

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

<b>Submission date</b> 09/07/2021	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2021	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2025	<b>Condition category</b> 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

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apollo@liverpool.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

270224

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## Study type(s)

Treatment

## 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 patients<sup>15</sup> 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(s)**

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)

## **Key secondary outcome(s)**

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

## **Completion date**

30/09/2024

## **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

## **Eligibility**

### **Key inclusion criteria**

1. Males and female subjects  $\geq 16$  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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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**

United Kingdom

England

Scotland

Wales

**Study participating centre**  
**The Clatterbridge Cancer Centre**  
Clatterbridge Road  
Bebington  
United Kingdom  
CH63 4JY

**Study participating centre**  
**Arrove Park Hospital**  
Wirral University Teaching Hospital NHS Foundation Trust  
Arrove 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

**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

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No