

PLATO - Personalising anal cancer radiotherapy d

Submission date 13/07/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/08/2016	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/11/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

1. <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-lower-dose-of-chemoradiotherapy-or-observation-for-early-stage-anal-cancer>
2. <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-higher-doses-of-chemoradiotherapy-for-people-with-locally-advanced-anal-cancer>
3. <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-lower-dose-of-chemoradiotherapy-for-people-with-anal-cancer-that-hasnt-spread>

Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

204585

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 31184, IRAS 204585

Study information

Scientific Title

PLATO - Personalising Anal cancer radioTherapy dOse - Incorporating Anal Cancer Trials (ACT) ACT3, ACT4 and ACT5

Acronym

PLATO

Study objectives

PLATO is an integrated protocol, comprising 3 separate trials (ACT3, ACT4 and ACT5) which aims to optimise radiotherapy dose (in combination with chemotherapy) for low-, intermediate- and high-risk anal cancer.

ACT3:

ACT3 is a non-randomised phase II trial for patients with early, small tumours who have undergone surgery (local excision). The aim of this study is to determine whether a treatment strategy of surgery alone, i.e. no further treatment, for patients with margins >1mm, and highly selective low-dose radiotherapy with chemotherapy for patients with close margins \leq 1mm, results in acceptably low rates of cancer recurrence.

ACT4:

ACT4 is a randomised phase II trial for patients with intermediate-risk disease. The aim of this study is to compare standard-dose chemoradiotherapy (50.4Gy in 28 fractions) with reduced-dose chemoradiotherapy (41.4Gy in 23 fractions), to see if less radiotherapy is able to maintain the excellent success rates in treating the cancer, while reducing the side effects of treatment.

ACT5:

ACT5 is a randomised seamless pilot/phase II/phase III trial for patients with locally advanced anal cancer. The aim of this study is to compare standard-dose chemoradiotherapy (53.2Gy in 28 fractions) with two higher doses of chemoradiotherapy (58.8Gy and 61.6Gy, both in 28 fractions), to see if giving a higher dose of radiotherapy reduces the chance of the cancer coming back, whilst not causing too many extra side effects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 06/07/2016, ref: 16/YH/0157

Study design

Both; Interventional; Design type: Treatment, Drug, Radiotherapy, Active Monitoring

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anal cancer

Interventions

Current interventions as of 03/04/2023:

ACT3 (recruitment end date: 31/10/2023):

Observation arm

No further treatment after local excision.

Intervention arm

Either a 3D conformal plan or a single phase inverse-planned IMRT treatment plan delivered with multiple fields, or arc techniques. Choice of delivery technique is at the discretion of the treating clinician.

PTV_A = 41.4Gy in 23F (1.8Gy per F) in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT4 (recruitment end date: 01/12/2020):

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV_E) and to the areas of gross tumour (PTV_A). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV_A: 50.4Gy in 28F in 5.5 weeks

PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 28 days

Reduced-dose (experimental) arm

PTV_A: 41.4Gy in 23F in 4.5 weeks

PTV_E: 34.5Gy in 23F in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT5 (recruitment end date: 31/08/2023):

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV_E) and to the areas of gross tumour (PTV_A and PTV_N). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV_A: 53.2.Gy in 28F in 5.5 weeks

PTV_N: 50.4Gy in 28F in 5.5 weeks (involved nodes ≤3cm)

53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Dose escalation arm 1

PTV_A: 53.2Gy in 28F in 5.5 weeks

PTV_Boost: 58.8Gy in 28F in 5.5 weeks

PTV_N: 53.2Gy in 28F in 5.5 weeks (involved nodes ≤ 3 cm)

53.2Gy in 28F in 5.5 weeks (involved nodes > 3 cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Dose escalation arm 2

PTV_A: 53.2Gy in 28F in 5.5 weeks

PTV_Boost: 61.6Gy in 28F in 5.5 weeks

PTV_N: 53.2Gy in 28F in 5.5 weeks (involved nodes ≤ 3 cm)

