

# Chart review assessing venetoclax treatment outcomes for AML - AML Real World Evidence Initiative (ARC)

<b>Submission date</b> 29/09/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study investigates venetoclax use in the treatment of acute myeloid leukaemia (AML) in Great Britain (GB). Venetoclax is a treatment for AML that was recently approved in GB. Venetoclax is given as a combination with other medications, with different combinations available, for AML patients who have never received a previous treatment and who cannot receive intensive chemotherapy. Clinical trials have shown venetoclax works well compared to other medications, but currently, there is limited information on how it works in everyday clinics. This study will help provide information on how this treatment is used in the real world. The study aims to describe how well this treatment works, including survival, the time the treatment continues to work for the patient, how often patients have to visit their doctor or hospital when taking the treatment, and how different treatment combinations are used in GB overall.

### Who can participate?

Adult patients with AML aged 18 years or older at AML diagnosis who are taking a venetoclax combination treatment (for at least 28 days) because they cannot receive chemotherapy

### What does the study involve?

This multi-centre study will be run across eight to nine sites. Doctors will review medical records for AML patients treated with different venetoclax combinations and enter patient information into an online form. Patients themselves are not directly involved, and there will be no changes to their care.

Patient demographics (e.g. age, sex), clinical characteristics (e.g. other diseases or medical conditions a patient has at the time), treatment patterns (e.g. when the treatment was taken and how much was taken), effectiveness (how well the medicine works including survival), and how often patients visit their doctor or hospital whilst taking the treatment will be collected. Information that cannot reveal the patient's identity will be collected, and this will be anonymised in the final database.

What are the possible benefits and risks of participating?

Patients will not directly participate in this study but their medical records will be reviewed by hospital staff, who will identify which records are eligible for the study. Waiver for Informed Consent has been granted by HRA, as no personal or sensitive data is collected as part of this research. Any medical record data collected will be pseudonymised.

Where is the study run from?

AbbVie (UK)

When is the study starting and how long is it expected to run for?

November 2022 to May 2024

Who is funding the study?

AbbVie Inc (US)

Who is the main contact?

Abbvie UK Medical Information, ukmedinfo@abbvie.com

## Contact information

### Type(s)

Principal Investigator

### Contact name

Prof Paresh Vyas

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### Type(s)

Public, Scientific

### Contact name

Dr Abbvie UK Medical Information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
326050

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
H18.Oncology12-SR1812, IRAS 326050, CPMS 55421

## Study information

**Scientific Title**  
A centre-based chart review study to assess treatment outcomes of venetoclax for the treatment of acute myeloid leukemia (AML)

**Study objectives**  
To describe the real world outcomes and treatment patterns in newly diagnosed AML patients who are ineligible for intensive chemotherapy receiving venetoclax-based combinations in Great Britain

**Ethics approval required**  
Ethics approval required

**Ethics approval(s)**  
1. Approved 13/04/2023, HRA (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)207 104 8000; [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)), ref: 23/PR/0342  
2. Approved 13/04/2023, Health and Care Research Wales (HCRW) (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)207 104 8000; HCRW. [approvals@wales.nhs.uk](mailto:approvals@wales.nhs.uk)), ref: 23/PR/0342

**Study design**  
Non-interventional retrospective multicentre cohort study

**Primary study design**  
Observational

**Secondary study design**  
Retrospective chart review

**Study setting(s)**  
Medical and other records

**Study type(s)**

Other, Efficacy

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Acute myeloid leukaemia

**Interventions**

Patients receiving venetoclax combination therapies for their acute myeloid leukaemia (AML) will be eligible for inclusion in the study, as per the inclusion criteria. This study is retrospective in design and so patients will not be consented to participate, instead under the NHS guidance, their data will be accessed by their direct care team only. Once a patient has been identified for inclusion, they will be enrolled and their data will be accessed and entered into the electronic data capture (EDC) system. As the study is retrospective, the patients will not be followed up for any prespecified amount of time. The observation period for the study is from diagnosis of AML up to the most recently available data at the time of data entry. Their data will simply be entered into the EDC and once all data has been entered for each patient, and all data queries have been answered, the study will close.

