

# A Phase 1-2 Master Protocol to Study Intravenous ATTR-01 in Adult Participants with Select Epithelial Solid Tumours Under Multiple sub-protocols (ATTEST)

<b>Submission date</b> 22/08/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/08/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This is a Phase 1-2 trial which is testing a new drug called ATTR-01 to find out if it may work to treat different types of cancer. ATTR-01 has not been approved as a medicine by any health authority.

### What is ATTR-01 and how does it work?

ATTR-01 is a new drug designed to target cancer. ATTR-01 is made from a weakened adenovirus (Ad5). An Ad5 is a common human virus that causes cold like symptoms. Normally, an Ad5 will infect many cells in the body. ATTR-01 has been developed so that it should infect and only replicate (multiplies itself) in cancer cells. The drug is designed so that it does not kill healthy cells. This should make the drug better at killing cancer and cause fewer drug side effects. ATTR-01 is a type of immunotherapy (it stimulates the body's immune system). ATTR-01 is injected into a patient participants' blood stream. Once in the blood, ATTR-01 circulates and should infect cancer cells.

ATTR-01 may kill cancer cells in two ways:

1. Inside the cancer cell, ATTR-01 may force the cancer cell to make and release a potent (strong) drug. This drug can kill cancer cells by activating the body's immune system to fight the cancer.
2. ATTR-01 may kill cancer cells when the virus replicates (it bursts the cancer cell).

### Who can use ATTR-01?

ATTR-01 has been developed to bind to a receptor (a type of 'hook') on cancer cells. Not all cancer types have this receptor on their surface. Only people with cancers that usually have this receptor may receive ATTR-01.

### Who can participate?

Adult patients with solid epithelial tumours who meet the inclusion criteria.

What does the study involve?

Trial visits will take place at hospitals taking part in the trial. This may require more visits to the hospital than are usual for cancer care, but expenses will be paid for by Accession Therapeutics. A participant may be followed up for up to approximately five years in total. In the last four years, most follow-up can be as phone calls with the trial doctor. Participants can have other cancer treatments after ATTR-01, without having to leave trial follow-up. Participants can withdraw from the trial at any time, without giving any reason. Medical care or legal rights of a participant will not be affected if they choose to withdraw.

The trial will involve having tests and procedures to check health and find out about the cancer. The tests will include blood and urine samples, tumour biopsies and scans. Participants who receive ATTR-01 will have swabs to see how ATTR-01 leaves the body (mouth and rectal swabs). Accession Therapeutics will collect and use information (data) needed for the trial from the participants medical records and the samples they supply. Participant's data will be de-identified to protect their privacy (this means data is linked to a unique study code, and not the participant's actual name). The data that is held by Accession Therapeutics will be safely and securely stored on databases that are managed by it and the companies that work for Accession Therapeutics.

What are the possible benefits and risks of participating?

This is the first time that ATTR-01 has been tested in humans. It is not yet known if the drug works or what the side effects may be. Participants that receive the drug may have mild cold-like symptoms, similar to receiving a vaccine. These could include fever, loss of appetite, tiredness, weakness, difficulty breathing, diarrhoea or inflamed bowel, feeling or being sick, skin changes (dryness, itching, rash), joint pains, urine infections and headaches. Taking part in a trial involves having more tests and hospital visits than in usual care. Taking part in research like this may not help you but may help other people with cancer in the future. There is no placebo drug in this trial.

It is not known if the virus may spread by sexual activity. The effect of ATTR-01 on unborn children or nursing infants is not known. For these reasons, participants must agree to the contraceptive requirements for the trial for up to a year after receiving the last dose of the drug.

Where is the study run from?

Accession Therapeutics Limited (UK)

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

August 2024 to December 2034

Who is funding the study?

Accession Therapeutics Limited (UK)

Who is the main contact?

Recruitment enquiries: [attest@precisionformedicine.com](mailto:attest@precisionformedicine.com)

## Contact information

**Type(s)**

Scientific

**Contact name**

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## **Additional identifiers**

**EudraCT/CTIS number**

2024-516722-59-00

**IRAS number**

1010660

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

ATTR-01-01, CPMS 57739

## **Study information**

**Scientific Title**

A Phase 1-2 Master Protocol to Study Intravenous ATTR-01 in Adult Participants with Select Epithelial Solid Tumours Under Multiple Sub-protocols (ATTEST)

**Acronym**

ATTEST

**Study objectives**

Master protocol primary objectives :

1. Primary: To evaluate the safety and tolerability of ATTR-01 in participants with select epithelial solid tumours.
2. To evaluate the anti-tumour activity of ATTR-01 in participants with select epithelial solid tumours.
3. To determine the optimal dose of ATTR-01 for further development of ATTR-01 in participants with select epithelial solid tumours.

Master protocol secondary objectives:

1. To evaluate the viral persistence and immunogenicity of ATTR-01 in participants with select epithelial solid tumours.
2. To further evaluate the anti-tumour activity of ATTR-01 in participants with select epithelial solid tumours.

