Canadian Cancer Clinical Trials Network

Y3 Performance Report

April 1, 2016 – March 31, 2017

Report Created: June 8, 2017

Canadian Cancer Clinical Trials Network

Table of Contents

Section A: Progress at Adult Network Sites 2

Section B: Progress at Pediatric Network Sites 12

Section C: Portfolio Efficiency 20

Section D: Other metrics 20

Appendix: Additional Notes 23

Legend:

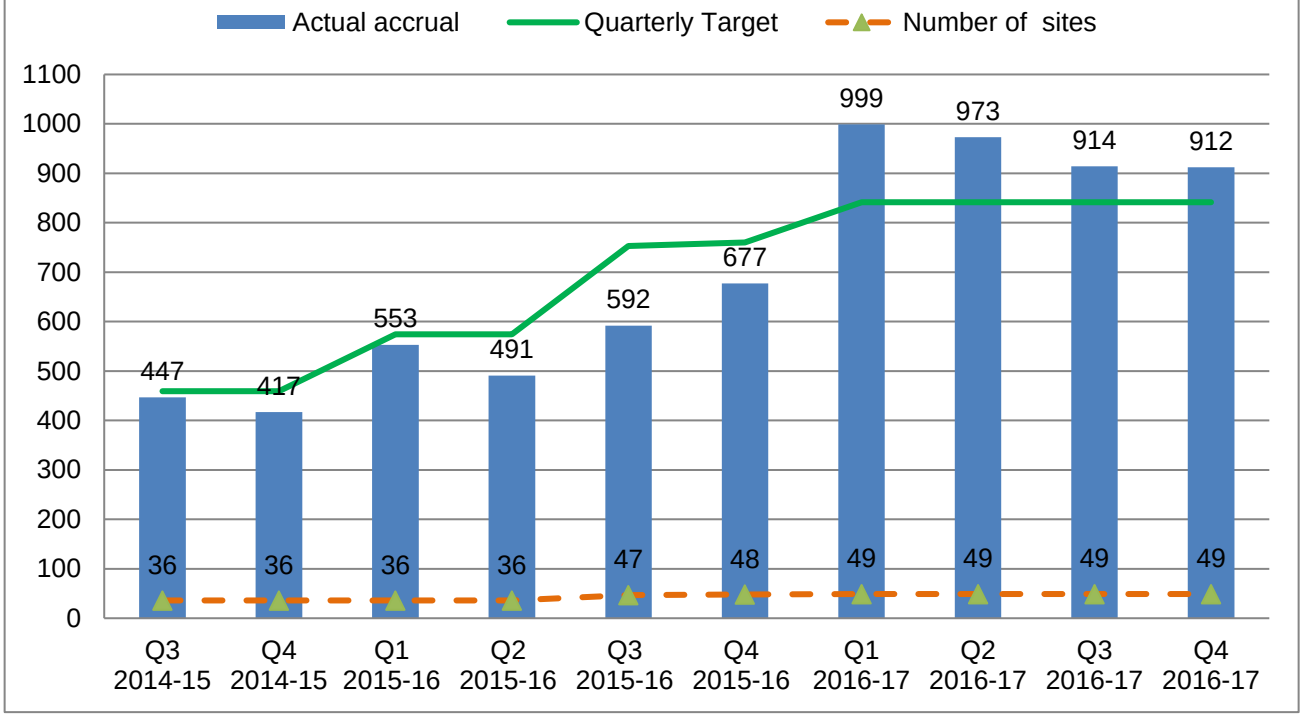
	below quarter baseline
	exceed quarter baseline

Canadian Cancer Clinical Trials Network

Section A: Progress at Adult Network Sites

Objective: To improve patient access to academic clinical trials: a) Improve adult patient recruitment by greater than 50% within four years

Figure 1. Number of Patients Recruited to Adult Portfolio Trials, Q3 2014/15 - Q4 2016/17



	2016/17 progress against quarterly 2016/17 Network Target			
	Actual	**Target**	**Difference**	**Y3 Baseline**
Accrual	3798	2546	1252	2448
% above baseline	155%	138%	✓	100%

Notes:

- 3798 patients were recruited to adult Portfolio trials in 2016/17. The annual Network target for 2016/17 is 2546 patients (about 37.5% over baseline). The Network is 18% above its annual network target if calculating based on cumulative contract targets.
- Data includes adult sites with formal Agreements with 3CTN (N=49).
- The Network target is the target recruitment per year, as defined in the 3CTN business plan. The site target is the target recruitment per year as defined in the Agreement between 3CTN and sites.

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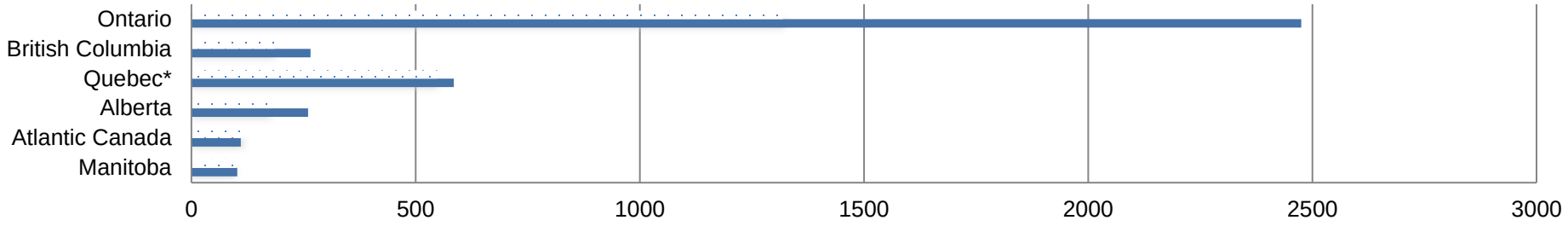
Figure 2. Number of patients recruited to adult Network sites per region in 2016/17



	Manitoba	Atlantic Canada	Alberta	Quebec*	British Columbia	Ontario
Annual Baseline	99	116	178	548	187	1320
Y3 Actual	102	110	260	585	266	2475

Figure 3. Number of patients recruited to adult Network sites per local-regional node (NCC + NACC) in 2016/17

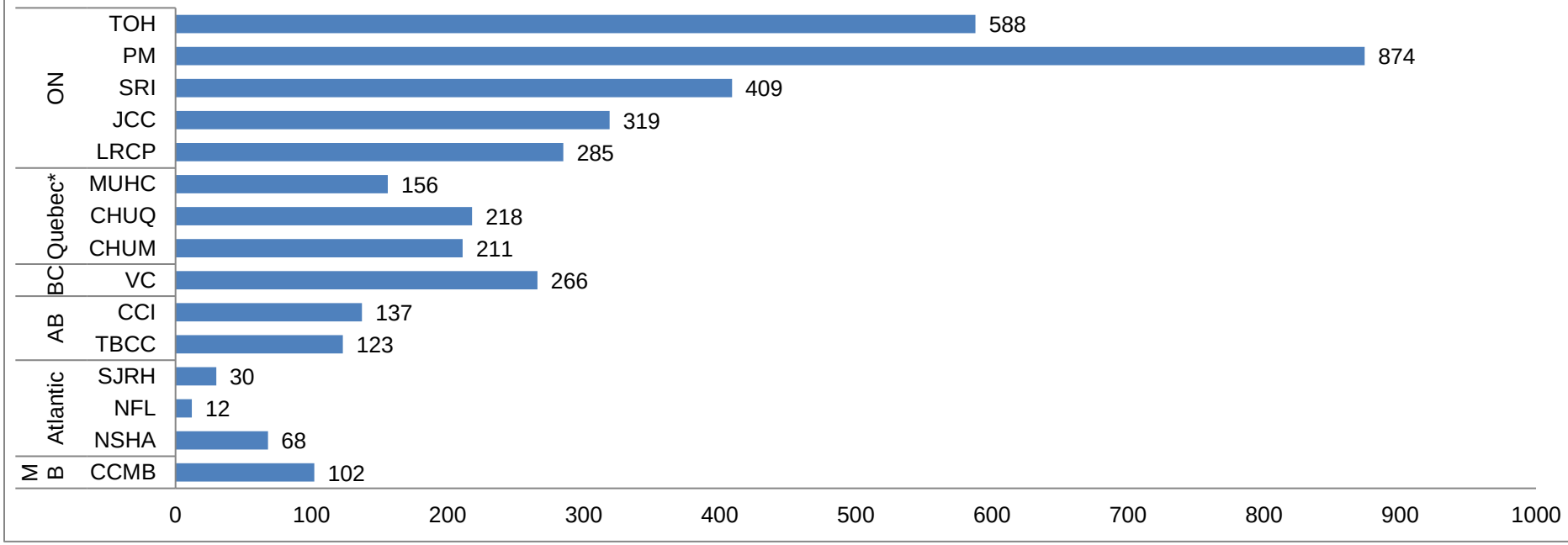


Figure 4. Progress to recruitment baseline at adult Network sites per region in 2016/17

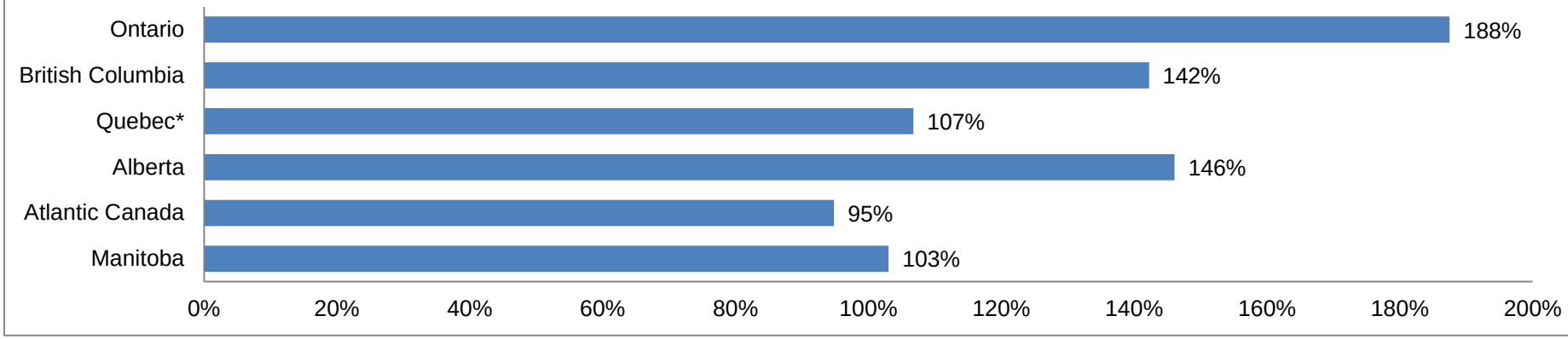


Figure 5. Percentage of patients recruited to baseline of adult Network sites per local-regional node (NCC + NACC) in 2016/17

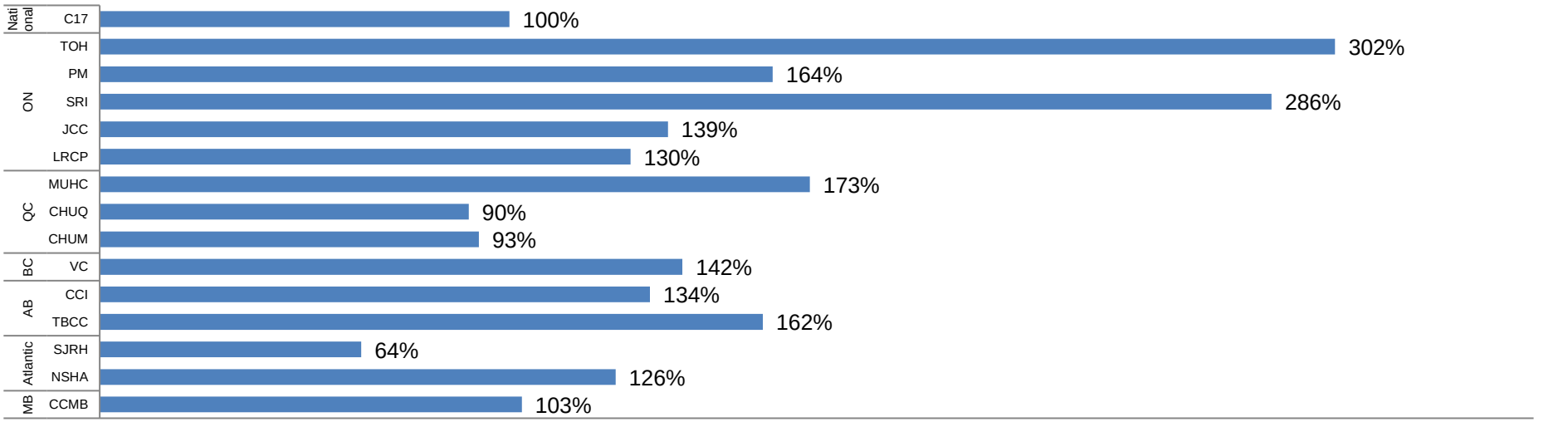


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Table 1. Number of patients recruited per adult Network site (by fiscal year)

Network Site (by fiscal year)	**Y3 Baseline	Y1 Total	% of Y1 baseline	Y2 Total	% of Y2 baseline	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Y3 YTD Total
London Regional Cancer Program	186	72	77	171	92	51	41	35	52	179
Grand River Regional Cancer Centre	20	12	120	13	65	16	11	12	4	43
Windsor Regional Hospital	14	8	114	17	121	12	29	15	7	63
Juravinski Cancer Centre	181	110	122	231	128	64	57	53	73	247
Niagara Health System	17	4	47	22	129	2	6	4	1	13
Cambridge Memorial Hospital	11	2	36	2	18	2	2	0	1	5
St.Joseph Healthcare Hamilton*	21	-	-	30	500	8	14	16	16	54
Sunnybrook Research Institute	141	113	160	231	164	94	78	101	126	399
North York General Hospital	0	3	**NA**	4	**NA**	2	1	4	1	8
Toronto East General Hospital	2	0	0	2	100	0	0	0	1	1
Humber River Hospital	0	0	**NA**	2	**NA**	0	1	0	0	1
Princess Margaret Cancer Centre	396	152	77	380	96	147	129	122	110	508
Northeast Cancer Centre - Health Sciences North	24	2	17	17	71	1	2	2	7	12
Trillium Health Partners	27	5	37	5	19	7	28	10	6	51
Thunder Bay Regional Health Sciences Centre	26	2	15	3	12	17	11	9	9	46
Southlake Regional Health Centre	10	1	20	15	150	17	32	18	8	75
Royal Victoria Hospital	8	8	200	18	225	15	22	8	13	58
St. Michael's Hospital	19	4	42	0	0	1	6	0	20	27
William Osler Health System	1	0	0	0	0	10	8	11	0	29
Markham Stouffville Hospital	0	0	**NA**	0	**NA**	10	7	10	1	28
Mount Sinai Hospital*	21	-	-	12	109	17	12	5	6	40
The Ottawa Hospital	132	59	89	238	180	86	85	111	114	396
Kingston General Hospital	41	24	117	58	141	33	29	39	21	122
Lakeridge Health	22	6	55	26	118	24	24	8	14	70
CancerCare Manitoba	99	39	79	72	73	30	21	26	25	102

