

# Global registry for long-term follow-up of patients participating in clinical trials with Posoleucel (ALVR105)

<b>Submission date</b> 08/06/2022	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 03/11/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Posoleucel (or ALVR105) is a research medicine that contains T-cells made from healthy human donors to defend patients against specific viruses. The purpose of this registry study is to follow up with children and adult patients who were enrolled in Posoleucel clinical trials, in order to obtain long-term safety, effectiveness, and healthcare utilization information after treatment with Posoleucel or placebo. Recording patient health information over time can help to supplement the original study results and improve the care of patients in the future.

### Who can participate?

Patients who previously participated in an Allovir-sponsored PSL clinical trial,

### What does the study involve?

Analysis of registry data.

### What are the possible benefits and risks of participating?

No registry specific procedures will be performed, thus there are no increased risks related to participation other than potential loss of confidentiality. The Sponsor is dedicated to maintaining confidentiality and privacy of patients. The Investigator is responsible for maintaining confidentiality throughout the registry study.

All data used in the analysis and reporting of this evaluation will be without identifiable reference to the patient. The Sponsor, Institution and all Registry Personnel will comply with applicable data protection and privacy laws, including all applicable General Data Protection Requirements (GDPR).

### Where is the study run from?

ICON Clinical Research Ltd (Poland)

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

June 2022 to October 2027

Who is funding the study?  
AlloVir, Inc. (USA)

Who is the main contact?  
Dr Renuka Palanicawandar, renuka.palanicawandar@nhs.net

## Contact information

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Scientific

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Principal investigator

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2022-000763-45

**Integrated Research Application System (IRAS)**  
1005578

**Central Portfolio Management System (CPMS)**  
51835

**Protocol serial number**  
P-105-401

# Study information

## Scientific Title

Global registry for long-term follow-up of posoleucel

## Study objectives

1. To evaluate the long-term safety of Posoleucel (PSL).
2. To evaluate the long-term effectiveness of PSL.
3. To evaluate rates of overall mortality and non-relapse mortality.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 10/08/2022, Yorkshire & The Humber - Sheffield Research Ethics Committee (HS Blood and Transplant Blood Donor Centre Holland Drive, Newcastle upon Tyne Tyne and Wear, NE2 4NQ, United Kingdom; +44 (0)207 104 8388; sheffield.rec@hra.nhs.uk), ref: 22/YH/0139

## Study design

Observational registry study

## Primary study design

Observational

## Study type(s)

Safety

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

Adenovirus (AdV), BK virus (BKV), John Cunningham virus (JCV), human herpesvirus 6 (HHV- 6), Epstein-Barr virus (EBV), and cytomegalovirus (CMV) infections and/or disease in patients at high risk for these viruses following allogeneic hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

## Interventions

Participants will be enrolled at sites participating in Allovir-Sponsored PSL clinical trials (Protocol Number AVM-003-HC, Protocol Number P-105-202, Protocol Number P-105-303) and will be followed for 4 years following their first dose of PSL or placebo in the parent study. Registry data will be entered at enrolment and then at 1 year, 2 years, 3 years, and 4 years after the first dose of PSL or placebo.

## Intervention Type

Drug

## Phase

Phase IV

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

Posoleucel

## Primary outcome(s)

Incidence of adverse drug reactions (ADRs) related to PSL at enrolment visit and follow up measured using patient records

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

Measured using patient records:

1. Incidence of clinical infection with viruses targeted by PSL at enrolment visit and follow up
2. Overall mortality at follow up
3. Non-relapse mortality (defined as death without recurrent or progressive disease after transplantation) at follow up

### **Completion date**

18/10/2027

## **Eligibility**

### **Key inclusion criteria**

1. Participation in an Allovir-sponsored PSL clinical trial, regardless of treatment assignment (PSL or placebo) and completion status (completion, early discontinuation).
2. Patient received at least one infusion of PSL or placebo.
3. Patient is willing and able to provide written informed consent to participate in the registry, or a parent or legal guardian is willing and able to provide written informed consent and the potential paediatric participant is able to provide assent in a manner approved by the Institutional Review Board/Independent Ethics Committee and local regulations.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

10/01/2022

### **Date of final enrolment**

01/10/2027

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Belgium

Canada

France

Italy

Korea, South

Spain

Sweden

Türkiye

United States of America

**Study participating centre**

**Bristol Haematology and Oncology Centre**

22 Horfield Rd  
Bristol  
United Kingdom  
BS2 8ED

**Study participating centre**

**University College London Hospital**

University College London Hospitals NHS Foundation Trust  
Department of Womens Health  
250 Euston Road  
London  
United Kingdom  
NW1 2PG

**Study participating centre**

**Queen Elizabeth University Hospital**

1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**  
**Queen Elizabeth Hospital**  
Queen Elizabeth Medical Centre  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**St. Mary's Hospital**  
Imperial College Healthcare NHS Trust  
Praed Street  
London  
United Kingdom  
W2 1NY

**Study participating centre**  
**Royal Hospital for Sick Children (Glasgow)**  
1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**  
**Birmingham Childrens Hospital (ladywood)**  
Ladywood Middleway  
Ladywood  
Birmingham  
United Kingdom  
B16 8ET

**Study participating centre**  
**Kings College Hospital**  
King's College Hospital NHS Foundation Trust  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**

**Bristol Royal Hospital for Children**

Paul O'Gorman Building  
Upper Maudlin Street  
St Michael's Hill  
Bristol  
United Kingdom  
BS2 8BJ

**Study participating centre**

**Sheffield Children's NHS Foundation Trust**

Western Bank  
Sheffield  
United Kingdom  
S10 2TH

**Study participating centre**

**Royal Manchester Childrens Hospital**

Hospital Road  
Pendlebury  
Swinton  
Manchester  
United Kingdom  
M27 4HA

**Study participating centre**

**Hammersmith Hospitals NHS Trust**

Hammersmith Hospital  
Du Cane Road  
London  
United Kingdom  
W12 0HS

**Study participating centre**

**Great Ormond Street Hospital for Children**

Great Ormond Street  
London  
United Kingdom  
WC1N 3JH

**Study participating centre**

## **Nottingham University Hospitals NHS Trust - City Campus**

Nottingham City Hospital  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

### **Study participating centre**

#### **Royal Marsden Hospital**

Royal Marsden Hospital  
Downs Road  
Sutton  
United Kingdom  
SM2 5PT

### **Study participating centre**

#### **Addenbrookes**

Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

## **Sponsor information**

### **Organisation**

ICON Clinical Research Ltd

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

AlloVir, Inc

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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