

Communications toolkit

for discussing risk of recurrence with HR+/HER2- early breast cancer patients

HCP guidance document

This Communication toolkit has been developed to assist healthcare professionals (HCPs) to effectively engage and educate patients with HR+/HER2- early breast cancer on the risk of recurrence, with the aim of helping patients to understand and adhere to their treatment regimen. The Communication toolkit consists of this **HCP guidance document** and two accompanying materials which have been designed for HCPs to use with patients:

- **Understanding your early breast cancer treatment pathway:** A simple guide to treatment steps for HR+/HER2- early breast cancer patients
- **Patient education leaflet:** Understanding risk of recurrence for patients with HR+/HER2- early breast cancer

This document provides some background to the rationale for need to create these two patient-focused materials and includes practical guidance for their use in conversations with patients.

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The HCP-Patient Dialogues Steering Committee

This Communications toolkit was developed in collaboration with an independent multidisciplinary Steering Committee, formed of oncologists, a psycho-oncologist, and patient advocates, some of whom have or are currently living with breast cancer.

The Steering Committee are all committed to supporting improvements in quality of life and clinical outcomes for those living with breast cancer. Their expert insights informed the integral vision upon which this toolkit was developed, and their continued perspectives and feedback enriched and shaped the final materials presented here.

Meet our Steering Committee below:



Anne O'Dea (Chair)

Medical Director, Breast Cancer Survivorship, University of Kansas Cancer Center, Kansas City (US)



Bertha Aguilar

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Nicole Zernik

Honorary President of the French Forum, Europa Donna (France)

Foreword

As a global community of healthcare professionals and patient advocates, we have all professionally and personally experienced the impact breast cancer has on patients and their families. We know that for patients to thrive beyond their breast cancer diagnosis, they need to understand the treatments they are recommended and be supported to act upon the information that we provide them. We recognize that this is an extremely challenging time for patients, and that we as a community must do more to empower them to fully understand their risk of recurrence and support them to live with HR+/HER2- early breast cancer. Our multidisciplinary group was convened to explore enhancement of two-way communication in achieving this goal.

The task of preparing patients for what lies ahead begins at diagnosis. We know how important it is as healthcare professionals to provide information to patients about breast cancer and the treatments for it. We also know as patients how hard it is to focus on the conversation when emotions are clouding your thoughts and making it difficult to listen and process what is happening. As such, it is critical to effectively prepare patients for each treatment step by **setting expectations for their whole treatment pathway during early discussions.**

When patients transition from actively being treated in the healthcare setting to long-term living with breast cancer, there are two key issues that must be addressed:

1. Patients often do not understand that recurrence is possible or what risk of recurrence means
2. Patients often underestimate the importance of their role in reducing risk of recurrence over the long-term

This is underscored by the fact that approximately 45% of patients discontinue adjuvant endocrine therapy before the recommended 5 years of treatment.¹ To help increase patient understanding and motivation, we have explored approaches to effectively communicate the **risk of recurrence and the value of continued adjuvant endocrine therapy in reducing this risk.**

Our efforts to help address these key challenges have culminated in the **Communications Toolkit for Discussing Risk of Recurrence with HR+/HER2- Early Breast Cancer Patients**, which has been designed to be used by healthcare professionals together with their patients. Alongside this HCP Guidance Document, the toolkit contains two materials to be used with patients:

- **Understanding your early breast cancer treatment pathway:** A simple guide to treatment steps for HR+/HER2- early breast cancer patients
- **Patient Education Leaflet:** Understanding risk of recurrence for patients with HR+/HER2- early breast cancer

In our evolving environment, we are constantly adapting the way that we connect with one another across all walks of life. As technology continues to grow and requires change in how we communicate, maximizing the small amount of time that we have during conversations remains crucially important. We sincerely hope that this Toolkit can enhance the dialogue between patients and HCPs, to better educate and support them as they adapt to living with early breast cancer.

The HCP-Patient Dialogues Steering Committee

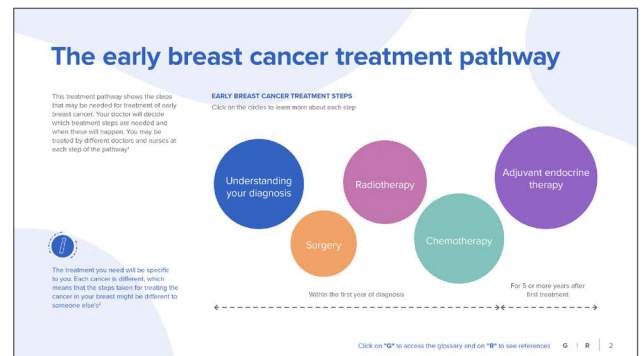
Setting patient expectations

“

Patients feel very out of control, so by discussing what is important to them makes them feel that they have an active role in their treatment, which gives them a sense that they have some level of control over their lives.”

Melissa Bollmann-Jenkins
Community Director at Breastcancer.org, USA

The emotional strain of diagnosis and treatment can leave patients feeling overwhelmed and they struggle to process the information they are given.² This can result in some patients being unaware that their treatment will be a multi-step pathway and they are unpleasantly surprised when more treatment is needed, especially following surgery or at the initiation of adjuvant endocrine therapy.^{2,3} As such, ensuring patients understand their complete treatment pathway is an important first step in discussions about breast cancer management and relies on a careful balance of clear communication, emotional support and education.⁴



Adherence is significantly greater among patients who are prepared for therapy⁵

Understanding their role in the treatment process can significantly improve patients' ability to adhere to treatment.^{5,6} For example, one study found that patients who were prepared for the side effects of adjuvant endocrine therapy were significantly more likely to remain adherent to treatment after 4 years compared with those who were less well informed about side effects (85% vs 62%, $p < 0.0001$).⁶

Understanding your early breast cancer treatment pathway:

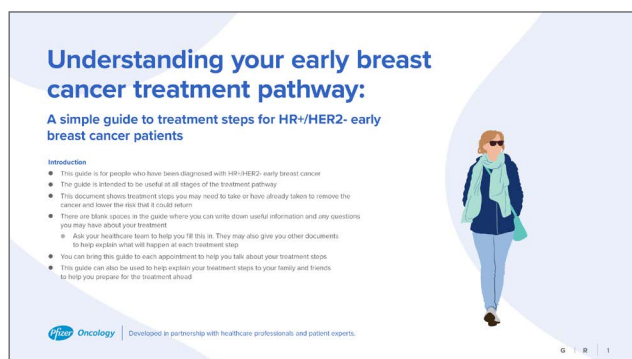
A simple guide to treatment steps for HR+/HER2- early breast cancer patients



Patients need to see the whole picture to be prepared for long-term adjuvant endocrine therapy.”

Bertha Aguilar
MILC Foundation, Mexico

This document has been developed to help set patient expectations early by introducing them to the “whole picture” of their treatment pathway. Following the principles of patient-centered care,⁴ **the treatment pathway is designed to be used by HCPs with their patients when starting discussions about treatment, and can be tailored to the individual’s treatment pathway.**



The pathway:

- Includes general information about each step of treatment in a consistent framework, allowing HCPs to discuss specific information relevant to each patient's course of treatment
- Allows for gradual introduction of information about each step of the treatment pathway to prevent overwhelming patients
- Provides areas where HCPs or patients can capture personalized information
- Can be:
 - Taken home by patients (in an electronic or printed format) as a reference document to inform further research or to explain their treatment pathway to their family and friends
 - Used at each appointment to introduce each new treatment step and allow patients to keep a record of key information discussed



Completing the treatment pathway

This document can be completed as a digital document and printed or emailed directly to patients. Alternatively, it can be printed out and annotated in paper format. Clicking on Print in your PDF reader will automatically generate a version of the document that is printer-friendly.

Guidance for use

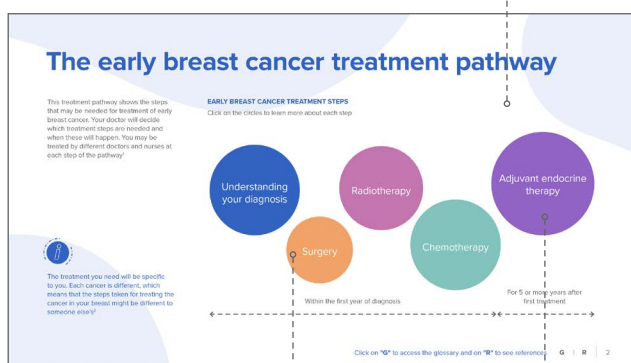


Many patients do not have any idea that they will undergo treatment for more than six months, yet alone over a year.

Luzia Travado

Psycho-Oncologist, Clinician and Researcher at Champalimaud Clinical Centre, Champalimaud Foundation, Portugal

The goal of this page is to introduce patients to the overall treatment pathway before going into detailed discussions about any specific step

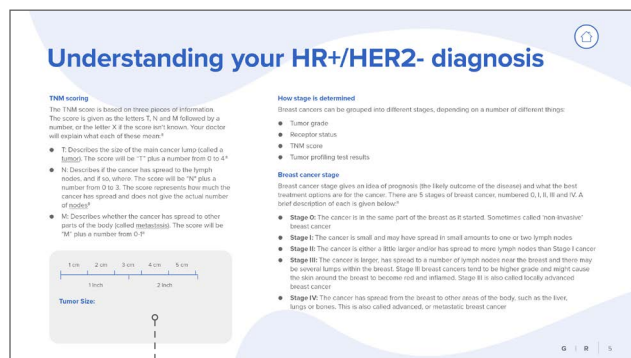


If using a printed version, you may want to number the circles to show patients the order they will be having treatment

If using a digital version, click on a circle to move to the corresponding section of the pathway document

Home Page

The home page can be used to introduce patients to each step of their treatment pathway, with a brief explanation for each step. As each patient's treatment will differ depending on their diagnosis, the treatment steps have been laid out as "stepping-stones" that can be explained to patients in the order that they will take them. This treatment pathway has been designed as a reference document for patients to guide them through their treatment. Encourage patients to bring it with them to each appointment throughout the course of their treatment.



This ruler can be used to help patients visualize the size of the tumor in their breast. Consider relating the size of the tumor to everyday objects, such as a pea, grape, or orange

Understanding your diagnosis

The **Understanding your diagnosis** page can be used with patients to explain simple information about their diagnosis to help them understand why they are being recommended certain treatments.



Where to access the treatment pathway resource

The document can be accessed online using this link: www.breastcancervision.com/educate#nav

A printable version can also be found at the bottom of this document. Please contact your local Pfizer representative to request more information about these resources.

Guidance for use – Continued



Patients often want to know what it is about their cancer that made me recommend a certain treatment.”

Anne O’Dea

Medical Director, Breast Cancer Survivorship,
University of Kansas Cancer Center, Kansas City, USA

Treatment step overview

The document is split into sections according to the treatment steps. Each treatment step has more detailed information about what the patient can expect for that step of the treatment and a patient card that can be filled in with personalized patient treatment information.

The surgery step is shown below as an example.

If using a digital version, click on a stepping stone to move to the relevant part of the document

The appointment card contains spaces to be filled in with practical information for patients

Simple patient-friendly information is provided to help introduce patients to the treatment step

Encourage patients to use this card at home to write down any questions they might have for you



Patient education leaflet: Understanding risk of recurrence for patients with HR+/HER2-early breast cancer

The **patient leaflet** can be used to support discussions around the Adjuvant Endocrine Therapy step. The leaflet can be used to introduce recurrence and the risk of recurrence to patients to help them understand the need for adjuvant endocrine therapy.

Discussing risk of recurrence and the role of adjuvant endocrine therapy in HR+/HER2- eBC



The most challenging thing about discussing risk of recurrence is that you are uncertain about prognosis and who will recur. This uncertainty makes it extremely difficult to give patients a clear picture – the only option is to be honest with them.”

Frederik Marmé

Professor of Gynecology, University of Heidelberg, Germany

The knowledge gap between patients' understanding of medical science and medical terminology such as the complex concepts of risk of recurrence, can pose a substantial barrier to patient understanding and acceptance of adjuvant endocrine therapy.^{7,8} Patients often rely on their healthcare team to bridge this knowledge gap and provide information in ways that they can understand.² However, this can be a challenge as each patient has individualized communication needs that dictate the optimal approach to conversations.⁸

The challenges of conveying information in ways that patients can understand are compounded by the emotional context of the conversation.² As recurrence cannot be predicted with absolute certainty, there is an inherent challenge when communicating risk to patients, who primarily seek reassurance about their future.⁹ The need to balance hope with honesty adds a further layer of complexity to discussions surrounding risk of recurrence.⁷

Many recommendations for enhancing communication with patients and explaining complex risk data exist within the scientific literature.⁷⁻¹⁰ This section of the Communications Toolkit and the accompanying **Patient education leaflet: Understanding risk of recurrence for patients with HR+/HER2- early breast cancer** resource have been developed using these behavioral science principles to facilitate effective communication about risk of recurrence.



