OCTRU FORM: OF-019
Data Management and Sharing Plan (DMP)

Trial Title: UK STAR	
Funder(s): NIHR	
Chief Investigator: Professor Matthew Costa	**Sponsor:** University of Oxford
Project start and end dates: 01 April 2016- 31 May 2019	**Duration:** 3 years
Partner organisation (s):	

Date DMP finalised:	**19Jul2016**	**Protocol version number and date:**	**V1.1 06 Apr 2016**
Names of Personnel involved:	**Role:**	**Names of Personnel involved:**	**Role:**
1. Anna Liew	Lead Author (Trial Manager)	2. Damian Haywood	Reviewer (Senior Trial Manager)
3. Michael Schlussel	Reviewer (Trial Statistician)	4. Matthew Costa	Approver (Chief Investigator)

OCTRU FORM: OF-019
Data Management and Sharing Plan (DMP)

For every update to the finalised DMP, please insert the following table:

Date of revised DMP:	**V2.0 28 Mar 2018**	**Protocol version number and date:**	**V5.0 23/Oct/2017**
Reason for updated DMP:	In order to accommodate new data rulings made as they have arisen from completed questionnaires. In order to include the use of electronic questionnaires.		
Summary of changes:	*- Addition of data rulings* *- Addition of information around sending emails and texts to patients in regard to the questionnaires and the receipt of the electronic questionnaires* *- Reference to GDPR 2016* *- Added name and date of person making data rulings, for data rulings made since 1st March 2018, for better auditing of decisions* *- Correction of minor typographical errors and clarifications of wording*		
Names of Personnel involved:	**Role:**	**Names of Personnel involved:**	**Role:**
1. Susan Wagland	Lead Author (Trial Manager)	2. Damian Haywood	Reviewer (Senior Trial Manager)
3. Ioana Marian	Reviewer (Trial Statistician)	4. Matthew Costa	Approver (Chief Investigator)

Date of revised DMP:	**V3.0 17 May 2018**	**Protocol version number and date:**	**V5.0 23/Oct/2017**
Reason for updated DMP:	1. In order to accommodate new data rulings made as they have arisen from completed questionnaires. 2. To remove regular check that back-ups are functioning.		
Summary of changes:	1. Addition of data rulings made by Trial Manager, Chief Investigator, Trial Statistician, or in TMG meetings. Agreed with OCTRU QA (15 May 2018) that database back-up checks will not be performed on an individual trial basis. The CTU will check back-ups for the whole clinical trials unit.		
Names of Personnel involved:	**Role:**	**Names of Personnel involved:**	**Role:**
5. Susan Wagland	Lead Author (Trial Manager)	6. Damian Haywood	Reviewer (Senior Trial Manager)
7. Ioana Marian	Reviewer (Trial Statistician)	8. Matthew Costa	Approver (Chief Investigator)

Date of revised DMP:	**V4.0 17 Jan 2019**	**Protocol version number and date:**	**V7.0 13 Nov 2018**
Reason for updated DMP:	1. Adding new data rulings made as queries have arisen from completed questionnaires. 2. Changes to post-out and follow-up as data collection nears completion. 3. Removal of paragraph relating to a Study Within A Trial (SWAT) as the SWAT is not being implemented.		
Summary of changes:	1. Part 4, Data management, documentation and curation: Addition of data rulings made by Trial Manager, Chief Investigator, Trial Statistician, or in TMG meetings. *2.* Including thank you letters sent out at the end of the trial. *3.* Part 3, Data collection and entry: Changes to post-out schedule. *4.* Part 3, Data collection and entry: removal of SWAT paragraph		
Names of Personnel involved:	**Role:**	**Names of Personnel involved:**	**Role:**
1. Susan Wagland	Lead Author (Trial Manager)	2. Juul Achten	Reviewer (Senior Trial Manager)
3. Ioana Marian	Reviewer (Trial Statistician)	4. Matthew Costa	Approver (Chief Investigator)

