

A data and sample collection study for patients with diffuse large B-cell lymphoma

| | | |
|--|--|--|
| Submission date 09/07/2021 | Recruitment status Stopped | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 16/08/2021 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/04/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Diffuse large B-cell lymphoma (DLBCL) is a cancer of the lymphatic system where B-cells (a type of white blood cell) grow uncontrollably. The standard treatment for DLBCL is a combination of chemotherapy and immunotherapy, referred to as chemo-immunotherapy. Currently, the best results in the treatment of DLBCL is with a chemo-immunotherapy combination called R-CHOP. R-CHOP is not suitable for all patients with DLBCL as one of the drugs can damage the heart. If patients have heart disease or other problems, it may be too risky for them to receive full dose R-CHOP. There have also been some research studies showing that R-CHOP may also be unsuitable for people over the age of 80 years. If this is the case, many patients either receive a reduced dose called mini R-CHOP, or receive one of two alternatives, R-GCVP or R-CEOP. Additionally, some patients are treated with R-CHOP but do not respond or may respond initially before relapsing. For these patients, treatment is not standardised and practice varies between hospitals.

This study aims to bring together data about the diagnosis, management and outcomes of patients with DLBCL who are unsuitable for standard treatment because they are not well enough to tolerate the side effects or because they have not responded or relapsed following initial treatment. In doing so, it will improve research into DLBCL leading to a better understanding of this condition.

Who can participate?

Patients aged 16 years and over who have previously untreated DLBCL (new disease that is unsuitable for full-dose R-CHOP or relapsed/refractory disease, i.e. that has come back or does not respond to treatment)

What does the study involve?

Data will be captured by participating centres at the start of the study, at each cycle of treatment, at the post-treatment visit and for a further 12 months during follow up. Optional consent will be sought from patients in order to collect blood and tissue samples for future research.

What are the possible benefits and risks of participating?

Participants will be informed that they are unlikely to benefit directly. The study won't involve

any extra visits or procedures outside of the standard of care treatment other than optional sample collection. This will involve the minor discomfort associated with blood sampling.

Where is the study run from?

The Clatterbridge Cancer Centre NHS Foundation Trust (UK)

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

May 2019 to September 2024

Who is funding the study?

F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?

Dr Hannah Short

apollo@liverpool.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Hannah Short

Contact details

Trial Manager

Liverpool Clinical Trials Centre

The University of Liverpool

Liverpool

United Kingdom

L69 3BX

+44 (0)151 794 9768

apollo@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

270224

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 48169, IRAS 270224

Study information

Scientific Title

A prospective 'real-world data' registry and sample collection study for patients with diffuse large B-cell lymphoma

Acronym

APOLLO+

Study objectives

This is a descriptive study and there is no a priori hypothesis to be tested. It is anticipated that the results of this study will be used for hypothesis generation to be tested in future studies. Addressing these areas of unmet need is critical to inform future therapeutic strategies and trials.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/04/2021, Wales Research Ethics Committee 5 REC (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF 11 9AB, UK; +44 (0)7787 371748, +44 (0)2920 230457; Wales.REC5@wales.nhs.uk), REC ref: 21/WA/0025

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Diffuse large B-cell lymphoma

Interventions

APOLLO+ is designed to collect prospective demographic and clinical data from patients with DLBCL falling into one of two cohorts:

1. Patients ineligible for first-line treatment with R-CHOP (a maximum of 1,283 patients)
2. Patients with relapsed/refractory DLBCL (256-385 patients)

A maximum of 1,668 patients will be recruited across 81 sites in the UK.

Sample size calculations are based on the incidence and prevalence rates of DLBCL. Considering that the prevalence of DLBCL is approximately 8.5 per 100,000 patients¹⁵ across the UK and that the patients will be sampled across ~81 treatment centres in the UK population, it can be inferred that approximately 770 -1,283 patients will be available for recruitment into cohort A and 256 -385 patients will be available for recruitment into cohort B during study recruitment period (18 months).

After obtaining written, informed consent, data will be captured by participating centres at baseline, at each cycle of treatment, at the post-treatment visit and for a further 12 months during follow up. This data will be entered directly into the study RedCAP database by participating sites. The schedule for data entry is flexible (at least every 6 months).

Optional consent will be sought from patients in order to collect blood and tissue samples for biobanking to promote future translational research. This consent will be monitored at the Liverpool Clinical Trials Centre where NHS numbers and patient names will be stored securely, separate to other study data.

Further optional consent will be sought for enrolment into the Quality of Life sub-study. If patients consent, they will be asked to complete an EQ-5D-5L Quality of Life Questionnaire at baseline and post-treatment in order to assess the impact of treatments on quality of life. Only patients registered prior to treatment start will be eligible for the sub-study.

Analysis will be carried out by the study statistician at the Liverpool Clinical Trials Centre.

Intervention Type

Other

Primary outcome measure

Progression-free survival at 12 months (PFS12), defined as disease progression or recurrence, or death from any cause (defined as days from the date of cohort assignment to event) occurring within 12 months (from the date of cohort assignment) as assessed by the investigator using the revised Lugano response criteria for malignant lymphoma (2016)

Secondary outcome measures

1. Time to next treatment measured as days from the start date of initial treatment to the start day of the next treatment
2. Demographic and clinical characteristics (e.g. age, sex, ethnicity, duration of disease, comorbidities, disease activity/severity, blood results) collected at baseline
3. Investigator-assessed Interim (post-cycle 4) and end of treatment responses as assessed by the investigator using the revised Lugano response criteria for malignant lymphoma (2016)
4. Overall survival (OS) measured as the time from recruitment until death by any cause
5. Relapses following treatment as assessed by the investigator using the revised Lugano response criteria for malignant lymphoma (2016) every 6 months after the end of treatment
6. Treatment pathways, including chemo-immunotherapy, concomitant treatments (including radiotherapy) and salvage therapy, recorded at treatment start and during treatment (cycles 1 to 8)
7. Quality of life measured using the EQ-5D-5L patient-completed questionnaire at baseline and end of treatment
8. Co-morbidity/frailty assessments using echocardiography or nuclear medicine examination (MUGA) pre- and post-treatment

Overall study start date

30/05/2019

Completion date

30/09/2024

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Males and female subjects ≥ 16 years of age at the time of enrolment
2. Ability to understand and sign written informed consent
3. Histologically proven diffuse large B cell non-Hodgkin's lymphoma (DLBCL) according to current World Health Organisation 2016 guidelines that fall into one of two cohorts that will be independently evaluated/reported:
 - 3.1. DLBCL patients with de novo disease unfit for full dose R-CHOP
- OR
- 3.2. DLBCL patients with relapsed/refractory disease
4. Patients fulfilling the above criteria who are on other trials/studies are eligible for recruitment

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 1668; UK Sample Size: 1668

Total final enrolment

0

Key exclusion criteria

Patients commencing index treatments >6 months prior to trial enrolment (Cohorts A or B). In other words, patients can be retrospectively entered (for Cohorts A or B). This exclusion does not apply to prior therapies before the index treatment event for Cohort B.

Date of first enrolment

01/06/2022

Date of final enrolment

31/03/2023

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre**The Clatterbridge Cancer Centre**

Clatterbridge Road

Bebington

United Kingdom

CH63 4JY

Study participating centre**Arrowe Park Hospital**

Wirral University Teaching Hospital NHS Foundation Trust

Arrowe Park Road

Upton

United Kingdom

CH49 5PE

Study participating centre**Airedale General Hospital**

Airedale NHS Foundation Trust

Skipton Road

Steeton

United Kingdom

BD20 6TD

Study participating centre**Bradford Royal Infirmary**

Bradford Teaching Hospitals NHS Foundation Trust

Duckworth Lane

Bradford

United Kingdom

BD9 6RJ

Study participating centre

John Radcliffe Hospital

Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre**Countess of Chester Hospital**

Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre**Derriford Hospital**

University Hospitals Plymouth NHS Trust
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre**NHS Forth Valley**

33 Spittal Street
Stirling
United Kingdom
FK8 1DX

Study participating centre**Colchester Dist General Hospital**

East Suffolk and North Essex NHS Foundation Trust
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre

Ysbyty Gwynedd

Betsi Cadwaladr University LHB
Executive Offices
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre**Gartnavel Royal Hospital**