Canadian Cancer Clinical Trials Network

Network Site	**Y3 Baseline	Y1 Total	% of Y1 baseline	Y2 Total	% of Y2 baseline	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Y3 YTD Total	% of Y3 baseline
Saint John Regional Hospital	37	11	59	16	43	4	2	7	9	22	59%
Dr. Everett Chalmers Hospital	1	1	200	0	0	1	1	0	3	5	500%
Dr. Léon-Richard Oncology Centre	9	2	44	4	44	2	1	0	0	3	33%
Nova Scotia Health Authority	39	4	21	31	79	16	9	13	10	48	123%
PEI Cancer Treatment Centre	8	1	25	8	100	0	0	2	0	2	25%
Nova Scotia Health Authority, Hematology	7	12	343	25	357	7	4	5	2	18	257%
Eastern Regional Health Authority (NFL)	15	0				0	1	3	8	12	80%
BC Cancer Agency - Vancouver Centre	106	67	126	117	110	34	44	29	43	150	142%
Abbotsford Centre	16	10	125	28	175	6	3	4	0	13	81%
Centre for the North, Prince George	1	2	400	6	600	0	1	2	1	4	400%
Sindi Ahluwalia Hawkins Centre for the Southern Interior	38	27	142	38	100	14	7	4	5	30	79%
Vancouver Island Centre	26	9	69	44	169	14	18	15	22	69	265%
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal(CIUSSS CODIM)*	87	0	-	72	164	41	35	43	33	152	175%
CISSS de l'Outaouais*	3	0	-	0	0	0	0	0	4	4	133%
CHU de Québec – Université Laval*	180	0	-	11	12	46	36	29	31	142	79%
CISSS du Bas-Saint-Laurent(CISSS-BSL)*	4	0	-	0	0	0	0	4	2	6	150%
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke (CIUSSS-Estrie-CHUS)*	46	0	-	16	70	12	13	19	26	70	152%
Centre Hospitalier de l'Université de Montréal (CHUM)*	153	0	-	59	77	49	39	32	4	124	81%
CIUSSS de la Mauricie-et-du-Centre-du-Québec (CIUSSS MCQ) *	8	0	-	1	25	3	6	5	3	17	213%
CISSS de Laval*	4	0	-	3	150	1	2	5	4	12	300%
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)*	3	0	-	0	0	0	6	1	0	7	233%
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)*	60	0	-	12	40	10	12	14	15	51	85%

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Network Site	**Y3 Baseline	Y1 Total	% of Y1 baseline	Y2 Total	% of Y2 baseline	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Y3 YTD Total	% of Y3 baseline
Tom Baker Cancer Centre	76	41	108	140	184	28	35	33	27	123	162%
Cross Cancer Institute	102	51	100	113	111	45	42	26	24	137	134%
Adult Patient Sites (N=49 for Y3, 48 for Y2, and 36 for Y1)	**2448**	864	94	**2313**	**108**	**999**	**973**	**914**	**912**	**3798**	155%

Note:
* Not had full year reports, baseline and target numbers were prorated based on the number of quarters they reported
**The baseline is the average number of patients recruited to the 3CTN portfolio from 2011-2013. Y1 is prorated to 0.5 annual baseline as it started Oct 2014
*** No reports available
****Future potential NACC
° Year 2 overall target is 25% over the baseline, but some sites have less than 25% target in their contracts. The additional 12 sites have % growth target.

Updated June 1, 2017

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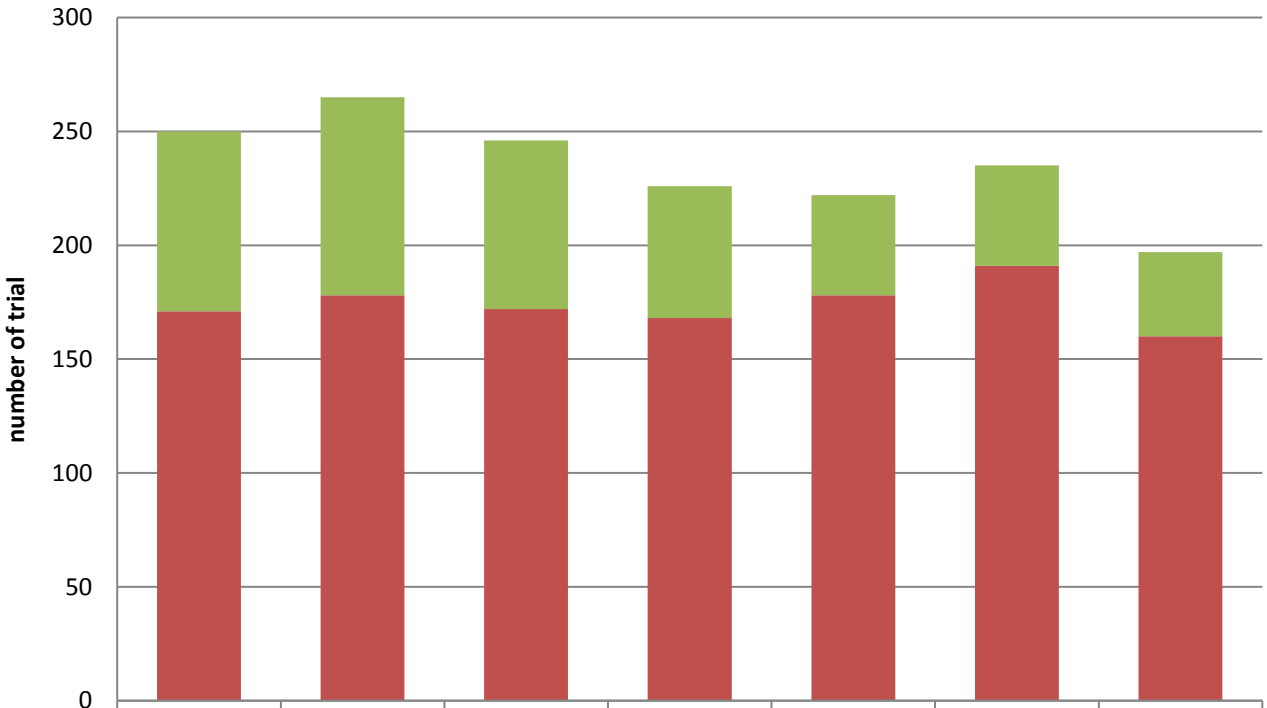
Objective: To demonstrate impact of the Network and academic trials on the Canadian Health Care System: a) Develop and maintain a portfolio of academic trials that will ensure the enthusiastic participation of academic trialists and patients and impact patient care.

Figure 6. Total Portfolio Trials Year over Year for Network Sites (2011-2017YTD)



	2011	2012	2013	2014	2015	2016	2017(YTD)
Peds	79	87	74	58	44	44	37
Adults	171	178	172	168	178	191	160

Notes:

- These trials are reported based on calendar year 2011- June 2017.
- There were 185 Portfolio trials for adult network sites in year 3.
- Four available at both adult and pediatric Network sites in 2016 and is included in both adult and pediatric figures
- The data provided in Figure 7 are a snapshot of the Portfolio as of June 8, 2017

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Figure 7. Breakdown of 2016 Fiscal Year Portfolio trials at adult Network sites

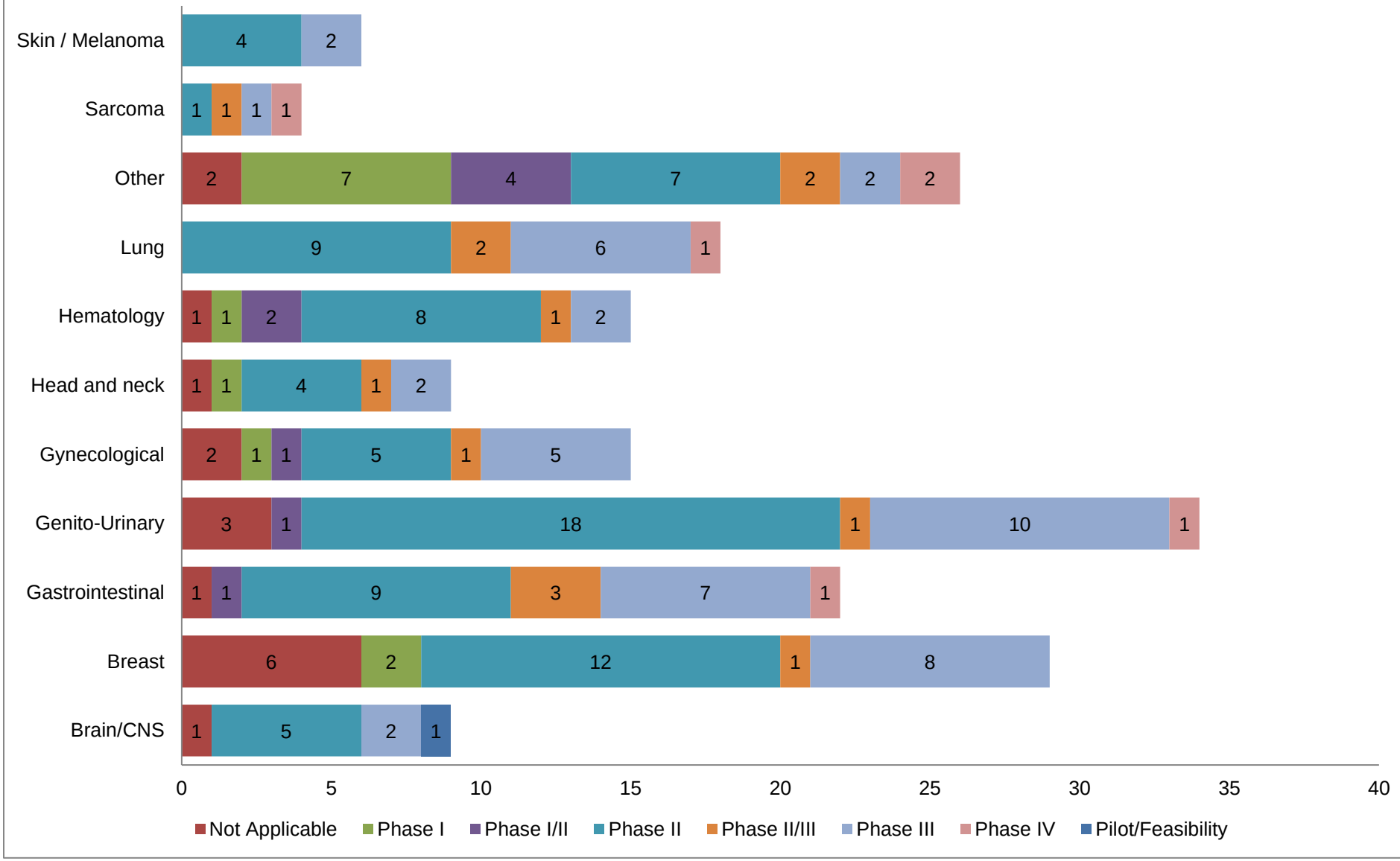
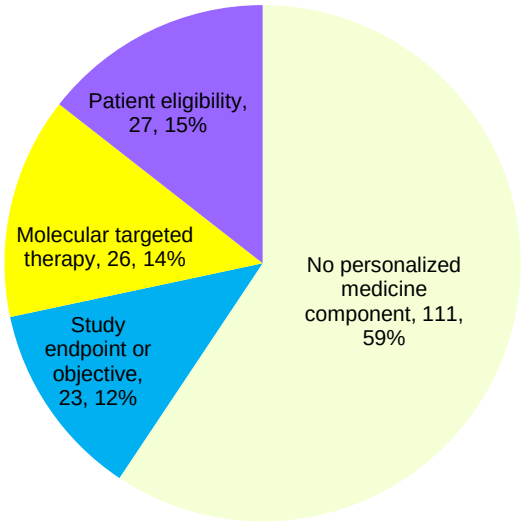


Figure 8. Breakdown of personalized medicine trials at adult Network sites for 2016/2017 Portforlio Trials



Notes:

- Personalized medicine trials open to recruitment at adult Network sites, as of May 31, 2017 (n=185)
- 49% of all trials at adult Network sites have a personalized medicine component; 12% of adult trials are immunotherapy related.
- Four trials were available at both adult and pediatric Network sites in fiscal year 3 and are included in both adult and pediatric figures

Category	Definition
Patient eligibility	Use of a genetic marker or other individualized biologic factor to determine if patient is eligible for the trial (i.e. included in trial design via the inclusion/exclusion criteria)
Study endpoint	Use of a genetic marker or other individualized biologic factor to correlate with study endpoint (i.e. included in trial design as an objective or endpoint)
Stratify into different groups	After patient enrollment, trial design uses a genetic marker or other individualized biologic factor to stratify into different groups (i.e. included in trial design to stratify for treatment or analysis groups)
Targeted therapy	Trial is using a molecular targeted therapy; drug used in a “targeted” patient population (i.e. HER2+ breast cancer gets a HER2 targeted agent)

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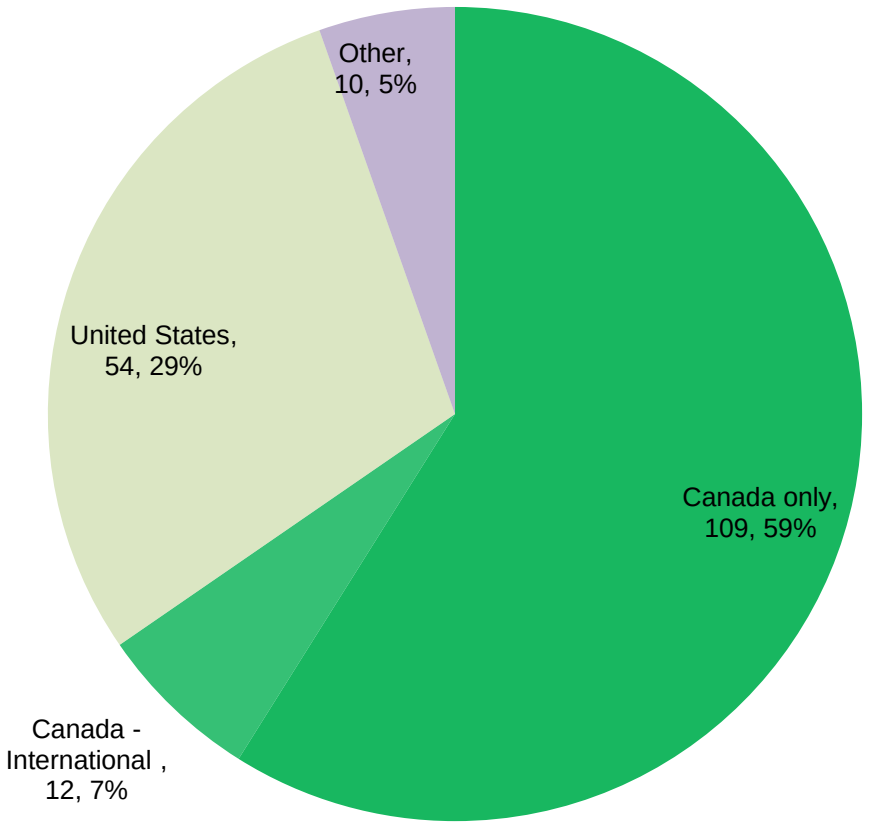
Figure 9. Breakdown of Portfolio trials at adult Network centres by lead country for 2016/2017 Portforlio Trials



Notes:

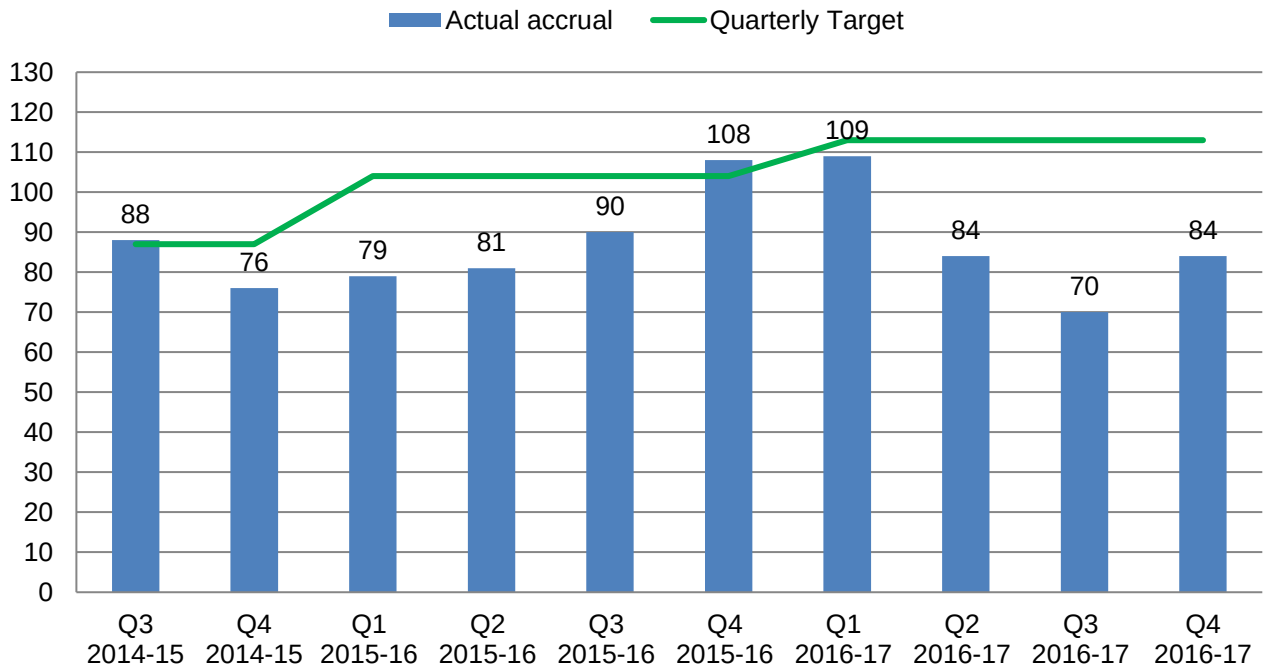
- Breakdown of trials at adult Network sites by lead country, as of May 31, 2017 (n=185)
- Approx. 63% of all trials at adult Network sites are led by Canada – 7% of which are international, multicentered studies
- The average number of Network sites per trial led by Canada (including international multicentered) is 5.98.
- Four trials were available at both adult and pediatric Network sites in fiscal year 2016 and are included in both adult and pediatric figures.

Canadian Cancer Clinical Trials Network

Section B: Progress at Pediatric Network Sites

Objective: To improve patient access to academic clinical trials: Improve recruitment of pediatric patients

Figure 10. Number of patients recruited to Portfolio trials at pediatric Network sites
Q3 2014/15 - Q4 2016/17



Notes:

- 347 patients were recruited to Portfolio trials at pediatric Network sites in 2016/17. The annual target is 451 patients. Pediatric Network sites are 30% below its quarterly target for recruitment
- Data include pediatric sites associated with the C17 Council (n=17)

	2016/17 progress against 2016/17 Network Target			
	Accrual	Target	Difference	Annual baseline
Accrual	347	451	104	347
% above baseline	100%	130%		100%

Figure 11. Number of paitents recruited per pediatric Network site in 2016/2017

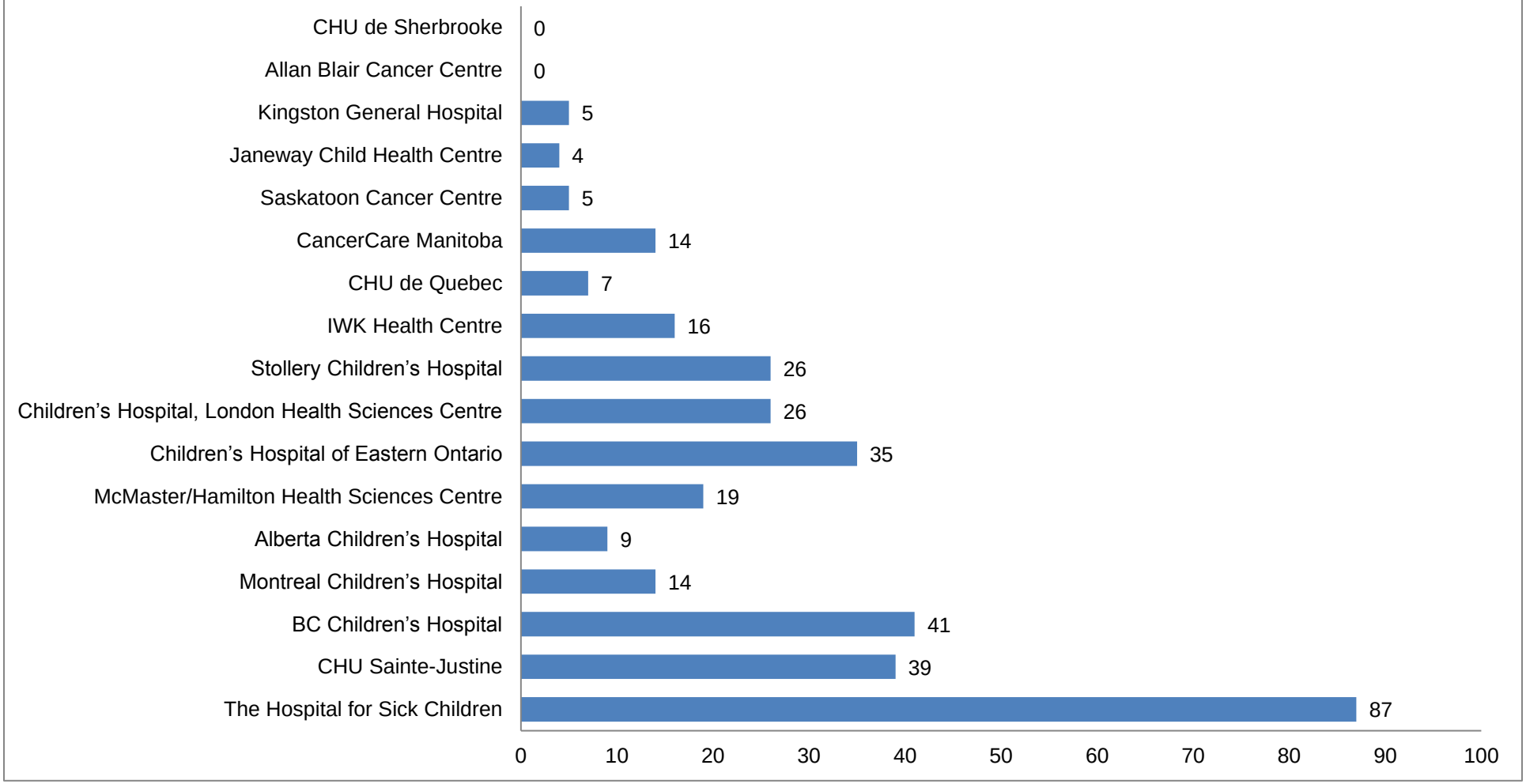


Figure 12. Progress to baseline recruitment per pediatric Network site in 2016/17

