Canadian Cancer Clinical Trials Network

# 3CTN Y5 Performance Report

April 1, 2018 – March 31, 2019

Report Created: June 3, 2019

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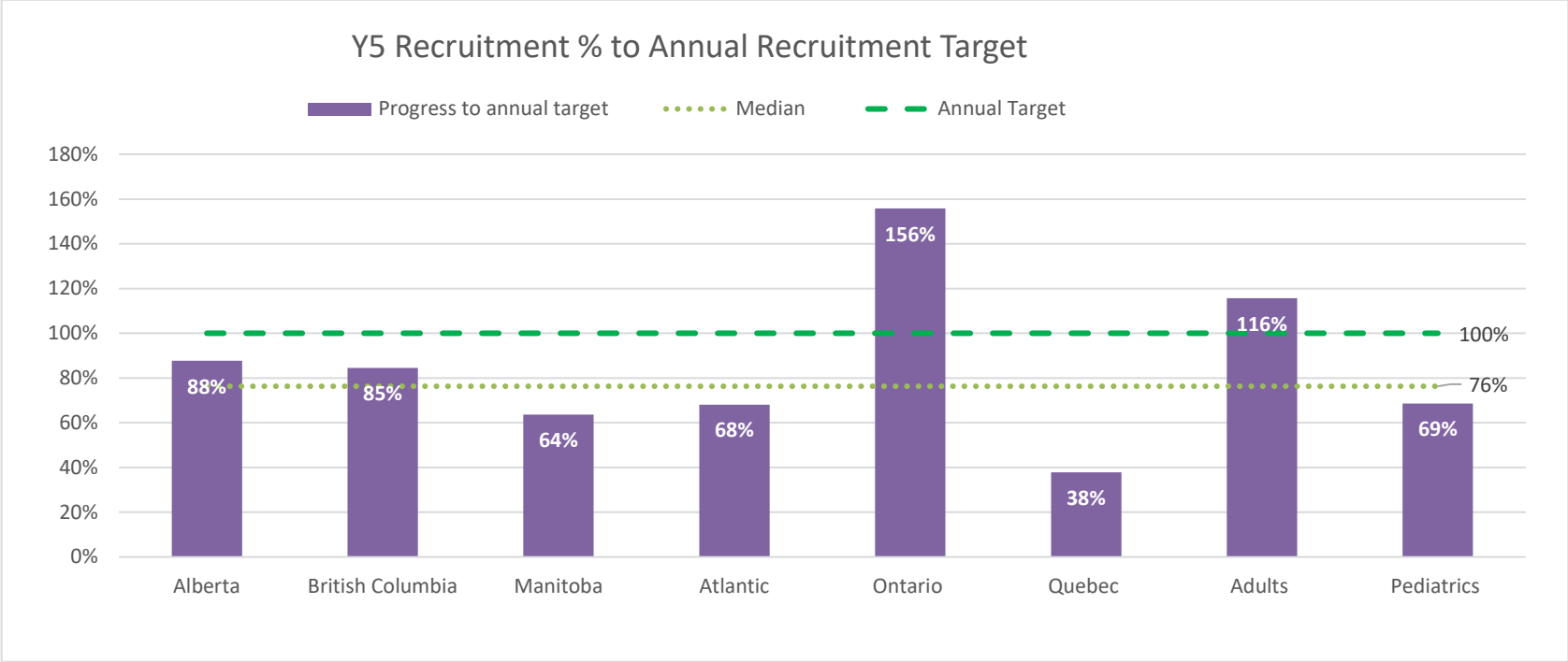
# Section A: Patient access and recruitment to the 3CTN Portfolio Trials

## 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)

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## 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)

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## 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%** |

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## 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%** |

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## 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%** |

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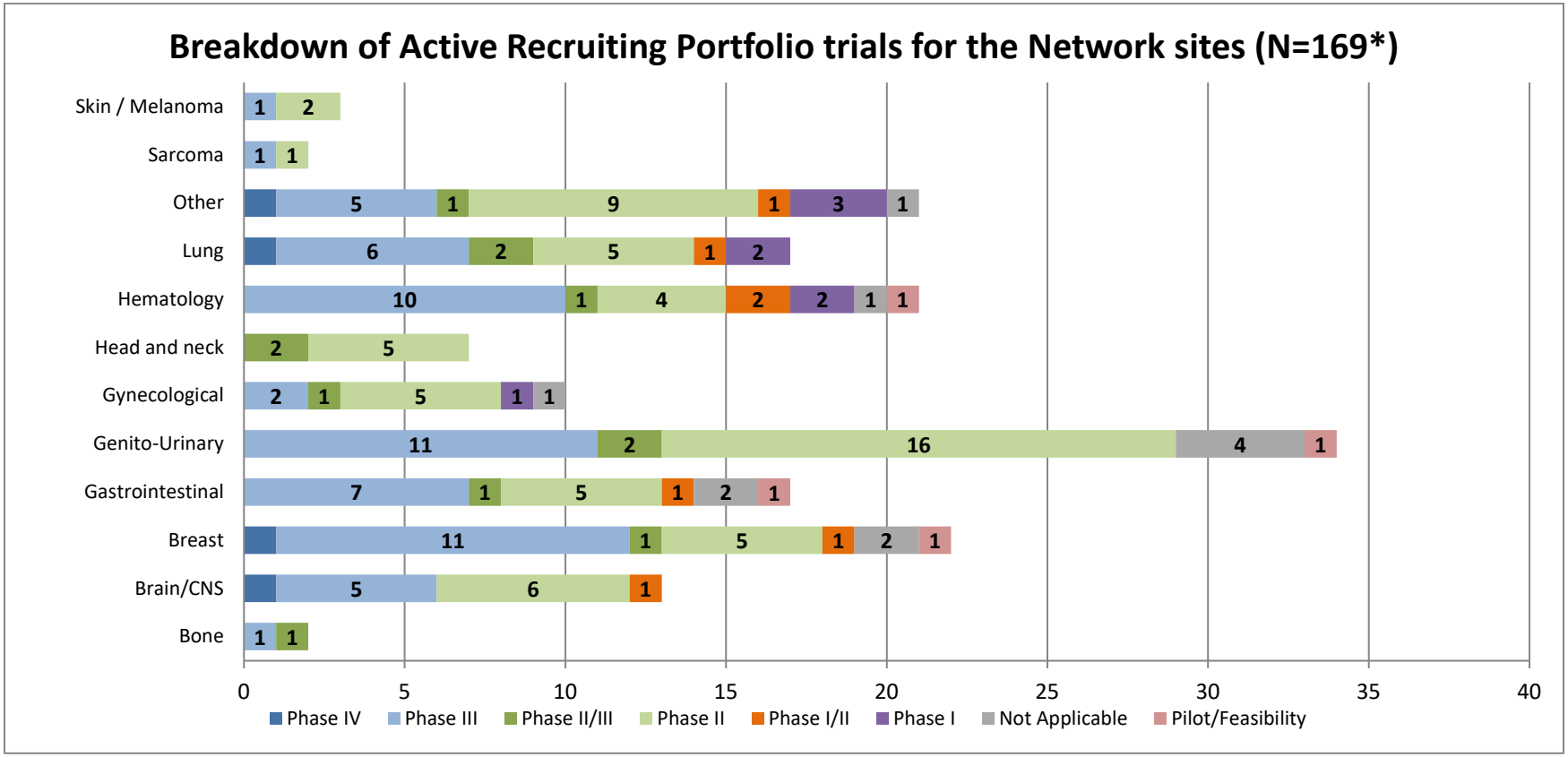
# Section B: 3CTN Portfolio Metrics

