NON-INTERVENTIONAL (NI) STUDY PROTOCOL

PASS information

Title	Understanding Early and Ongoing Treatment Utilization of Palbociclib in a US Community Oncology Setting
Protocol number	A5481062
Protocol version identifier	1
Date of last version of protocol	12 June 2015
Active substance	Palbociclib
Medicinal product	Palbociclib
Research question and objectives	1. To describe the demographic and clinical characteristics of patients newly initiating Palbociclib therapy. 2. To describe early treatment utilization of patients newly initiating Palbociclib therapy including time to discontinuation.
Author	Robyn Harrell, MS Outcomes Researcher, McKesson Specialty Health – US Oncology Network, Clinical Services Tel: 832-250-5263 Email: robyn.harrell@mckesson.com

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McKesson Specialty Health Protocol/Statistical Analysis Plan Sign off Page

This final protocol and statistical analysis plan has been reviewed and agreed upon by Pfizer Pharmaceuticals and McKesson Specialty Health. This sign-off page is required to be completed prior to submission to McKesson Specialty Health's Privacy and Compliance Review.

Pfizer, Study Lead

Signature: DocuSigned by: AE84871BDAEC4F7...

Name: Ruslan Horblyuk, PhD, MBA

Tile: Director, Outcomes & Evidence, Oncology

Date: June 22, 2015

McKesson Specialty Health, Principal Clinical Investigator

Signature: DocuSigned by: Debra Patt 1638E60B5EC24DE...

Name: Debra Patt, MD, MPH, MBA

Title: Medical Oncologist, US Oncology Research & Medical Director for Health Informatics, McKesson Specialty Health

Date: June 22, 2015

McKesson Specialty Health, Outcomes Researcher & Study Lead

Signature: DocuSigned by: Robyn Harrell EE39981886A64B5...

Name: Robyn Harrell, MS

Title: Outcomes Researcher

Date: June 22, 2015

** upon execution, the SAP is now considered locked and any further changes or requests for additional analysis will result in additional charges*

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1. LIST OF ABBREVIATIONS

Abbreviation	Definition
BMI	Body Mass Index
ECOG	Eastern Cooperative Oncology Group
EHR	Electronic Health Record
ER	Estrogen Receptor
FDA	Food and Drug Administration
HER2-	Human epidermal growth factor receptor 2-negative
iKM	iKnowMed
LOT	Line of Therapy
mBC	Metastatic breast cancer
MSH	McKesson Specialty Health
NI	Non-Interventional
PR	Progesterone Receptor
USON	US Oncology Network

2. RESPONSIBLE PARTIES

Principal Investigator(s) of the Protocol

Name, degree(s)	Title	Affiliation	Address
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Debra Patt, MD, MPH, MBA	Medical Oncologist, US Oncology Network & Medical Director for Health Informatics at McKesson Specialty Health Study Principal Clinical Investigator	Texas Oncology | The US Oncology Network	6204 Balcones Drive Austin, Texas 78731
Robyn Harrell, MS	Outcomes Researcher, Health Economics and Outcomes Research MSH Study Lead	The US Oncology Network | McKesson Specialty Health	Office Affiliation: 10101 Woodloch Forest Drive, The Woodlands, Texas 77380

3. ABSTRACT

3.1. Title

Understanding Early and Ongoing Treatment Utilization of Palbociclib in a US Community Oncology Setting

3.1.1. Version and Date of Protocol

3.1.2. Main Author: Robyn Harrell, MS

3.2. Rationale and background

Breast cancer is one of the most prevalent and challenging cancers to manage worldwide. In the U.S., one in eight women will have invasive breast cancer diagnosed during her lifetime[1,2]. It is estimated that at least 6-10% of breast cancers are metastatic at the time of diagnosis and that between 20% and 30% of early stage breast cancer cases will progress to metastatic disease[3,4]. Over 230,000 new cases of invasive breast cancer are estimated to be newly diagnosed in the U.S. in 2015[2]. Therefore, approximately 23,000 new cases of de novo metastatic breast cancer will be diagnosed in 2015. There is no cure for metastatic breast cancer. A recent study suggests that median survival for metastatic breast cancer patients is 33 months[5]. Nearly three-fourths of breast cancers are subtyped as HR-positive/HER2-negative[10].

The FDA granted accelerated approval for Palbociclib, an oral targeted agent, in combination with Letrozole, for the treatment of postmenopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer who have not received previous systemic treatment for their advanced disease. Approval was granted based on findings from the phase II PALOMA-1 trial. Patients were randomized to Palbociclib plus Letrozole or Letrozole alone. The median progression-free survival (PFS) with Palbociclib was 20.2 versus 10.2 months for Letrozole alone (HR = 0.488; P = .0004)[1] This study is designed to evaluate real world usage patterns of early palbociclib clinical prescribing.

3.3. Research question and objectives

3.3.1. Study design

This is a descriptive, retrospective longitudinal study.

3.4. Population

3.4.1. Setting

Community oncology practices that are part of the US Oncology Network and utilize the full capabilities of the iKnowMed (iKM) EHR.

3.4.2. Study Population

MSH will identify adult primary breast cancer patients with a new prescription for Palbociclib in US Oncology's iKM EHR, in rolling 60 day periods over a 12 month period.