Date of revised DMP:	**V4.5.0 16 May 2019**	**Protocol version number and date:**	**V7.0 13 Nov 2018**
Reason for updated DMP:	1. Added rulings for management of date received when data entered via LimeSurvey		
Summary of changes:	1. Part 4, Data management, documentation and curation: Date entered is missing when 3, 6 or 9 month questionnaire entered Addition of data rulings made by Trial Manager, Chief Investigator, Trial Statistician, or in TMG meetings. *2.* Part 3, Data collection and entry: Clarification to post-out schedule.		
Names of Personnel involved:	**Role:**	**Names of Personnel involved:**	**Role:**
5. Susan Wagland	Lead Author (Trial Manager)	6. Juul Achten	Reviewer (Senior Trial Manager)
7. Ioana Marian	Reviewer (Trial Statistician)	8. Matthew Costa	Approver (Chief Investigator)

Glossary and definitions

AE – Adverse Event
ATRS – Achilles Tendon Rupture Score
CI – Chief Investigator
CRF – Clinical Reporting Form
DMC – Data Monitoring Committee
EQ-5D – EuroQol
HE – Health Economy/Economist
HTA – Health Technology Assessment
MCAR – Missing completely at random
MCID – Minimal Clinically Important Difference
NHS – National Health Service

N.B. The terms functional bracing and walking boot are equivalent and are used synonymously throughout the protocol, CRFs and patient documentation.

OCTRU – Oxford Clinical Trials Research Unit
PI – Principal Investigator
QA – Quality Assurance
RCT – Randomised Controlled Trial
REC – Research Ethics Committee
RF – Research Fellow
SAE – Serious Adverse Event
SAP – Statistical Analysis Plan
SD – Standard Deviation
STAR – Study of Tendo Achilles Rupture
TMG – Trial Management Group
TSC – Trial Steering Committee
QALY – Quality Adjusted Life Year

Part 1: Introduction and Context

- **Aim and purpose of the trial**

The aim of this project is to improve functional outcome by determining the best rehabilitation strategy for non-operatively managed patients with a rupture of the Achilles tendon.

The primary objective is:
To quantify and draw inferences on observed differences in Achilles Tendon Rupture Score between the trial treatment groups at 9 months after injury.

The secondary objectives are:
1. To quantify and draw inferences on observed differences in Achilles Tendon Rupture Score between the trial treatment groups at 8 weeks, 3 and 6 months after the injury.

2. To identify any differences in health-related quality of life between the trial treatment groups in the first 9 months after the injury.
3. To determine the complication rate between the trial treatment groups in the first 9 months after the injury.
4. To investigate, using appropriate statistical and economic analytical methods, the resource use, costs and comparative cost effectiveness between the trial treatment groups.

- **Policies/procedures/guidelines/regulations that apply to this trial**

All OCTRU Standard Operating Procedures
Research Governance Framework

Part 2: Data and Databases

- **OCTRU/CTU Databases / systems used within the trial**

Database / system	Provided by	Location	System	Validation of system undertaken by
Registration/Randomisation system	OCTRU	University of Oxford web server	Bespoke System - RRAMP	Trial Manager, Trial Statistician and Trial Programmers
CRF database	OCTRU	University of Oxford web server	OpenClinica	Trial Manager and Trial Programmers
Safety database (may be part of the trial management database)	OCTRU	University of Oxford local server	OpenClinica	Trial Manager and Trial Programmers
Trial management database	OCTRU	University of Oxford local server	Bespoke System – OC-TMS	Trial Manager and Trial Programmers
Lime Survey	OCTRU	University of Oxford local server	Lime Survey	Trial Manager and Trial Programmers
OXSMS	University of Oxford	University of Oxford central server	OXSMS	Trial Manager and Trial Programmers

- **Non-OCTRU/CTU Databases / systems used within the trial**

  N/A

- **Data types**

Data type	Specifics
Quantitative	Medical history, Demographics, Medication History, Complications
~~Interviews~~ /Questionnaires	EQ-5D-5L, EQ-VAS, Achilles Tendon Rupture Score, Resource Use Questionnaires

Data type	Specifics
Medical records	Screening Data, Medical history, Medication History, Complications
Electronic health records	Screening Data, Medical history, Medication History, Complications
Administrative records	Demographics

- **List of CRFs/Events**

  This list is held in the TMF and in the Documentation Checklist (OCTRU Template: OT-026) so it will not be repeated here.