53.2Gy in 28F in 5.5 weeks (involved nodes > 3 cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy in all ACT5 arms (centre choice):

Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 28 days,

or

Mitomycin C 12mg/m² iv Day 1 & 5-FU 1000mg/m² per 24 hours by continuous iv infusion Days 1-4 and Days 29-32

Follow-up (ACT3, ACT4 and ACT5)

All patients will be followed up at the following time points:

1. 6 weeks
2. 3-monthly (Years 1-2)
3. 6 monthly (Year 3), then
4. Annually Annually (Years 4+ until 3 years after the last participant has completed treatment or death)+

All timings are from the end of treatment, except the ACT3 observation arm, which is from the date of registration.

Registration / Randomisation process

Following confirmation of written informed consent and eligibility, participants will be registered (ACT3) or randomised (ACT4/5) into the trial by an authorised member of staff at the trial site. Registration/randomisation will be performed centrally using the CTRU automated 24-hour system which can be accessed via the web or telephone.

ACT4:

Patients will be randomised on a 1:2 basis (standard-dose:reduced-dose) to receive either standard-dose IMRT in combination with chemotherapy or reduced-dose IMRT in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T1, T2)
2. N-stage (N0, NX)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Randomising centre

ACT5:

For the pilot study and Phase II trial, patients will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or one of two increased-dose

experimental arms of IMRT with SIB in combination with chemotherapy. In the Phase III trial, participants will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or an increased dose arm of IMRT with SIB in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T2/3, T4)
2. N-stage (NX/0/1, N2/3)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Chemotherapy regimen (5FU, Capecitabine)
6. Randomising centre

Previous interventions:

ACT3:

Observation arm

No further treatment after local excision.

Intervention arm

Either a 3D conformal plan or a single phase inverse-planned IMRT treatment plan delivered with multiple fields, or arc techniques. Choice of delivery technique is at the discretion of the treating clinician.

PTV_A = 41.4Gy in 23F (1.8Gy per F) in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT4:

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV_E) and to the areas of gross tumour (PTV_A). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV_A: 50.4Gy in 28F in 5.5 weeks

PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 28 days

Reduced-dose (experimental) arm

PTV_A: 41.4Gy in 23F in 4.5 weeks

PTV_E: 34.5Gy in 23F in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT5:

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV_E) and to the areas of gross tumour (PTV_A and PTV_N). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV_A: 53.2.Gy in 28F in 5.5 weeks

PTV_N: 50.4Gy in 28F in 5.5 weeks (involved nodes ≤3cm)

53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Dose escalation arm 1

PTV_A: 53.2Gy in 28F in 5.5 weeks

PTV_Boost: 58.8Gy in 28F in 5.5 weeks

PTV_N: 53.2Gy in 28F in 5.5 weeks (involved nodes ≤3cm)

53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Dose escalation arm 2

PTV_A: 53.2Gy in 28F in 5.5 weeks

PTV_Boost: 61.6Gy in 28F in 5.5 weeks

PTV_N: 53.2Gy in 28F in 5.5 weeks (involved nodes ≤3cm)

53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)

PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy in all ACT5 arms (centre choice):

Mitomycin C 12mg/m² iv Day 1 & Capecitabine 852mg/m² oral bd 5 days/week (on days of radiotherapy) for 28 days,

or

Mitomycin C 12mg/m² iv Day 1 & 5-FU 1000mg/m² per 24 hours by continuous iv infusion Days 1-4 and Days 29-32

Follow-up (ACT3, ACT4 and ACT5)

All patients will be followed up at the following time points:

1. 6 weeks
2. 3-monthly (Years 1-2)
3. 6 monthly (Year 3), then
4. Annually (Years 4+ until 3 years post close of recruitment or death)

All timings are from the end of treatment, except the ACT3 observation arm, which is from the date of registration.

Registration / Randomisation process

Following confirmation of written informed consent and eligibility, participants will be registered (ACT3) or randomised (ACT4/5) into the trial by an authorised member of staff at the trial site. Registration/randomisation will be performed centrally using the CTRU automated 24-hour system which can be accessed via the web or telephone.