Patients will be followed through the end of the 12 month period or until date of last record. A treatment index date will be established as the date of the first prescription of Palbociclib. The planned study observation period will begin at the time of Palbociclib launch and continue for 12 months. Reporting will be conducted every 60 days on a rolling basis. Patient accrual will be cumulative over time. The patient cohort for each report will be cumulative – all patients accrued through the given report time period. At 12 months post-launch, we will assess whether the number of patients initiating Palbociclib is sufficient for a formal protocol driven outcomes research study.

3.5. Variables

3.5.1. Exposures

The data will include information on Palbociclib utilization including start and stop dates.

3.5.2. Outcomes

Outcomes will include time to treatment discontinuation, reason for treatment discontinuation, Palbociclib line of therapy (LOT), RDI, CBC monitoring schedule, dose reductions, and proportion of patients still on Palbociclib at 1 month, 2 months, 3 months, etc.

3.5.3. Co-Variates

Co-variates will include patient age at index date, gender, practice region, stage at initial diagnosis, performance status, height/weight, BMI, histology, hormone receptor status, menopausal status, metastatic site(s), count of CBC labs, neutrophil counts under 500, neutrophil counts under 1000, prescribed dose, prior antineoplastic therapies, prior supportive care therapies and concomitant medications.

3.6. Data sources

Structured data will be extracted from the MSH/USON database iKM. These data primarily capture outpatient medical oncology care across 19 U.S. states and include over 400 practice sites. Overall, the iKM EHR database captures data on approximately 10% of newly diagnosed cancer patients in the United States. All data will be merged into one master dataset for analysis. Data is handled in compliance with HIPAA.

3.7. Study size

MSH will identify adult patients with a new prescription for Palbociclib in US Oncology's iKM ER, in rolling 60 day periods over a 12 month period. Patients will be followed through the end of the 12 month period or until date of last record. A treatment index date will be established as the date of first prescription of Palbociclib.

The planned study observation period will begin at the time of Palbociclib launch and continue for 12 months. Reporting will be conducted every 60 days on a rolling basis. Patient accrual will be cumulative over time. The patient cohort for each report will be cumulative – all patients accrued through the given report time period.

3.8. Data analysis

The main unit of analysis is the patient. All analyses are descriptive and unadjusted. Results will be reported in aggregate. The number and percent of patients along with descriptive statistics (mean, standard deviation, median, minimum, maximum) will be reported for continuous data. Categorical variables will have the frequency (n,%) reported. Patient demographics, clinical characteristics, treatment patterns, and clinical burden will be summarized. The analyses will be conducted using SAS® 9.2 or higher (SAS Institute Inc., Cary, NC, US) and/or R: A Language and Environment for Statistical Computing (R Foundation for Statistical Computing, Vienna, Austria).

3.9. Milestones

Milestone	Start Date	Due Date
Cohort 1 - Data Collection	6/1/15	6/10/15
Cohort 1 - Analytic File Construction Variable Recording and Scoring	6/10/15	6/15/15
Cohort 1 -Rolling Report	6/16/15	6/30/15
Cohort 2 - Data Collection	8/1/15	8/10/15
Cohort 2- Analytic File Construction Variable Recording and Scoring	8/10/15	8/14/15
Cohort 2 -Rolling Report	8/14/15	8/31/15
Cohort 3 - Data Collection	10/1/15	10/9/15
Cohort 3- Analytic File Construction Variable Recording and Scoring	10/9/15	10/16/15
Cohort 3 -Rolling Report	10/16/15	10/30/15
Cohort 4 - Data Collection	12/1/15	12/11/15
Cohort 4 - Analytic File Construction Variable Recording and Scoring	12/11/15	12/18/15
Cohort 4 -Rolling Report	12/18/15	12/31/15
Cohort 5 - Data Collection	2/1/16	2/10/16
Cohort 5 - Analytic File Construction Variable Recording and Scoring	2/10/16	2/16/16
Cohort 5 -Rolling Report	2/16/16	2/28/16
Cohort 6 - Data Collection	4/1/16	4/10/16
Cohort 6 - Analytic File Construction Variable Recording and Scoring	4/11/16	4/16/16

Cohort 6 -Rolling Report	4/16/16	4/30/16

4. AMENDMENTS AND UPDATES

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment(s)	Reason

5. MILESTONES

Milestone	Start Date	Due Date
Cohort 1 - Data Collection	6/1/15	6/10/15
Cohort 1 - Analytic File Construction Variable Recording and Scoring	6/10/15	6/15/15
Cohort 1 -Rolling Report	6/16/15	6/30/15
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Cohort 2 -Rolling Report	8/14/15	8/31/15
Cohort 3 - Data Collection	10/1/15	10/9/15
Cohort 3- Analytic File Construction Variable Recording and Scoring	10/9/15	10/16/15
Cohort 3 -Rolling Report	10/16/15	10/30/15
Cohort 4 - Data Collection	12/1/15	12/11/15
Cohort 4 - Analytic File Construction Variable Recording and Scoring	12/11/15	12/18/15
Cohort 4 -Rolling Report	12/18/15	12/31/15
Cohort 5 - Data Collection	2/1/16	2/10/16
Cohort 5 - Analytic File Construction Variable Recording and Scoring	2/10/16	2/16/16
Cohort 5 -Rolling Report	2/16/16	2/28/16
Cohort 6 - Data Collection	4/1/16	4/10/16
Cohort 6 - Analytic File Construction Variable Recording and Scoring	4/11/16	4/16/16
Cohort 6 -Rolling Report	4/16/16	4/30/16

6. RATIONALE AND BACKGROUND

Pfizer has completed its NDA submission to the United States Food and Drug Administration (FDA) in August 2014 for approval of Palbociclib, an oral targeted agent, in combination with Letrozole, for the treatment of postmenopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer who have not received previous systemic treatment for their advanced disease. The FDA granted accelerated approval for Palbociclib on February 3, 2015.

