Site ID: | | Date (DD/MM/YY): | | | | | | Participant Trial ID Number: | | |

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Participant 'weekly' data collection file

COVER SHEET

For Study Investigator Completion

1. **Date patient was randomised (DD/MM/YY)** | | | | | | |

Signature of nurse completing question 1 (randomisation date)	
Please print name	
Date form completed	

2. **Date patient took first dose of IMP (DD/MM/YY)** | | | | | | |

3. What time of day does the participant take their AVURT capsules? *Please circle*			
Morning	Afternoon	Evening	Varies

Signature of nurse completing questions 2 and 3.	
Please print name	
Date form completed	

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Participant 'weekly' data collection file

For Study Investigator Completion

Week number: 1

If the participant is not seen this week, and therefore you are unable to complete the weekly data collection file, please give reason(s) in the table below and fax this page only alongside Form F, Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number

	Yes	No
1. No scheduled appointment		
2. Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been reported previously? **If you answered 'Yes' to this question, please complete Section 8 of this form and the adverse event log**		
*2b Date of missed appointment (DD/MM/YY)		
3. Change of circumstances **If you answered 'Yes' to this question, please complete form F (Change to study status)**		
4. Other**		
**If other please give reason:		

The nurse completing the above table OR the weekly file to sign here please

Signature of nurse completing form	
Please print name	
Date form completed	

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 1

1. Is the questionnaire being completed (please circle one answer)	
In presence of participant	Over the telephone‡.

‡.If completed over the telephone please go directly to section 2

	Yes	No†
2. Please confirm a photograph of the reference ulcer has been taken		

† If **NO** please trace the ulcer and confirm the ulcer size in cm^2	☐☐☐ . ☐☐ cm^2

Section 2

	Yes	No
1. Has the Reference Ulcer healed?		

If **No** please go to section 3.

If **Yes** please answer questions 1a to 1b and fax this form to York Trials Unit today

Please answer **'Yes'** to one of the following questions.

	Yes	No	
1a. Is this the first appointment that the ulcer has been assessed as healed?			If 'yes' form D to be completed in 2 weeks time*
1b. If you answered 'yes' to question 1a please ensure that form D is to be completed in week no 3			

Section 3

1. How often has the participant taken their AVURT capsules (300mg Aspirin/placebo per day) this week? *(please circle one reason)*			
Every day	Most days	Some days	Not at all

2. If participant has not taken their AVURT capsules each day please record reasons *(please circle all that apply)*

Illness	Couldn't swallow capsule	Forgot	Couldn't open container	Medic advised to stop taking*	Other**

*Record details of this here	**If other please specify here

If participant has stopped taking medication **due to an adverse reaction please complete section 8 of this form and the adverse event log**

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 4

1. Is the participant currently receiving compression therapy?	**Yes*** ☐ **No** ☐

1a, If **YES***, has the participant complied with their treatment *(please circle one statement below)*

Fully	Partially*	Not at all*

***If partially** or **not at all** please record reason

2. Has the level of compression changed since the Baseline form was completed?	**Yes*** ☐ **No** ☐

***If YES please complete form A**

Section 5

3. Has the type of primary dressing or bandage changed since the Baseline form was completed?	**Yes*** ☐ **No** ☐

***If YES please complete form B**

Section 6

1. Approximately how many other wound consultations (excluding this one) has the participant had in the last week?	☐

Add additional information (such as if the participant is an inpatient)

Section 7

1. How many ulcers are present on the REFERENCE LEG	☐

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

Section 8

	Yes	No
1. Has the participant experienced any adverse events		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse reactions		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file
All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . **If patients stop taking IMP due to an AE or SAE please complete Form F**

Section 9

	Yes	No
1. Please confirm participant has been asked if there is a change to ANY, medications they take?		
2. Has there been a change to concomitant medication since baseline questionnaire completion*		
*If **YES please complete Form C ensuring a named doctor is consulted**		

Thank you for completing this form
Please fax to:

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Participant 'weekly' data collection file

For Study Investigator Completion

Week number:
2, 3, 7-24, 26,27

If the participant is not seen this week, and therefore you are unable to complete the weekly data collection file, please give reason(s) in the table below and fax this page only alongside Form F, Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number

	Yes	No
1. No scheduled appointment		
2. Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been reported previously? **If you answered 'Yes' to this question, please complete Section 8 of this form and the adverse event log**		
*2b Date of missed appointment (DD/MM/YY) ☐☐☐☐☐☐		
3. Change of circumstances **If you answered 'Yes' to this question, please complete form F (Change to study status)**		
4. Other**		
**If other please give reason:		

The nurse completing the above table or the weekly file to sign here please

Signature of nurse completing form	
Please print name	
Date form completed	

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 1

1. Is the questionnaire being completed (please circle one answer)	
In presence of participant	Over the telephone‡

‡If completed over the telephone please go to Section 2

	Yes	No†
2. Please confirm a photograph of the reference ulcer has been taken		

† If **NO** please trace the ulcer and confirm the ulcer size in cm^2	☐☐☐ . ☐☐ cm^2

Section 2

	Yes	No
1. Has the Reference Ulcer healed		

If **NO** please go to Section 3.

If **YES** please answer questions 1a to 1d and fax this form to York Trials Unit today

Please answer '**yes**' to one of the following questions.

	Yes	No	
1a. Is this the first appointment that the ulcer has been assessed as healed?			If 'yes' form D to be completed in 2 weeks time*
1b. Was the ulcer first assessed as healed at last week's appointment?			If 'yes' form D to be completed next week*
1c. Was the ulcer first assessed as healed 2 weeks ago?			If 'yes' form D to be completed today.

	Week no.
1d. If you answered 'yes' to question 1a or 1b please state week number that form D is to be completed	

Section 3

1. How often has the participant taken their AVURT capsules (300mg Aspirin/placebo per day) this week? *(please circle one reason)*			
Every day	Most days	Some days	Not at all

2. If participant has not taken their AVURT capsules each day please record reasons *(please circle all that apply)*

Illness	Couldn't swallow capsule	Forgot	Couldn't open container	Medic advised to stop taking*	Other**

*Record details of this here	**If other please specify here

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

If participant has stopped taking medication **due to an adverse reaction please complete section 8 of this form and the adverse event log.**

Section 4

1. Is the participant currently receiving compression therapy?	**Yes*** ☐ **No** ☐

1a, If **YES***, has the participant complied with their treatment *(please circle one statement below)*

Fully	Partially**	Not at all**

****If partially** or **not at all** please record reason

2. Has the level of compression changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form A**

Section 5

1. Has the type of primary dressing or bandage changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form B**

Section 6

1. Approximately how many other wound consultations (excluding this one) has the participant had in the last week?	☐

Add additional information (such as if the participant is an inpatient)

Section 7

1. How many ulcers are present on the REFERENCE LEG	☐

Site ID: | | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

Section 8

	Yes	No
1. Has the participant experienced any adverse events that have not been previously reported?		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse reactions that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . **If patients stop taking IMP due to an AE or SAE please complete Form F**

Section 9

	Yes	No
1. Please confirm participant has been asked if there is a change to ANY, non-trial, medications they take?		
2. Has there been a change to concomitant medication since last reported (including doses and frequency of existing medication)?*		
*If **YES please complete Form C ensuring a named doctor is consulted**		

Thank you for completing this form
Please fax to:

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Participant 'weekly' data collection file

For Study Investigator Completion

Week number: 4-6

If the participant is not seen this week, and therefore you are unable to complete the weekly data collection file, please give reason(s) in the table below and fax this page only alongside Form F, Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number

	Yes	No
1. No scheduled appointment		
2. Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been reported previously? **If you answered 'Yes' to this question, please complete Section 8 of this form and the adverse event log**		
*2b Date of missed appointment (DD/MM/YY)		
3. Change of circumstances **If you answered 'Yes' to this question, please complete form F (Change to study status)**		
4. Other**		
**If other please give reason:		

The nurse completing the above table or the weekly file to sign here please

Signature of nurse completing form	
Please print name	
Date form completed	

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 1

1. Is the questionnaire being completed (please circle one answer)	
In presence of participant	Over the telephone‡

‡If completed over the telephone please go directly to Section 2

	Yes	No†
2. Please confirm a photograph of the reference ulcer has been taken		

†If **NO** please trace the ulcer and confirm the ulcer size in cm^2	☐☐☐ . ☐☐ cm^2

Section 2

	Yes	No
1. Has the Reference Ulcer healed		

If **NO** please go to section 3.

If **YES** please answer questions 1a to 1d and fax this form to York Trials Unit today

Please answer '**yes**' to one of the following questions.

	Yes	No	
1a. Is this the first appointment that the ulcer has been assessed as healed?			If 'yes' form D to be completed in 2 weeks time*
1b. Was the ulcer first assessed as healed at last week's appointment?			If 'yes' form D to be completed next week*
1c. Was the ulcer first assessed as healed 2 weeks ago?			If 'yes' form D to be completed today.

	Week no.
1d. If you answered 'yes' to question 1a or 1b please state week number that form D is to be completed	

Section 3

1. How often has the participant taken their AVURT capsules (300mg Aspirin/placebo per day) this week? *(please circle one reason)*			
Every day	Most days	Some days	Not at all

2. If participant has not taken their AVURT capsules each day please record reasons *(please circle all that apply)*					
Illness	Couldn't swallow capsule	Forgot	Couldn't open container	Medic advised to stop taking*	Other**

*Record details of this here	**If other please specify here

If participant has stopped taking medication **due to an adverse reaction please complete section 8 of this form and the adverse event log.**

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 4

1. Is the participant currently receiving compression therapy?	**Yes*** ☐ **No** ☐

1a, If **YES***, has the participant complied with their treatment *(please circle one statement below)*

Fully	Partially*	Not at all*

*If **partially** or **not at all** please record reason

2. Has the level of compression changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form A**

Section 5

1. Has the type of primary dressing or bandage changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form B**

Section 6

1. Approximately how many other wound consultations (excluding this one) has the participant had in the last week?	☐

Add additional information (such as if the participant is an inpatient)

Section 7

1. How many ulcers are present on the REFERENCE LEG	☐

Site ID: | | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

Section 8

	Yes	No
1. Has the participant experienced any adverse events that have not been previously reported?		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse reactions that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file
All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . **If patients stop taking IMP due to an AE or SAE please complete Form F**

Section 9

	Yes	No
1. Please confirm participant has been asked if there is a change to ANY, non-trial, medications they take?		
2. Has there been a change to concomitant medication since last reported (including doses and frequency of existing medication)?*		
*If **YES please complete Form C ensuring a named doctor is consulted**		

Section 10

Visual Analogue Score

Instructions for completing the scale:
Place a cross in one of the boxes below to indicate the intensity of pain from your ulcer(s) over the last 24 hours, ranging from no pain to the worst pain imaginable.

1. How intense has the pain from your leg ulcer(s) been over the past 24 hours?

0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100

No Pain **Worst pain imaginable**

			(For office use only)

Thank you for completing this form
Please fax to:

Site ID: ☐☐ Date (DD/MM/YY): ☐☐/☐☐/☐☐ Participant ID No: ☐☐☐

AVURT

Aspirin for Venous Ulcers: Randomised Trial

Participant 'weekly' data collection file

For Study Investigator Completion

Week number: 25

If the participant is not seen this week, and therefore you are unable to complete the weekly data collection file, please give reason(s) in the table below and fax this page only alongside Form F, Section 8 and/or the adverse event log if appropriate, to the YTU, Fax number

	Yes	No
1. No scheduled appointment		
2. Participant missed appointment*		
*2a. Was the appointment missed due to an AE or AR that has not been reported previously? **If you answered 'Yes' to this question, please complete Section 8 of this form and the adverse event log**		
*2b Date of missed appointment (DD/MM/YY) ☐☐☐☐☐☐		
3. Change of circumstances **If you answered 'Yes' to this question, please complete form F (Change to study status)**		
4. Other**		
**If other please give reason:		

The nurse completing the above table OR the weekly file to sign here please

Signature of nurse completing form	
Please print name	
Date form completed	

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 1

1. Is the questionnaire being completed (please circle one answer)	
In presence of participant	Over the telephone‡

‡If completed over the telephone please go directly to Section 2

	Yes	No
2. Please confirm a photograph of the reference ulcer has been taken		

3. Please trace the ulcer and confirm the ulcer size in cm^2	☐☐☐ . ☐☐ cm^2

Section 2

	Yes	No
1. Has the Reference Ulcer healed		

If **NO** please go to Section 3.

If **YES** please answer questions 1a to 1d and fax this form to York Trials Unit today

Please answer '**yes**' to one of the following questions.

	Yes	No	
1a. Is this the first appointment that the ulcer has been assessed as healed?			If 'yes' form D to be completed in 2 weeks time*
1b. Was the ulcer first assessed as healed at last week's appointment?			If 'yes' form D to be completed next week*
1c. Was the ulcer first assessed as healed 2 weeks ago?			If 'yes' form D to be completed today.

