Non-Interventional Study Protocol
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Palbociclib Combinations in HR+ve/HER2-ve Metastatic Breast Cancer Patients: A Non-Interventional Prospective Study on the Treatment Patterns & Clinical Outcomes Africa Middle East

Statistical Analysis Plan (SAP)

Version: 1

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1. AMENDMENTS FROM PREVIOUS VERSION(S)

None.

2. INTRODUCTION

Note: in this document, any text taken directly from the non-interventional (NI) study protocol is ***italicised***. The protocol version 2.0, dated in 13 December 2021 was used to develop the SAP.

Breast cancer (BC) is a complex, heterogenous disease encompassing multiple tumor entities with specific pathologic features and biological behaviors.[1] It is the most common neoplasm among women with an estimated incidence of 2.4 million cases and 523,000 deaths in the year 2015.[2] Approximately 6%-10% of new BC cases are diagnosed as stage IV metastatic disease and an estimated 20%-30% patients with early BC experience relapse with distant metastatic disease.[3]

Absolute rates of BC incidence are higher in high-income countries (HICs), however incidence rates are also increasing in lower-middle–income countries (LMICs).[2] The age-standardized rate (ASR) per 100,000 population for BC worldwide is 43.1.[4] The highest BC incidence rates are in North America, Australia, New Zealand, and Northern and Western Europe.[5] The incidence rate varies from 19.4 per 100,000 people in East Africa to 89.7 per 100,000 in West Europe.[6] Mortality rates of BC depend on the availability of early detection and treatment.[4] Hence, the mortality rates are higher in many LMICs, such as those in sub-Saharan Africa due to their late stage diagnosis and limited access to treatment as compared to HICs.[5] The 5 year survival rate is 85% or higher in the United States, Canada, Australia, Israel, Brazil, and many Northern and Western European countries, whereas it is 60% or lower in many LMICs, such as South Africa, Mongolia, Algeria, and India.[5]

Breast cancer is one of the most prevalent cancers in the Middle East (ME), where it is also the most common cause of death among females.[7] The BC cases diagnosed in this geography are more aggressive and associated with worse outcomes compared to cases evidenced in other parts of the world, which may partly be explained by late diagnosis.[7]

Indeed, most Arab women do not present themselves for regular medical examination due to social customs, leading to diagnosis of BC at an advanced stage, which is more challenging to treat.[7] According to Kuwait cancer registry, BC constitutes 36.4% of newly reported cancer cases among females.[7] In Kingdom of Saudi Arabia (KSA), BC constitutes 29.1% of all women's cancer, as reported by KSA cancer registry 2013.[8] The age-standardized incidence and mortality rate of BC in KSA was 22.4 and 10.4 per 100,000 women, respectively in the year 2008.[9] In United Arab Emirates (UAE), BC constitutes 43% of cancers diagnosed among females and 25% of all cases of cancer, with an incidence rate of approximately 38 per 100,000 women.[10] Based on the National Population-Based Registry Program of Egypt (2008–2011), BC was the second most frequent cancer constituting 15.41% of all cancers with an age specific incidence rate of 35.8 per 100,000 women.[11] Similarly, in Algeria, BC represents 59% of all women's tumors with crude incidence rate of 54.4 per 100,000 women and a standardized incidence rate of

65.2 per 100,000 women.[12] In Lebanon, between the years 2003 and 2008, BC was the most commonly reported cancer in women, with an increase in age-standardized incidence rate from 78.3 to 95.7 per 100,000 women from year 2003 to 2008.[13] A similar trend was observed in Morocco where the age-standardized incidence rate of BC increased from 35.0 to 39.0 per 100,000 women between the years 2004 and 2008, showing an annual increase of 2.85 %.[14]

Molecular classification differentiates BC on the basis of gene expression pattern, clinical and biological properties, histologic correlation and response to treatment and prognosis.[14] The classification is on the basis of presence or absence of hormone receptors (HR) such as estrogen receptors (ER) or progesterone receptors (PR) and human epidermal growth factor receptor 2 (HER2). These receptors have an important role in the prognosis of the disease.[1] The 5 subtypes of BC are: luminal A (HR+/HER2−), luminal B (HR+/HER2+), HER2-enriched (hormone receptor negative [HR-]/HER2+), basal-like (80%–90% are triple negative), and normal breast-like/unclassified BC.(15) Approximately 70% of the BC express HR.[16] The majority of the diagnosed BC are estrogen receptor positive (ER+) and HER2-, and 75% of metastatic breast cancer (MBC) patients are HR+ (either ER+ or progesterone receptor positive [PR+]).[3,16]

Endocrine therapy is the major treatment of choice for HR+/HER2- MBC.[17] In premenopausal women with HR+ BC, endocrine therapy with or without ovarian ablation (by surgery, chemotherapy or luteinizing hormone-releasing hormone (LHRH)) is the preferred option.[18] In post-menopausal HR+/HER2- MBC (without extensive visceral involvement), anastrazole, letrozole and exemestane are the standard hormonal therapies along with selective estrogen receptor modulators like tamoxifen or selective estrogen receptor degraders like fulvestrant.[3] These treatment options are associated with a time to progression (TTP) and prolongation of progression free survival (PFS) ranging from 5 to 15 months.[18] These treatment options are supported by clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) as preferred first-line options in patients who are antiestrogen naïve or who had prior estrogen therapy within one year.[19] For MBC with significant visceral burden or rapid progression of disease, chemotherapy is recommended.[3] The response rates associated with these endocrine therapies as first-line agents are up to 40% with all initial responders eventually acquiring resistance over time.[3] Moreover, single-agent treatment with an aromatase inhibitor or tamoxifen has shown limited clinical benefit as well as selective ER degrader fulvestrant has modest activity in this patient population.[20-22] Hence, clinically it's important to identify new targets to develop effective therapies to improve patients' outcomes. Some potential molecular targets that are altered in BC patients are cyclin-dependent kinase 4 and 6 (CDK4/6), phosphatidylinositol 3-kinase/mammalian target of rapamycin (PI3K/mTOR) pathway, and poly adenosine diphosphate ribose polymerase.[16] PI3K/mTOR and CDK4/6 inhibitors can reduce the resistance to endocrine therapy. CDK4/6 inhibitors control the cyclin D–CDK–retinoblastoma (Rb) pathway and may have a synergistic activity when combined with hormonal therapy, as well as, reduce the resistance acquired to that class of treatment.[16]

Palbociclib (IBRANCE®) is one such oral targeted agent that selectively inhibits cyclin-dependent kinases (CDKs) - CDK4 and CDK6 resulting in cell cycle arrest. It is indicated for the treatment of HR+/ HER2-MBC in combination with letrozole as initial endocrine-based therapy in post-menopausal women.[23]

The efficacy and safety of palbociclib was assessed in PALOMA-1 trial: a randomized Phase 2 study of palbociclib in combination with letrozole versus letrozole alone. The study showed that participants who were treated with Ibrance® plus letrozole had median PFS of 20.2 months as compared to those treated with letrozole alone who reported median PFS of 10.2 months (p=0.0004).[24] Following its success, the Food and Drug Administration (FDA) granted accelerated approval of palbociclib in combination with letrozole in February 2015 and became the first CDK4/6 inhibitor to be approved as a cancer therapy by the FDA.[25] The label was later expanded to include aromatase inhibitor in this indication based on the follow-up of PALOMA-2 trial which was a Phase III study for post-menopausal patients with metastatic HR+/HER- BC receiving letrozole in combination with palbociclib versus patients receiving letrozole and placebo. The study showed that participants treated with Ibrance® in combination with letrozole had a greater PFS compared with patients treated with letrozole plus placebo (24.8 months vs. 14.5 months; p<0.001, respectively).[26] A regular approval was granted to palbociclib in February 2016 for a second indication: treatment of HR+, HER2- MBC in combination with fulvestrant in women with disease progression following endocrine therapy. This was following the success of Phase III PALOMA-3 trial, that showed that Ibrance® in combination with fulvestrant prolonged PFS (median PFS of 9.5 months) compared with placebo with fulvestrant (median PFS of 4.6 months; p <0.0001) in women with metastatic HR+/HER2- BC that had relapsed or progressed during endocrine therapy.[26]

Palbociclib utilization and clinical outcomes have been examined in the real-world setting in both retrospective and prospective studies. One retrospective real-world study, based on data from a US electronic medical record (EMR) database, assessed the settings in which palbociclib was being initiated and examined in the real-world occurrence of associated adverse events (AEs) like neutropenia.[27] The study reported that 80.2% of the patients received palbociclib concomitantly with letrozole. Overall, 39.5% of patients initiated palbociclib plus letrozole in first-line therapy while 15.7% in second-line therapy followed by 13.1% and 31.7% in third-line and fourth- line (or later) therapies, respectively. Overall, 74.6% of patients had a neutropenic event during follow-up including 47.3% and 8.0% of patients with a Grade 3 or 4 occurrence, respectively.(27) In other retrospective study based on EMR data from the Flatiron Health Analytic database, real-world best tumor responses, which occurred at least 30 days after the date of therapy initiation, were assessed.[27] For patients using palbociclib plus aromatase inhibitor, complete response was achieved in 9.5% of patients, and partial response was achieved in 50.5% of patients. For patients using palbociclib plus letrozole, complete response was achieved in 9.7% of patients, and partial response was achieved in 50.2% of patients. (28)

The Ibrance Real World Insights (IRIS) study, based on retrospective chart review, evaluated treatment patterns and clinical outcomes among patients using palbociclib in various countries globally. In the Argentina patient subgroup, the 6-month PFS rate was 94% for patients treated with palbociclib plus letrozole and 95% for patients treated with

palbociclib plus fulvestrant.[29] Six-month survival rates were 98% for palbociclib plus letrozole and 98% for palbociclib plus fulvestrant; 93% and 89% of patients treated with palbociclib plus letrozole were alive at 12 and 18 months, respectively.[29]

In the United States (US) patient subgroup, the 12-month progression free rate was 84.1% for patients treated with palbociclib plus aromatase inhibitor and 79.8% for those treated with palbociclib plus fulvestrant; 12-month survival rates were 95.1% for palbociclib plus aromatase inhibitor and 87.9% for palbociclib plus fulvestrant.[30] In another retrospective chart review study conducted in the US, real- world effectiveness was evaluated among patients using palbociclib plus letrozole as first- line treatment; the 6-month, 12-month and 18-month PFS rates were 92.7%, 75.5%, and 51.6%, respectively, while the 6-month, 12-month, and 18-month overall survival rates were 97.5%, 95.3% and 92.5%, respectively.[31]

In a prospective real-world study, "Palbociclib in Hormone Receptor–Positive Advanced Breast Cancer: a Prospective Multicenter Noninterventional Study (POLARIS)", measures of functional status were assessed in adults aged ≥70 years who were using palbociclib combination therapy.[32] The results showed that measures of functional status (as assessed via the Activities of Daily Living [ADL] screening tool, Geriatric 8 [G8] screening tool, and Eastern Cooperative Oncology Group [ECOG] performance status) were generally maintained during the first 6 months of therapy, indicating that functional status was essentially preserved in elderly population receiving palbociclib combination therapy.[32]

In the AfME region, palbociclib was first approved in UAE in early 2015 in combination with letrozole for the treatment of post-menopausal women with ER+/HER2- MBC as initial endocrine-based therapy for their disease. Since then, approval in Lebanon and KSA followed, and now palbociclib is available in most AfME countries.

2.1. Study Design

This is a prospective, non-interventional (NI), multicentre study being conducted in Africa Middle East (AfME) countries. The aim is to understand palbociclib treatment patterns, clinical outcomes and QoL of patients with metastatic/locally advanced BC being treated in routine clinical practice in seven AfME countries: Egypt, Jordan , Lebanon, UAE, Qatar , Morocco and KSA.

Participation in this study is not intended to change the routine treatment patients reveice, as determined by their prescribing phycisians; all treatment decisions, type and timing of the disease monitoring are per routine clinical care, and at the discretion of the treating phycisian and patient.

Study population

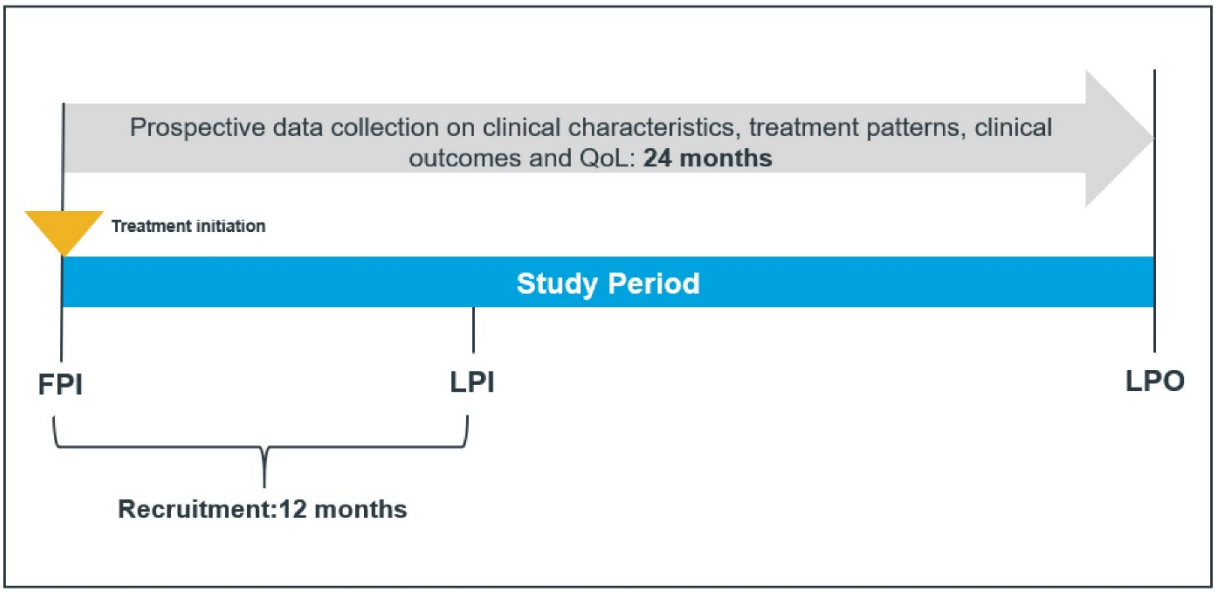
Patients with HR+/HER2- metastatic/locally advanced BC within Egypt, Jordan, Lebanon, UAE, Qatar, Morocco and KSA will be enrolled from a geographically representative population as well as from diverse treatment settings (eg, academic and community sites). Patients whose treatment decision with palbociclib combination has been made by their treating physician and meet the eligibility criteria will be invited to participate in the study in a consecutive manner and over 12 months of recruitment.

Approximately 350-410 patients from 19 centers across the seven countries will be enrolled. The recruitment period (ie, from first patient in to last patient in) will span over 12 months.

Patients will be enrolled at the time of treatment initiation with palbociclib, and will be followed up over a maximum of *24-month period at time intervals per routine care, or until* the end of Palbociclib treatment, progression or *patients' withdrawal from the study (whichever comes first). Eligibility will be assessed at the date of the enrollment.*

*Prospective data on clinical characteristics, treatments patterns, clinical outcomes and QoL will be collected in accordance with routine standard of care visits (*Figure 1*). Data will be collected at enrollment (time of treatment initiation), during treatment with Palbociclib (at time intervals per routine care) and after treatment with palbociclib. After the end of treatment with palbociclib, data related to the first immediate subsequent treatment received will be collected.*

Figure 1. Study Design



FPI: first patient in; LPI: last patient in; LPO: last patient out; QoL: quality of life

2.1.1. *Inclusion Criteria*

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

1. *Age ≥18 years or older with diagnosis of adenocarcinoma of the breast with evidence of metastatic/locally advanced disease not amenable to treatment with curative intent.*
2. *Documented HR+ (ER+ and/or PR+) tumor based on local standards.*
3. *Documented HER2- tumor based on local standards.*
4. *Will initiate treatment with palbociclib plus letrozole/aromatase inhibitor or palbociclib plus fulvestrant in line with the licensed indication(s), as first or second line therapy for metastatic/locally advanced BC at enrollment.*
5. *Evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study.*
6. *Patients who in the opinion of the investigator are willing and able to comply with regular clinic visits*

2.1.2. *Exclusion Criteria*

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

1. *Patients participating in any interventional clinical trial.*
2. *Patients on active treatment for malignancies other than metastatic/locally advanced BC at the time of enrollment.*
3. *Patients who are unable to understand the nature of the study and are unwilling to sign an informed consent.*

<u>Data source</u>

All data collected in this study are intended to capture the real-world treatment patterns and outcomes for patients with HR+/HER2- metastatic/locally advanced BC. An electronic case report form (eCRF) will be used for data collection. The eCRF must be signed by the investigator. The signature serves to attest that the information contained in the eCRF is true. At all times, the investigator has the final responsibility for the accuracy and authenticity of all clinical and laboratory data entered into the eCRFs.

Data for this study will be obtained via the sources outlined below.

2.1.3. *Patient Medical Charts*

The investigator or authorized medical staff will record clinical and treatment data from patients' existing medical records into an eCRF following each patient's standard of care clinic visit.

2.1.4. *Patient Questionnaires and Quality of Life*

All patients enrolled in the study will be asked to participate in completing the Quality of Life Questionnaire, EORTC QLQ-C30, to be collected at baseline (before starting palbociclib) then every 3 months ±2 weeks after initiating treatment with palbociclib, for the first year of treatment, in accordance with routine standard of care visits. After the first year of treatment with palbociclib, EORTC QLQ-C30 will be collected every 6 months ±4 weeks until the end of treatment with palbociclib, in accordance with routine standard of care visits.

Patients will complete these questionnaires on a paper form.

2.2. *Study Objectives*

With the introduction of palbociclib across different markets, this study aims to provide prospective, observational data of use of palbociclib in a real-world setting in terms of treatment patterns, clinical outcomes and QoL.

2.2.1. *Primary Objectives*

To determine clinical outcomes including (but not limited to):

- *Proportion of patients who are progression free and alive at specific intervals (6, 12, 18 and 24 months).* Patients who are not censored (see Section 3.1) at a certain time point will be included in the analysis.
- *Proportion of patients alive after 1 and 2 years post palbociclib combination initiation.*

2.2.2. *Secondary Objectives*

- *To determine objective response rate (ORR).*
- *To describe the demographic and clinical characteristics of patients who have received palbociclib combination treatment in line with locally approved indications.*
- *To describe dosing and dose changes, interruptions, delays and discontinuations associated with palbociclib use in clinical practice.*
- *To describe supportive therapies received by patients while receiving palbociclib combination treatment.*
- *To summarize adjuvant therapies received for the treatment of early of locally advanced BC (Stages 0-IIIa).*
- *To describe treatments received in the advanced/metastatic setting, before and after palbociclib combination use.*
- *To assess QoL of patients receiving palbociclib combination treatment.*

2.2.3. *Exploratory Objectives*

- *To evaluate time to response (TTR), time to progression (TTP)/ PFS associated with palbociclib combination treatment – depending on availability of follow-up data.*

- *To describe the first immediate subsequent treatment used following end of treatment with palbociclib.*

3. ANALYSIS SETS/POPULATIONS

3.1. Full Analysis Set

The Full Analysis Set will contain all patients who fulfil the eligibility criteria. Date of enrollment is the date of Palbociclib treatment initiation (baseline).

Censoring rules*:* The maximum follow-up of a patient is 24 months. Patients will be censored at the end of Palbociclib treatment, or if the treatment continues, at 24 months. Other censoring events before 24 months are patient's withdrawal, disease progression or death, whichever occurs first. Patients' subsequent treatments after Palbociclib treatment discontinuation /disease progression will be recorded. Patients who are lost to follow-up will be censored at their last visit. For some clinical outcomes, different censoring rules will be applied as described in Section 6.1, Section 6.2, and Section 6.3.

Data collection is estimated to start in Q2 2021 and it will end in Q4 2024.

Table and Figure Shells are presented in ANNEX 2.

Patient inclusion and exclusion criteria are explained in Section 2.1. Summary of patient enrolment per country and study site will be described as shown in Table Shell 1.

3.2. Subgroups

Exploratory stratifications will be conducted (where adequate numbers of patients permit) to explore differences by eg, country, line of therapy (first or second)*, menopausal status, age (<55, 55-64, ≥65 years*)*, combination therapy (ie, palbociclib plus letrozole/aromatase inhibitor vs. palbociclib plus fulvestrant), menopausal status,* metastatic status (de-novo vs. recurrent disease) and metastatic site (visceral vs. non-visceral). For each stratification variable, the full analysis set will be segmented into non-overlapping subgroups based on the stratification variable values. The stratifications may not be meaningful, if there are no patients in some of the groups or there are many variables with a lot of missing data.

The exploratory stratifications will be conducted for the following study objectives describing the Palbociclib treatment, if enough data are available:

1. *Primary objectives: To determine clinical outcomes, including (but not limited to):*

    - *Proportion of patients who are progression free at multiple intervals (6, 12, 18 and 24 months).*
    - *Proportion of patients alive 1 and 2 years post palbociclib combination initiation - depending on availability of follow-up data.*

2. *Secondary objectives:*

    - *Objective response rate (ORR) - depending on availability of follow-up data*
    - *To describe dosing and dose changes, interruptions, delays and discontinuations associated with palbociclib use in clinical practice.To describe supportive therapies received by patients while receiving palbociclib combination treatment.*
    - *To summarize adjuvant therapies received for the treatment of early or locally advanced breast cancer (Stages 0-IIIa).*
    - *To describe treaments received in the advanved/metastatic setting, before and after palbociclib combination use.*
    - *To assess quality of life of patients receiving palbociclib combination treatment.*

3. *Exploratory objectives:*

    - *To evaluate time to response (TTR), time to progression (TTP)/Progression free survival (PFS) associated with palbociclib combination treatment.*
    - *To describe the first immediate subsequent treatment used following end of treatment with palbociclib.*

The specific stratifications, and their corresponding reporting labels will be the following:

- *Combination therapy (ie, palbociclib plus letrozole/aromatase inhibitor, palbociclib plus fulvestrant).* The combination of therapies will be determined at the Palbociclib treatment initiation. Palbociclib plus letrozole/aromatase inhibitor group will be defined as patients receiving Palbociclib and either Anastrozole, Letrozole or Exemastane. Palbociclib plus fulvestrant group will be defined as patients receiving Palbociclib and Fulvestrant. Other endocrine therapies will not be considered in this definition. Descriptive summary tables for the subgroup analysis by combination therapy line for the specified study objectives will be created as shown in Table Shells 3, 15, 23, 31, 39, 46, 55, 63.
- *Line of therapy (1st or 2nd).* Line of therapy will be determined at the Palbociclib treatment initiation and defined as whether Palbociclib has been used as the first or second line endocrine therapy for metastatic/locally advanced BC. Descriptive summary tables for the subgroup analysis by combination therapy line for the specified study objectives will be created as shown in Table Shells 4, 16, 24, 32, 40, 48, 56, 64.

- *Country (Egypt, Jordan , Lebanon, UAE, Qatar , Morocco and KSA).* Descriptive summary tables for subgroup analysis by country for the specified study objectives will be created as shown in Table Shells 5, 17, 25, 33, 41, 49, 57, 65.
- *Menopausal status (premenopausal vs. postmenopausal).* Menopausal status will be assessed at the Palbociclib treatment initiation. Descriptive summary tables for the subgroup analysis by menopausal status for the specified study objectives will be created as shown in Table Shells 6, 18, 26, 34, 42, 50, 58, 66.
- *Metastatic status (de novo vs. recurrent disease)* The recurrence of the disease will be assessed at the Palbociclib treatment initiation. Descriptive summary tables for the subgroup analysis by disease recurrence for the specified study objectives will be created as shown in Table Shells 7, 19, 27, 35, 43, 51, 59, 67.
- *Metastatic site (visceral vs. non-visceral). Visceral metastases refers to lung, liver, brain, pleural, and peritoneal involvement. Metastatic site* will be defined according to the baseline lesion data. Visceral metastases will refer to lung, liver, brain, pleural, and peritoneal involvement. Non-visceral metastases include lesions in bone and skin/soft tissues. Lesions in lymph nodes will be categorised to neither of the groups. Lesions in bone may also be caterogised to bone-only category. Descriptive summary tables will be presented as shown in Table Shells 8, 20, 28, 36, 44, 52, 60, 68.
- *Age (<55, 55-64, >=65).* The age of the patient will be determined at the Palbociclib treatment initiation. Descriptive summary tables for the subgroup analysis by age for the specified study objectives will be created as shown in Table Shells 9, 21, 29, 37, 45, 53, 61, 69.

Additional stratifications can be conducted by eg, ECOG performance (stratified into groups 0-5), endocrine sensitivity vs. endocrine resistance (primary and secondary), if relevant and/or enough data are available.

4. ENDPOINTS AND COVARIATES

Descriptive summary tabulations will describe the clinical outcomes of Palbociclib treatment, demographic and clinical characteristics of the patients as well as the treatment patterns in the study population. The patients' clinical profiles will be described at the time of BC diagnosis. The patients' demographics, clinical profiles of BC and characteristics of Palbociclib treatment will be described at the time of the Palbociclib treatment initiation. The adjuvant and supportive therapies as well as the Palbociclib treatments received by the study population during the observational period will be described.

4.1. Primary Endpoints

This study focuses on the patients who have received Palbociclib treatment for BC. The primary endpoints that describe the primary objectives in the study population will be:

- The clinical outcomes of Palbociclib treatment patients (proportion of patients that are progression free and alive after certain time intervals post palbociclib combination initiation)

4.2. Secondary Endpoints

The secondary endpoints that describe the secondary objectives in the study population and in the subgroups will be:

- Objective response rate (ORR);
- The clinical characteristics (*Time from* initial breast cancer *diagnosis to recurrence, staging, node status, menopause status, diagnosis for which palbociclib combination was prescribed, sites of metastases, de novo vs. recurrent disease*) of the study population;
- The demographics (*age, ethnicity, weight, family history of BC (BRCA;*
- *Testing performed)*) of the study population;
- Palbociclib treatment characteristics (schedule, dose, accompanying treatments, interruption, delays, discontinuation, duration);
- Supportive therapies received during palbociclib combination treatment;
- Adjuvant therapies (name, dose, frequency, initiation time, duration of the adjuvant therapies, and reasons for adjuvant therapy interruption, initiation, and failure) received for the treatment of early/locally advanced BC;
- Treatments received (treatment type, duration, and reasons for treatment changes) in the advanced/metastatic BC setting before and after Palbociclib treatment;Quality of life (QoL) of the patients during Palbociclib treatment.

4.3. Exploratory Endpoints

The exploratory endpoints that describe the exploratory objectives in the study population and in the subgroups will be:

- The clinical outcomes of Palbociclib treatment patients (time to response, time to progression and progression free survival);
- The first immediate subsequent treatment used following end of treatment with palbociclib.

4.4. Covariate and Variable Definitions

Patient demographics, clinical characteristics, comorbid conditions and concomitant medications, early/locally advanced and metastatic BC treatment history, current BC treatment, performance status (ECOG), clinical outcomes, laboratory investigations and QoL will be collected. Detailed definitions of the Data Entry Schedule and variables and are provided in Table 1 and Table 3 (Annex 1).

The definitions of clinical outcomes are presented in Section 6.1, Section 6.2, and Section 6.3.

