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

Submission date 09/07/2021	<b>Recruitment status</b> Stopped	<ul><li>[X] Prospectively registered</li><li> Protocol</li></ul>
Registration date 16/08/2021	Overall study status Stopped	<ul><li>Statistical analysis plan</li><li>Results</li></ul>
<b>Last Edited</b> 29/04/2025	<b>Condition category</b> Cancer	<ul><li>Individual participant data</li><li>Record updated in last year</li></ul>

#### 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

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 15 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 ≥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 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

#### **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

#### 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

#### 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

#### 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

#### 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

#### **Southend University Hospital**

Prittlewell Chase Westcliff-On-Sea United Kingdom SSO 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

#### 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

### **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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes