ISRCTN17281696 https://doi.org/10.1186/ISRCTN17281696

# Impact of abemaciclib on patients' roles and responsibilities

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|---|---|---|
| **Submission date**<br>16/06/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>16/06/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/04/2025 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-the-effect-abemaciclib-has-on-the-daily-life-of-people-who-take-it-impactor

**Study website**
https://shore-c.sussex.ac.uk/impactor.html

## Contact information

**Type(s)**
Public

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Scientific

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**
279088

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
IRAS 279088

# Study information

**Scientific Title**
Impact of abemaciclib on patients' roles and responsibilities: a multi-centre observational quality of life study with nested qualitative interview study

**Acronym**
IMPACTOR

**Study objectives**
The principal objective of the study is to investigate breast cancer patients’ experiences of abemaciclib treatment outside of a clinical trial setting. The primary aim is to chart any changes in their quality of life in the first 6 months of treatment, and the impact of this treatment on patients’ ability to perform their normal roles and responsibilities. The researchers will conduct semi-structured interviews with a subset of the participants to achieve a more in-depth, richer understanding of their experiences of treatment, both positive and negative, side effects, and ways in which their day to day activities have been affected. One of the side effects more

commonly associated with abemaciclib is diarrhoea. The researchers will ask participants to record their experiences of diarrhoea, and the measures they took to manage it, using a diarrhoea diary. This will enable them to assess whether treatment-related diarrhoea is manageable and decreases over time, as current trial data suggests.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 17/04/2020, North East Tyne and Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 972 2496; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0101

## Study design
Multi-centre observational quality of life study with nested qualitative interview study

## Primary study design
Observational

## Secondary study design
Longitudinal study

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## Participant information sheet
The participant information sheet will be made available at https://shore-c.sussex.ac.uk /impactor.html

## Health condition(s) or problem(s) studied
Quality of life of women receiving abemaciclib for breast cancer

## Interventions
This is a quality of life observational study. Participants will complete validated quality of life measures at baseline, 1, 3 and 6 months and a weekly diarrhoea management diary. A subset of the participants will take part in a semi-structured qualitative interview study after 3 months.

## Intervention Type
Drug

## Phase
Phase III/IV

## Drug/device/biological/vaccine name(s)
Abemaciclib

## Primary outcome measure

1. Quality of life assessed using the Functional Assessment of Cancer Treatment general scale (FACT-G) with diarrhoea (DS) and endocrine symptom (ES) subscale at baseline, 1, 3 and 6 months
2. Role function assessed using the Patient Roles and Responsibilities Scale (PRRS) at baseline, 1, 3 and 6 months

### Secondary outcome measures
1. Qualitative evidence of patients' experience of treatment collected via a semi-structured interview at 3 months
2. Treatment-related diarrhoea measured using the Diarrhoea Management Diary (DMD) completed weekly for 6 months
3. Strategies employed to counter diarrhoea, including non-adherence to treatment, measured using the DMD completed weekly for 6 months

### Overall study start date
24/04/2019

### Completion date
08/03/2023

## Eligibility

### Key inclusion criteria
1. Patients with locally advanced or metastatic breast cancer who are prescribed either:
1.1. Abemaciclib in combination with fulvestrant (for women who have relapsed after endocrine therapy), or
1.2. Abemaciclib in combination with an aromatase inhibitor (for women who have not previously been treated)
2. Patients who are able to give fully informed consent and are able to read and speak in English
3. Patients who are 18 years old and over

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
150

### Total final enrolment
46

### Key exclusion criteria

1. Patients with cancers other than breast or receiving treatments other than abemaciclib
2. Patients who are not able to provide fully informed consent or who are not able to read and speak English
3. Patients under 18 years of age
4. Patients who are currently inpatients or who are too distressed to participate

### Date of first enrolment
01/09/2020

### Date of final enrolment
31/12/2022

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

### Study participating centre
**Brighton and Sussex University Hospitals NHS Trust**
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

### Study participating centre
**The Clatterbridge Cancer Centre NHS Foundation Trust**
Clatterbridge Road
Bebington
Wirral
United Kingdom
CH63 4JY

### Study participating centre
**The Royal Marsden NHS Foundation Trust**
Fulham Road
London
United Kingdom
SW3 6JJ

**Study participating centre**
**The Christie NHS Foundation Trust**
Wilmslow Road
Manchester
United Kingdom
M20 4BX

**Study participating centre**
**Airedale General Hospital**
Airdale NHS Foundation Trust
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

**Study participating centre**
**Kent and Canterbury Hospital**
East Kent Hospitals University NHS Foundation Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

**Study participating centre**
**The Royal Bournemouth Hospital**
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

**Study participating centre**
**Royal Surrey NHS Foundation Trust**
Egerton Road
Guildford
United Kingdom
GU2 7XX

### Study participating centre
**Lothian Health Board**
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

### Study participating centre
**Yeovil District Hospital NHS Foundation Trust**
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

## Sponsor information

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University of Sussex

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### Sponsor type
University/education

### Website
http://www.sussex.ac.uk/

### ROR
https://ror.org/00ayhx656

## Funder(s)

### Funder type
Industry

### Funder Name
Eli Lilly and Company

### Alternative Name(s)
Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co

### Funding Body Type
Government organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
United States of America

## Results and Publications

### Publication and dissemination plan
Current publication and dissemination plan as of 28/04/2025:
The researchers published the findings from this research in a high-impact peer-reviewed journal (Supportive Care of Cancer, April 2025; please see https://doi.org/10.1007/s00520-025-09440-7 and https://doi.org/10.1007/s00520-025-09444-3). A plain language summary of the findings will be sent to all study participants and published on the study website: https://shore-c.sussex.ac.uk/impactor.html. Additional documents are not currently available.

Previous publication and dissemination plan:
The researchers plan to publish the findings from this research in a high-impact peer-reviewed journal. A plain language summary of the findings will be sent to all study participants and published on the study website: https://shore-c.sussex.ac.uk/impactor.html. Additional documents are not currently available.

### Intention to publish date
26/04/2025

### Individual participant data (IPD) sharing plan
The anonymised datasets generated during and/or analysed during the current study will be available upon (reasonable) request after publication of the findings from Sussex Health Outcomes Research and Education in Cancer (adminshore-c@sussex.ac.uk).

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 26/07/2023 | No | No |
| Other publications | Qualitative analysis | 26/04/2025 | 28/04/2025 | Yes | No |

| | | | | |
|---|---|---|---|---|
| Results article | 26/04/2025 | 28/04/2025 | Yes | No |