## 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

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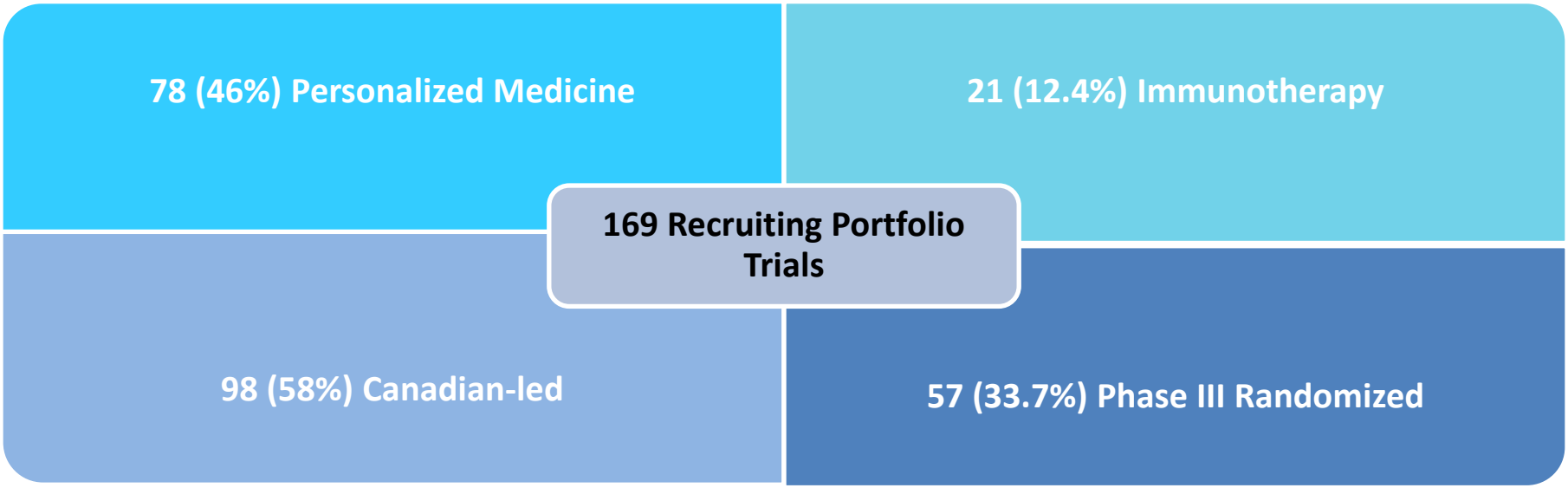
**Active Recruiting Portfolio trials by study type and noted features**




**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% |

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**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.