Objectives may differ per sub-protocol.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 30/12/2024, London - West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048075; westlondon.rec@hra.nhs.uk), ref: 24/LO/0686

**Study design**

Interventional non randomized

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Safety, Efficacy

**Participant information sheet**

Available from recruiting principal investigators

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

Select solid epithelial tumour; Pancreatic cancer; Lung cancer; Bladder cancer; Head and neck cancer; Endometrial cancer; Cholangiocarcinoma

**Interventions**

ATTR-01, the investigational medicinal product (IMP), is a Category 1/Biological Safety Level 1 genetically modified adenovirus type-5 (Ad5), which is targeted to specifically infect and replicate in tumour cells that express the protein alpha v beta 6 ( $\alpha v\beta 6$ ) integrin. ATTR-01 has been engineered to express a licensed anti-Programmed Death-Ligand 1 (PD-L1) human antibody cancer immune therapy, in cells expressing  $\alpha v\beta 6$  integrin. The proposed tumour types of participants to be enrolled in this study are epithelial solid tumours which typically demonstrate a high frequency ( $\geq 75\%$ ) of  $\alpha v\beta 6$  integrin expression.

The IMP is delivered intravenously. Multiple doses will be tested.

Trial ATTR-01-01 will study the IMP under a Master Protocol design whereby sub-protocol A is a first in human dose escalation.

The UK will only participate in sub-protocol A.

**Intervention Type**

Drug

**Pharmaceutical study type(s)**

Pharmacokinetic, Pharmacodynamic, Dose response, Therapy

**Phase**

Phase I/II

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

ATTR-01

**Primary outcome measure**

Main Protocol (MP):

1. Incidence of adverse events (AEs), serious adverse events (SAEs), dose-limiting toxicities (DLTs), discontinuation of the investigational medicinal product(s) (IMP) due to toxicity and clinically significant alterations in vital signs or other clinical safety assessments
2. Objective Response Rate (ORR) from the first scan onwards, per RECIST V1.1
3. Duration of Response (DoR)

**Secondary outcome measures**

Main Protocol per RECIST V1.1 from the first scan onwards:

1. Disease Control Rate (DCR)
2. Time To Response (TTR)
3. Progression Free Survival (PFS)
4. Overall Survival (OS)
5. Maximum reduction in tumour size

Individual sub-protocols may have modified outcome measures

**Overall study start date**

19/08/2024

**Completion date**

31/12/2034

## Eligibility

**Key inclusion criteria**

Main Protocol (MP): The following is applicable to all Sub-Protocols (SPs). Additional SP criteria may apply.

1. Consenting male and female adults (18 years of age) with select solid epithelial tumour indications known to have high frequency (75%) of  $\alpha v\beta 6$  integrin receptor expression as detailed in the applicable SP.
2. Received and failed/intolerant of Standard of Care (SoC) therapy where eligible (not including neoadjuvant).
3. Tumour lesion (not previously irradiated), suitable for safe pre- and post-treatment biopsies.
4. Measurable disease by Response Evaluation Criteria in Solid Tumours (RECIST) Version 1.1.
5. Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) of 0 or 1.
6. Minimum life expectancy anticipated to be greater than three months
7. Willing to undertake appropriate measures of hygiene to prevent any spread of virus and protection of vulnerable individuals.
8. Adequate organ function.
9. Compliant with requirements for prior treatment washout and contraceptive measures applicable to genetically modified organisms (GMOs) and cancer therapies
10. Prior immune checkpoint antibody therapies as single agents or in combination with other anti-cancer agents is permissible.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Differs per sub-protocol. Up to 72 participants may be dosed under sub-protocol A.

**Key exclusion criteria**

Master Protocol key exclusion criteria (additional sub-protocol specific criteria may apply):

1. Significant degree of fibrotic disease, including autoimmune diseases (e.g. systemic lupus, rheumatoid arthritis) or idiopathic and occupation-related pulmonary fibrosis.
2. Known prior history of intolerance to anti-programmed cell death protein 1 (PD-1) and/or anti-PD-L1 immunotherapy due to toxicity.
3. Has any of the comorbid conditions listed in the detailed exclusion criteria (MP or applicable SP).

**Date of first enrolment**

24/02/2025

**Date of final enrolment**

15/11/2029

## **Locations**

**Countries of recruitment**

England

Scotland

Spain

United Kingdom

Wales

**Study participating centre**

**St James University Hospital**

Beckett Street

Bexley Wing

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**Churchill Hospital**

Old Road

Headington

Oxford

United Kingdom

OX3 7LE

**Study participating centre**

**Velindre Cancer Centre**

Velindre Road

Cardiff

United Kingdom

CF14 2TL

**Study participating centre**

**Beatson West of Scotland Cancer Centre**  
1053 Great Western Rd  
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United Kingdom  
G61 1BD

**Study participating centre**  
**Royal Preston Hospital**  
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United Kingdom  
PR2 9HT

## **Sponsor information**

### **Organisation**

Accession Therapeutics Limited

### **Sponsor details**

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### **Sponsor type**

Industry

### **Website**

<https://www.accessiontherapeutics.com/>

## **Funder(s)**

### **Funder type**

Industry



**Funder Name**

Accession Therapeutics Limited

## **Results and Publications**

**Publication and dissemination plan**

Peer-reviewed scientific journals

Conference presentation

Publication on website

Other publication

Submission to regulatory authorities

Data will be coded and pseudonymised. Participant's data will be protected in accordance with accepted industry standards and applicable laws including ICH GCP, Regulation (EU) 2016/679, UK Data Protection Act 2018, UK GDPR and other local requirements.

**Intention to publish date**

31/12/2035

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Published as a supplement to the results publication