	Week no.
1d. If you answered 'yes' to question 1a or 1b please state week number that form D is to be completed	

Section 3

1. How often has the participant taken their AVURT capsules (300mg Aspirin/placebo per day) this week? *(please circle one reason)*			
Every day	Most days	Some days	Not at all

2. If participant has not taken their AVURT capsules each day please record reasons *(please circle all that apply)*					
Illness	Couldn't swallow capsule	Forgot	Couldn't open container	Medic advised to stop taking*	Other**

*Record details of this here	**If other please specify here

If participant has stopped taking medication **due to an adverse reaction please complete section 8 of this form and the adverse event log.**

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

Section 4

1. Is the participant currently receiving compression therapy?	**Yes*** ☐ **No** ☐
1a, If **YES***, has the participant complied with their treatment *(please circle one statement below)*	
Fully / Partially* / Not at all*	
***If partially** or **not at all** please record reason	
2. Has the level of compression changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form A**

Section 5

1. Has the type of primary dressing or bandage changed since this form was last completed?	**Yes*** ☐ **No** ☐

***If YES please complete form B**

Section 6

1. Approximately how many other wound consultations (excluding this one) has the participant had in the last week?	☐
Add additional information (such as if the participant is an inpatient)	

Section 7

1. How many ulcers are present on the REFERENCE LEG	☐

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

Section 8

	Yes	No
1. Has the participant experienced any adverse events that have not been previously reported?		
1a. If yes, was this a serious adverse event (SAE)?		
2. Has the participant experienced any adverse reactions that have not been previously reported?		
2a. If yes, was this a serious adverse reaction (SAR)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file
All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs and SARs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on or E-mailed to . **If patients stop taking IMP due to an AE or SAE please complete Form F**

Section 9

	Yes	No
1. Please confirm participant has been asked if there is a change to ANY, non-trial, medications they take?		
2. Has there been a change to concomitant medication since last reported (including doses and frequency of existing medication)?*		
*If **YES please complete Form C ensuring a named doctor is consulted**		

At week 25 please collect the AVURT medication from the participant. Return this medication to St Georges pharmacy

Thank you for completing this form
Please fax to:

Site ID: | | Date (DD/MM/YY): | | / | | / | | Participant ID No: | | | |

AVURT: Form A
Changes to compression therapy

Week number:

Date of completion
Day Month Year

What level of compression is the new treatment aiming for? *Please tick*			
Low ≤19mmHG	**Medium** 20-39mmHG	**High** 40mmHG & above	**None**

Signature of nurse filling in form A	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT: Form B
Changes to dressing or bandages Page 1 of 2

Week number:	

Date of completion		
Day	Month	Year

1. What is the primary dressing (that is in contact with the ulcer)? Select one in the table below

If no dressing, please state 'no dressing' in 'other' box below

New Dressing	Select one
Silver-containing	
Iodine-containing	
Honey-containing	
Alginate	
Hydrogel	
Soft polymer	
Hydrocolloid	
Foam	
Basic wound contact (absorbent dressing/low adherence dressing)	
Film	
Other antimicrobial dressing (please state)	
Other (please state)	

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | Participant ID No: | | | |

AVURT: Form B

Changes to dressing or bandages CONTINUED page 2 of 2

Week number:	

Date of completion		
Day	Month	Year

2. What type of bandage is now being used as the primary bandage? Select one in the table below

If no bandage, please state 'no bandage' in 'other' box below

New bandage	Select one
Four Layer	
3 layer	
3 layer reduced compression	
Reduced compression	
2 layer hosiery (aiming to deliver high compression)	
Reduced compression hosiery	
Other (please state)	

Signature of nurse filling in form B	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT: Form C
Changes to medication

Week number:		Date of completion Day Month Year 					

Please complete giving details of ALL CHANGES to patient's medication

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT: Form C
Changes to medication CONTINUED

Week number:	

Date of completion		
Day	Month	Year

Signature of nurse filling in form C	
Please print name	
Date (DD/MM/YY)	

Please pass to the named doctor as detailed on the study delegation log to confirm that the patient is still eligible for participation in AVURT

To be completed by named doctor to determine eligibility

	Yes	No*
Following assessment of the changes to medication – is the participant eligible to continue their participation in the AVURT Trial		
***If no please specify reasons**		