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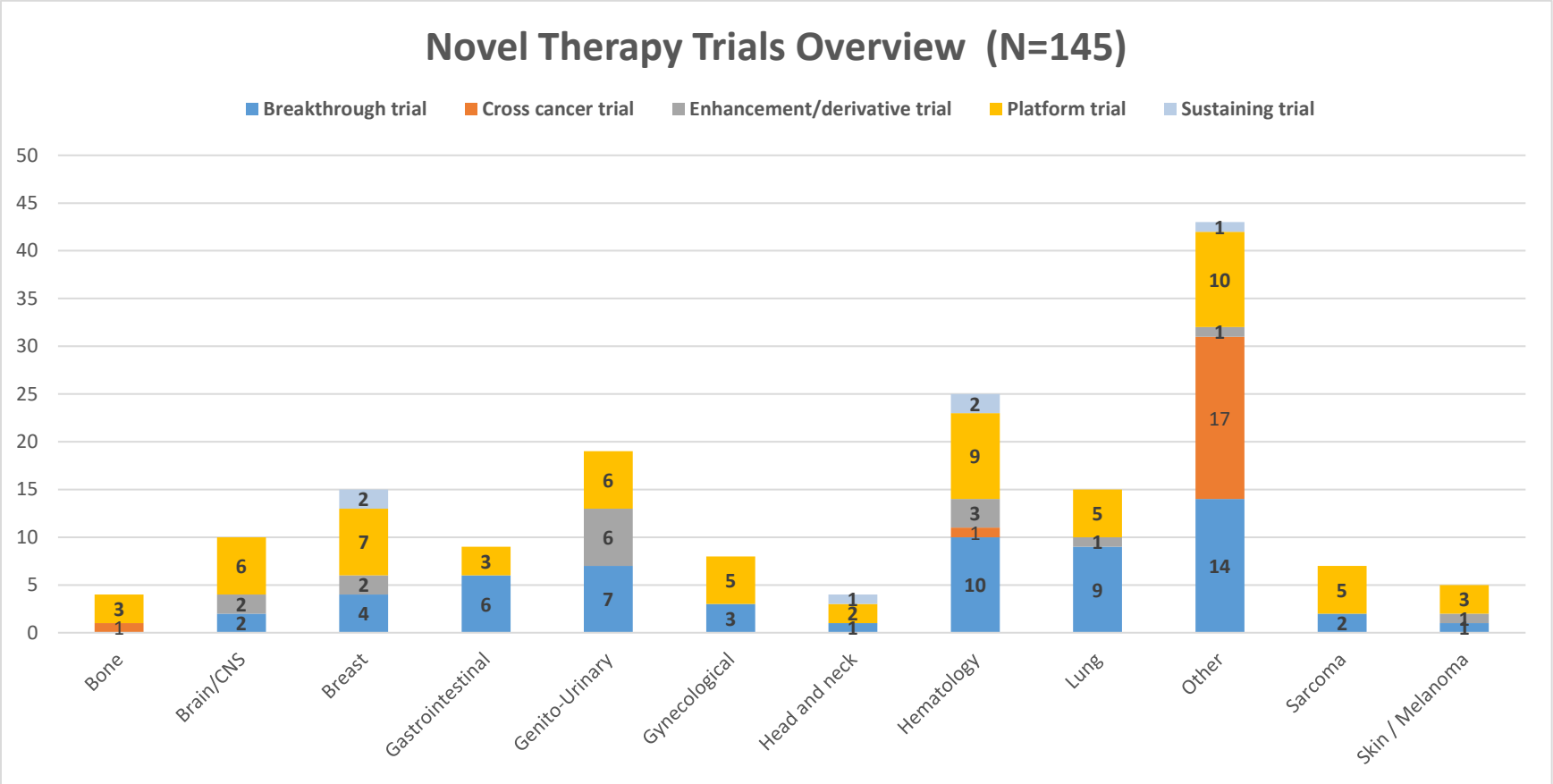
## Breakdown of Novel Therapy Trials by Disease Site