Table 1. Data Entry Schedule

Data collection and entry[1]	***Baseline***	***During treatment with Palbociclib***	***Post treatment with Palbociclib***
	SOC Visit 1	***SOC Follow-up visits[2] through End of Treatment with Palbociclib***	***SOC Follow-up visits through End of Study[3]***
Informed Concent & Inclusion/Exclusion criteria	*x*		
Patient Demographics, Medical History, Baseline Metastatic Disease Status	*x*		
BC Diagnosis and Recurrence History	*x*		
Comorbid Conditions	*x*	*x*	
Concomitant Medications	*x*	*x*	
BC Treatment[4]	*x*	*x*	*x[5]*
Performance Status (ECOG)	*x*	*x*	
Clinical Outcomes[6]	*x*	*x*	
Laboratory Investigations, including CBC[7]	*x*	*x*	
EORTC QLQ-C30[8]	*x*	*x*	

BC=Breast cancer; SOC=Standard of care; CBC=complete blood count; ECOG=Eastern Cooperative Oncology Group; EORTC QLQ-C30=European Organization for the Reaserach and Treatment of Cancer Quality of Life Questionnaire C30.

1. *Data is collected in accordance with normal standard of care visits; enter all data available per Data Entry Schedule into the electronic data capture system.*
2. *For all visits to be considered a follow-up visit, clinical outcomes data must be collected at minimum, in accordance with SOC.*
3. *Follow-up through End of Study; Enter data at SOC visits post palbociclib treatment.*
4. *BC treatment: including surgery, radiation, systemic chemotherapy, hormone therapy, and/or targeted therapy, in both neoadjuvant/adjuvant and metastatic disease settings, prior to, during and after palbociclib treatment; supportive care is also collected in the metastatic setting.*
5. *Data on the first immediate subsequent treatment used after the end of palbociclib treatment should be collected.*
6. *Clinical outcomes: overall clinical response as judged by treating physician, at intervals per standard of care schedule: progression free survival/time to progression, objective response rate, time to response and overall survival.*
7. *CBC: Baseline and during palbociclib treatment, enter any CBC during the 1st 3 cycles, then enter Day 1 (or prior to start of new cycle) CBC for the subsequent cycles as per standard of care.*
8. *EORTC QLQ-C30 will be collected at baseline (before starting palbociclib) then every 3 months ± weeks after initiating treatment with palbociclib for the first year of treatment. After the first year of treatment with palbociclib, EORTC QLQ-C30 will be collected every 6 months ±4 weeks until the end of treatment with palbociclib.*

5. HANDLING OF MISSING VALUES

Should missing data occur, the data will be analysed as they are recorded in the eCRFs, and no imputation of missing data will be performed.

All data analysis in this study will be performed on the Full Analysis Set containing all patients who fulfil the eligibility criteria, and thus missing data is not used as criteria for excluding the patients from the data analysis. However, due to the nature of the study, there will likely be missing data for data elements, ie, data that are not documented in the patient's medical record.

For both categorical and continuous variables, the amount of missing data will be reported. For categorical variables, the missing values will be analysed in the descriptive summary tables as a category. The missing values in the continuous variables will be ignored when calculating the summary statistics of mean, median, standard deviation and quantiles. If some of the variables of interest show to have a large amount or proportion of missing data, the summary statistics of the variable should be interpreted accordingly.

6. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

This is a descriptive study, and as such, no statistical testing will be conducted. Summary statistics for patient demographics, clinical characteristics, treatment patterns and QoL will be performed. Summary statistics for continuous variables will include number of observations, mean, standard deviation, median, 1st and 3rd quartiles, minimum, and maximum. Summary statistics for categorical data will include number of observations, counts and percentages. Kaplan-Meier analyses will be performed on time-to-event outcomes, eg, TTP, response and death.

Analyses will be conducted using Statistical Analysis System (SAS, version 9.4 or higher) or R version 3.5 or higher.

6.1. Analysis for the Primary Objectives

Patients enrollment per country and site will be summarized as shown in Table Shell 1.

For the primary objectives, clinical outcomes including the proportion of progression free and alive patients at different time intervals (6, 12, 18 and 24 months) and the proportion of patients who are alive 1 and 2 years post Palbociclib treatment initiation will be reported as shown in Table Shell 2. The stratified tables will be presented as in Table Shells 3 - 9. The stratifications will be performed as described in Section 3.2 by at least combination therapy and line of therapy.

The progression of the disease will be considered whenever the overall tumor response reported at any follow-up visit is progressive disease. The Kaplan-Meier (KM) method (product-limit method) will be used to estimate the proportion of subjects who are progression-free. The KM-estimate will be presented by 6 month intervals (6, 12, 18 and

24 months since the beginning of Palbociclib treatment) including the number of patients who were progression-free, those still at risk and the proportion of progression-free patients.

The proportion of the patients who are alive 1 and 2 years after Palbociclib treatment initiation will be calculated as the ratio of the number of patients who are alive 1 and 2 years over the number of patients who started the treatment (eligible patients).

6.2. Analysis for the Secondary Objectives

The objective response rate (ORR) will be described as shown in Table Shell 2 and stratified in Table Shells 3-9. The objective response will be defined as a state when either complete or partial response or stable disease has been reported as the overall tumor response in the last follow-up visit. ORR will be calculated as the ratio of the number of patients who are responsive to Palbociclib treatment (ie, have partial or complete response or stable disease for Palbociclib treatment recorded) over the number of patients who initiated Palbociclib treatment.[34] Censoring will be considered as described in Section 3.1.

The demographic characteristics of the study population at breast cancer diagnosis for those receiving Palbociclib as first or second line therapy for metastatic/locally advanced BC will be described as shown in Table Shells 10 and 11. Clinical characteristics of the study population at the initiation of Palbociclib treatment (baseline)those receiving Palbociclib as first or second line therapy will be described as shown in Table Shells 12 and 13.

The dosing and dose changes, interruptions, delays and discontinuations associated with Palbociclib use in clinical practice will be described as shown in Table Shell 14. The stratified tables will be presented as in Table Shells 15 – 21.

The ten most common supportive therapies received by patients while receiving palbociclib combination treatment will be listed as shown in Table Shell 22. The stratified tables will be presented as in Table Shells 23 - 29.

The most common adjuvant therapies including systemic therapies, radiotherapy and surgeries will be described for early or locally advanced BC (stages 0-IIIa) patients as shown in Table Shell 30. The stratified tables will be presented as in Table Shells 31– 37.

The most common adjuvant therapies received by the advanced/metastatic BC patients (stages IIIb-IV) will be described both before and immediately after the first Palbociclib treatment as shown in Table Shells 38 and 62, respectively. The stratified tables will be presented as in Table Shells 39-45 and 63-69.

Quality of life of the patients receiving Palbociclib treatment at different follow-up visits will be described as shown in Table Shell 47. The stratified tables will be presented as in Table Shells 48-53. The EORTC quality of life questionnaire (QLQ-C30) will be used according to CRF. EORTC QLQ-30 scoring manual (version 3.0) will be used to group the items of the questionnaire into five functional scales, nine symptom scales, and a global health status, and to calculate scores for them. All of the scales and single-item measures range from 0 to 100;

a higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms. The procedure for scoring the scales is the same for all classes:

1. Estimate the average of the items that contribute to the scale; this is the raw scale.
2. Use a linear transformation to standardise the raw score so that scores range from 0 to 100.

Coding for SAS is provided in the appendix of EORTC QLQ-30 scoring manual.[35]

Subgroup analyses will be performed as described in Section 3.2.

6.3. Analysis for the Exploratory Objectives

For the exploratory analyses, time to response (TTR), time to progression (TTP)/ progression free survival (PFS) will be studied and results will be presented as shown in Table Shell 54. The stratified tables will be presented as in Table Shells 55-61.

TTR is defined as the length of time (in days) from the initation of Palbociclib treatment until the first reported disease response (complete or partial).[34] Censoring rules presented in Section 3.1 will be applied.

TTP is defined as the length of time (in days) from the initation of Palbociclib treatment until the first reported disease progression.[34] Patients will be censored at the end of Palbociclib treatment, death, time of withdrawal, or end of the 24-month follow-up, whichever occurs first, at the respective time point. Specifically, death is not included in TTP but is considered as censoring event.

PFS is defined as the length of time (in days) from the initation of Palbociclib treatment until the first reported disease progression or death due to any cause, whichever occurs first.[34] The disease progression will be considered at the first follow-up visit after the Palbociclib treatment initiation when the overall tumor response recorded is progressive disease. Patients with no disease progression documented will be censored at the last available medical record entry or end of the follow-up period. Patients who are lost to follow-up will be censored at their last visit.

Survival analyses will be used to estimate time to event endpoints TTR, TTP and PFS. The results of the survival analysis will be presented as the Kaplan-Meier survival curves and their 95% confidence intervals (CIs) that will be calculated using the log-log transformation of the survival probabilities.[36] Together with the Kaplan-Meier plots, the number of patients at risk at time intervals (eg, 90 days or as seen appropriate for the study) will be reported. Figure Shells 1 and 2 show how time to response (TTR) and progression free survival (PFS) will be visualized as Kaplan-Meier plots including the number of patients at different time intervals. Kaplan-Meier plots can be presented by other categories (see Section 3.2), if enough data are available. Moreover, the results of the survival analysis will be reported as a descriptive summary table including the number of patients at risk, the number of patients

with event and the number of censored patients, and the outcome's median, 1st and 3rd quartile with their 95% CIs, as shown in Table Shell 54.

The first immediate subsequent treatments used following end of treatment with Palbociclib will be summarised as shown in Table Shell 62. The stratified tables will be presented as in Table Shells 63-69.

7. LIST OF TABLE AND FIGURE SHELLS

Table 2. List of Table and Figure Shells

Objective	Number	Description
	Table Shell 1	Summary of patients enrollment per country and site
Primary objectives 1, 2,	Table Shell 2	Descriptive summary table of clinical outcomes of Palbociclib treatment.
Secondary objective 1	Table Shell 3	Descriptive summary table of clinical outcomes of Palbociclib treatment by combination of therapies.
	Table Shell 4	Descriptive summary table of clinical outcomes of Palbociclib treatment by line of endocrine therapy.
	Table Shell 5	Descriptive summary table of clinical outcomes of Palbociclib treatment by country.
	Table Shell 6	Descriptive summary table of clinical outcomes of Palbociclib treatment by menopausal status.
	Table Shell 7	Descriptive summary table of clinical outcomes of Palbociclib treatment by metastatic status.
	Table Shell 8	Descriptive summary table of clinical outcomes of Palbociclib treatment by metastatic site.
	Table Shell 9	Descriptive summary table of clinical outcomes of Palbociclib treatment by age group.
	Figure Shell 1	Kaplan Meier plot to describe progression free survival by type of combination therapy.
Secondary objective 2	Table Shell 10	Descriptive summary table of the demographic and initial clinical profiles of BC patients who have received Palbociclib treatment as first line therapy for metastatic/locally advanced BC.
	Table Shell 11	Descriptive summary table of the demographic and initial clinical profiles of BC patients who have received Palbociclib treatment as second line therapy for metastatic/locally advanced BC.
	Table Shell 12	Descriptive summary table of the clinical profiles of BC patients at the initiation of Palbociclib treatment as first line therapy for metastatic/locally advanced BC.
	Table Shell 13	Descriptive summary table of the clinical profiles of BC patients at the initiation of Palbociclib treatment as second line therapy for metastatic/locally advanced BC.
Secondary objective 3	Table Shell 14	Descriptive summary table of Palbociclib treatment characteristics.
	Table Shell 14	Descriptive summary table of Palbociclib treatment

Objective	Number	Description
		characteristics by combination of therapies.
	Table Shell 15	Descriptive summary table of Palbociclib treatment characteristics by line of endocrine therapy.
	Table Shell 16	Descriptive summary table of Palbociclib treatment characteristics by country.
	Table Shell 17	Descriptive summary table of Palbociclib treatment characteristics by menopausal status.
	Table Shell 18	Descriptive summary table of Palbociclib treatment characteristics by metastatic status at the initiation of Palbociclib treatment.
	Table Shell 19	Descriptive summary table of Palbociclib treatment characteristics by metastatic site at the initiation of Palbociclib treatment.
	Table Shell 20	Descriptive summary table of Palbociclib treatment characteristics by age group at the initiation of Palbociclib treatment.
Secondary objective 4	Table Shell 21	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment.
	Table Shell 22	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by combination of treatments.
	Table Shell 23	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by line of therapy.
	Table Shell 24	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by country.
	Table Shell 25	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by menopausal status.
	Table Shell 26	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by metastatic status.
	Table Shell 27	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by metastatic site.
	Table Shell 28	Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by age group.
Secondary objective 5	Table Shell 29	Descriptive summary table of therapies for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
	Table Shell 30	Descriptive summary table of the therapies by combination therapy for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

Objective	Number	Description
	Table Shell 31	Descriptive summary table of the therapies by line of endocrine therapy for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
	Table Shell 32	Descriptive summary table of the therapies by country for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment
	Table Shell 33	Descriptive summary table of the therapies by menopausal status for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
	Table Shell 34	Descriptive summary table of the therapies by metastatic status for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
	Table Shell 35	Descriptive summary table of the therapies by metastatic site for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
	Table Shell 36	Descriptive summary table of the therapies by age group for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.
Secondary objective 6	Table Shell 37	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) before Palbociclib treatment.
	Table Shell 38	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by combination of therapies before Palbociclib treatment.
	Table Shell 39	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by line of endocrine therapy before Palbociclib treatment.
	Table Shell 40	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by country before Palbociclib treatment.
	Table Shell 41	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by menopausal status before Palbociclib treatment.
	Table Shell 42	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by metastatic status before Palbociclib treatment.
	Table Shell 43	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by metastatic site before Palbociclib treatment.
	Table Shell 44	Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by age group before Palbociclib treatment.