7. RESEARCH QUESTION AND OBJECTIVES

To describe the demographic and clinical characteristics of patients newly initiating Palbociclib therapy.

To describe early treatment utilization of patients newly initiating Palbociclib therapy including time to discontinuation.

8. RESEARCH METHODS

8.1. Study design

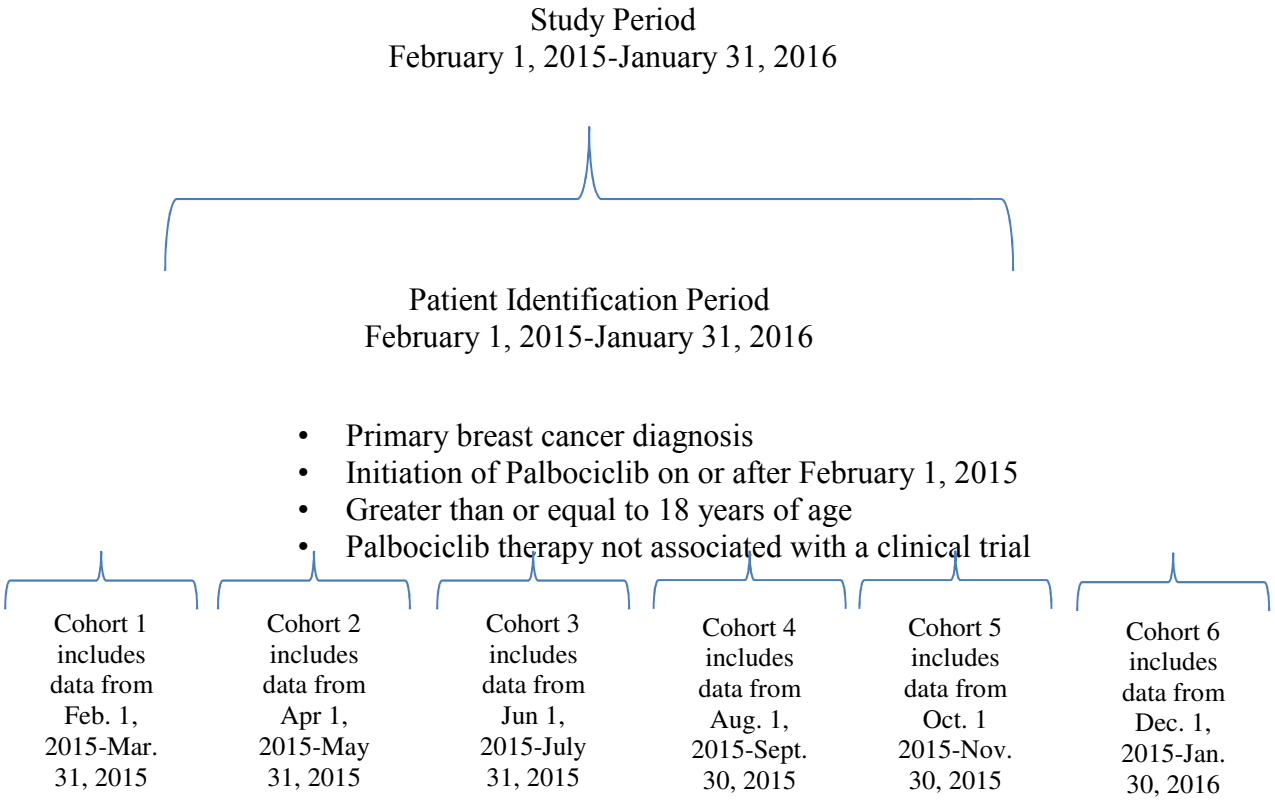
This study is a longitudinal, retrospective observational study. It is descriptive in nature.

8.2. Setting

This study utilizes the iKM electronic health record data within the US Oncology Network community practices. Specifically, breast cancer patients who initiate Palbociclib between February 2015 and January 2016 will be analyzed.

When examining treatment patterns, reasons for *discontinuation* may include but is not limited to economic, patient or physician choice, toxicity, completion of intended treatment, response achieved, treatment holiday, progression, patient's death, patient enters hospice, or unknown reasons due to loss to follow-up or to lack of documentation. The date a patient is *lost to follow-up* is defined as the date of the last visit observed or a record of death, prior to the end of the study period.

Figure 1. Illustration of Patient Sample Selection



8.2.1. Inclusion criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. Primary breast cancer patients who initiated Palbociclib between February 1, 2015-January 31, 2016.
2. Greater than or equal to 18 years of age at Palbociclib initiation.

8.2.2. Exclusion criteria

Patients meeting any of the following criteria will not be included in the study:

1. Patients who received Palbociclib on clinical trial will be excluded.

8.3. Variables

Variable	Role	Source	Operational definition
Demographic & Clinical Characteristics			
Date of birth to calculate age at start of Palbociclib (index date, first prescription of Palbociclib)	Baseline characteristic	iKM	
Gender	Baseline characteristic	iKM	
Geographic region of the Practice	Baseline characteristic	iKM	
Stage at diagnosis	Baseline characteristic	iKM	First stage documented for breast cancer diagnosis
ECOG/Karnofsky performance status at index date	Baseline characteristic	iKM	May not be documented. Performance status may be captured as Karnofsky Performance Score or as ECOG. The closest status on or prior to Palbociclib initiation will be recorded. Statuses recorded as Karnofsky Scores will be recoded to ECOG using conversion in Table 3. ECOG will be reported by category: 0, 1, 2, 3, and 4.

Variable	Role	Source	Operational definition
Height (meters)	Baseline Characteristic	iKM	The patient's first recorded height will be captured. For validation of heights >2.15 m (~7 ft), the height on/closest prior to Palbociclib initiation will be substituted. Height will be used to calculate BMI and will not be reported separately.
Weight (kilograms)	Baseline Characteristic	iKM	The weight on/closest prior to Palbociclib initiation will be captured. Values <30kg (~66 lbs) will be considered clinically invalid and ignored. Weight will be used to calculate BMI and will not be reported separately.
BMI at index date (calculated)			Patients will be categorized as underweight, normal, overweight, or obese per BMI will be calculated, following the formula below, using the patient's height and weight described above. BMI's <10 will be considered clinically invalid and set to unknown. [(weight in kg) / (height in cm/100 x height in cm/100)]
Histology	Baseline characteristic	iKM	Last histology documented for breast cancer diagnosis
ER status	Baseline	iKM	Last ER status

Variable	Role	Source	Operational definition
	characteristic		documented for breast cancer diagnosis
PR status	Baseline characteristic	iKM	Last PR status documented for breast cancer diagnosis
HER2 status	Baseline characteristic	iKM	Last HER2 status documented for breast cancer diagnosis
Menopausal status	Baseline characteristic	iKM	If not documented, use 55 years of age for derived menopausal status
Site(s) of metastases	Baseline characteristic	iKM	Report on bone, brain, liver, lungs, lymph nodes, other and none documented.
Treatment and Utilization Patterns			
Date of CBC labs		iKM	
Frequency of CBC labs		iKM	Capture the frequency of CBCs per cycle for the duration of treatment. Define cycle length as the time from the prescription date + 30 (assuming treatment schedule of 3 weeks on, followed by 1 week off)
Neutrophil counts		iKM	
First Palbociclib prescription date		iKM	
Last Palbociclib prescription date		iKM	
Prescribed dose of Palbociclib		iKM	
Time to treatment discontinuation		iKM	
Reason for treatment discontinuation		iKM	May not be well documented,
RDI		Calcula ted	To be defined.
Palbociclib LOT		iKM	1st, 2nd, Not documented
Last date patient was seen in the clinic		iKM	Visits are defined as medical encounters with the practice, detected by vital signs record or documented treatment

Variable	Role	Source	Operational definition
			administration.
Prior antineoplastic therapies 6 months prior to the index date		iKM	Specific list to be finalized after first report delivered.
Date of prior antineoplastic therapies 6 months prior to the index date		iKM	
Prior antineoplastic therapies at any time of available pre-index observation period		iKM	Specific list to be finalized after first report delivered.
Date of prior antineoplastic therapies at any time of available pre-index observation period		iKM	
Prior supportive care therapies – G-CSF & anti-nausea medications 6 months prior to the index date		iKM	Specific list to be finalized after first report delivered.
Date of prior supportive care therapies – G-CSF & anti-nausea medications 6 months prior to the index date		iKM	
Prior supportive care therapies – G-CSF & anti-nausea medications at any time of available pre-index observation period		iKM	Specific list to be finalized after first report delivered.
Date of prior supportive care therapies – G-CSF & anti-nausea medications at any time of available pre-index observation period		iKM	
Concomitant medications given with Palbociclib		iKM	Specific list to be finalized after first report delivered.
Date of concomitant medications given with Palbociclib		iKM	Medications given 7 days prior or during Palbociclib treatment

8.4. Data sources

Data will be extracted from the MSH/USON practices that have fully implemented the iKM electronic health record. These data primarily capture outpatient medical oncology care for patients treated across 19 US states and over 400 sites of care. Overall, the iKM EHR database captures data on approximately 10% of newly diagnosed cancer patients in the United States.

All patients within iKM are assigned a unique patient identifier (patId) by iKM version (e.g., some large practices have separate installations by location). The data sources for this study include the structured data from iKM and chart review. These data and all derived variables will be merged into one master dataset for analysis. Data is handled in compliance with HIPAA.

iKnowMed (iKM)

iKM is an integrated web-based database of oncology-specific electronic health records (EHR) maintained by MSH. iKM captures outpatient practice encounter histories for patients under community-based care, including (but not limited to) patient demographics such as age and sex; clinical information such as disease diagnosis, diagnosis stage, and laboratory testing results; treatment information such as lines of therapy, treatment administration; comorbidities; and performance status. This EHR is implemented across The US Oncology Network.

8.5. Study size

A specific power calculation was not performed as this is a descriptive analysis. Additionally, this is a longitudinal retrospective study with data collection every 60 days for one year.

