ISRCTN17717066 https://doi.org/10.1186/ISRCTN17717066

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

Submission date 09/07/2021	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol
Registration date 16/08/2021	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 29/04/2025	**Condition category** Cancer	[ ] Individual participant data [ ] 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