- **Data Matrix**

  The initial and final Data Matrices are held in the TMF and will not be repeated here.

- **Critical data - Critical data**

Critical data field	CRF or Other Media	Reason why considered critical
Data field		*Reason why critical*
Randomisation: Site Code	Randomisation CRF	Stratification by site
ATRS data at 9 months	9 Month CRF	Primary outcome measure
ATRS data at 8 weeks, 3 months and 6 months	8 Week, 3 and 6 month CRFs	Secondary outcome measure
EQ-5D-5L, Resource Use and Complications Data	Baseline, 8 Week, 3, 6 and 9 month CRFs	Secondary outcome measure
Age: > 16 years	Randomisation CRF	Inclusion criteria
Primary rupture of Achilles Tendon	Randomisation CRF	Inclusion criteria
Patient agreed to non-operative treatment	Randomisation CRF	Inclusion criteria

Critical data field	CRF or Other Media	Reason why considered critical
Presenting to the treating hospital more than 14 days after injury	Randomisation CRF	Exclusion criteria
There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires; for example, a history of permanent cognitive impairment	Randomisation CRF	Exclusion criteria

- **Protocol deviations**

Protocol deviation	
Item	*How the trial will deal with this*
Patient did not receive allocated treatment	The 8 week CRF is set up so that it asks if the patient received their randomised treatment or not and then asks sites to detail the reasons why not received. There is also a protocol deviation form that can be completed by sites if needs be.
Patient recruited to trial in violation of eligibility criteria	Comprehensive training will be provided to Research Associates and Principal Investigators responsible for identifying suitable patients and assessing eligibility. If a recruited patient is subsequently found to be ineligible they will be kept in the trial unless 1) it is not in the patient's safety to keep them in the trial, or 2) the patient wants to withdraw from the trial.
The patient attends the wrong treatment allocation (cross over)	This information will be recorded. The patient will remain in the group they were allocated to for the intention to treat analysis. There will be a secondary per-treatment analysis.
Age	Validation rule written into randomisation program to check this.

Part 3. Data collection & entry

- **Source data**

Unless stated in the subsection labelled 'Data to be recorded directly onto CRFs' - all data to be transcribed in the CRFs will first be recorded in source documents

- **Data to be recorded directly onto CRFs**

CRFs	Time point
Baseline questionnaire	Baseline
8 week questionnaire	8 weeks post injury
3 month questionnaire	3 months post injury
6 month questionnaire	6 months post injury
9 month questionnaire	9 months post injury

- **Data collection**

Tool/generated variable	Time point	Comment
Trial Entry form (Eligibility/Randomisation)	Baseline	Bespoke – trial specific
Patient contact details	Baseline	Bespoke – trial specific
Baseline CRF (Background information)	Baseline	Bespoke – trial specific
Baseline questionnaire	Post randomisation	Bespoke – trial specific
8 week CRF	8 weeks	Bespoke – trial specific
8 week questionnaire	8 weeks	Bespoke – trial specific
3 months follow-up questionnaire	3 months post randomisation	Bespoke – trial specific
6 months follow-up questionnaire	6 months post randomisation	Bespoke – trial specific
9 months follow-up questionnaire	9 months post randomisation	Bespoke – trial specific
DVT/PE form	When arises	Bespoke – trial specific
Serious Adverse Event Form	When arises	Bespoke – trial specific
Protocol Deviation Form	When arises	Bespoke – trial specific
Withdrawal / Death Notification Form	When arises	Bespoke – trial specific

- **Patient questionnaire collection and management**

See Tables 1-3 below for time limits referred to in this section.