8.6. Data management

This study will utilize electronic queries of structured fields in the iKM EHR database and review of electronic medical charts. An electronic case report form will be developed, in collaboration with Pfizer, to identify the data to be collected from the electronic chart review. Variables to be collected from both data sources were described in detail in *8.3 Variables*. All data will be handled in accordance with HIPAA and MSH/USON best practices. Data will be integrated into one or more analytic data file(s), and analyses will be conducted using SAS® 9.2 or higher (SAS Institute Inc., Cary, NC, US) and/or R: A Language and Environment for Statistical Computing (R Foundation for Statistical Computing, Vienna, Austria). All data will be stored and maintained according to MSH's retention policy.

8.7. Data analysis

The main unit of analysis is the patient. The analyses, described below, are descriptive; therefore, no formal statistical testing will be performed. Detailed methodology for summary and statistical analyses of data collected in this study is documented herein, following the requirements of the Statistical Analysis Plan (SAP) template; therefore a separate SAP document will not be necessary. Any modifications of primary endpoint definitions or their analyses from what is described herein and is mutually agreed between MSH/USON and Pfizer would be reflected in a protocol amendment.

8.7.1. Hypotheses and decision rules

There are no hypotheses as no statistical testing will be performed.

8.7.2. Analysis sets / populations

All analyses will be conducted on the study sample, patients with a diagnosis of breast cancer who initiated Palbociclib therapy between February 1, 2015 and January 31, 2016. The selection criteria are detailed and illustrated in *Section 8.2*. Analysis will largely focus around the index date, the initiation of Palbociclib therapy.

8.7.3. Full analysis set

All analyses will be conducted on the study sample, patients with a diagnosis of breast cancer who initiated Palbociclib therapy between February 1, 2015 and January 31, 2016. Six cohorts will be established and determined based on Palbociclib initiation. If the patient initiates Palbociclib between February 1, 2015 and Mar 30, 2015, then the patient will be included in Cohort 1. If the patient initiates Palbociclib between April 1, 2015 and May 31, 2015, then the patient will be included in Cohort 2. If the patient initiates Palbociclib between June 1, 2015 and July 31, 2015, the patient will be included in Cohort 3. If the patient initiates Palbociclib between August 1, 2015 and September 31, 2015, the patient will be included in Cohort 4. If the patient initiates Palbociclib between October 1, 2015 and November 30, 2015, the patient will be included in Cohort 5. If the patient initiates Palbociclib between December 1, 2015 and January 31, 2016, the patient will be included in Cohort 6.

8.7.4. Endpoints and covariates

Section 8.3 Variables covers the description of baseline characteristics, and other variables to be used within these analyses.

Cycle length
Cycle length shall be defined as the time from the prescription date + 30 (assuming treatment schedule of 3 weeks on, followed by 1 week off) to account for additional time that may be needed for the patient to have the prescription filled.

Time to treatment discontinuation
Duration of Palbociclib therapy shall be defined as the time from the first prescription of Palbociclib until documentation of Palbociclib discontinuation or start of new treatment, whichever occurs first.

Dose reduction
A dose reduction shall be defined as any dose prescribed that is lower than the starting dose prescribed.

Relative Dose Intensity
RDI shall be defined as the ratio of delivered dose intensity to standard dose intensity where the delivered dose intensity is defined as the total dose delivered divided by the total time to complete therapy. RDI will be reported at the study end to include the maximum duration of treatment for all cohorts.

The relative dose intensity of Palbociclib will be defined as the ratio of delivered dose of Palbociclib and the planned dose of Palbociclib.

8.7.5. Handling of missing data

The use of data structured from the iKM database will reduce but not eliminate missing values. Missing data will be identified and reported as percentages.

8.7.6. Statistical analyses

Results will be reported in aggregate by cohort and will describe the sample of patients meeting the inclusion criteria. The number and percent of patients along with descriptive statistics (mean, standard deviation, median, minimum and maximum) will be reported for continuous data. Categorical variables will have the frequency (n, %) reported. Patient demographics, clinical characteristics and treatment patterns will be reported. No p-values will be reported as no statistical testing will be performed.

Refer to Table 3. and Table 4. for the shells that will be populated for reporting.

8.8. Quality control

The McKesson Specialty Health study team and associates conduct quality assurance checks on all analytics projects. The process includes both technical and clinical quality reviews. The quality assurance process covers the following areas:

- Protocol/Statistical analysis plan (SAP) development
- Data extraction and integrity
- Population of tables
- Study report development

During quality assurance, we confirm:

- The source of the data and/or results will be documented
- Data collected and results reported are aligned with the agreed upon scope and study rules
- The medical research data presented has internal consistency
- The conclusions are objective, balanced and consistent with the study results
- The format and content of the deliverables are aligned with the agreed upon templates and standards

All identifiable patient information is removed prior to submission of the populated tables and the study report. The HEOR analytics team and clinical investigators ensure an IRB waiver has been received for each study in compliance with 45 CFR 46.101(b)(4).

8.9. Limitations of the research methods

Strengths: The strengths of this study lie in the clinically rich 'real world clinical practice' data that will be used to provide Pfizer with the patterns of care and outcomes of advanced or metastatic breast cancer patients who initiated Palbociclib in the community-based setting.

Scientific rigor is incorporated into the methods and analysis from trained staff and clinical rigor through the inclusion of practicing oncologists.