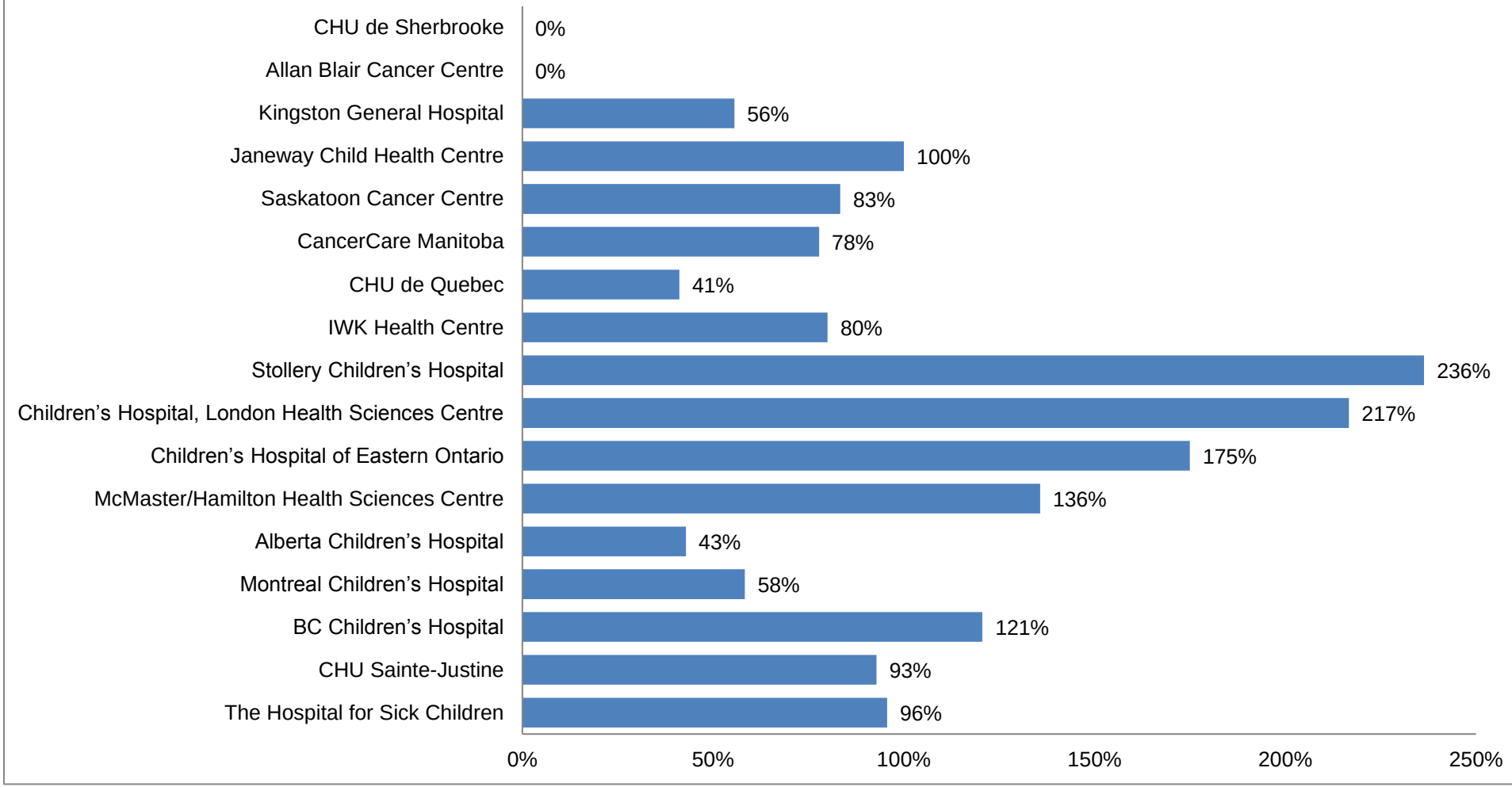


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Table 2. Number of patients recruited per pediatric Network site (by fiscal year)

Network Site	**Y3 Baseline	Y1 Total	% of Y1 baseline	Y2 Total	% of Y2 baseline	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Y3 YTD Total	% of Y3 baseline
The Hospital for Sick Children	91	50	110	109	120	29	20	16	22	87	96%
CHU Sainte-Justine	42	18	86	26	62	14	10	8	7	39	93%
BC Children's Hospital	34	13	76	46	135	9	12	5	15	41	121%
Montreal Children's Hospital	24	9	75	23	96	6	1	2	5	14	58%
Alberta Children's Hospital	21	10	95	21	100	3	5	0	1	9	43%
McMaster/Hamilton Health Sciences Centre	14	6	86	20	143	10	2	3	4	19	136%
Children's Hospital of Eastern Ontario	20	10	100	18	90	7	8	13	7	35	175%
Children's Hospital, London Health Sciences Centre	12	7	117	15	125	5	9	5	7	26	217%
Stollery Children's Hospital	11	8	145	10	91	10	7	6	3	26	236%
IWK Health Centre	20	6	60	20	100	6	1	2	7	16	80%
CHU de Quebec	17	7	82	14	82	0	3	2	2	7	41%
CancerCare Manitoba	18	5	56	20	111	3	4	3	4	14	78%
Saskatoon Cancer Centre	6	9	300	6	100	2	1	2	0	5	83%
Janeway Child Health Centre	4	1	50	3	75	2	0	2	0	4	100%
Kingston General Hospital	9	5	111	7	78	3	1	1	0	5	56%
Allan Blair Cancer Centre	4	0	0	0	0	0	0	0	0	0	0%
CHU de Sherbrooke	0	0	NA	0	NA	0	0	0	0	0	NA
Ped sites (N=17) total	**347**	164	95	**358**	**103**	**109**	**84**	**70**	**84**	**347**	100%

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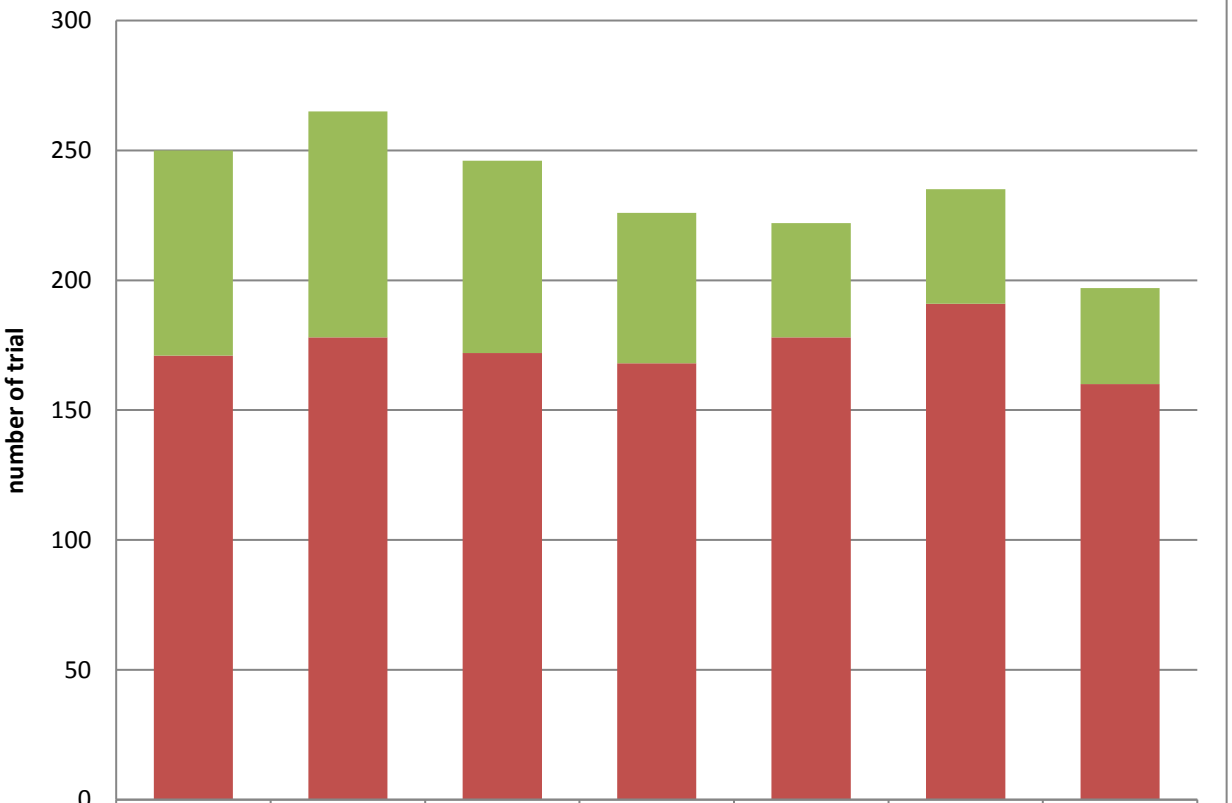
Objective: To demonstrate impact of the Network and academic trials on the Canadian Health Care System: a) Develop and maintain a portfolio of academic trials that will ensure the enthusiastic participation of academic trialists and patients and impact patient care.

Figure 13. Total Portfolio Trials Year over Year for Network Sites (2011-2017YTD)



	2011	2012	2013	2014	2015	2016	2017(YTD)
Peds	79	87	74	58	44	44	37
Adults	171	178	172	168	178	191	160

Notes:

- There were 37 Portfolio trials available at pediatric Network sites, 6 new trials added at the end of Quarter 4
- The data provided in Figure 13 is a snapshot of the Portfolio as of June 8, 2016
- Two trials were available at both adult and pediatric Network sites in 2016 and are included in both adult and pediatric figures

Figure 14. Breakdown of Fiscal 2016 Portfolio trials at pediatric Network sites

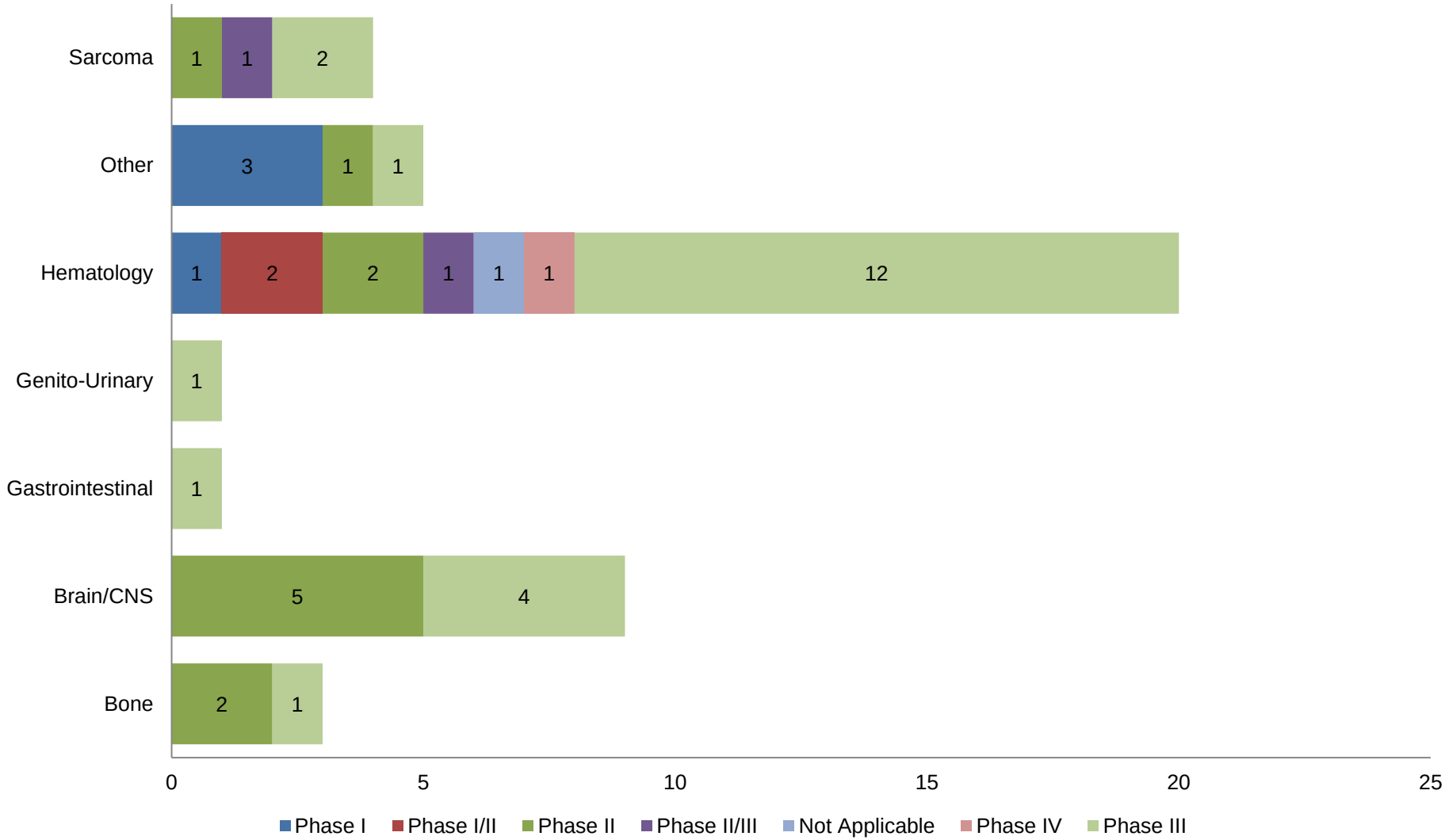


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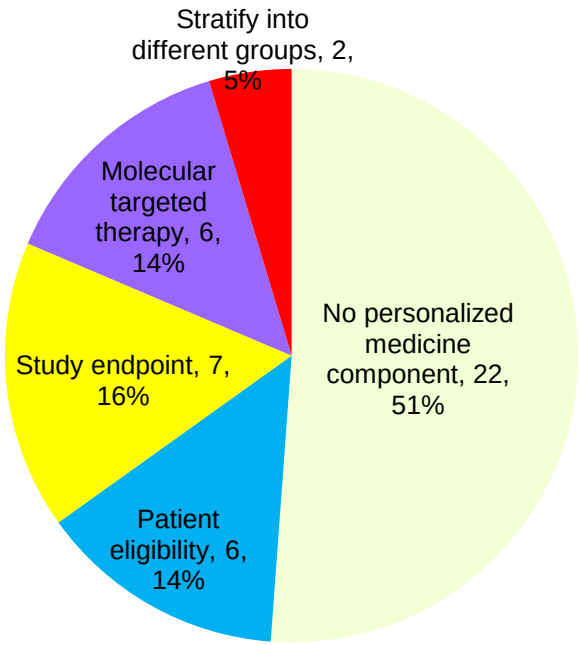
Figure 15. Breakdown of personalized medicine trials at pediatric Network sites in fiscal year 2016/2017

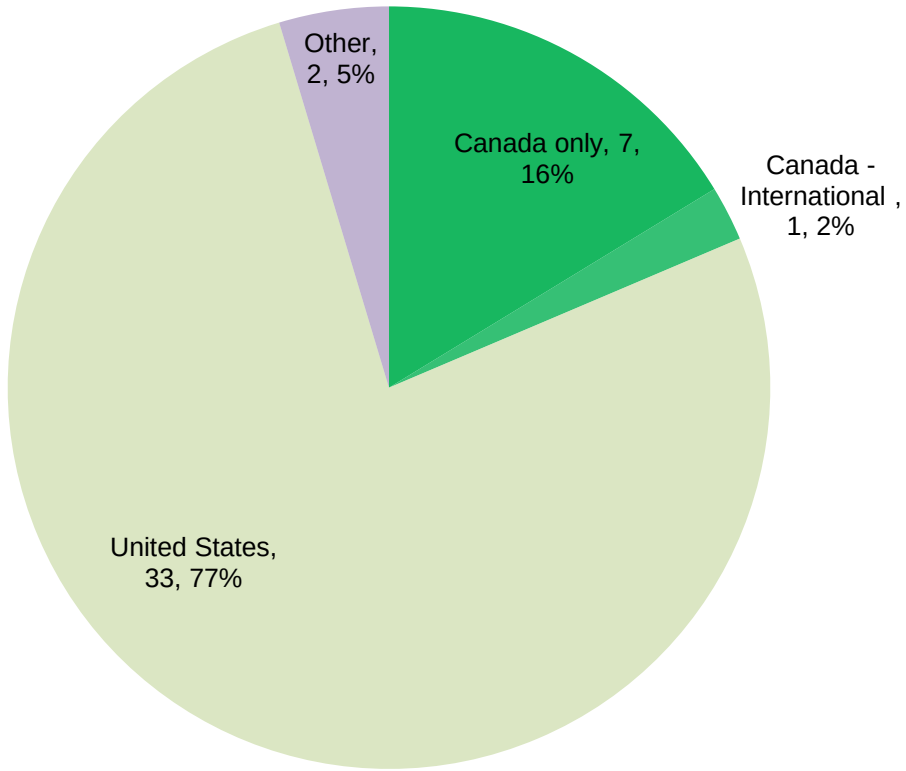


Notes:

- Personalized medicine trials at pediatric Network sites, as of June 8, 2017 (n=43)
- 49% of all trials at pediatric Network sites have a personalized medicine component; 21% of trials are immunotherapy related.
- Four trials were available at both adult and pediatric Network sites in fiscal year 2016 and are included in both adult and pediatric figures

Category	Definition
Patient eligibility	Use of a genetic marker or other individualized biologic factor to determine if patient is eligible for the trial (i.e. included in trial design via the inclusion/exclusion criteria)
Study endpoint	Use of a genetic marker or other individualized biologic factor to correlate with study endpoint (i.e. included in trial design as an objective or endpoint)
Stratify into different groups	After patient enrollment, trial design uses a genetic marker or other individualized biologic factor to stratify into different groups (i.e. included in trial design to stratify for treatment or analysis groups)
Targeted therapy	Trial is using a molecular targeted therapy; drug used in a “targeted” patient population (i.e. HER2+ breast cancer gets a HER2 targeted agent)

Figure 16. Breakdown of Portfolio trials at pediatric Network centres by lead country, in 2016/2017



Notes:

- Breakdown of trials at pediatric Network sites by lead country, as of June 8, 2017 (n=43)
- 16% of all trials at pediatric Network sites are led by Canada – 2% of which are international, multicentered studies
- The average number of Network sites per trial led by Canada (including international multicentered) is 7.89.
- Four trials were available at both adult and pediatric Network sites in fiscal year 2016 and are included in both adult and pediatric figures

Canadian Cancer Clinical Trials Network

Section C: Portfolio Efficiency

Objective: To improve patient access and increase in successful completion of trials

Portfolio approval process timeline:

Calendar Year	# Application Completed	Average Application Processing Time (days)
2015	89	24
2016	70	24
2017	17	12

Calendar Year	# Application Completed	Average FPR Time (days)
2015	6	47
2016	10	98

Note: 1) from application received to approve/decline the application since Jan 13, 2015 to May 2017; 2) from date site agreed to pursue peer review to date last reviewer submitted completed peer review package to 3CTN (approved as peer reviewed).