Objective	Number	Description
Secondary objective 7	Table Shell 45	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.
	Table Shell 46.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus letrozole/aromatase inhibitor.
	Table Shell 46.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus fulvestrant.
	Table Shell 47.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. First line.
	Table Shell 47.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. Second line.
	Table Shell 48.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Egypt.
	Table Shell 48.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Jordan.
	Table Shell 48.3	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Lebanon.
	Table Shell 48.4	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Kingdom of Saudi Arabia.
	Table Shell 48.5	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Qatar.
	Table Shell 48.6	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Morocco.
	Table Shell 48.7	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. United Arab Emirates.
	Table Shell 49.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Premenopausal.
	Table Shell 49.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Postmenopausal.
	Table Shell 50.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. De novo.
	Table Shell 50.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. Recurrent.

Objective	Number	Description
	Table Shell 51.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Visceral.
	Table Shell 52.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Non-visceral.
	Table Shell 53.1	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group <55 years.
	Table Shell 53.2	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group 55-64 years.
	Table Shell 53.3	Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group ≥65 years.
	Table Shell 54	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients.
	Table Shell 55	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by treatment combination.
	Table Shell 56	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by line of therapy.
	Table Shell 57	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by country.
	Table Shell 58	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by menopausal status.
	Table Shell 59	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by metastatic status.
Exploratory objective 1	Table Shell 60	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by metastatic site.
	Table Shell 61	Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by age group.
	Figure Shell 2	Kaplan Meier plot to describe time to response by type of combination therapy.
Exploratory objective 2	Table Shell 62	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib.

Objective	Number	Description
	Table Shell 63	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by combination of treatments.
	Table Shell 64	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by line of treatment.
	Table Shell 65	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by country.
	Table Shell 66	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by menopausal status.
	Table Shell 67	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by metastatic status.
	Table Shell 68	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by metastatic site.
	Table Shell 69	Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by age group.

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9. ANNEX 1

Table 3. Study Variables

Variable	Role	Time point(s)	Data source(s)	Operational definition
Age, continuous	Demographics (secondary endpoint)	At initial diagnosis of BC At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer medical History, Palbociclib treatment initiation	Age will be reported in years (YY)
Age, categorical	Stratification variable	At the initiation of Palbociclib treatment	CRF sheet: Palbociclib treatment initiation	Two variables, age categorized into the following groups: • <55 years or >=55 years • <65 years or >=65 years
Year of initiation of Palbociclib treatment	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	Palbociclib Treatment Initiation	Year of initiation of Palbociclib treatment
Time since initial diagnosis of breast cancer (days)	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	Palbociclib Treatment Initiation	Date of initiation of Palbociclib treatment – date of initial diagnosis of BC
Gender	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Gender (sex) is defined as: Male Female
Country	Demographics (secondary endpoint), stratification variable	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	There are nine countries in the study: Egypt Jordan Lebanon UAE (United Arab Emirates) Qatar Morocco KSA (Kingdom of Saudi Arabia)
Ethnicity	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	There are nine ethnic groups: • Middle Eastern • Caucasian / White • Black • Hispanic • Native American • Asian / Pacific Islander • Australian / South European • Australian (Aboriginal) • Unknown

Variable	Role	Time point(s)	Data source(s)	Operational definition
				• Other
Insurance	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	There are two insurance types: • Public • Private
Weight	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Weight will be reported in kilograms (kg).
Height	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Height will be reported in meters (m).
BMI	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	BMI will be calculated automatically based on the reported weight and height in the unit of kilograms over squared meters (kg/m^2).
BMI category	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	The calculated BMI will be categorized as: · Underweight (BMI: <18.5 kg/m^2) · Normal weight (BMI: 18.5-<25 kg/m2) · Overweight (BMI: 25-<30 kg/m2) · Class I obesity (BMI: 30-<35 kg/m2) · Class II obesity (BMI: 35-<40 kg/m2) · Class III obesity (BMI: ≥40 kg/m2)
Family history of BC	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Family history of breast cancer • Yes • No
Smoking habits	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Smoking habits are categorised as: • Current smoker • Ex-smoker • Non-smoker • Unknown
Age at menarche	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Age at menarche (in years, YY)
Age at menopause	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Age at menopause (in years, YY)
Number of children	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	Number of children (NN)
History of breast feeding	Demographics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Demographic Characteristics	• Yes • No
Menopausal status	Clinical characteristics (secondary		CRF sheets: Palbociclib Initiation	Menopausal status at initiation of Palbociclib treatment

Variable	Role	Time point(s)	Data source(s)	Operational definition
	endpoint), stratification variable	At the initiation of Palbociclib treatment	Medical History,	For females, menopausal status is reported as binary: Premenopausal Postmenopausal
Clinical stage of BC	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheet: Early Breast Cancer Medical History	For the early breast cancer diagnosis, there are five clinical stage categories for the breast cancer stage: · IIA · IIB · IIIA · IIIB · IIIC
Pathological stage of BC	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheet: Early Breast Cancer Medical History	For the early breast cancer diagnosis, there are seven pathological stages for the breast cancer stage: · 0 · I · IIA · IIB · IIIA · IIIB · IIIC
TNM stage of BC	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheet: Early Breast Cancer Medical History	For the breast cancer stage, there are eight categories for the tumor (T): · Tis · T0 · T1 · T2 · T3 · T4 · TX · unknown There are six categories for the node (N):

Variable	Role	Time point(s)	Data source(s)	Operational definition
				· N0 · N1 · N2 · N3 · NX · unknown There are four categories for the metastasis (M): · M0 · M1 · MX · unknown Based on the reported stage of the breast cancer at diagnosis, only the corresponding TNM choices are available in the CRF.
Histo-pathology type	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbocicilib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	Histopathology types are: · Ductual carcinoma in situ (DCIS) · Lobular carcinoma in situ · Invasice ductual carcinoma (ductual breast cancer) · Invasive lobular carcinoma · Medullary carcinoma · Mucinous (colloid) carcinoma · Tubular carcinoma · Papillary carcinoma · Metaplastic breast cancer (MBC) · Phyllodes tumors · Mammary paget disease (MPD) · Inflammatory breast cancer · Other (specify)

Variable	Role	Time point(s)	Data source(s)	Operational definition
Histologic grade	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbocicilib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	Histologic grade will be reported as: · G1 · G2 · G3 · Unknown
Nuclear grade	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	Nuclear grade will be reported as: · G1 · G2 · G3 · Unknown
FISH test (HER2 testing)	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	FISH test result is categorized as: · Positive · Negative

Variable	Role	Time point(s)	Data source(s)	Operational definition
IHC score (HER2 testing)	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	IHC test result is categorized as: · 0-1 · 2+ · 3+
ICH score (Hormone receptor testing)	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	ICC test result reported as the combination of the ER and PR status. The ICH score has thus four categories: · ER and PR positive · ER positive and PR negative · ER negative and PR positive · ER and PR negative
Ki67	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	Ki67 results are reported as a percentage.

Variable	Role	Time point(s)	Data source(s)	Operational definition
TILs	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	TILs test result reported as percentage.
PLD-1	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	PLD-1 test result reported as percentage.
gBRCA	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	gBRCA results are reported as binary: · positive · negative

Variable	Role	Time point(s)	Data source(s)	Operational definition
HRD	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	HRD test result is categorized as: · Positive · Negative
ESR-1 mutation	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	ESR-1 mutation test result is categorized as: · Positive · Negative
Androgen receptor	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheets: Early Breast Cancer Medical History, Advanced Breast Cancer Medical History, Palbociclib Initiation Mediacal History	Androgen receptor test result is categorized as: · Positive · Negative
Complete blood count (CBC)	Clinical characteristics (secondary endpoint)	At diagnosis At the initiation of Palbociclib treatment	CRF sheet: lab Tests Form	Laboratory value, open field
Number of patients	Adjuvant	Prior to Palbociclib	CRF sheet:	The number of patients in each of the

Variable	Role	Time point(s)	Data source(s)	Operational definition
receiving adjuvant therapies	therapies (secondary endpoint)	treatment	Early Breast Cancer Treatment Form	following categories (adjuvant therapy received by patients for treatment of early/locally advanced BC): • Systemic therapy • Adjuvant chemotherapy • Adjuvant hormonal therapy • Experimental adjuvant therapy • Neoadjuvant chemotherapy • Neoadjuvant hormonal therapy • Radiotherapy • Surgery • Other • Unknown
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)	Adjuvant therapies (secondary endpoint)	Prior to Palbociclib treatment	CRF sheet: Early Breast Cancer Treatment Form	Date of initiation of Palbociclib treatment – date of end of therapy for early/locally advanced therapy
Number of patients receiving adjuvant therapies	Adjuvant therapies (secondary endpoint)	Prior to Palbociclib treatment	CRF sheet: Advanced Breast Cancer Treatment Form (prior to palbociclib)	The number of patients in each of the following categories (adjuvant therapy received by patients for treatment of advanced/metastatic BC): • Systemic therapy • MBC chemotherapy • MBC hormonal therapy (other than Palbociclib combination) • Radiotherapy • Surgery • Other • Unknown
Duration of therapy (days)	Adjuvant therapies (secondary endpoint)	Prior to Palbociclib treatment	CRF sheet: Advanced Breast Cancer Treatment Form (prior to palbociclib)	Stop date – start date of therapy
Number of patients receiving adjuvant therapies	Adjuvant therapies (exploratory endpoint)	After Palbociclib treatment	CRF sheet: Subsequent Treatment post-Palbociclib	• The number of patients in each of the following categories: • Systemic therapy • Radiotherapy • Surgery • Other • Unknown
Metastatic status	Clinical characteristics (secondary	At Palbociclib treatment initiation	CRF sheet: Palbociclib Initiation	Metastatic status of advanced BC is categorized as:

Variable	Role	Time point(s)	Data source(s)	Operational definition
	endpoint), stratification variable		Medical History, Palbociclib Baseline Tumor Assessment	• De-novo metastatic BC • Recurrent/relapse advanced BC
Number of patients with lesions	Clinical characteristics (secondary endpoint)	At diagnosis of advanced/metastatic BC	CRF sheet: Palbociclib Baseline Tumor Assessment	Number of patients with lesions according to site. Sites of lesions are categorized as: • Brain (visceral) • Lung/pleura (visceral) • Liver (visceral) • Bone (non-visceral/bone-only) • Breast/chest wall (non-visceral) • Lymph nodes (none) • Skin/soft tissue (non-visceral) • Ovary (non-visceral) • Other (e.g. peritoneal (visceral))
ECOG performance	Clinical characteristics (secondary endpoint)	At diagnosis of advanced/metastatic BC	CRF sheet: Palbociclib Baseline Tumor Assessment	ECOG status will be categorised as • 0: Fully active, able to carry on all pre-diseae performance without restriction • 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedetary nature, e.g. light housework, office work • 2: Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about 50% of waking hours • 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours • 4: Completely disabled, cannot carry on any self-care. Totally confined to bed or chair. • 5: Dead

Variable	Role	Time point(s)	Data source(s)	Operational definition
Overall tumor response	Clinical outcomes (primary endpoint)	At follow-up visits	CRF sheet: Tumor Assessment form	Overall tumor response will be categorised as: • Progressive disease, defined as an increase in visible disease and/Or presence of any new lesions, including cases where the clinician idicates progressive disease • Complete response, defined as complete reduction of all visible disease • Partial response, defined as partial reduction in size of visible disease in some or all areas without any areas of increase in visible disease • Stable disease, defined as no change in overall size of visible disease, also including cases where some lesions increased in size and some lesions decreased in size
Endocrine sensitivity	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	Endocrine sensitivity will be reported in five categories: • Endocrine therapy naïve • Endocrine sensitive • Primary endocrine resistant • Secondary endocrine resistant • Not applicable
Combination therapy	Stratification variable	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	• Palbociclib plus letrozole/aromatase (Palbociclib and either Anastrozole, Letrozole or Exemastane) • Palbociclib plus fulvestrant
Line of endocrine therapy	Stratification variable	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	Palbociclib as first or second line endocrine therapy • first line • second line
Prior chemotherapy for advanced/metastatic disease	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	• Yes • No
Schedule 3 weeks on, 1 week off	Palbociclib treatment	At Palbociclib treatment initiation	CRF sheet: Palbociclib	Palbociclib treatment schedule

Variable	Role	Time point(s)	Data source(s)	Operational definition
	characteristics (secondary endpoint)		Treatment Initiation	• Yes • No
Reasons for different schedule	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation At follow-up visits	CRF sheet: Palbociclib Treatment Initiation, Palbociclib Treatment Cycle Form	Reason for treatment schedule different from 3 weels on, 1 week off • To avoid toxicity • Due to line of therapy received • ECOG performance score • Age • Presence of comorbidities • Patient request • Metastases status • Stage at advanced breast cancer diagnosis • Concomitant medications • Other
Cycle interrupted	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	Palbociclib Treatment Cycle Form	• Yes • No
Reasons for cycle interruption	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	CRF sheet: Palbociclib Treatment Cycle Form	Reasons for Palbociclib cycle interruption are categorised as: • Lab abnormalities • Decline in ECOG performance score • Presence of comorbidities • Patient request • Concomitant medications • Other
Cycle delayed	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	Palbociclib Treatment Cycle Form	• Yes • No
Reasons for cycle delay	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	CRF sheet: Palbociclib Treatment Cycle Form	Reasons for Palbociclib cycle delays are categorised as: • Lab abnormalities

Variable	Role	Time point(s)	Data source(s)	Operational definition
				• Adverse events • Decline in ECOG performance score • Presence of comorbidities • Patient request • Concomitant medications • Other
Dose	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation At follow-up visits	CRF sheet: Palbociclib Treatment Initiation, Palbociclib Treatment Cycle Form	Dose of Palbociclib treatment 75 mg 100 mg 125 mg
Reasons for other than 125 mg dose	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	If dose of Palbociclib treatment is not 125 mg, why: • To avoid toxicity • Due to line of therapy received • ECOG performance score • Age • Presence of comorbidities • Patient request • Metastases status • Stage at advanced breast cancer diagnosis • Concomitant medications • Other
Dose or schedule modified	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	Palbociclib Treatment Cycle Form	• Dose modified • Schedule modified • Both modified • Neither modified
Reasons for dose/schedule change	Palbociclib treatment characteristics (secondary endpoint)	At follow-up visits	CRF sheet: Palbociclib Treatment Cycle Form	Reasons for dose or schedule change are categorised as: • To avoid toxicity • Due to line of therapy received • ECOG performance score • Age

Variable	Role	Time point(s)	Data source(s)	Operational definition
				• Presence of comorbidities • Patient request • Disease progression • Poor adherence • Developed resistance to endocrine treatment • Metastases status • Stage at the breast cancer diagnosis • Concomitant medications • Other
Accompanying endocrine treatments	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment initiation	CRF sheet: Palbociclib Treatment Initiation	Accompanying endocrine treatments during Palbociclib treatment: • Tamoxifen/NOLVADEX • Toremifene / FARESTON • Raloxifene / EVISTA • Anastrozole / ARIMIDEX • Letrozole / FEMARA • Exemestane / AROMASIN • Fulvestrant / FASLODEX • Goserlin Acetate / Zoaldex • Leuprorelin / Lupron • Triptorelin / Decapeptyl • Degarelix / Firmagon
Interruption in the cycle	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment discontinuation	CRF sheet: Palbociclib treatment discontinuation form	Palbociclib treatment was interrupted: • Yes • no
Reasons for discontinuation	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment discontinuation	CRF sheet: Palbociclib treatment discontinuation form	Reasons for Palbociclib treatment discontinuation are categorised as: • Toxicities of side effects • Patient decision • Patient physical status • Disease progression • Completion of plannet course of treatment • Developed resistance to endocrine treatment • Poor adherence • Death • Treatment related toxicity

Variable	Role	Time point(s)	Data source(s)	Operational definition
				• Non-treatment related toxicity • Patient request • Lost to follow-up • Other
Treatment completed	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment discontinuation	CRF sheet: Palbociclib treatment discontinuation form	• Yes (reason of discontinuation is "Completion of planned course of treatment"); no (other reason or censored)
Duration of Palbociclib treatment	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment discontinuation	CRF sheet: Palbociclib treatment discontinuation form	• Time (in days) from first to last day in Palbociclib treatment
Another treatment after discontinuing treatment with Palbociclib	Palbociclib treatment characteristics (secondary endpoint)	At Palbociclib treatment discontinuation	CRF sheet: Palbociclib treatment discontinuation form	• Yes • No
Reason for end of follow-up	Clinical outcomes (primary endpoint)	At last visit	CRF sheet: End of Observation/ End of Study Follow Up	End of follow-up will be categorised as: • Death • Patient withdrawal • Lost to follow-up • End of 24-months follow-up period
Concomitant medications	Clinical characteristics (secondary endpoint)	At Palbociclib treatment initiation, At follow-up visits	CRF sheet: Concomitant Medications Form	Open field. 10 most common will be listed.
Supportive therapies	Supportive therapies (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Supportive Therapies Form	The type of the supportive therapies received by the patients since the BC diagnosis. Open field. 10 most common will be listed.
Comorbidites	Clinical characteristics (secondary endpoint)	At the initiation of Palbociclib treatment	CRF sheet: Comorbidities form	Open field. 10 most common comorbidities will be listed
Proportion of progression free patients	Clinical outcomes (primary endpoint)	At the follow-up visits	CRF sheet: Tumor Assessment Form and End of follow-up	The proportion of the patients who are alive and for whom no progression of the disease has been reported.
Progression free survival (PFS)	Clinical outcomes (exploratory endpoint)	At the follow-up visits	CRF sheet: Tumor Assessment Form and End of follow-up	The time from the Palbociclib treatment initiation until the progression of the disease or death to any cause, whichever occurs first.

Variable	Role	Time point(s)	Data source(s)	Operational definition
Time to progression (TTP)	Clinical outcomes (exploratory endpoint)	At the follow-up visits	CRF sheet: Tumor Assessment Form and End of follow-up	The time from the first breast cancer diagnosis to the first reported progression of the disease or death from the disease, whichever occurs first.
Objective response rate (ORR)	Clinical outcomes (secondary endpoint)	At the follow-up visits	CRF sheet: Tumor Assessment Form	The proportion of the patients who have been reported to be responsive (partial or complete response or stable disease) for the treatment.
Time to first response	Clinical outcomes (exploratory endpoint)	At the follow-up visits	CRF sheet: Tumor Assessment Form	The time from the first breast cancer diagnosis to the first reported reponse (partial or complete response) for the treatment.
Proportion of overall survival	Clinical outcomes (primary endpoint)	At 1 and 2 years after the treatment initiation	CRF sheet: Tumor Assessment Form and End of follow-up	The proportion of alive patients over all patients who intiated the treatment.
Item	Quality of life (secondary endpoint)	At follow-up visits	CRF sheet: Patient reported outcomes (PROs)	There are 28 questions (items) in EORTC-QLQ-30 questionnaire that are classified as follows: 1: Not at all 2: A little 3: Quite a bit 4: Very much
Item	Quality of life (secondary endpoint)	At follow-up visits	CRF sheet: Patient reported outcomes (PROs)	There are 4 questions (items) in EORTC-QLQ-30 questionnaire that are classified as follows: 1 (Very Poor) - 7 (Excellent)

BC=breast cancer; CBC=complete blood count; ECOQ=Eastern Cooperative Oncology Group; EORTC QLQ-C30=European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30; MBC=metastatic breast cancer.

10. ANNEX 2

Table Shell 1 – Summary of patients enrollment per country and site.

		Non eligible patients	Non eligible patients (Due to exclusion criteria of "Patients participating in any interventional clinical trial")	Non eligible patients (Due to exclusion criteria of "Patients with active treatment for malignancies other than metastatic/locally advanced BC at the time of enrollment")	Non eligible patients (Due to exclusion criteria of "Patients who are unable to understand the nature of the study and are unwilling to sign an informed consent")	Eligible patients
All countries	**Overall**	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
Egypt	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					
Jordan	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					
Lebanon	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					
United Arab Emirates	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					

Table Shell 1 – Summary of patients enrollment per country and site.

Qatar	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					
Morocco	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					
Kingdom of Saudi Arabia	Overall	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 1	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	Site 2	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)
	…					

Table Shell 2 - Descriptive summary table of clinical outcomes of Palbociclib treatment.

Variable	Summary statistics
Progression free patients / Patients still at risk (% [95% CI])	
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive	
at initiation	XX
1 year after the initation of Palbociclib treatment	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)
Overall tumor response at the end of Palbociclib treatment	
Number of patients	XX
Progressive disease	XX (xx%)
Complete response	XX (xx%)
Partial response	XX (xx%)
Stable disease	XX (xx%)
Missing	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)

Table Shell 3 - Descriptive summary table of clinical outcomes of Palbociclib treatment by combination of therapies.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Progression free patients / Patients still at risk (% [95% CI])		
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive		
at initiation	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment		
Number of patients	XX	XX
Progressive disease	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)

Table Shell 4 - Descriptive summary table of clinical outcomes of Palbociclib treatment by line of endocrine therapy.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Progression free patients / Patients still at risk (% [95% CI])		
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive		
at initiation	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment		
Number of patients	XX	XX
Progressive disease	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)

Table Shell 5 - Descriptive summary table of clinical outcomes of Palbociclib treatment by country.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Progression free patients / Patients still at risk (% [95% CI])							
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive							
at initiation	XX	XX	XX	XX	XX	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment							
Number of patients	XX	XX	XX	XX	XX	XX	XX
Progressive disease	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 5 - Descriptive summary table of clinical outcomes of Palbociclib treatment by country.

Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)

Table Shell 6 - Descriptive summary table of clinical outcomes of Palbociclib treatment by menopausal status.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Progression free patients / Patients still at risk (% [95% CI])		
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive		
at initiation	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment		
Number of patients	XX	XX
Progressive disease	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)

Table Shell 7 - Descriptive summary table of clinical outcomes of Palbociclib treatment by metastatic status.

	Metastatic status	
Variable	**De novo**	**Recurrent**
Progression free patients / Patients still at risk (% [95% CI])		
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive		
at initiation	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment		
Number of patients	XX	XX
Progressive disease	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)

Table Shell 8 - Descriptive summary table of clinical outcomes of Palbociclib treatment by metastatic site.

	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Progression free patients / Patients still at risk (% [95% CI])		
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive		
at initiation	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment		
Number of patients	XX	XX
Progressive disease	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)

Table Shell 9 - Descriptive summary table of clinical outcomes of Palbociclib treatment by age group.

	Age		
Variable	**<55 years**	**55-64 years**	**≥65 years**
Progression free patients / Patients still at risk (% [95% CI])			
At 6 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 12 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 18 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
At 24 months	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])	XX / XX (XX.X% [XX.X% - XX.X%])
Patients alive			
at initiation	XX	XX	XX
1 year after the initation of Palbociclib treatment	XX (xx%)	XX (xx%)	XX (xx%)
2 years after the initiation of Palbociclib treatment	XX (xx%)	XX (xx%)	XX (xx%)
Overall tumor response at the end of Palbociclib treatment			
Number of patients	XX	XX	XX
Progressive disease	XX (xx%)	XX (xx%)	XX (xx%)
Complete response	XX (xx%)	XX (xx%)	XX (xx%)
Partial response	XX (xx%)	XX (xx%)	XX (xx%)
Stable disease	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Objective reponse rate (ORR) [%]	XX / XX (xx%)	XX / XX (xx%)	XX / XX (xx%)

Table Shell 10 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Variable	Summary statistics
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX
Age at initial diagnosis of BC [year]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Sex	
Female	XX (xx%)
Country	
Algeria	XX (xx%)
Egypt	XX (xx%)
KSA	XX (xx%)
Kuwait	XX (xx%)
Lebanon	XX (xx%)
Morocco	XX (xx%)
UAE	XX (xx%)
Missing	XX (xx%)
Ethnicity	
Middle Eastern	XX (xx%)
Caucasian / White	XX (xx%)
Black	XX (xx%)
Hispanic	XX (xx%)
Native American	XX (xx%)
Asian / Pacific Islander	XX (xx%)
Australian / South European	XX (xx%)
Australian (Aboriginal)	XX (xx%)
Unknown	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Insurance type	
Public	XX (xx%)
Private	XX (xx%)
Missing	XX (xx%)
Family history of breast cancer	
Yes	XX (xx%)

Table Shell 10 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

No	XX (xx%)
Missing	XX (xx%)
Smoking habits	
Current smoker	XX (xx%)
Ex-smoker	XX (xx%)
Non-smoker	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Age at menarche [year]	
Number of females	
Mean (SD)	XX (xx%)
Q1, median, Q3	XX (xx%)
Min, max	XX (xx%)
Missing	XX (xx%)
Age at menopause [year]	
Number of females	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Number of children	
Number of female patients having children	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
History of breast feeding	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Clinical stage of early BC	
I	XX (xx%)
IIA	XX (xx%)
IIB	XX (xx%)
IIIA	XX (xx%)
IIIB	XX (xx%)
IIIC	XX (xx%)
Missing	XX (xx%)
Pathological stage of early BC	

Table Shell 10 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

0	XX (xx%)
I	XX (xx%)
IIA	XX (xx%)
IIB	XX (xx%)
IIIA	XX (xx%)
IIIB	XX (xx%)
IIIC	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the tumor (T)	
Tis	XX (xx%)
T0	XX (xx%)
T1	XX (xx%)
T2	XX (xx%)
T3	XX (xx%)
T4	XX (xx%)
TX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the node (N)	
N0	XX (xx%)
N1	XX (xx%)
N2	XX (xx%)
N3	XX (xx%)
NX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the metastasis (M)	
M0	XX (xx%)
M1	XX (xx%)
MX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
Histopathology type at initial diagnosis of BC	
Ductal carcinoma in situ (DCIS)	XX (xx%)
Lobular carcinoma in situ	XX (xx%)
Invasive ductal carcinoma (ductal breast cancer)	XX (xx%)
Invasive lobular carcinoma	XX (xx%)
Medullary carcinoma	XX (xx%)
Mucinous (colloid) carcinoma	XX (xx%)
Tubular carcinoma	XX (xx%)

Table Shell 10 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Papillary carcinoma	XX (xx%)
Metaplastic breast cancer (MBC)	XX (xx%)
Phyllodes carcinoma	XX (xx%)
Mammary Paget disease (MPD)	XX (xx%)
Inflammatory breast cancer	XX (xx%)
Other	XX (xx%)
Missing	
Histologic grade (Nottingham grading system) at initial diagnosis of BC	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Nuclear grade at initial diagnosis of BC	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
HER-2 at diagnosis: ICH score at initial diagnosis of BC	
0-1	XX (xx%)
2+	XX (xx%)
3+	XX (xx%)
Missing	XX (xx%)
HER-2 at diagnosis: Fish test result at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Hormone reseptor testing: IHC score at initial diagnosis of BC	
ER and PR positive	XX (xx%)
ER positive and PR negative	XX (xx%)
ER negative and PR positive	XX (xx%)
ER and PR negative	XX (xx%)
Missing	XX (xx%)
Ki67 at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x

Table Shell 10 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Missing	XX (xx%)
TILs at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
PDL-1 at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
gBRCA at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HRD at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
ESR-1 mutation at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Androgen receptor at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)