**Intervention Type**

Drug

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Venetoclax

**Primary outcome measure**

1. Overall survival (OS) will be measured as the number of days between the initiation of the studied line of therapy (i.e., venetoclax-based regimen) until death (event) or end of follow-up (censoring).
2. Event-free survival (EFS) will be measured as the number of days between initiating the studied line of therapy and disease progression, refractory disease, or death; both outcomes will be censored at the end of follow-up.

**Secondary outcome measures**

1. AML healthcare resource utilisation (HRU) measured using data entered into the electronic data capture (EDC) system at one timepoint
2. AML treatment patterns for the venetoclax cohort measured using data entered into the electronic data capture (EDC) system at one timepoint

**Overall study start date**

01/11/2022

**Completion date**

06/05/2024

## Eligibility

**Key inclusion criteria**

1. The patient received a diagnosis for AML, if available, suggested diagnosis codes: ICD-9 205.0x or ICD-10 C92.0x, C92.4x, C92.5x
2. The patient was at least 18 years old at AML diagnosis date
3. The patient was initiated on the studied line of therapy (see Table 1 for the list of eligible treatments included based on NCCN guidelines and clinical input) for previously untreated AML:
  - 3.1. Venetoclax in combination with an HMA (on or after 28th May 2021) or LDAC (on or after 25th February 2022), the date of MHRA approvals of venetoclax (for the treatment of adult patients with newly diagnosed AML who are ineligible for intensive chemotherapy)
4. The patient was treated with the studied line of therapy at least 28 days prior to the date of data collection
5. Information on the patient's treatments, selected (or important) clinical characteristics, and outcomes is available from the start of the studied line of therapy onwards

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

99 Years

**Sex**

Both

**Target number of participants**

150-200

**Total final enrolment**

168

**Key exclusion criteria**

1. The patient received the studied line of therapy as part of a clinical trial
2. The patient received prior lines of therapy for AML
3. The patient has a history of malignancies within 2 years prior to the studied line of therapy, other than AML, and with the exception of:
  - 3.1. Myelodysplastic syndromes (MDS), myeloproliferative neoplasm (MPN) or chronic myelomonocytic leukemia (CMML)
  - 3.2. Adequately treated in situ carcinoma of the cervix uteri or carcinoma in situ of the breast

3.3. Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin  
3.4. Previous malignancy confined and surgically resected (or treated with other modalities) with curative intent

**Date of first enrolment**

31/10/2023

**Date of final enrolment**

08/04/2024

## **Locations**

**Countries of recruitment**

England

United Kingdom

Wales

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

Oxford

United Kingdom

OX3 7LE

**Study participating centre**

**University Hospital Wales, Cardiff**

Cardiff

United Kingdom

CF14 4XW

**Study participating centre**

**St James University Hospital, Leeds**

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**Northwick Park Hospital**

Harrow

United Kingdom

HA1 3UJ

**Study participating centre**  
**Nottingham University Hospital**  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**University Hospitals Birmingham**  
Birmingham  
United Kingdom  
B15 2GW

**Study participating centre**  
**University College London Hospital**  
London  
United Kingdom  
NW1 2BU

**Study participating centre**  
**Queen Alexandra Hospital, Portsmouth**  
Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**  
**Royal Hallamshire Hospital, Sheffield**  
Sheffield  
United Kingdom  
S10 2JF

## **Sponsor information**

**Organisation**  
AbbVie (United Kingdom)

**Sponsor details**  
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**Sponsor type**

Industry

**Website**

<http://www.abbvie.co.uk/>

**ROR**

<https://ror.org/04tnbfn25>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

AbbVie

**Alternative Name(s)**

AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## **Results and Publications**

**Publication and dissemination plan**

Intend to publish the data through conference posters and a manuscript approximately 1 year after the end date of the study

**Intention to publish date**

06/05/2025

**Individual participant data (IPD) sharing plan**

For data privacy reasons, there are no plans to share individual patient level data (IPD). AbbVie will only have access to summary data tables.

**IPD sharing plan summary**

Not expected to be made available