Section D: Other metrics

Objective: To provide overall metrics to all sites.

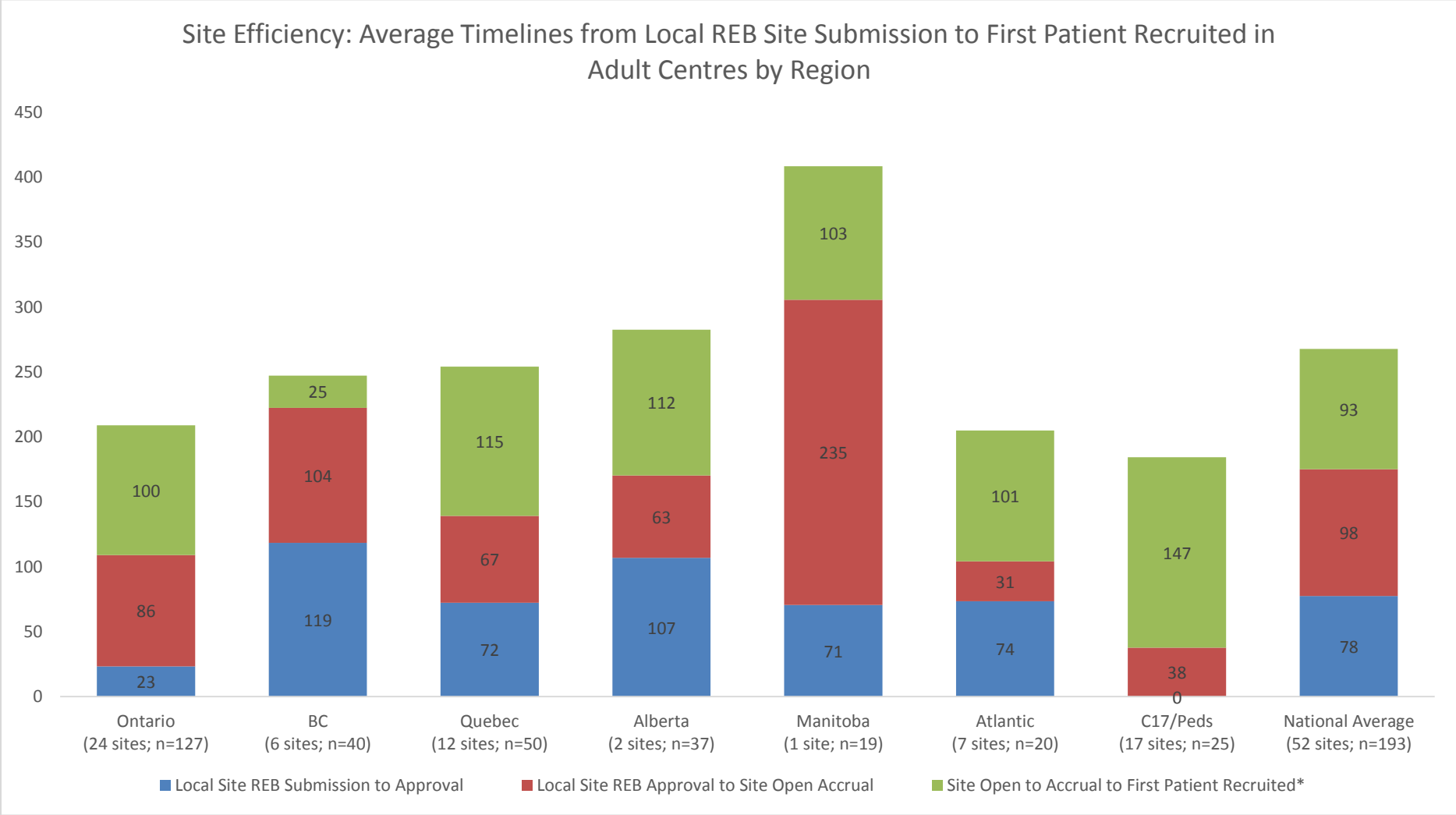
Complexity mix by number of total portfolio trials and patients accrued.

Patient Scope	Low		Standard		High	
	# of trials	Accrual (total)	# of trials	Accrual (total)	# of trials	Accrual (total)
Overall	31%	50%	58%	40%	11%	10%
Adults	32%	51%	59%	42%	9%	6%
Peds	23%	31%	50%	14%	27%	56%

*total data updated May 31, 2017

Canadian Cancer Clinical Trials Network

Site efficiency – National



Canadian Cancer Clinical Trials Network

Region	Sites	# of portfolio Studies in 2016 (228 portfolio studies total, 69 recruiting sites)	fiscal year 2016 accrual (YTD total)	Total trials included for this efficiency calculation	Activation Timeline from NOL/Sponsor Approval/Central Approval to Site Open to Accrual *	Local Site REB Processing Time (site submission to approval)	Local Site REB Approval to First Patient Recruited	Site Open to Accrual to First Patient Recruited**	Recruiting Period (from open to closed to accrual	Site Accrual vs. Site Target
Ontario	24	157	2145	147	261	23	186	100	393	56%
BC*	6	65	292	44	218	119	129	25	541	106%
Quebec	10	97	585	67	250	72	182	115	316	74%
Alberta	2	60	260	43	247	107	176	112	475	51%
Manitoba	1	12	102	22	450	71	338	103	613	44%
Atlantic	7	43	110	19	257	74	131	101	421	75%
C17/Peds	17	44	347	26	225	-	184	147	362	163%
National (adult network sites)	50	189	4145	147	280	78	190	93	460	68%

Definitions and formula:

Timeline	Formula
Activation Timeline from NOL/Sponsor Approval/Central Approval to Site Open to Accrual *	=site open to accrual - central approval or sponsor open to accrual or NOL (for C17 only)
Local Site REB Processing Time (site submission to approval)	=local site REB approval date - local site submission date
Local Site REB Approval to First Patient Recruited	=first patient recruited to the site - local site REB approval date
Site Open to Accrual to First Patient Recruited	=first patient recruited to the site - site open to accrual date
Recruiting Period (from open to closed to accrual)	= site closed to accrual date - site open to accrual date
Site Accrual vs. Site Target	= total accrual when closed/ site accrual set when the site open to accrual

Note:

- *Centralized approval dates were used for BC and Ontario, Peds used NOL, other sites used "sponsor approval"
- first patients of peds and Alberta are by month and not exact dates
- under setup trials not included

- only for portfolio start date greater than April 1, 2014 and site open greater than April 1, 2014
- Due to various available data, the above metrics are for references only.

Appendix: Additional Notes

Table 3. Reporting periods and dates Q4 2014/15 – Q4 2016/17

Quarter	Period	Recruitment Database Lock
Q3 2014/15	October – December 2014	NA*
Q4 2014/15	January – March 2015	NA*
Q1 2015/16	April – June 2015	NA*
Q2 2015/16	July – September 2015	October 20, 2015
Q3 2015/16	October – December 2015	March 31, 2016
Q4 2015/16	January – March 2016	May 31, 2106
Q1 2016/17	April – June 2016	August 31, 2016
Q2 2016/17	July – September 2016	November 15, 2016
Q3 2016/17	October – December 2016	February 15, 2017
Q4 2016/17	January – March 2017	May 31, 2107

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