Limitations: The iKM data, despite its wealth of information about community-based oncology, may be limited in various aspects. As well, all retrospective database analyses have certain limitations. Lastly, as a descriptive study, results add information about the sampled population but cannot be used to compare and contrast against similar or different metastatic breast cancer patients and experiences. More specifically, limitations of the data and study design include:

- The iKM data were retrospectively collected for clinical practice and not research purposes. As such, associations but not causality can be detected. Additionally, data entry errors at the point of care cannot be detected nor corrected during analysis.

- Missing data can result from physician and practice established behaviors or from care or services utilized outside of The US Oncology Network that was not reported to or documented by the patient's US Oncology physician. Missing data cannot confirm the absence of a condition or value in a patient's medical history; only that it was not documented.

- Not all U.S. community oncology practices are included in the iKM data set. US Oncology Network practices may differ from non-participating community oncology practices such as in the patient population seen, their compliance with evidence-based treatment guidelines or other recommended behaviors. Therefore, results cannot be generalized to the U.S. population or all community practices without further evaluation.

- Oral therapies are recorded in or prescribed through iKM but unless given in the office as part of their administered treatment, the fulfillment or consumption of oral medications cannot be observed. Chart review may provide supplementary information.

8.10. Other aspects

Not applicable.

9. PROTECTION OF HUMAN SUBJECTS

9.1. Patient Information and Consent

All parties will ensure protection of patient personal data and will not include patient names on any sponsor forms, reports, publications, or in any other disclosures, except where required by laws. No patient level data transfer will occur between MSH and Pfizer.

MSH will submit a request for exemption and waiver of informed consent and authorization to an IRB. This study involves the analysis of existing data and the analysis will be

performed by the MSH study team in such a manner that research participants will not be directly identified.

9.2. Patient withdrawal

Not Applicable.

9.3. Institutional Review Board (IRB)/Independent Ethics Committee (IEC)

It is the responsibility of the investigator to have prospective approval of the study protocol, protocol amendments, and informed consent forms, and other relevant documents, (e.g., recruitment advertisements), if applicable, from the IRB/IEC. All correspondence with the IRB/IEC should be retained in the Investigator File. Copies of IRB/IEC approvals should be forwarded to Pfizer.

9.4. Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and follow generally accepted research practices described in Guidelines for Good Pharmacoepidemiology Practices (GPP) issued by the International Society for Pharmacoepidemiology (ISPE), Good Epidemiological Practice (GEP) guidelines issued by the International Epidemiological Association (IEA), Good Practices for Outcomes Research issued by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), European Medicines Agency (EMA) European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology.

10. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study includes data that already exists as structured data in an electronic database. In these data sources, it is not possible to link (i.e. identify a potential association between) a particular product and medical event for any individual. Thus, the *minimum criteria for reporting an adverse event (i.e., identifiable patient, identifiable reporter, a suspect product, and event) are not available* and adverse events are not reportable as individual AE reports. Reference: CT24-GSOP-RF06 *Safety Reporting Language: Secondary Data Study – Does Not Include Protocol-Required Human Review of Unstructured Data.*

11. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

COMMUNICATION OF STUDY RESULTS

All study results, interim and final, will be shared directly with the Pfizer NI study team to disseminate within Pfizer as they deem appropriate. There is no required submission of study results or reports to external organizations or agencies.

Submission of an abstract to scientific conference or a manuscript to a peer-reviewed medical or scientific journal may be agreed by both Pfizer and MSH/USON if the study results yield sufficiently new information to warrant addition to public information. Any and all

publications will adhere to the study statement of work terms and applicable MSH and Pfizer policies and procedures.

COMMUNICATION OF ISSUES

In the event of any prohibition or restriction imposed (e.g., clinical hold) by an applicable Competent Authority in any area of the world, or if the investigator is aware of any new information which might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately.

In addition, the investigator will inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study patients against any immediate hazard, and of any serious breaches of this NI study protocol that the investigator becomes aware of.

12. REFERENCES

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13. LIST OF TABLES

Table 1. Body Mass Index Categorization [15]

BMI Value	CDC Category
< 18.5	Underweight
≥ 18.5 and ≤ 24.9	Normal
≥ 25.0 and ≤ 29.9	Overweight
≥ 30.0	Obese

Table 2. Karnofsky Performance Status: Primary Conversion to ECOG [12,13]

Karnofsky Performance Status	ECOG Performance Status	ECOG Performance Status Description [14]
100	0	Fully active
80, 90	1	Restricted in physically strenuous activity
60, 70	2	Ambulatory and capable of self-care but unable to work
40, 50	3	Capable only of limited self-care
10, 20, 30	4	Completely disabled
0	5	Dead

Table 3. Shell for Reporting Patient Characteristics Overall

Patient Characteristics	All Patients (%) (N=x)
Age at initiation	
N obs	
Mean (SD)	
Median	
Min-Max	
Stage at diagnosis	
Stage I	
Stage II	
Stage IIA	
Stage IIIA	
Stage IIIB	
Stage IIIC	
Stage IV	
Unknown	
Menopausal status	
Pre Menopausal	
Post Menopausal	
KPS	
N obs	
Mean (SD)	
Median	
Min-Max	
ER status	
Negative	

Patient Characteristics	All Patients (%) (N=x)
Positive	
Unknown	
HR status	
ER+/HER2+	
ER+/HER2-	
ER-/HER2+	
TNBC	
Other/Unknown/Missing	
PR status	
Negative	
Positive	
Unknown	
HER2 status	
Negative	
Positive	
Unknown	
Prior antineoplastic therapies at any time prior to index[1]	
Yes	
No	
Prior antineoplastic therapies at any time prior to index (list)	
A	
B	
C	