ACT4:

Patients will be randomised on a 1:2 basis (standard-dose:reduced-dose) to receive either standard-dose IMRT in combination with chemotherapy or reduced-dose IMRT in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T1, T2)
2. N-stage (N0, NX)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Randomising centre

ACT5:

For the pilot study and Phase II trial, patients will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or one of two increased-dose experimental arms of IMRT with SIB in combination with chemotherapy. In the Phase III trial, participants will be randomised on a 1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or the most 'acceptable' increased dose arm of IMRT with SIB in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T2/3, T4)
2. N-stage (NX/0/1, N2/3)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Chemotherapy regimen (5FU, Capecitabine)
6. Randomising centre

Intervention Type

Other

Primary outcome(s)

Locoregional failure (failure at the primary site (local) and/or surrounding nodal sites (regional) i. e. any failure within the pelvis up to the level of the sacral promontory) at 3 years post close of recruitment.

Key secondary outcome(s)

1. Acute toxicities, assessed according to the current NCI-CTCAE or RTOG (for skin toxicity) criteria, during each week of treatment (with the exception of the ACT3 observation arm)
2. Late toxicities, measured by patient reported outcomes via EORTC QLQ-C30 and CR29 questionnaires at 6 weeks, 6, 12, 24 and 36 months post the end of treatment
3. Treatment compliance, measured on a weekly basis by assessment of total dose of radiotherapy received, duration of treatment, delays to treatment due to toxicity, and any chemotherapy dose modifications
4. Clinical response rate (cRR) (ACT4 and 5), assessed by MRI imaging in accordance with the Tumour Regression Grading System at 3 and 6 months post end of treatment
5. Disease-free survival (DFS), defined as time from randomisation to first documented evidence of pelvic failure.
6. Colostomy-free survival (CFS), measured at baseline, prior to the start of treatment and throughout follow-up and will look at patients who have a pre-treatment colostomy that is still present at 12 months post end of treatment, patients who have a colostomy fitted due to a treatment related toxicity or local disease failure
7. Progression-free survival (PFS), defined as time from randomisation to first documented evidence of disease progression or death from any cause
8. Overall survival (OS), defined as time from randomisation to date of death from any cause
9. Patient Reported Outcome Measures (PROMs), assessed by EORTC QLQ-C30 and CR29 questionnaires at baseline, end of treatment and 6 weeks, 6, 12, 24 and 36 months post the end of treatment

Descriptive outcomes:

1. Pattern of pelvic failures i.e. site and position of failure
2. Proportion of participants undergoing salvage surgery (ACT4 and 5)

Completion date

28/02/2027

Eligibility

Key inclusion criteria

Key inclusion criteria for all three trials include:

1. Provision of written informed consent
2. Histologically-proven, invasive primary squamous, basaloid, or cloacogenic carcinoma of the anus
3. Adequate bone marrow, hepatic and renal function
4. HIV negative or HIV positive and receiving effective antiretroviral therapy and CD4 count >200
5. Aged 16 years or over
6. Fit for all protocol defined treatments
7. Prepared to practice methods of contraception during treatment and until 6 months post end of treatment
8. Able to undergo all mandated staging and follow-up investigations, including MRI

Trial-specific inclusion criteria:

ACT3

T1 N0 or Nx anal margin tumour treated by local excision; ECOG performance status 0-2

ACT4

T1-2 up to 4cm N0 or Nx anal canal or anal margin tumour; ECOG performance status 0-1

ACT5

T2 N1-3 or T3-4 Nany anal canal or anal margin tumour; ECOG performance status 0-1

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 years

Upper age limit

100 years

Sex

All

Total final enrolment

709

Key exclusion criteria

Key exclusion criteria for all three trials include:

1. Definite evidence of metastatic disease
2. Prior invasive malignancy unless disease-free for a minimum of 3 years (excluding basal cell carcinoma of the skin or other in situ carcinomas)
3. Prior systemic chemotherapy for anal cancer
4. Prior radiotherapy to the pelvis
5. Uncontrolled cardiorespiratory comorbidity
6. Pregnant or lactating
7. Immunocompromised (organ transplant)

Trial-specific exclusion criteria:

ACT3

Where a piecemeal local excision precludes assessment of tumour size and margin status

Date of first enrolment

01/09/2016

Date of final enrolment

31/08/2023

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Ireland

Study participating centre

St James's University Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)

Beckett Street

Leeds

England

LS9 7TF

Study participating centre

Oxford Cancer and Haematology Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)

Churchill Hospital

Old Road

Headington

Oxford
England
OX3 7LE

Study participating centre

Mount Vernon Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)
Rickmansworth Road
Northwood
England
HA6 2RN

Study participating centre

Velindre Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)
Velindre Road
Whitchurch
Cardiff
Wales
CF14 2TL

Study participating centre

Bristol Haematology and Oncology Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)
Horfield Road
Bristol
England
BS2 8ED

Study participating centre

Sussex Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)
Royal Sussex County Hospital
Brighton
England
BN2 5BE

Study participating centre

Guy's Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)
Great Maze Pond
London
England
SE1 9RT

Study participating centre

Royal Surrey County Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)

Egerton Road

Guildford

England

GU2 7XX

Study participating centre

The Royal Marsden Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)

Fulham Road

London

England

SW3 6JJ

Study participating centre

The Royal Marsden Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)

Downs Road

Sutton

England

SM2 5PT

Study participating centre

Cambridge University Hospitals NHS Foundation Trust (ACT3, ACT4 or ACT5 from pilot phase onwards)

Addenbrooke's Hospital

Hills Road

Cambridge

England

CB2 0QQ

Study participating centre

Beatson West of Scotland Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)

1053 Great Western Road

Glasgow

Scotland

G12 0YN

Study participating centre

Edinburgh Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)

Western General Hospital

Crewe Road
Edinburgh
Scotland
EH4 2XU

Study participating centre

North Wales Cancer Treatment Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)

Glan Clwyd Hospital
Rhyl
Wales
LL18 5UJ

Study participating centre

Aberdeen Royal Infirmary

Foresterhill
Aberdeen
Scotland
AB25 2ZN

Study participating centre

Castle Hill Hospital

Castle Road
Cottingham
England
HU16 5JQ

Study participating centre

Charing Cross Hospital

Fulham Palace Road
London
England
W6 8RF

Study participating centre

Cheltenham General Hospital

Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Road
Bebington
Wirral
England
CH63 4JY

Study participating centre
Colchester General Hospital
Turner Road
Colchester
England
CO4 5JL

Study participating centre
Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
England
NN1 5BD

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston

Birmingham
England
B15 2GW

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
Wales
SA2 8QA

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
St Bartholomew's Hospital
West Smithfield
London
England
EC1A 7BE

Study participating centre
The Christie Hospital
Wilmslow Road
Manchester
England
M20 4BX

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
University College Hospital
235 Euston Road
London
England
NW1 2BU

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield

England
S10 2SJ

Sponsor information

Organisation

University of Leeds

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available on request from the Clinical Trials Research Unit at the University of Leeds.

De-identified individual participant data datasets generated during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generate datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/11/2025	17/11/2025	Yes	No
Abstract results		01/10/2019	14/11/2022	No	No
HRA research summary			28/06/2023	No	No
Interim results article		02/05/2025	08/05/2025	Yes	No
Other publications	investigation of prognostic factors	20/05/2021	25/05/2021	Yes	No
Plain English results	ACT4 early results summary version 1.0	05/06/2023	05/06/2023	No	Yes
Plain English results	ACT5 early results summary version 1.0	23/06/2023	26/06/2023	No	Yes
Plain English results	ACT4		24/08/2023	No	Yes
Plain English results	ACT3 early results summary version 1.0	25/08/2022	22/10/2025	No	Yes
Poster results			14/11/2022	No	No
Protocol file	version 8.0	07/02/2024	10/10/2024	No	No
Protocol file	version 9.0	04/12/2024	24/01/2025	No	No