Invitations

At the 3, 6 and 9 month time points the questionnaires will be sent to patients in the form of an invitation to complete the follow-up questionnaire

- By post with a FREEPOST envelope for patients who do not supply an email address or mobile number, or who have requested a paper questionnaire
- By email if patients supply an email address
- By SMS text message if patient supply a mobile number.

First reminders

If no response is received within time limit, the patients are sent a first reminder

- By post with a FREEPOST envelope for patients who do not supply an email address or mobile number, or who have requested a paper questionnaire
- By email if patients supply an email address
- By SMS text message if patient supply a mobile number

Second reminders

If no response is received to the first reminder within time limit, the patients are sent a second reminder

- By post with a FREEPOST envelope for patients who have not responded to emails or texts ('Last resort post')
- By phone for all other patients.

Follow-up phone calls

If no response is received to the approaches above within time limit, patients are telephoned, depending on staff availability. Patients may complete the questionnaire over the phone, or request paper, email or text questionnaires.

Table 1: 3 month questionnaire follow-up time limits

			Postal			Digital			
	Accept for 3M	**3M due date: time after randomisation**	**To be sent: time after randomisation**	**1st reminder due (post)**	**2nd reminder due (phone)**	**To be sent: time after randomisation**	**1st reminder due (digital)**	**2nd reminder due (post)**	**Last date for response to 3M: time after randomisation**
Days after randomisation	70 days	92 days/26.1 weeks/ 6 months	78 days/ 11.1 weeks	14 days after invitation	14 days after 1st reminder sent	85 days/ 12.1 weeks/ 2.8 months	7 days after invitation	14 days after 1st reminder	154 days/ 22.0 weeks/ 9 months

Table 2: 6 month questionnaire follow-up time limits

			Postal			Digital			
	Accept for 6M	**6M due date: time after randomisation**	**To be sent: time after randomisation**	**1st reminder due (post)**	**2nd reminder due (phone)**	**To be sent: time after randomisation**	**1st reminder due (digital)**	**2nd reminder due (post)**	**Last date for response to 6M: time after randomisation**
PATIENTS RANDOMISED BEFORE MAY 2018									
Days after randomisation	155 days	183 days/ 26.1 weeks/6 months	169 days/24.1 weeks	14 days after invitation	14 days after 1st reminder sent	174 days/24.9 weeks/5.7 months	7 days after invitation	14 days after 1st reminder	245 days/35 weeks/8.1 months
Example: Pt randomised31/ May/2018	155	30 Nov	16 Nov	30 Nov	14 Dec	21 Nov	28 Nov		31 Jan
PATIENTS RANDOMISED IN MAY 2018 – Implement from 12 November 2018									
Days after randomisation	155	183 days	169 days	none	12 days after 1st post sent	169 days	7 days after invitation	7 days after 1st reminder	245 days / 8.1 months

							Also, no response to invitation = Phoning can begin	Also, phone from 7 days after post reminder sent	
Example: Pt randomised 31/May/2018	155	30 Nov	16 Nov	none	28 Nov	16 Nov	23 Nov Phoning can begin	30 Nov No response = Phone 07 Dec	31 Jan