***Please confirm the participant has been informed to stop taking their AVURT medication** ☐

***Please ensure a change to Study status form (Form F) is completed**

Signature of doctor assessor	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT: Form C

Changes to medication

Supplementary page _____(page number)

Week number:	

Date of completion		
Day	Month	Year

Please complete giving details of ALL CHANGES to patient's medication

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Name of medication			
Reason for taking/change			
Dose		Frequency	
Start date		End date	

Please fax to York Trials Unit on: [redacted]

Site ID: | | Date (DD/MM/YY): | | / | | / | | Participant ID No: | | | |

AVURT: Form D
Reference ulcer healing check/confirmation

Week number:

Date of completion
Day Month Year

To be completed two weeks after initial assessment of healing as recorded in the participant data collection file

Please record the following information

1. **Is the reference ulcer healed? Yes*** ☐ **No**** ☐

***If YES,** Please inform the participant today to stop taking the AVURT medication immediately and arrange for the remaining trial medication to be returned to St George's Research Pharmacy.

*1a Has the participant been informed to stop taking the trial medication?

Yes ☐ **No** ☐

*1b Arrange a date and time to call participant for telephone assessment in week 25 of the study [*Note this will not be required if this form is being completed in weeks 25-27*]

****If NO, the participant will continue in the trial** and you should continue to record patient data in the participant data weekly collection file

2a. Please confirm a photograph of the reference ulcer/wound site has been taken ☐

2b. Please confirm a tracing of the reference ulcer has been made ☐

Signature of nurse filling in form D	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]

Site ID: ☐☐ Date (DD/MM/YY): ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

AVURT: Form E
Recurrence assessment*

Week number: ☐	Date of completion Day ☐☐ Month ☐☐ Year ☐☐

***To be completed for all participants in week 25 if their reference ulcer healed in week 24 or earlier in the trial (nurse to phone participant to collect data) or if a participant's ulcer recurs.**

1. Is there any new ulcer on the reference leg **Yes**** ☐ **No** ☐

****If YES date of recurrence** Day ☐☐ Month ☐☐ Year ☐☐

2. Please indicate how notification was received ***Please tick one box below***

2a. Nurse phoned participant in 'week 25'	
2b. Participant telephoned clinic to advise ulcer has broken down	
2c. Participant seen in clinic and ulcer/wound site clinically assessed	
2d. Other	

	Yes	No
3. Has the participant experienced any adverse events since last data collection point?		
3a. If yes, was this a serious adverse event (SAE)?		

If YES to any of these questions, please follow the Adverse Event SOP as detailed in the site file
All Adverse Events whether serious or not will be recorded in the clinic notes in the first instance. A record must also be kept in the Sponsor's AE Log JREOLOG0007. SAEs must be notified to the sponsor immediately when the investigator becomes aware of the event (within 24 hours). Refer to JREOSOP0006 and ensure the completed SAE report form JREODOC0012 is sent to the sponsor via fax on [redacted] or E-mailed to [redacted]. If patients stop taking IMP due to an AE or SAE please complete Form F

Signature of nurse filling in form E	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]

Site ID: ☐☐ Date (DD/MM/YY) ☐☐ / ☐☐ / ☐☐ Participant ID No: ☐☐☐

AVURT: Form F
Change to study status page 1 of 2

Week number: ☐	Date of completion Day Month Year ☐☐ ☐☐ ☐☐

Please complete this form when there is a change in the status of a participant

Reasons for change in patient follow-up: *(Place a cross in the appropriate box)*

- ☐ **Participant is being withdrawn from treatment and agrees to further follow up**
- ☐ **Participant is being fully withdrawn from the study**
- ☐ **Participant is lost to follow up**
- ☐ **Participant is being withdrawn from the study and has asked for their data not to be used.**

Reason(s) for withdrawal etc (if known)

Site ID: | | Date (DD/MM/YY): | | | / | | | / | | | Participant ID No: | | | |

AVURT: Form F

Change to study status CONTINUED page 2 of 2

Week number:

Date of completion
Day Month Year

☐ **Participant has died**

A Serious Adverse Event form has been completed Yes ☐ **No** ☐

Date of death Day | | Month | | Year | |

Signature of nurse filling in form F	
Please print name	
Date (DD/MM/YY)	

Confirmed by lead PI/medic	
Please print name	
Date (DD/MM/YY)	

Please fax to York Trials Unit on: [redacted]