Communication principles^{8,9}

- **Use simple language:** Use of medical terminology is confusing for patients and hinders their ability to understand information. Minimizing the use of technical terms, and ensuring that those that are required are defined and given context, can help patients to understand and participate in conversations
- **Relate to the patient:** Take time to understand the patient's medical knowledge of breast cancer, their experience with breast cancer through friends and family, their beliefs, biases and misconceptions. This will allow linking of information directly to the patient which can help them to process and retain important details
- **Break up the monologue:** Patients can find it difficult to process multiple ideas or pieces of information when presented to them in a single block of speech. Inviting patients to speak breaks up the conversation and makes it easier for patients to understand the information they are being given. Note that many patients are unwilling to ask clarifying questions, especially those with low literacy. As such, proactively checking for understanding or asking patients to explain back what they have been told can be good methods for improving engagement

Patient education leaflet:

Understanding risk of recurrence for patients with HR+/HER2- early breast cancer

The **patient leaflet** provides a framework for introducing the concept of recurrence, the risk of recurrence without adjuvant endocrine therapy, and the role patients can play in managing risk.

This material:

- Uses behavioral science principles to support patient understanding
- Contains patient-friendly visuals and language to facilitate discussions
- Can be given to patients to take home (in an electronic or printed format) as a reference document for them or to help discussions with their loved ones

This section of the Communications Toolkit also contains sample phrases that could be useful for discussions with patients.

Understanding risk of recurrence for patients with HR+/HER2- early breast cancer

WHAT IS RECURRENCE?
It is possible for breast cancer to return after initial treatment, either in the breast or somewhere else in the body. If it does this it is called a recurrence.¹

There are several types of recurrence:

- LOCAL RECURRENCE**
Is when the cancer comes back to the same location it was originally diagnosed?²
- REGIONAL RECURRENCE**
Is when the cancer spreads to nearby tissue or lymph nodes?²
- DISTANT RECURRENCE**
Is also known as metastatic, advanced or stage IV breast cancer. This is when cancer cells have spread from the breast to other areas of the body, such as the lymph nodes, bone, lung, or bowel.²

WHAT DOES EACH RECURRENCE MEAN?
If the breast cancer does return, treatment may depend on the type of recurrence.³

- 1. Treatment for local recurrence can depend on a number of factors including what therapies you previously received, when and where the recurrence has occurred.⁴ Treatment may include surgery, radiotherapy, chemotherapy and hormonal therapy.⁵
- 2. Because the cancer has spread, the primary treatment for a regional recurrence is systemic therapy such as chemotherapy, which treats the whole body.⁶ Treatment may also include surgery and/or radiotherapy.⁷
- 3. There are treatments for metastatic breast cancer that can shrink the cancer or slow its progress.⁸ Treatment may include chemotherapy, endocrine therapy, targeted therapy or less commonly surgery.⁹

For more information on recurrence and adjuvant endocrine therapy please refer to the **Understanding your early breast cancer treatment pathway document**.

WHAT IS MY RISK OF RECURRENCE?

For at least 10 years after treatment for HR+/HER2- early breast cancer, there is a risk that breast cancer may return.¹ This risk of recurrence is highest in the first 5 years following breast cancer treatment.²

Each recurrence with HR+/HER2- early breast cancer has a different risk of recurrence based on a number of factors.³

Our treatment goal is to reduce the risk of recurrence as much as we can.

HOW CAN I MANAGE AND REDUCE MY RISK OF RECURRENCE?

There are things you can do to help reduce your risk:⁴

1. Be sure to complete your doctor's advice on how to manage your treatment and possible side effects.⁵
2. Consider these lifestyle choices:⁶
 - Maintain a healthy weight.
 - Exercise regularly.
 - Choose a healthy diet.
 - Limit alcohol consumption.
3. CONTINUE GOOD BREAST AWARENESS:⁷
 - Know what is normal for you.
 - Know what changes to look and feel for in your body.
 - Regularly check the top and back of your breasts.
 - Report any changes to your doctor.
 - Take your mammogram and ultrasound tests as often as they suggest.

TAKING ADJUVANT ENDOCRINE THERAPY FOR 5 YEARS CAN REDUCE THE RISK OF RECURRENCE BY AT LEAST HALF.⁸

Combined evidence from multiple clinical trials shows:

- Without endocrine therapy for 5 years: 50-65% risk of recurrence.
- With adjuvant endocrine therapy for 5 years: 25-35% risk of recurrence.

Relative reduction in risk by 50-65% with adjuvant endocrine therapy for at least 5 years.

The risk of recurrence also stays lower over the long term for people who complete at least 5 years of adjuvant endocrine therapy.⁹

While doctors do not know who will recur, they can estimate your risk of recurrence. Your doctor may use a specific tool to help estimate your risk of recurrence.

Pfizer Oncology

Where to access the Patient Education Leaflet

The patient education leaflet: resource can be accessed online using this link: www.breastcancervision.com/educate#nav

A printable version can also be found at the bottom of this document. Please contact your local Pfizer representative to request more information about these resources.

Patient education leaflet:

Understanding risk of recurrence in HR+/HER2- early breast cancer – Continued



Life has to be continued and the treatment has to be integrated into the patient's life, not to stop their life. It's important for the doctor to recognize this when communicating with their patients."

Daniel Serin

Former Department head of Senology (radiotherapy and medical oncology), St. Catherine's Clinic, France

Communication is considered to be the most important “non-specific” element of medical treatment.¹⁰ Each patient has their own needs, concerns, biases, fears, experience with the disease from friends and family and level of understanding, and it is beneficial to tailor conversations to the individual wherever possible.² The framework below provides 4 suggested communication points that can be used to structure conversations with patients about adjuvant endocrine therapy and tailored to their individual needs:

A framework for discussing risk of recurrence

Communication goals	Acknowledge the patient's experience so far	Introduce recurrence and the risk of recurrence	Position adjuvant endocrine therapy as the way to manage risk	Instill confidence for self-management
Rationale for step	People are more willing to take on an additional burden if their efforts to date are recognized ⁷	Understanding risk of recurrence helps patients to take ownership of their care and sets up the need for adjuvant endocrine therapy ⁶	Describing what adjuvant endocrine therapy does and how it reduces risk of recurrence can help patients to feel more active and in control of cancer: ^{5,6} Adjuvant endocrine therapy thereby becomes a tool of hope to combat uncertainty	Patients often feel uncertain about managing adjuvant endocrine therapy: as well as giving information, empowering patients to make more active decisions can improve long-term adherence ^{5,6}

Guidance for use

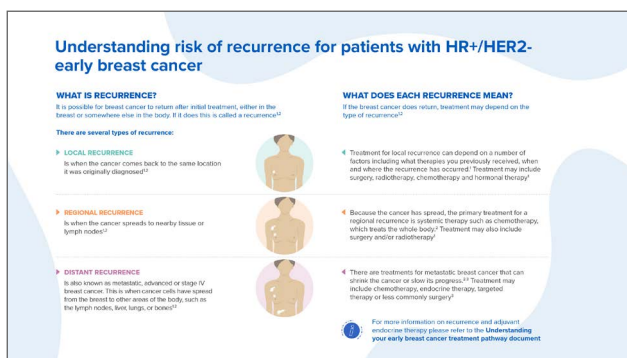


It's important to ask patients how they are feeling and help them acknowledge what they are going through. We need to give them the chance to think about their emotions and let them know it's ok to feel stressed. We need to support both the rational and emotional side to help patients succeed."

Rosanna D'Antona
President of Europa Donna, Italy

Introducing recurrence

The first page of the leaflet can be used to introduce patients to the concept of recurrence and what it means if the disease recurs. Some patients will want to know all of the information at the beginning of their treatment, while others will prefer to hear it later. Setting patient expectations about recurrence early could prevent challenging conversations later in treatment, though it is recognized that the the appropriate time for this discussion will vary from patient to patient.



Sample phrases

"It is possible that the cancer will come back, either in your breast or a different part of your body. It could happen in 2 years, in 10 years, or it might never happen. If you look at the left hand side of the page, you can see the different ways that it could come back."

"If the cancer does come back, then where and how it comes back has a big impact on what we can do to treat it. If the cancer spreads to other areas of your body it is called metastatic breast cancer. If this happens it will impact your future health and survival - but there are treatments that can be used to slow it down."

Patient perspectives



When speaking about recurrence, consider speaking about "the cancer" rather than "your cancer". When patients hear "your cancer" they think "it's your cancer, that means it's your fault". We want to do what we can to avoid putting this thought in the patient's mind."