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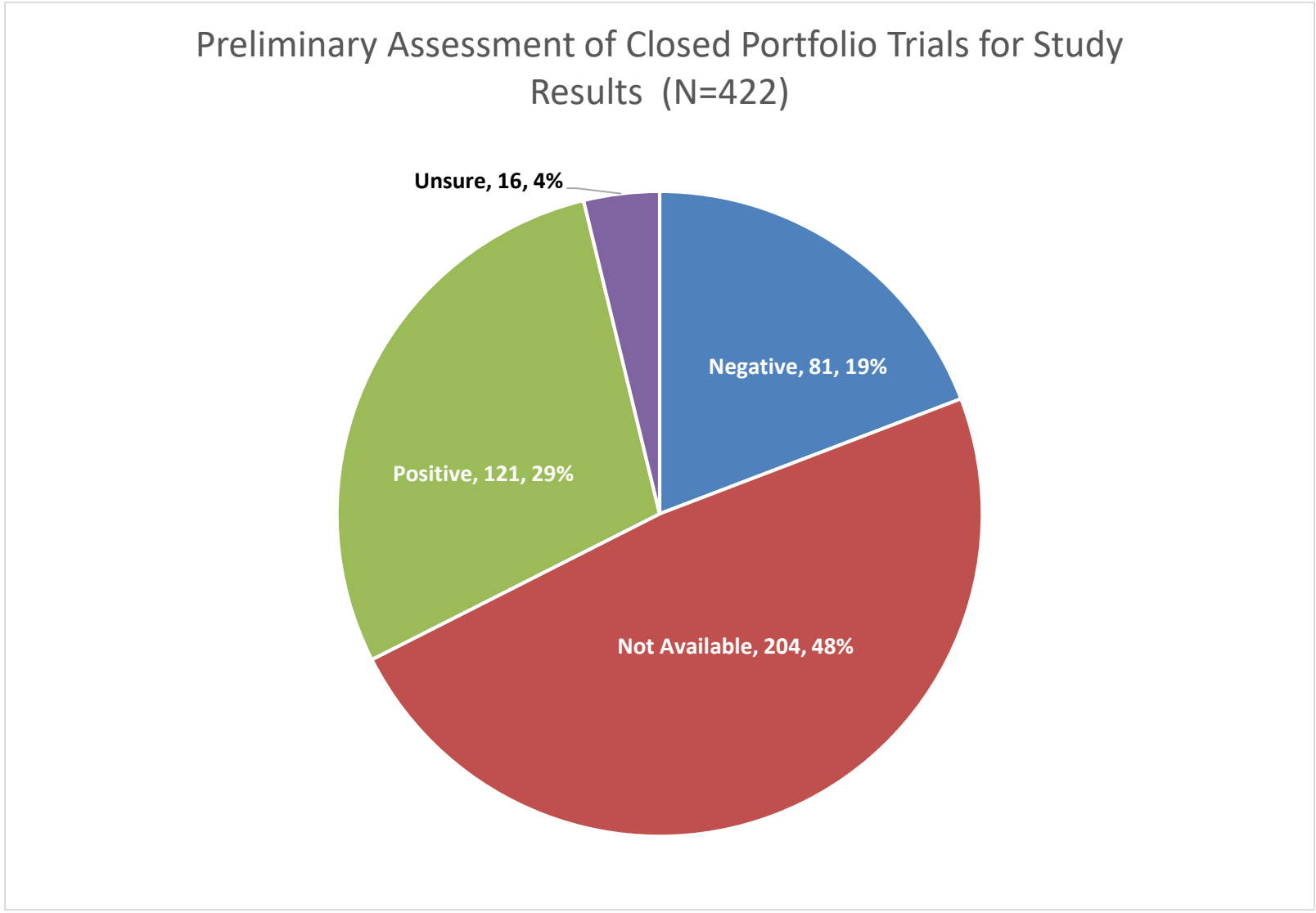


Note: assessments were based on primary end point results as reported from study publications.