Table 3: 9 month questionnaire follow-up time limits

			Postal			Digital			
	Accept for 9M	**9M due date: time after randomisation**	**To be sent: time after randomisation**	**1st reminder due (post)**	**2nd reminder due (phone)**	**Invitation to be sent: time after randomisation**	**1st reminder due (digital)**	**2nd reminder due (post)**	**Last date for response to 9M**
PATIENTS RANDOMISED BEFORE MAY 2018									
Days after randomisation	246	273 days/ 39.0 weeks/ 0.0 months	262 days/ 37.4 weeks/ 8.6 months	14 days after invitation	14 days after 1st reminder sent	269 days/ 38.4 weeks/ 8.8 months	7 days after invitation	14 days after 1st reminder	365
Example: Pt randomised 01/Apr/2018	246 01 Dec	29 Dec	18 Dec	02 Jan	15 Jan	25 Dec	09 Jan	23 Jan	31 Mar
Example: Pt randomised 01/May/2018	246 02 Jan	29 Jan	18 Jan	02 Feb	15 Feb	25 Jan	01 Feb	15 Feb	30 Apr
Example: Pt randomised 31/May/2018	246 01 Feb	28 Feb	17 Feb	03 Mar	17 Mar	24 Feb	02 Mar	16 Mar	30 May
PATIENTS RANDOMISED IN MAY 2018 – Implement from 02/Jan/2019 for all remaining patients									
Days after randomisation	246	273 days	246 days	None	14 days after post	246 days	7 days after invitation Also, no response to invitation = Phoning acceptable	7 days after 1st reminder Also, phone from 7 days after post reminder sent	End of follow-up phase

Example: Pt randomised 01/May/2018	246 02 Jan	29 Jan	02 Jan		16 Jan	02 Jan	09 Jan	16 Jan	31 Mar
Example: Pt randomised 31/May/2018	246 01 Feb	28 Feb	01 Feb		15 Feb	01 Feb	08 Feb	15 Feb	31 Mar

[1] **Lost to follow-up**

The list of patients to receive questionnaires by post is generated in OCTMS. The list of patients to receive questionnaires by email is generated in OCTMS and the emails are sent through Lime Survey with a personal URL for online completion. Responses are automatically logged in Lime Survey.

The list of patients to receive questionnaires by SMS text is generated in OCTMS and the emails are sent through OXSMS with a personal URL for online completion. Responses are automatically logged in Lime Survey.

All contacts and responses are logged manually in the Patient Tracker in OCTMS by Trials Office staff.

Thank you letters

All patients will receive a thank you letter by post after completing their 9 month questionnaire or after the window for completing the 9 month questionnaire is complete. The sending of the thank you letter will be logged manually in the Patient Tracker in OCTMS by Trials Office staff.

- **Data entry**

The data will be entered onto the Openclinica database held by OCTRU.

When paper CRFs / questionnaires are returned to the study office, the data will be entered into OpenClinica (single entry) by a member of the UKSTAR trial team. A 10% data quality check will be carried out periodically to ensure accurate data entry is maintained.

Data received from online entry (email or text) feeds directly into OpenClinica. Online validation ensures that 10% checks are not required.

If the OCTRU Openclinica database/University of Oxford Server were to be down, the CRFs can wait until the server is back up and running to be entered.

Part 4. Data management, documentation and curation

- **Data receipt**

OCTRU SOP GEN-028 for paper CRFs will be followed.

Data will be collected on paper CRFs by each of the sites and the originals will be sent by post back to the UKSTAR Trial Management Team. Confidential patient data will be sent in a separate envelope, or will be scanned and sent via NHS secure email. Sites will keep either paper copies or scanned electronic copies of the completed CRFs. CRF instructions will be provided alongside the CRFs. The CRFs (both patient completed and Clinician completed) will be processed through manual data entry in to OpenClinica.

Once a CRF is received by the trials office it will be opened on the day it is received (unless the coordinator is on annual leave) and will be date stamped on every page. If the coordinator is on annual leave, depending on the amount of time off, cover will be arranged for the post to still be opened and date stamped. The CRFs will be checked for completeness and legibility, (usually the same day as they are received unless there is a backlog). Entry will take place as soon as possible (checks and entry may take place at the same time or separately).

- **Data queries / query handling**

OCTRU SOP GEN-028 for paper CRFs will be followed.

The main contact at each site to deal with data queries will be the lead research nurse or PI.

Outstanding CRF reports will be generated each month and sites will be followed-up for outstanding data. All CRFs that are returned to the trial office will be logged and data queries will be raised for missing or incorrect data. Data queries and discrepancies will be automatically raised from the rules within OpenClinica. Steps will be taken to reduce the reoccurrence of data queries in discussion with sites.