Nicole Zernik
Honorary President of the French Forum, Europa Donna, France



Understanding your early breast cancer treatment pathway: A simple guide to treatment steps for HR+/HER2- early breast cancer patients

The patient education leaflet has been designed to be used together with the adjuvant endocrine therapy step of the **treatment pathway resource**. The corresponding section of the pathway document contains space to give patients tailored, practical advice about managing their adjuvant endocrine therapy

Describing risk of recurrence and how to manage risk of recurrence



Some patients want all of the statistics, while others don't want any. Patients should be asked what information they need to make their decisions."

*Eva Schumacher-Wulf
Chief Editor of Mamma Mia!, Germany*

Describing risk of recurrence and how to manage risk of recurrence

The second page shows patients the risk of recurrence if they do not take any therapy. The aim of this information is to demonstrate to patients the benefits of taking adjuvant endocrine therapy in reducing this risk and why it is so important that they do everything they can to adhere to their medication schedule. The right-hand side of the page shows patients what they can do to actively reduce their risk, supporting physicians to transfer responsibility of care to their patients by explaining how lifestyle changes can continue the work of treating early breast cancer.

Sample phrases:

"Breast cancer is fed by hormones, which is why we are giving you medicine called endocrine therapy to reduce the amount of hormones your body makes. By reducing the amount of hormones your body makes we starve any leftover cancer cells – if there are any – so they are less likely to grow. But as soon as you stop taking the medicine the hormones come back, which means there's a risk that any leftover breast cancer cells can start growing again. That's why it's so important to take the pills every day, to keep this risk as low as possible."



Communication of risk to patients⁹

- **Present risks as frequencies:** For patients with lower numeracy, phrasing risk as "N out of 100" is easier to understand than "N%"
- **Establish the reference population clearly:** To understand the information being given, patients need to know the context of the statistics. For example: "N out of 100 women with diagnoses like yours who took the drug for 5 years"
- **Express relative risks as incremental changes:** It can be easier for patients to understand the impact of an intervention if the change in risk is presented as "N fewer people out of 100" than an "N% reduction". An additional advantage of using a fixed denominator to compare risks is that it helps patients to visualize the size of the effect in absolute terms
- **Avoid using descriptive words without accompanying numbers:** Describing risk as "high" or "low" can be unsatisfying for patients and may not convey the necessary meaning. However, use of qualifying terms alongside numbers can help patients to interpret the information they are given

Describing risk of recurrence and how to manage risk of recurrence – Continued

This visual shows the relative risk reduction with tamoxifen or AIs taken from a meta-analysis of clinical studies. If you have more specific data for a patient, especially if an absolute risk can be provided, that could be beneficial for them to see

Sample phrases:

“We can't know for certain if the cancer will come back or not. We can estimate how likely we think that is - whether you have a high risk, a low risk, or something in between. Based on what we know about the tumor that was in your breast, I would say the risk of recurrence is about [N] out of 100, which we would think of as a [high/low] risk”

“The best way we have to lower the risk that the cancer comes back is called endocrine therapy. We know that this treatment can reduce your risk by half, maybe even by two-thirds. If you look at this diagram on the left, you can see the difference - the risk with endocrine therapy is much smaller than the risk without”

“Beating cancer is a team effort: my job is to get the cancer out of your body, your job is to do everything you can to stop it from coming back and it's time for you to take over now. Let's look at the right hand side of the page to see some ways you can do that”

“Taking endocrine therapy might take some getting used to. You've been through so much already and done so well, don't waste that effort by not taking your endocrine therapy. If you need help managing the side effects call this office, as there are things we can do.”

References

1. Moon Z, et al. *Patient Pref Adherence*. 2017;11:305–22
2. Pfizer Data on File: eBC Patient Journey Global Report, March 2020.
3. Santana MJ, et al. *Health Expect*. 2018;21:429–40.
4. Kahn KL, et al. *Med Care*. 2007;45:431–9.
5. Hibbard J and Gilbert H. Supporting people to manage their health: https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/supporting-people-manage-health-patient-activation-may14.pdf. Accessed: July 2020.
6. Halbach SM, et al. *Patient Edu Counsel*. 2016;99(9):1511–8.
7. Shim E-J, et al. *BMC Women's Health*. 2016;16:65.
8. Roter DL. *Nurs Outlook*. 2011;59:79–84.
9. Spiegelhalter D. *Annu Rev Stat Appl*. 2017;4:31–60.
10. McCabe R and Healey PGT. *Top Cogn Sci*. 2018;10(2):209–24.
11. Murphy CC, et al. *Breast Cancer Res Treat*. 2012;134(2):459–78.