NHS Greater Glasgow and Clyde
J B Russell House
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre**Lincoln County Hospital**

United Lincolnshire Hospitals NHS Trust
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre**St Thomas' Hospital**

Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre**Colchester Dist General Hospital**

East Suffolk and North Essex NHS Foundation Trust
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre

Watford General Hospital

West Hertfordshire Hospitals Nhs Trust
Trust Offices
Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre

Kent & Canterbury Hospital

East Kent Hospitals University NHS Foundation Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre

Kettering General Hospital

Rothwell Road
Kettering
United Kingdom
NN16 8 UZ

Study participating centre

Leicester Royal Infirmary

University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre

University Hospital Lewisham

Lewisham and Greenwich NHS Trust
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre

Milton Keynes University Hospital

Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre**Musgrove Park Hospital**

Taunton and Somerset NHS Foundation Trust
Taunton
United Kingdom
TA1 5DA

Study participating centre**St Cadoc's Hospital**

Aneurin Bevan University LHB Headquarters
Lodge Road
Caerleon
Newport
United Kingdom
NP18 3XQ

Study participating centre**Norfolk and Norwich University Hospital**

Norfolk and Norwich University Hospitals Nhs Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre**Northwick Park Hospital**

London North West University Healthcare NHS Trust
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre

Queens Medical Centre

Nottingham University Hospitals NHS Trust
Trust Headquarters
Derby Road
Nottingham
United Kingdom
NG7 2 UH

Study participating centre**Hillingdon Hospital**

The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre**Queen Alexandra Hospital**

Portsmouth Hospitals NHS Trust
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre**Queen Elizabeth Hospital**

The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre**NHS Highland**

Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

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

Study participating centre
Amersham Hospital
Buckinghamshire Healthcare NHS Trust
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
Cardiff & Vale University LHB
Woodland House
Maes-Y-Coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Russells Hall Hospital
The Dudley Group NHS Foundation Trust
Pensnett Road
Dudley
United Kingdom
DY1 2 HQ

Study participating centre

St Helier Hospital

Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre**The Royal London Hospital**

Barts Health NHS Trust
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre**Gartnavel Royal Hospital**

NHS Greater Glasgow and Clyde
J B Russell House
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre**St. James's University Hospital**

Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre**Royal Liverpool University Hospital**

Liverpool University Hospitals NHS Foundation Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre

Manchester University NHS Foundation Trust

Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Southmead Hospital

North Bristol NHS Trust
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre

Royal Cornwall Hospital

Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre

Salford Royal

Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre

Northern General Hospital

Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre

Warwick Hospital

South Warwickshire NHS Foundation Trust
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre**Southend University Hospital**

Prittlewell Chase
Westcliff-On-Sea
United Kingdom
SS0 0RY

Study participating centre**St George's Hospital**

St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre**Whiston Hospital**

St Helens and Knowsley Teaching Hospitals NHS Trust
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre**Torbay Hospital**

Torbay and South Devon NHS Foundation Trust
Newton Road
Torquay
United Kingdom
TQ2 7 AA

Study participating centre

Royal Stoke University Hospital

University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-On-Trent
United Kingdom
ST4 6QG

Study participating centre**Southampton General Hospital**

University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre**York Hospital**

York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre**Freeman Hospital**

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre**Victoria Hospital**

Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre

Christie Hospital

The Christie NHS Foundation Trust
550 Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX

Study participating centre**City Hospital**

Sandwell and West Birmingham Hospitals NHS Trust
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre**The Maidstone Hospital**

Maidstone and Tunbridge Wells NHS Trust
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Sponsor information**Organisation**

Clatterbridge Cancer Centre NHS Foundation Trust

Sponsor details

c/o Maria Maguire
Clatterbridge Road
Bebington
Wirral
England
United Kingdom
CH63 4JY
+44 (0)1515565321
maria.maguire2@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.clatterbridgecc.nhs.uk/>

ROR

<https://ror.org/05gcq4j10>

Funder(s)

Funder type

Industry

Funder Name

F. Hoffmann-La Roche; Grant Codes: ML41801

Alternative Name(s)

Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Additional files aren't currently available.

Intention to publish date

30/09/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |