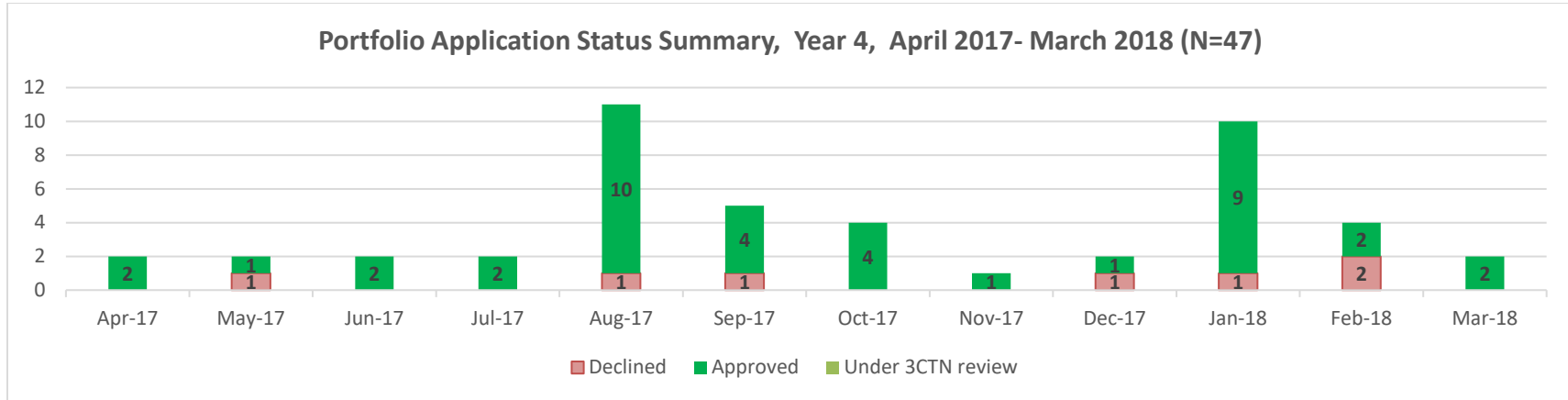


Note: assessments were based on primary end point results as reported from study publications.

Overview of Portfolio Applications

Since Jan. 2015, a total of 274 applications were received, with an acceptance rate of 82%.

A total of 48 applications were received in Y5, which was comparable to Y4.



Portfolio Application Process Efficiency

Objective: To improve portfolio application processing time

Portfolio Approval Processing Time

Calendar Year	# Applications Completed	Average Processing Time (Days)	Median Processing Time (Days)
2015	89	24	8
2016	70	24	6
2017	45	19	5
2018	46	21	5
2019	21	17	0
Overall	271	22	6

From application received to approve/decline the application since Jan 13, 2015 to May 2019

Facilitated Peer Review (FPR) Process

Calendar Year	# Applications 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
2019	4	73	77
Overall	34	80	73

From date site agreed to pursue peer review to date last reviewer submitted completed peer review package to 3CTN (approved as peer reviewed)

Site Efficiency Metrics

Objective: To improve trial initiation time and forecasting of recruitment targets.

Province/ Population	Sites	# of Active Portfolio Studies in Y5	Activation Timeline		Local Site REB Processing Time		Local Site REB Approval to First Patient Recruited		Site Open to Accrual to First Patient Recruited		Recruiting Period (from Trial Open - Closed to Accrual)		Site Accrual vs. Target	
			Average	Median	Average	Median	Average	Median	Average	Median	Average	Median	Average	Median
Alberta*	2	77	NA	NA	85	63	207	147	134	77	522	546	86%	80%
BC*	4	57	NA	NA	93	62	185	135	73	37	569	547	157%	120%
Manitoba	2	44	175	179	66	53	272	235	114	82	540	483	54%	50%
Newfoundland	1	13	183	145	93	62	172	185	125	90	323	322	70%	50%
Nova Scotia	1	31	211	236	67	64	171	157	102	52	536	491	160%	133%
Ontario	24	155	197	159	28	6	190	135	106	55	429	386	90%	75%
Quebec	6	90	245	202	74	53	173	104	120	62	438	439	154%	65%
Pediatrics	5	44	220	183	79	59	259	129	209	99	688	527	43%	0%
Overall	45	169	212	171	52	28	195	139	114	57	469	432	103%	75%

*Trial activation timeline days not available

Notes:

- Data extracted from EDGE as of May 27th 2019
- Data was taken for trials site open greater than or equal to Jan 1st 2014; definitions see Appendix
- Data that was negative or missing was excluded; projects in set up greater than or equal to 2014 included
- Accrual targets only counted for closed, terminated, archived and completed trials
- Data sourced currently active 3CTN member sites only; Data still includes outliers, median is used to help reflect a more accurate central data trend

Appendix: Additional Notes

Table 1: Site Efficiency Metrics 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	cancer that occurs in <6 out of 100,000 people each year
	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	Based 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