If there are discrepancies in the CRFs, these will be queried with the site. A large amount of the data that will be received back at the office will be patient reported outcomes (questionnaires) so there shouldn't be any extreme values of data identified. The CRF will also be logged as received into the OC-TMS System.

The CRFs have completion notes or site staff are referred to guidance notes elsewhere. The majority of data collected is from patients rather than clinical data.

Automated checks will be carried out by the database that have been programmed in from the information on the data matrix. Please refer to the data matrix for these checks.

- **Central Monitoring**

The Monitoring Plans including details of central monitoring are held in the TMF and will not be repeated here.

- **Coding of free text data**

Data items that are free text, or data items with coded values that allow entry of "other" and a free text explanation, will be reviewed during data cleaning. The table below describes the action to be taken for each of these free text data items.

Free text data items		
Form	*Data item (CRF/ questionnaire section)*	*Action to be taken*
8 week, 3, 6, 9 month questionnaires	Other complication (Section E1, E2 in 8 week and Complications 3 in 3,6,9 month)	Reviewed by CI for inclusion in predefined coded complications
3, 6, 9 month questionnaires	Treatment for other complication (Complications 4)	Reviewed by CI. Data used to confirm resource use of participant
8 week questionnaire	Other treatment received initially (Section A2)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	Other time point after which the patient was allowed to fully bear weight (Section B4, Section C4)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	Other time point after which the walking boot/plaster cast was removed (Section B5, Section B5)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	Other brand of walking boot the patient received (Section B6)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	Other reason the patient switched from walking boot/plaster cast to another intervention (Section B7, Section C6)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.

Free text data items		
8 week questionnaire	Other time point the intervention was changed at (Section B8, Section C7)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	Other intervention changed to (Section B9, Section C8)	If the text is a predefined category it will be moved to the relevant category. Alternatively it will be reviewed and reported by the statistician.
8 week questionnaire	VTE prophylaxis: if LMWH ticked, other text field (Section D2)	If name of medication is one of the predefined coded values, data included in these categories. Reviewed by CI for other values
8 week questionnaire	Other oral anticoagulant (Section D2)	If name of medication is one of the predefined coded values, data included in these categories. Reviewed by CI for other values
Baseline	Category of employment (Section B7)	Reviewed by trial manager for recoding into one of the predefined categories
Baseline	Baseline diagnosis (Section B5)	Reviewed by CI for recoding into one of the predefined categories
Baseline	Mechanism of injury (Section A2)	Reviewed by trial manager for recoding into one of the predefined categories. New categories added for common values: fall, trip or slip at low level; dancing, running, jumping, pushing an object.
Baseline	Previous regular medication (Section B4)	Reviewed by CI for recoding into one of the predefined categories. New category added for common values: anticoagulation medication.

- **Data rulings**

No obvious or self-evident corrections i.e. cleaning of CRF data will be undertaken without first querying with the site; **apart** from the rulings listed in this document. In the event that it is mutually convenient for the Trial Team and the site, the Trial Team may clean a data point but the query audit trail will include reference to the dialogue leading up to this and also the new value to which the site has agreed. (For example if the site has replied to a query by providing an updated value in the response to DCF audit trail; the data checker could update the CRF itself if mutually convenient).

Data ruling		
Item	*How will the trial deal with this*	*Person making data ruling, date and first patient applicable*
Date of Birth	These can be annotated to correct format as required	Signed off in V1.0 of DMP
Dates in incorrect format	These can be annotated to correct format as required	Signed off in V1.0 of DMP
Receipt of questionnaires/CRFs	All CRFs/Questionnaires can be logged in the database or equivalent as arrived following date stamping. The database will identify which forms the trial team have already received.	Signed off in V1.0 of DMP
All questionnaires	If the site staff signed the questionnaire but not added the name, this can be added by admin staff after checking the signature against the Site Contact and Responsibilities Sheet.	SW 20/06/2018 ST-RED-1487.
All questionnaires	Where questions have a variety of response options, where one is selected assume that is the response.	Signed off in V1.0 of DMP
All questionnaires	Where there is a space for patient to free-text data e.g. Q3 or Q4 of the complications section if this is left blank assume patient has nothing to add and there is no need to chase patient.	
All questionnaires Medications	If PRN or prn (*pro re nata*; as required) is entered in “Times per day” add this as a comment in a discrepancy note.	SW 17/May/2018 in line with practice on WHIST