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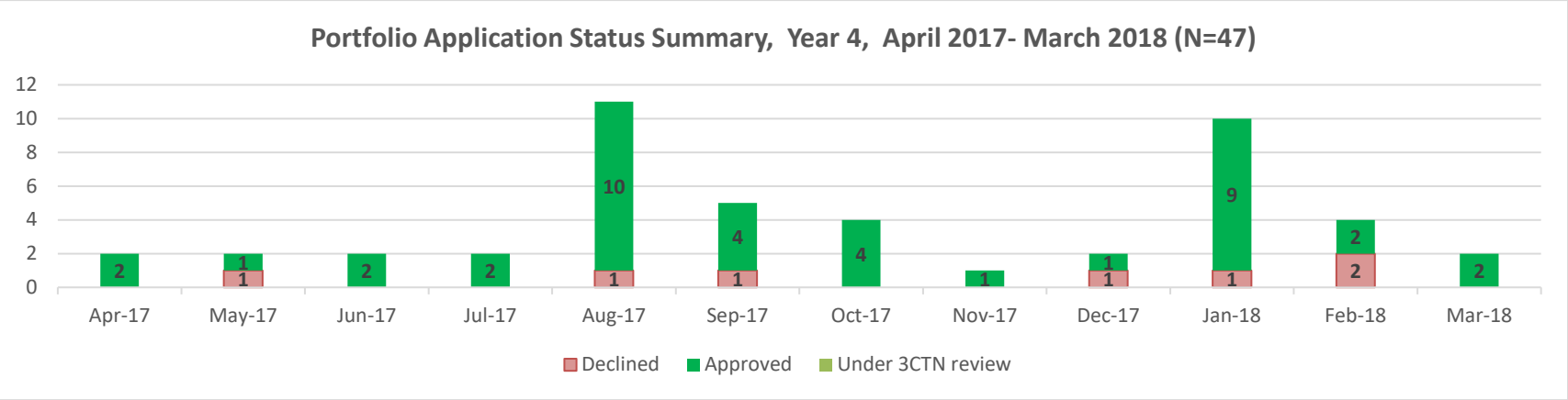
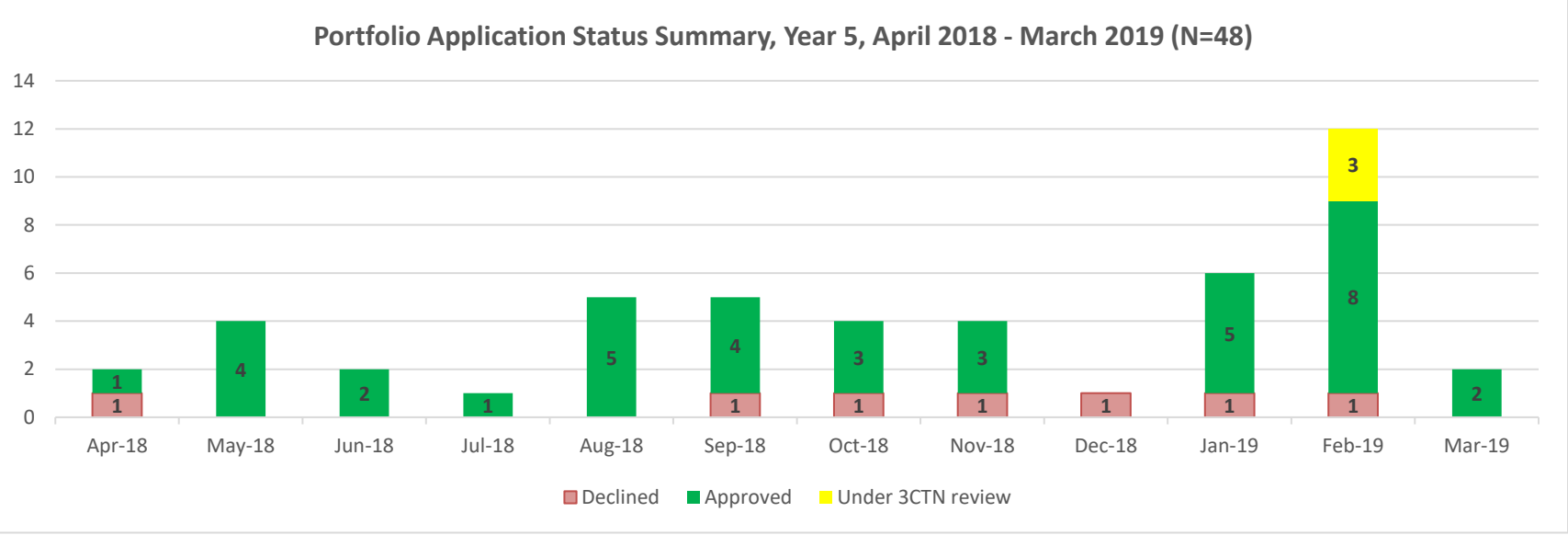
## Overview of Portfolio Applications

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.



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## 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)

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## 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

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## 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<br>**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):<br>1) access to the protocol;<br>2) the site PIs has expressed interest in the trial;<br>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)<br><br>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<br>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 |

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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 |

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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