	All Patients (%) (N=x)
Patient Characteristics	
Prior antineoplastic therapies 6 months prior to index[1]	
Yes	
No	
Prior antineoplastic therapies 6 months prior to index (list)	
A	
B	
C	
Prior supportive care therapies at any time prior to index[1]	
Yes	
No	
Prior supportive care therapies (list)	
A	
B	
C	
Prior supportive care therapies 6 months prior to index[1]	
Yes	
No	
Prior supportive care therapies 6 months prior to index (list)	
A	

Patient Characteristics	All Patients (%) (N=x)
B	
C	
Palbociclib LOT	
LOT 1	
LOT 2	
Not documented	
CBC labs count during first cycle	
N obs	
Mean (SD)	
Median	
Min-Max	
CBC labs count during second cycle	
N obs	
Mean (SD)	
Median	
Min-Max	
Average number of CBCs per patient per month	
N obs	
Mean (SD)	
Median	
Min-Max	
Time to treatment discontinuation	
N obs	
Mean (SD)	
Median	
Min-Max	
Reason for treatment discontinuation	

Patient Characteristics	All Patients (%) (N=x)
A	
B	
C	
Not documented	
Starting Dose	
N obs	
Mean (SD)	
Median	
Min-Max	
Dose reduction	
No	
Yes	
RDI[2]	
N obs	
Mean (SD)	
Median	
Min-Max	
Neutrophil counts	
N obs	
Mean (SD)	
Median	
Min-Max	
Neutrophil count under 500	
No	
Yes	
Unknown	
Neutrophil count under 1000	
No	
Yes	

Patient Characteristics	All Patients (%) (N=x)
Unknown	
Time to neutrophil count under 1000	
N obs	
Mean (SD)	
Median	
Min-Max	

Note-
*Cohort 1 includes data from Feb 2015-Mar 2015 (June deliverable)
*Cohort 2 includes data from Apr 2015-May 2015 (August deliverable)
*Cohort 3 includes data from June 2015-July 2015 (October deliverable)
*Cohort 4 includes data from August 2015-September 2015 (December deliverable)
*Cohort 5 includes data from October 2015-November 2015 (February deliverable)
*Cohort 6 includes data from December 2015-January 2016 (April deliverable)
[1] indicates drugs are not mutually exclusive as patients may have received more than one therapy, so the percentage could exceed 100%
[2] indicates RDI will not be reported until study end

Table 4. Shell for Reporting Patient Characteristics by Cohort

Patient Characteristics	Cohort 1* (%) (N=x)	Cohort 2* (%) (N=x)	Cohort 3* (%) (N=x)	Cohort 4* (%) (N=x)	Cohort 5* (%) (N=x)	Cohort 6* (%) (N=x)
Age at initiation						
N obs						
Mean (SD)						
Median						
Min-Max						
Stage at diagnosis						
Stage I						
Stage II						
Stage IIA						
Stage IIIA						
Stage IIIB						
Stage IIIC						
Stage IV						
Unknown						
Menopausal status						
Pre Menopausal						
Post Menopausal						
KPS						
N obs						
Mean (SD)						
Median						
Min-Max						

Patient Characteristics	Cohort 1* (%) (N=x)	Cohort 2* (%) (N=x)	Cohort 3* (%) (N=x)	Cohort 4* (%) (N=x)	Cohort 5* (%) (N=x)	Cohort 6* (%) (N=x)
ER status						
Negative						
Positive						
Unknown						
HR status						
ER+/HER2+						
ER+/HER2-						
ER-/HER2+						
TNBC						
Other/Unknown/Missing						
PR status						
Negative						
Positive						
Unknown						
HER2 status						
Negative						
Positive						
Unknown						
Prior antineoplastic therapies at any time prior to index[1]						
Yes						
No						
Prior antineoplastic therapies at any time prior to index (list)						

Patient Characteristics	Cohort 1* (%) (N=x)	Cohort 2* (%) (N=x)	Cohort 3* (%) (N=x)	Cohort 4* (%) (N=x)	Cohort 5* (%) (N=x)	Cohort 6* (%) (N=x)
A						
B						
C						
Prior antineoplastic therapies 6 months prior to index[1]						
Yes						
No						
Prior antineoplastic therapies 6 months prior to index (list)						
A						
B						
C						
Prior supportive care therapies at any time prior to index[1]						
Yes						
No						
Prior supportive care therapies (list)						
A						
B						
C						
Prior supportive care therapies 6 months prior to index[1]						

Patient Characteristics	Cohort 1* (%) (N=x)	Cohort 2* (%) (N=x)	Cohort 3* (%) (N=x)	Cohort 4* (%) (N=x)	Cohort 5* (%) (N=x)	Cohort 6* (%) (N=x)
Yes						
No						
`						
Prior supportive care therapies 6 months prior to index (list)						
A						
B						
C						
Palbociclib LOT						
LOT 1						
LOT 2						
Not documented						
CBC labs count during first cycle						
N obs						
Mean (SD)						
Median						
Min-Max						
CBC labs count during second cycle						
N obs						
Mean (SD)						
Median						
Min-Max						
Average number of CBCs per patient per month						
N obs						