Table Shell 11 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Variable	Summary statistics
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX
Age at initial diagnosis of BC [year]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Sex	
Female	XX (xx%)
Country	
Algeria	XX (xx%)
Egypt	XX (xx%)
KSA	XX (xx%)
Kuwait	XX (xx%)
Lebanon	XX (xx%)
Morocco	XX (xx%)
UAE	XX (xx%)
Missing	XX (xx%)
Ethnicity	
Middle Eastern	XX (xx%)
Caucasian / White	XX (xx%)
Black	XX (xx%)
Hispanic	XX (xx%)
Native American	XX (xx%)
Asian / Pacific Islander	XX (xx%)
Australian / South European	XX (xx%)
Australian (Aboriginal)	XX (xx%)
Unknown	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Insurance type	
Public	XX (xx%)
Private	XX (xx%)
Missing	XX (xx%)
Family history of breast cancer	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)

Table Shell 11 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Smoking habits	
Current smoker	XX (xx%)
Ex-smoker	XX (xx%)
Non-smoker	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Age at menarche [year]	
Number of females	
Mean (SD)	XX (xx%)
Q1, median, Q3	XX (xx%)
Min, max	XX (xx%)
Missing	XX (xx%)
Age at menopause [year]	
Number of females	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Number of children	
Number of female patients having children	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
History of breast feeding	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Clinical stage of early BC	
I	XX (xx%)
IIA	XX (xx%)
IIB	XX (xx%)
IIIA	XX (xx%)
IIIB	XX (xx%)
IIIC	XX (xx%)
Missing	XX (xx%)
Pathological stage of early BC	
0	XX (xx%)
I	XX (xx%)
IIA	XX (xx%)
IIB	XX (xx%)

Table Shell 11 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

IIIA	XX (xx%)
IIIB	XX (xx%)
IIIC	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the tumor (T)	
Tis	XX (xx%)
T0	XX (xx%)
T1	XX (xx%)
T2	XX (xx%)
T3	XX (xx%)
T4	XX (xx%)
TX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the node (N)	
N0	XX (xx%)
N1	XX (xx%)
N2	XX (xx%)
N3	XX (xx%)
NX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
TNM stage of early BC for the metastasis (M)	
M0	XX (xx%)
M1	XX (xx%)
MX	XX (xx%)
unknown	XX (xx%)
Missing	XX (xx%)
Histopathology type at initial diagnosis of BC	
Ductal carcinoma in situ (DCIS)	XX (xx%)
Lobular carcinoma in situ	XX (xx%)
Invasive ductal carcinoma (ductal breast cancer)	XX (xx%)
Invasive lobular carcinoma	XX (xx%)
Medullary carcinoma	XX (xx%)
Mucinous (colloid) carcinoma	XX (xx%)
Tubular carcinoma	XX (xx%)
Papillary carcinoma	XX (xx%)
Metaplastic breast cancer (MBC)	XX (xx%)
Phyllodes carcinoma	XX (xx%)
Mammary Paget disease (MPD)	XX (xx%)
Inflammatory breast cancer	XX (xx%)
Other	XX (xx%)

Table Shell 11 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Missing	
Histologic grade (Nottingham grading system) at initial diagnosis of BC	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Nuclear grade at initial diagnosis of BC	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
HER-2 at diagnosis: ICH score at initial diagnosis of BC	
0-1	XX (xx%)
2+	XX (xx%)
3+	XX (xx%)
Missing	XX (xx%)
HER-2 at diagnosis: Fish test result at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Hormone reseptor testing: IHC score at initial diagnosis of BC	
ER and PR positive	XX (xx%)
ER positive and PR negative	XX (xx%)
ER negative and PR positive	XX (xx%)
ER and PR negative	XX (xx%)
Missing	XX (xx%)
Ki67 at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
TILs at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)

Table Shell 11 - Descriptive summary table of the *demographic and initial clinical* profiles of BC patients who have received Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

PDL-1 at initial diagnosis of BC [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
gBRCA at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HRD at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
ESR-1 mutation at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Androgen receptor at initial diagnosis of BC	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)

Table Shell 12 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Variable	Summary statistics
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX
Year of initiation of Palbociclib treatment	
2020	XX (xx%)
2021	XX (xx%)
2022	XX (xx%)
2023	XX (xx%)
…	…
Time from initial diagnosis of breast cancer to Palbociclib treatment initiation [days]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Time from initial diagnosis of breast cancer to recurrence [days]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Age at baseline [year]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Weight [kg]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Height [m]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
BMI [kg/m2]	
N	XX (xx%)

Table Shell 12 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
BMI category	
Underweight (BMI: <18.5 kg/m^2)	XX (xx%)
Normal weight (BMI: 18.5-<25 kg/m^2)	XX (xx%)
Overweight (BMI: 25-<30 kg/m^2)	XX (xx%)
Class I obesity (BMI: 30-<35 kg/m^2)	XX (xx%)
Class II obesity (BMI: 35-<40 kg/m^2)	XX (xx%)
Class III obesity (BMI: ≥40 kg/m^2)	XX (xx%)
Missing	XX (xx%)
Menopausal status	
Number of females	XX (xx%)
Premenopausal	XX (xx%)
Postmenopausal	XX (xx%)
Missing	XX (xx%)
Metastatic status	
De-novo metastatis	XX (xx%)
Recurrent metastasis	XX (xx%)
Relapsed metastasis (for first/second line therapy)	XX (xx%)
Missing	XX (xx%)
Histopathology type	
Ductal carcinoma in situ (DCIS)	XX (xx%)
Lobular carcinoma in situ	XX (xx%)
Invasive ductal carcinoma (ductal breast cancer)	XX (xx%)
Invasive lobular carcinoma	XX (xx%)
Medullary carcinoma	XX (xx%)
Mucinous (colloid) carcinoma	XX (xx%)
Tubular carcinoma	XX (xx%)
Papillary carcinoma	XX (xx%)
Metaplastic breast cancer (MBC)	XX (xx%)
Phyllodes tumors	XX (xx%)
Mammary Paget disease (MPD)	XX (xx%)
Inflammatory breast cancer	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Histologic grade	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)

Table Shell 12 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Unknown	XX (xx%)
Missing	XX (xx%)
HER-2 testing: FISH test	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HER2 testing: IHC test	
0-1	XX (xx%)
2+	XX (xx%)
3+	XX (xx%)
Missing	XX (xx%)
Hormone receptor testing	
ER and PR positive	XX (xx%)
ER positive and PR negative	XX (xx%)
ER negative and PR positive	XX (xx%)
ER and PR negative	XX (xx%)
Missing	XX (xx%)
Ki67 [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
TILs [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
PDL-1 [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
gBRCA	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HRD	
Positive	XX (xx%)
Negative	XX (xx%)

Table Shell 12 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

Missing	XX (xx%)
ESR-1 mutation	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Androgen receptor	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Complete blood count (CBC)	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Lesions	
Number of patients with lesions in brain	XX (xx%)
Number of patients with lesions in lung/pleura	XX (xx%)
Number of patients with lesions in liver	XX (xx%)
Number of patients with lesions in bone	XX (xx%)
Number of patients with lesions in breast/chest wall	XX (xx%)
Number of patients with lesions in lymph nodes	XX (xx%)
Number of patients with lesions in skin/soft tissue	XX (xx%)
Number of patients with lesions in ovary	XX (xx%)
Number of patients with lesions in other site	XX (xx%)
ECOG performance	
0	XX (xx%)
1	XX (xx%)
3	XX (xx%)
4	XX (xx%)
5	XX (xx%)
Not documented	XX (xx%)
Missing	XX (xx%)
Endocrine sensitivity	
Endocrine therapy naïve	XX (xx%)
Endocrine sensitive	XX (xx%)
Primary endocrine resistant	XX (xx%)
Secondary endocrine resistant	XX (xx%)
Not applicable	XX (xx%)
Missing	XX (xx%)
Comorbidities	
[disease/comorbidity 1]	XX (xx%)

Table Shell 12 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as first line therapy for metastatic/locally advanced BC.*

[disease/comorbidity 2]	XX (xx%)
…	
[disease/comorbidity 10]	XX (xx%)
Concomitant medications	
[medication 1]	XX (xx%)
…	
[medication 2]	XX (xx%)
[medication 10]	XX (xx%)

Table Shell 13 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Variable	Summary statistics
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX
Year of initiation of Palbociclib treatment	
2020	XX (xx%)
2021	XX (xx%)
2022	XX (xx%)
2023	XX (xx%)
…	…
Time from initial diagnosis of breast cancer to Palbociclib treatment initiation [days]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Time from initial diagnosis of breast cancer to recurrence [days]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Age at baseline [year]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Weight [kg]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Height [m]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
BMI [kg/m2]	
N	XX (xx%)

Table Shell 13 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
BMI category	
Underweight (BMI: <18.5 kg/m^2)	XX (xx%)
Normal weight (BMI: 18.5-<25 kg/m^2)	XX (xx%)
Overweight (BMI: 25-<30 kg/m^2)	XX (xx%)
Class I obesity (BMI: 30-<35 kg/m^2)	XX (xx%)
Class II obesity (BMI: 35-<40 kg/m^2)	XX (xx%)
Class III obesity (BMI: ≥40 kg/m^2)	XX (xx%)
Missing	XX (xx%)
Menopausal status	
Number of females	XX (xx%)
Premenopausal	XX (xx%)
Postmenopausal	XX (xx%)
Missing	XX (xx%)
Metastatic status	
De-novo metastatis	XX (xx%)
Recurrent metastasis	XX (xx%)
Relapsed metastasis (for first/second line therapy)	XX (xx%)
Missing	XX (xx%)
Histopathology type	
Ductal carcinoma in situ (DCIS)	XX (xx%)
Lobular carcinoma in situ	XX (xx%)
Invasive ductal carcinoma (ductal breast cancer)	XX (xx%)
Invasive lobular carcinoma	XX (xx%)
Medullary carcinoma	XX (xx%)
Mucinous (colloid) carcinoma	XX (xx%)
Tubular carcinoma	XX (xx%)
Papillary carcinoma	XX (xx%)
Metaplastic breast cancer (MBC)	XX (xx%)
Phyllodes tumors	XX (xx%)
Mammary Paget disease (MPD)	XX (xx%)
Inflammatory breast cancer	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Histologic grade	
G1	XX (xx%)
G2	XX (xx%)
G3	XX (xx%)

Table Shell 13 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Unknown	XX (xx%)
Missing	XX (xx%)
HER-2 testing: FISH test	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HER2 testing: IHC test	
0-1	XX (xx%)
2+	XX (xx%)
3+	XX (xx%)
Missing	XX (xx%)
Hormone receptor testing	
ER and PR positive	XX (xx%)
ER positive and PR negative	XX (xx%)
ER negative and PR positive	XX (xx%)
ER and PR negative	XX (xx%)
Missing	XX (xx%)
Ki67 [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
TILs [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
PDL-1 [%]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
gBRCA	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
HRD	
Positive	XX (xx%)
Negative	XX (xx%)

Table Shell 13 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

Missing	XX (xx%)
ESR-1 mutation	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Androgen receptor	
Positive	XX (xx%)
Negative	XX (xx%)
Missing	XX (xx%)
Complete blood count	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Lesions	
Number of patients with lesions in brain	XX (xx%)
Number of patients with lesions in lung/pleura	XX (xx%)
Number of patients with lesions in liver	XX (xx%)
Number of patients with lesions in bone	XX (xx%)
Number of patients with lesions in breast/chest wall	XX (xx%)
Number of patients with lesions in lymph nodes	XX (xx%)
Number of patients with lesions in skin/soft tissue	XX (xx%)
Number of patients with lesions in ovary	XX (xx%)
Number of patients with lesions in other site	XX (xx%)
ECOG performance	
0	XX (xx%)
1	XX (xx%)
3	XX (xx%)
4	XX (xx%)
5	XX (xx%)
Not documented	XX (xx%)
Missing	XX (xx%)
Endocrine sensitivity	
Endocrine therapy naïve	XX (xx%)
Endocrine sensitive	XX (xx%)
Primary endocrine resistant	XX (xx%)
Secondary endocrine resistant	XX (xx%)
Not applicable	XX (xx%)
Missing	XX (xx%)
Comorbidities	
[disease/comorbidity 1]	XX (xx%)

Table Shell 13 - Descriptive summary table of the *clinical* profiles of BC patients at the initiation of Palbociclib treatment *as second line therapy for metastatic/locally advanced BC.*

[disease/comorbidity 2]	XX (xx%)
…	
[disease/comorbidity 10]	XX (xx%)
Concomitant medications	
[medication 1]	XX (xx%)
…	
[medication 2]	XX (xx%)
[medication 10]	XX (xx%)

Table Shell 14 - Descriptive summary table of Palbociclib treatment characteristics.

	Summary statistics
Number of patients	XX
Prior chemotherapy for advanced/metastatic disease	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"	
To avoid toxicity	XX (xx%)
Due to line of therapy received	XX (xx%)
ECOG performance score	XX (xx%)
Age	XX (xx%)
Presence of comorbidities	XX (xx%)
Patient request	XX (xx%)
Metastases status	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)
Concomitant medications	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Dose	
75 mg	XX (xx%)
100 mg	XX (xx%)
125 mg	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Reasons for other than 125 mg dose	
To avoid toxicity	XX (xx%)
Due to line of therapy received	XX (xx%)
ECOG performance score	XX (xx%)
Age	XX (xx%)
Presence of comorbidities	XX (xx%)
Patient request	XX (xx%)
Metastases status	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)
Concomitant medications	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Accompanying endocrine treatments	

Table Shell 14 - Descriptive summary table of Palbociclib treatment characteristics.