Patient Characteristics	**Cohort 1* (%) (N=x)**	**Cohort 2* (%) (N=x)**	**Cohort 3* (%) (N=x)**	**Cohort 4* (%) (N=x)**	**Cohort 5* (%) (N=x)**	**Cohort 6* (%) (N=x)**
Mean (SD)						
Median						
Min-Max						
Time to treatment discontinuation						
N obs						
Mean (SD)						
Median						
Min-Max						
Reason for treatment discontinuation						
A						
B						
C						
Not documented						
Starting Dose						
N obs						
Mean (SD)						
Median						
Min-Max						
Dose reduction						
No						
Yes						
RDI[2]						
N obs						
Mean (SD)						
Median						
Min-Max						
Neutrophil counts						

Patient Characteristics	Cohort 1* (%) (N=x)	Cohort 2* (%) (N=x)	Cohort 3* (%) (N=x)	Cohort 4* (%) (N=x)	Cohort 5* (%) (N=x)	Cohort 6* (%) (N=x)
N obs						
Mean (SD)						
Median						
Min-Max						
Neutrophil count under 500						
No						
Yes						
Unknown						
Neutrophil count under 1000						
No						
Yes						
Unknown						
Time to neutrophil count under 1000						
N obs						
Mean (SD)						
Median						
Min-Max						

Note-
*Cohort 1 includes data from Feb 2015-Mar 2015 (June deliverable)
*Cohort 2 includes data from Apr 2015-May 2015 (August deliverable)
*Cohort 3 includes data from June 2015-July 2015 (October deliverable)
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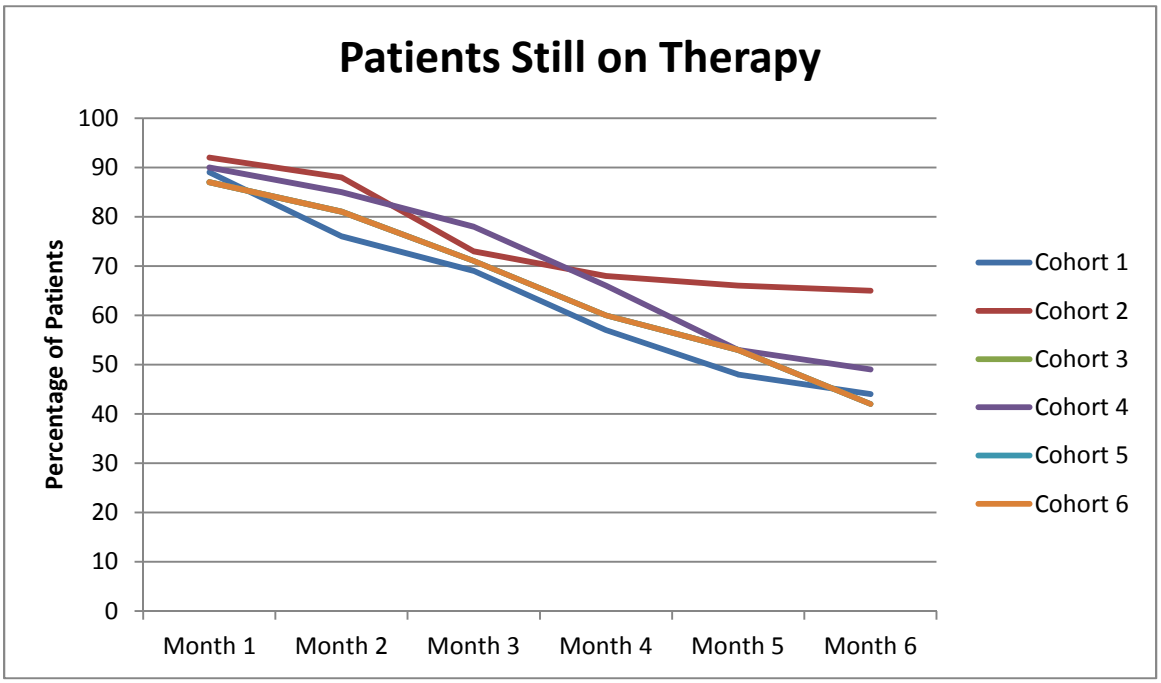
*Cohort 5 includes data from October 2015-November 2015 (February deliverable)
*Cohort 6 includes data from December 2015-January 2016 (April deliverable)
[1] indicates drugs are not mutually exclusive as patients may have received more than one therapy, so the percentage could exceed 100%
[2] indicates RDI will not be reported until study end

14. LIST OF FIGURES



ANNEX 1. LIST OF STAND ALONE DOCUMENTS

None.

ANNEX 2. ENCEPP CHECKLIST FOR STUDY PROTOCOLS

Not applicable.

ANNEX 3. ADDITIONAL INFORMATION

Not applicable.

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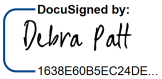
Debra Patt Debra.Patt@USOncology.com Debra Patt, MD Security Level: Email, Account Authentication (None) Electronic Record and Signature Disclosure: Accepted: 6/22/2015 4:17:27 PM CT ID: 598aab60-e341-4060-88ee-7e435b57bddf	DocuSigned by:  1638E60B5EC24DE... Using IP Address: 143.112.144.129	Sent: 6/22/2015 10:41:10 AM CT Viewed: 6/22/2015 4:17:27 PM CT Signed: 6/22/2015 4:17:38 PM CT
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