Missing	XX (xx%)
None, reason specified	XX (xx%)
Yes, specified treatment	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)
Toremifene / FARESTON	XX (xx%)
Raloxifene / EVISTA	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)
Letrozole / FEMARA	XX (xx%)
Exemestane / AROMASIN	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)
Leuprorelin / Lupron	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)
Degarelix / Firmagon	XX (xx%)
Interruption in the cycle	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Reasons for the cycle interruption	
Lab abnormalities	XX (xx%)
Decline in ECOG performance score	XX (xx%)
Presence of comorbidities	XX (xx%)
Patient request	XX (xx%)
Concomitant medications	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Modification in the dose and/or the schedule	
Dose modified	XX (xx%)
Schedule modified	XX (xx%)
Both modified	XX (xx%)
Neither modified	XX (xx%)
Missing	XX (xx%)
Reasons for the dose and/or schedule modifications	
To avoid toxicity	
Due to line of therapy received	XX (xx%)
ECOG performance score	XX (xx%)
Age	XX (xx%)
Presence of comorbidities	XX (xx%)
Patient request	XX (xx%)
Disease progression	XX (xx%)
Poor adherence	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)
Metastases status	XX (xx%)

Table Shell 14 - Descriptive summary table of Palbociclib treatment characteristics.

Stage at the breast cancer diagnosis	XX (xx%)
Concomitant medications	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Delays in the cycle	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)
Reasons for the delays in the cycle	
Lab abnormalities	XX (xx%)
Adverse events	XX (xx%)
Decline in ECOG performance score	XX (xx%)
Presence of comorbidities	XX (xx%)
Patient request	XX (xx%)
Concomitant medications	XX (xx%)
Other	XX (xx%)
Missing	XX (xx%)
Reasons for discontinuation	
Toxicities of side effects	XX (xx%)
Patient decision	XX (xx%)
Patient physical status	XX (xx%)
Disease progression	XX (xx%)
Completion of planner course of treatment	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)
Poor adherence	XX (xx%)
Death	XX (xx%)
Treatment related toxicity	XX (xx%)
Non-treatment related toxicity	XX (xx%)
Patient request	XX (xx%)
Lost to follow-up	XX (xx%)
Other	XX (xx%)
Treatment completed	
Yes	XX (xx%)
No, reason specified	XX (xx%)
Missing	XX (xx%)
Duration of Palbociclib treatment [days]	
N	XX (xx%)
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)
Another treatment after discontinuing treatment with	

Table Shell 14 - Descriptive summary table of Palbociclib treatment characteristics.

Palbociclib	
Yes	XX (xx%)
No	XX (xx%)
Missing	XX (xx%)

Table Shell 15 - Descriptive summary table of Palbociclib treatment characteristics by combination of therapies.

	Combination therapy	
	Palbociclib plus letrozole/aromatase inhibitor	**Palbociclib plus fulvestrant**
Number of patients	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Dose		
75 mg	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)

Table Shell 15 - Descriptive summary table of Palbociclib treatment characteristics by combination of therapies.

Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Accompanying endocrine treatments		
Missing	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)
Interruption in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the cycle interruption		
Lab abnormalities	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule		
Dose modified	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)

Table Shell 15 - Descriptive summary table of Palbociclib treatment characteristics by combination of therapies.

Missing	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications		
To avoid toxicity		
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Delays in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle		
Lab abnormalities	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for discontinuation		
Toxicities of side effects	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)

Table Shell 15 - Descriptive summary table of Palbociclib treatment characteristics by combination of therapies.

Death	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Treatment completed		
Yes	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]		
N	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 16 - Descriptive summary table of Palbociclib treatment characteristics by line of endocrine therapy.

	Line of endocrine therapy	
	1st	**2nd**
Number of patients	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Dose		
75 mg	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 16 - Descriptive summary table of Palbociclib treatment characteristics by line of endocrine therapy.

Accompanying endocrine treatments		
Missing	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)
Interruption in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the cycle interruption		
Lab abnormalities	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule		
Dose modified	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications		
To avoid toxicity		
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)

Table Shell 16 - Descriptive summary table of Palbociclib treatment characteristics by line of endocrine therapy.

Metastases status	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Delays in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle		
Lab abnormalities	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for discontinuation		
Toxicities of side effects	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Treatment completed		
Yes	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]		
N	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x

Table Shell 16 - Descriptive summary table of Palbociclib treatment characteristics by line of endocrine therapy.

Missing	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

	Country						
	Egypt	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Number of patients	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"							
To avoid toxicity	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dose							

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

75 mg	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose							
To avoid toxicity	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Accompanying endocrine treatments							
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Interruption in the cycle							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the cycle interruption							
Lab abnormalities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule							
Dose modified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

Neither modified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications							
To avoid toxicity							
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Delays in the cycle							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle							
Lab abnormalities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Decline in ECOG	XX	XX	XX (xx%)	XX	XX	XX	XX

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

performance score	(xx%)	(xx%)		(xx%)	(xx%)	(xx%)	(xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for discontinuation							
Toxicities of side effects	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Treatment completed							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Duration of Palbociclib							

Table Shell 17 - Descriptive summary table of Palbociclib treatment characteristics by country.

treatment [days]							
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib							
Yes	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 18 - Descriptive summary table of Palbociclib treatment characteristics by menopausal status.

	Menopausal status	
	Premenopausal	**Postmenopausal**
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Dose		
75 mg	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)

Table Shell 18 - Descriptive summary table of Palbociclib treatment characteristics by menopausal status.

Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Accompanying endocrine treatments		
Missing	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)
Interruption in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the cycle interruption		
Lab abnormalities	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule		
Dose modified	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications		
To avoid toxicity		
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)

Table Shell 18 - Descriptive summary table of Palbociclib treatment characteristics by menopausal status.

Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Delays in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle		
Lab abnormalities	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for discontinuation		
Toxicities of side effects	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Treatment completed		
Yes	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]		

Table Shell 18 - Descriptive summary table of Palbociclib treatment characteristics by menopausal status.

N	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 19 - Descriptive summary table of Palbociclib treatment characteristics by metastatic status at the initiation of Palbociclib treatment.

	Metastatic status	
	De-novo	**Recurrent**
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Dose		
75 mg	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)

Table Shell 19 - Descriptive summary table of Palbociclib treatment characteristics by metastatic status at the initiation of Palbociclib treatment.

Missing	XX (xx%)	XX (xx%)
Accompanying endocrine treatments		
Missing	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)
Interruption in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the cycle interruption		
Lab abnormalities	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule		
Dose modified	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications		
To avoid toxicity		
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)

Table Shell 19 - Descriptive summary table of Palbociclib treatment characteristics by metastatic status at the initiation of Palbociclib treatment.

Poor adherence	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Delays in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle		
Lab abnormalities	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for discontinuation		
Toxicities of side effects	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Treatment completed		
Yes	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]		
N	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x

Table Shell 19 - Descriptive summary table of Palbociclib treatment characteristics by metastatic status at the initiation of Palbociclib treatment.

Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 20 - Descriptive summary table of Palbociclib treatment characteristics by metastatic site at the initiation of Palbociclib treatment.

	Metastatic site	
	Visceral	**Non-visceral**
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Dose		
75 mg	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose		
To avoid toxicity	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)

Table Shell 20 - Descriptive summary table of Palbociclib treatment characteristics by metastatic site at the initiation of Palbociclib treatment.

Missing	XX (xx%)	XX (xx%)
Accompanying endocrine treatments		
Missing	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)
Interruption in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the cycle interruption		
Lab abnormalities	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule		
Dose modified	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications		
To avoid toxicity		
Due to line of therapy received	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)

Table Shell 20 - Descriptive summary table of Palbociclib treatment characteristics by metastatic site at the initiation of Palbociclib treatment.

Poor adherence	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Delays in the cycle		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle		
Lab abnormalities	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Reasons for discontinuation		
Toxicities of side effects	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Treatment completed		
Yes	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]		
N	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x

Table Shell 20 - Descriptive summary table of Palbociclib treatment characteristics by metastatic site at the initiation of Palbociclib treatment.

Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib		
Yes	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 21 - Descriptive summary table of Palbociclib treatment characteristics by age group at the initiation of Palbociclib treatment.

	Age group		
	<55 years	**55-64 years**	**>=65 years**
Number of patients who have received palbociclib combination treatment in line with locally approved indications	XX (xx%)	XX (xx%)	XX (xx%)
Prior chemotherapy for advanced/metastatic disease			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Treatment schedule is "3 weeks on, 1 week off"			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for treatment schedules other than "3 weeks on, 1 week off"			
To avoid toxicity	XX (xx%)	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Dose			
75 mg	XX (xx%)	XX (xx%)	XX (xx%)
100 mg	XX (xx%)	XX (xx%)	XX (xx%)
125 mg	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for other than 125 mg dose			
To avoid toxicity	XX (xx%)	XX (xx%)	XX (xx%)
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)
Stage at advanced breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 21 - Descriptive summary table of Palbociclib treatment characteristics by age group at the initiation of Palbociclib treatment.

Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Accompanying endocrine treatments			
Missing	XX (xx%)	XX (xx%)	XX (xx%)
None, reason specified	XX (xx%)	XX (xx%)	XX (xx%)
Yes, specified treatment	XX (xx%)	XX (xx%)	XX (xx%)
Tamoxifen/NOLVADEX	XX (xx%)	XX (xx%)	XX (xx%)
Toremifene / FARESTON	XX (xx%)	XX (xx%)	XX (xx%)
Raloxifene / EVISTA	XX (xx%)	XX (xx%)	XX (xx%)
Anastrozole / ARIMIDEX	XX (xx%)	XX (xx%)	XX (xx%)
Letrozole / FEMARA	XX (xx%)	XX (xx%)	XX (xx%)
Exemestane / AROMASIN	XX (xx%)	XX (xx%)	XX (xx%)
Fulvestrant / FASLODEX	XX (xx%)	XX (xx%)	XX (xx%)
Goserlin Acetate / Zoaldex	XX (xx%)	XX (xx%)	XX (xx%)
Leuprorelin / Lupron	XX (xx%)	XX (xx%)	XX (xx%)
Triptorelin / Decapeptyl	XX (xx%)	XX (xx%)	XX (xx%)
Degarelix / Firmagon	XX (xx%)	XX (xx%)	XX (xx%)
Interruption in the cycle			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the cycle interruption			
Lab abnormalities	XX (xx%)	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Modification in the dose and/or the schedule			
Dose modified	XX (xx%)	XX (xx%)	XX (xx%)
Schedule modified	XX (xx%)	XX (xx%)	XX (xx%)
Both modified	XX (xx%)	XX (xx%)	XX (xx%)
Neither modified	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the dose and/or schedule modifications			
To avoid toxicity			
Due to line of therapy received	XX (xx%)	XX (xx%)	XX (xx%)
ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)
Age	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 21 - Descriptive summary table of Palbociclib treatment characteristics by age group at the initiation of Palbociclib treatment.

Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)	XX (xx%)
Metastases status	XX (xx%)	XX (xx%)	XX (xx%)
Stage at the breast cancer diagnosis	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Delays in the cycle			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for the delays in the cycle			
Lab abnormalities	XX (xx%)	XX (xx%)	XX (xx%)
Adverse events	XX (xx%)	XX (xx%)	XX (xx%)
Decline in ECOG performance score	XX (xx%)	XX (xx%)	XX (xx%)
Presence of comorbidities	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Concomitant medications	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Reasons for discontinuation			
Toxicities of side effects	XX (xx%)	XX (xx%)	XX (xx%)
Patient decision	XX (xx%)	XX (xx%)	XX (xx%)
Patient physical status	XX (xx%)	XX (xx%)	XX (xx%)
Disease progression	XX (xx%)	XX (xx%)	XX (xx%)
Completion of planner course of treatment	XX (xx%)	XX (xx%)	XX (xx%)
Developed resistance to endocrine treatment	XX (xx%)	XX (xx%)	XX (xx%)
Poor adherence	XX (xx%)	XX (xx%)	XX (xx%)
Death	XX (xx%)	XX (xx%)	XX (xx%)
Treatment related toxicity	XX (xx%)	XX (xx%)	XX (xx%)
Non-treatment related toxicity	XX (xx%)	XX (xx%)	XX (xx%)
Patient request	XX (xx%)	XX (xx%)	XX (xx%)
Lost to follow-up	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Treatment completed			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No, reason specified	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Duration of Palbociclib treatment [days]			
N	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 21 - Descriptive summary table of Palbociclib treatment characteristics by age group at the initiation of Palbociclib treatment.

Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Another treatment after discontinuing treatment with Palbociclib			
Yes	XX (xx%)	XX (xx%)	XX (xx%)
No	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 22 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment.

Variable	Summary statistics
Number of patients receiving Palbociclib combination treatment	XX
Supportive therapy	
[therapy 1]	XX (xx%)
[therapy 2]	XX (xx%)
…	XX (xx%)
[therapy 10]	XX (xx%)

Table Shell 23 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by combination of treatments.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Number of patients receiving Palbociclib combination treatment	XX	XX
Supportive therapy		
[therapy 1]	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)

Table Shell 24 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by line of therapy.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Number of patients receiving Palbociclib combination treatment	XX	
Supportive therapy		
[therapy 1]	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)

Table Shell 25 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by country.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Number of patients receiving Palbociclib combination treatment	XX	XX	XX	XX	XX	XX	XX
Supportive therapy							
[therapy 1]	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 26 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by menopausal status.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Number of patients receiving Palbociclib combination treatment	XX	XX
Supportive therapy		
[therapy 1]	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)

Table Shell 27 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by metastatic status.

	Metastatic status	
Variable	**De-novo**	**Recurrent**
Number of patients receiving Palbociclib combination treatment	XX	XX
Supportive therapy		
[therapy 1]	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)

Table Shell 28 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by metastatic site.

	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Number of patients receiving Palbociclib combination treatment	XX	XX
Supportive therapy		
[therapy 1]	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)

Table Shell 29 - Descriptive summary table of the supportive therapies received by the patients during the Palbociclib treatment by age group.

	Age group		
Variable	**<55 years**	**55-64 years**	**>=65 years**
Number of patients receiving Palbociclib combination treatment	XX	XX	XX
Supportive therapy			
[therapy 1]	XX (xx%)	XX (xx%)	XX (xx%)
[therapy 2]	XX (xx%)	XX (xx%)	XX (xx%)
…	XX (xx%)	XX (xx%)	XX (xx%)
[therapy 10]	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 30 - Descriptive summary table of therapies for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

Variable	Summary statistic
Number of patients who received adjuvant therapies	XX
Systemic therapy	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)
Radiotherapy	XX (xx%)
Surgery	XX (xx%)
Other	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)	
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)

Table Shell 31 - Descriptive summary table of the therapies by combination therapy for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 32 - Descriptive summary table of the therapies by line of endocrine therapy for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 33 - Descriptive summary table of the therapies by country for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Number of patients who received adjuvant therapies	XX	XX	XX	XX	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
- Experimental adjuvant therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
- Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
- Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)							

Table Shell 33 - Descriptive summary table of the therapies by country for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 34 - Descriptive summary table of the therapies by menopausal status for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 35 - Descriptive summary table of the therapies by metastatic status for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Metastatic status	
Variable	**De novo**	**Recurrent**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 36 - Descriptive summary table of the therapies by metastatic site for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 37 - Descriptive summary table of the therapies by age group for the treatment of early or locally advanced BC (stages 0-IIIa) who have received Palbociclib treatment at any point of time in the BC treatment.

	Age group		
Variable	**<55 years**	**55-64 years**	**≥65 years**
Number of patients who received adjuvant therapies	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)
-Adjuvant chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)
-Adjuvant hormonal therapy	XX (xx%)	XX (xx%)	XX (xx%)
-Experimental adjuvant therapy	XX (xx%)	XX (xx%)	XX (xx%)
-Neoadjuvant chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)
-Neoadjuvant hormonal therapy	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Time between start of palbociclib treatment and end of therapy for early/locally advanced BC (days)			
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 38 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) *before* Palbociclib treatment.

Variable	Summary statistic
Number of patients who received adjuvant therapies before Palbociclib treatment	XX
Systemic therapy	XX (xx%)
-MBC chemotherapy	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)
Radiotherapy	XX (xx%)
Surgery	XX (xx%)
Other	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)
Duration of therapy (days)	
Mean (SD)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x
Missing	XX (xx%)

Table Shell 39 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by combination of therapies *before* Palbociclib treatment.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Number of patients who received adjuvant therapies	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of therapy (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 40 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by line of endocrine therapy *before* Palbociclib treatment.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of therapy (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 41 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by country *before* Palbociclib treatment.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX	XX	XX	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Duration of therapy (days)							
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 42 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by menopausal status *before* Palbociclib treatment.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of therapy (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 43 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by metastatic status *before* Palbociclib treatment.

	Metastatic status	
Variable	**De novo**	**Recurrent**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of therapy (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 44 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by metastatic site *before* Palbociclib treatment.

	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)
Duration of therapy (days)		
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)

Table Shell 45 - Descriptive summary table of therapies of the advanced/metastatic BC patients (stages IIIb-IV) by age group *before* Palbociclib treatment.

	Age		
Variable	**<55 years**	**55-64 years**	**≥65 years**
Number of patients who received adjuvant therapies before Palbociclib treatment	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)
-MBC chemotherapy	XX (xx%)	XX (xx%)	XX (xx%)
-MBC hormonal therapy (other than Palbociclib combination)	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Duration of therapy (days)			
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 46 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					

Table Shell 46 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.

N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x

Table Shell 46 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.

Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)

Table Shell 46 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.

Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 46 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment.

	(xx%)				
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 47.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus letrozole/aromatase inhibitor.

	Palbociclib plus letrozole/aromatase inhibitor				
	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x

Table Shell 47.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus letrozole/aromatase inhibitor.

Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 47.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus letrozole/aromatase inhibitor.

Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:
Table Shell 47.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by combination. Palbociclib plus fulvestrant.

Table Shell 48.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. First line.

	1st				
	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 48.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. First line.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x

Table Shell 48.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. First line.

Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:
Table Shell 48.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by line of treatment. Second line.

Table Shell 49.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Egypt.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 49.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Egypt.

Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 49.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Egypt.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:

Table Shell 49.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Jordan.
Table Shell 49.3 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Lebanon.
Table Shell 49.4 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Kingdom of Saudi Arabia.
Table Shell 49.5 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Qatar.
Table Shell 49.6 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. Morocco.
Table Shell 49.7 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by country. United Arab Emirates.

Table Shell 50.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Premenopausal.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 50.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Premenopausal.

Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 50.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Premenopausal.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:

Table Shell 50.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by menopausal status. Postmenopausal.

Table Shell 51.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. De novo.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 51.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. De novo.

Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 51.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. De novo.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:

Table Shell 51.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic status. Recurrent.

Table Shell 52.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Visceral.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 52.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Visceral.

Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 52.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Visceral.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:

Table Shell 52.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by metastatic site. Non-visceral.

Table Shell 53.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group <55 years.

	12 months	18 months	24 months	30 months	36 months
Total number of patients	Xx	Xx	Xx	Xx	Xx
Global health status [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Functional scales					
Physical functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Role functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Emotional functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Cognitive functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)

Table Shell 53.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group <55 years.

Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Social functioning [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Symptom scales					
Fatigue [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Nausea or vomiting [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Pain [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Dyspnoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table Shell 53.1 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group <55 years.

Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Insomnia [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Appetite loss [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Constipation [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Diarrhoea [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Financial difficulties [score]					
N	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q1, median, Q3	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x	xx.x, xx.x, xx.x
Min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

The same format will be used to:

Table Shell 53.2 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group 55-64 years.
Table Shell 53.3 - Descriptive summary table of quality of life of the patients receiving Palbociclib combination treatment by age group. (Age is defined at the treatment initiation). Age group ≥65 years.

Table Shell 54 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients.

Variable	Summary statistics
Time to response (TTR)	
N at risk at the beginning	XX
N with event (response)	XX (xx%)
N censored	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)
Min, max	XX.x, xx.,x
Missing	XX (xx%)
Time to progression (TTP)	
N at risk at the beginning	XX
N with event (disease progression)	XX (xx%)
N censored	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)
Min, max	XX.x, xx.,x
Missing	XX (xx%)
Progression free survival (PFS)	
N at risk at the beginning	XX
N with event (disease progression)	XX (xx%)
N censored	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)
Min, max	XX.x, xx.,x
Missing	XX (xx%)

Table Shell 55 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by treatment combination.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Time to response (TTR)		
N at risk at the beginning	XX	XX
N with event (response)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Time to progression (TTP)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Progression free survival (PFS)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)

Table Shell 56 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by line of therapy.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Time to response (TTR)		
N at risk at the beginning	XX	XX
N with event (response)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Time to progression (TTP)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Progression free survival (PFS)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)

Table Shell 57 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by country.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Time to response (TTR)							
N at risk at the beginning	XX	XX	XX	XX	XX	XX	XX
N with event (response)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Time to progression (TTP)							
N at risk at the beginning	XX	XX	XX	XX	XX	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 57 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by country.

Progression free survival (PFS)							
N at risk at the beginning	XX	XX	XX	XX	XX	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 58 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by menopausal status.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Time to response (TTR)		
N at risk at the beginning	XX	XX
N with event (response)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Time to progression (TTP)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Progression free survival (PFS)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)

Table Shell 59 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by metastatic status.

	Metastatic status	
Variable	**De novo**	**Recurrent**
Time to response (TTR)		
N at risk at the beginning	XX	XX
N with event (response)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Time to progression (TTP)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Progression free survival (PFS)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)

Table Shell 60 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by metastatic site.

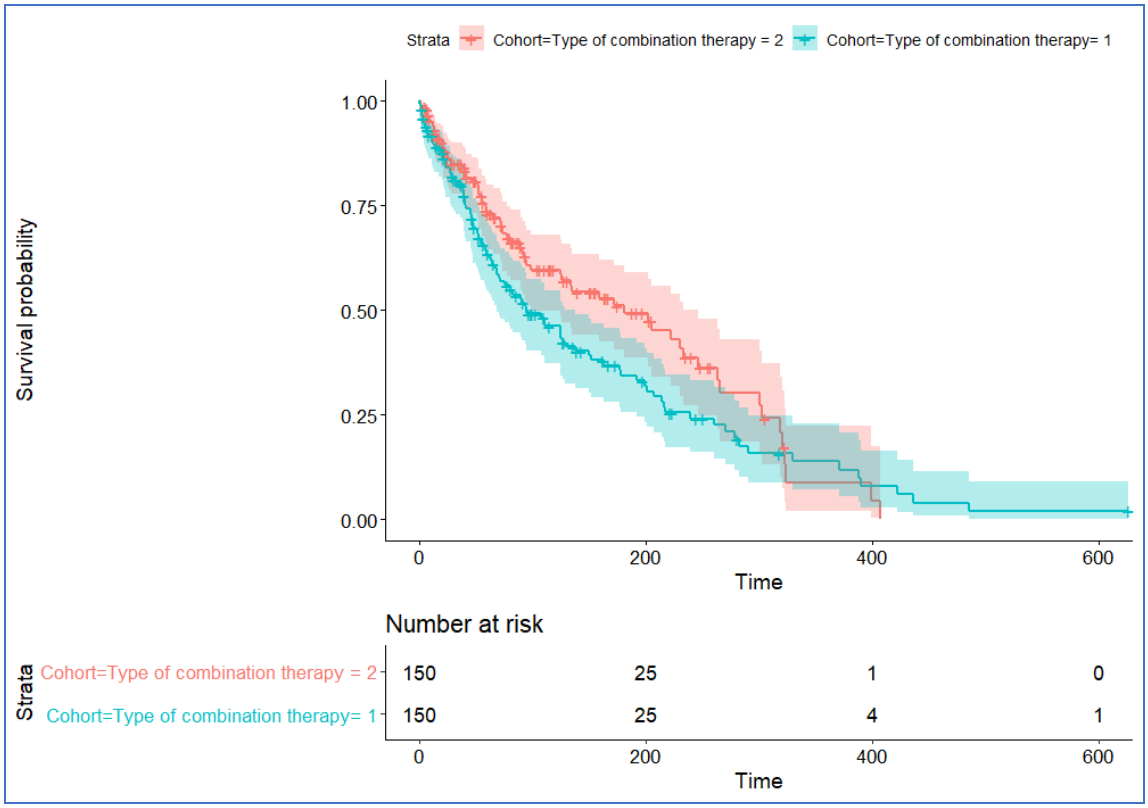
	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Time to response (TTR)		
N at risk at the beginning	XX	XX
N with event (response)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Time to progression (TTP)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)
Progression free survival (PFS)		
N at risk at the beginning	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)

Table Shell 61 - Descriptive summary table of the time to response, progression and progression free survival in Palbociclib treatment patients by age group.

	Age group		
Variable	**<55 years**	**55-64 years**	**≥65 years**
Time to response (TTR)			
N at risk at the beginning	XX	XX	XX
N with event (response)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Time to progression (TTP)			
N at risk at the beginning	XX	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)
Progression free survival (PFS)			
N at risk at the beginning	XX	XX	XX
N with event (disease progression)	XX (xx%)	XX (xx%)	XX (xx%)
N censored	XX (xx%)	XX (xx%)	XX (xx%)
Q1 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Q3 (95% CI)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Min, max	XX.x, xx.,x	XX.x, xx.,x	XX.x, xx.,x
Missing	XX (xx%)	XX (xx%)	XX (xx%)

Figure Shell 1 - Kaplan Meier plot to describe time to response by type of combination therapy.

Figure 2. Kaplan Meier plot to describe time to response by type of combination therapy.



The same format will be used to:

Figure Shell 2 - Kaplan Meier plot to describe time to progression by type of combination therapy.

Table Shell 62 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib.

Variable	Summary statistic
Number of patients who received adjuvant therapies after Palbociclib treatment	XX
Systemic therapy	XX (xx%)
Radiotherapy	XX (xx%)
Surgery	XX (xx%)
Other	XX (xx%)
Unknown	XX (xx%)
Missing	XX (xx%)

Table Shell 63 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by combination of treatments.

	Combination therapy	
Variable	**Palbociclib plus letrozole/aromatase inhibitor**	**Palbociclib plus fulvestrant**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 64 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by line of treatment.

	Line of endocrine therapy	
Variable	**1st**	**2nd**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 65 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by country.

	Country						
Variable	**Egypt**	**Jordan**	**Lebanon**	**KSA**	**Qatar**	**Morocco**	**UAE**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX	XX	XX	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)	XX (xx%)

Table Shell 66 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by menopausal status.

	Menopausal status	
Variable	**Premenopausal**	**Postmenopausal**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 67 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by metastatic status.

	Metastatic status	
Variable	**De novo**	**Recurrent**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 68 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by metastatic site.

	Metastatic site	
Variable	**Visceral**	**Non-visceral**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)

Table Shell 69 - Descriptive summary table of the first immediate subsequent treatment used following end of treatment with Palbociclib by age group.

	Age group		
Variable	**<55 years**	**55-64 years**	**≥65 years**
Number of patients who received adjuvant therapies after Palbociclib treatment	XX	XX	XX
Systemic therapy	XX (xx%)	XX (xx%)	XX (xx%)
Radiotherapy	XX (xx%)	XX (xx%)	XX (xx%)
Surgery	XX (xx%)	XX (xx%)	XX (xx%)
Other	XX (xx%)	XX (xx%)	XX (xx%)
Unknown	XX (xx%)	XX (xx%)	XX (xx%)
Missing	XX (xx%)	XX (xx%)	XX (xx%)

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