Data ruling		
EQ-5D-5L	Where patients have offered more than one response to a question, the most severe should be used.	Signed off in V1.0 of DMP
EQ-VAS	Where there is a discrepancy between the value marked in the scale and the number written in the box, the number in the box should be used.	Signed off in V1.0 of DMP
EQ-VAS	Where a range has been indicated the mid-point should be used	
ATRS	If a patient has drawn a cross between the boxes rather than in one box the lower value box should be used.	
ATRS	• If patient leaves the entry blank and **no comments** are added, enter as missing data. • If patient leaves the entry blank and **comments** are added suggesting that the action was not performed due to physical or other limitations (e.g. "Have not tried", "Scared to try", "Can't jump" enter as zero. • If patient leaves the entry blank and **comments** are added suggesting that the action was not performed (e.g. "Not applicable") enter as missing data. All handwritten comments and telephone clarifications on the ATRS missing items should be entered as a discrepancy note. During analysis, missing data will be imputed with an average of the remaining ATRS entries when at least 50% of the items in the questionnaire are available.	TMG 28/Mar/2018 ST-ABD-1313 Email IM 18/Apr/2018 further clarification Email IM 04/May/2018 further clarification Email IM 14/May/2018 further clarification TMG 16/May/2018
Site name/code on all forms	If the site code/name has been left blank and trial team knows where the person who has completed the form is from this can be completed by the trial team.	Signed off in V1.0 of DMP
Spelling mistakes	All spelling mistakes can be cleaned by the trial team when inputting the data.	Signed off in V1.0 of DMP
'other' boxes	Where other information is added but the 'other' box is not selected, this can be selected by the trial team.	Signed off in V1.0 of DMP

Data ruling		
Questions with “Yes”/”No” boxes in Health data /Complications data	Where yes/no boxes are provided, if ‘yes’ is selected study team can indicate ‘no’ in the follow on responses to that question where the first ‘yes’/’no’ response indicates the remaining options for that question are not relevant. Where yes/no boxes provided and patient selected ‘yes’ to one or more items, study team may assume ‘no’ to other options within the listing. If e.g. no follow on responses listed but patient has not ticked “Yes”/”No” box this can be taken as “No” and vice versa.	Signed off in V1.0 of DMP
Patient Contact Details	Study team may change this information as required if aids interpretation of handwriting. In addition if up to date information becomes available from the site staff, patient, the national database or GP.	Signed off in V1.0 of DMP
Missing data	Where data is missing that relates to the primary and secondary outcomes the site will be contacted to obtain this information where possible. For patient questions that are missing these core outcomes the patient will be contacted from the trial office.	Signed off in V1.0 of DMP
Baseline CRF: Baseline Demographics height	If height has been written or entered in feet and inches, perform a metric conversion to cm and round to nearest whole number	TMG 28/Mar/2018
Baseline CRF: Baseline Demographics weight	If weight has been written or entered in stones and pounds, or pounds, perform a metric conversion to kg and round to nearest whole number. If weight has been handwritten as a number with decimals, round to nearest whole number.	TMG 28/Mar/2018
Baseline CRF: smoking/vaping	If patient answers ‘Yes’ to regular smoker but then adds a comment to say ’only vaping ‘, the answer should be changed to ‘No’.	MC 16/Feb/2018 (email)
Baseline CRF QB6&B7 (Employment status)	If the patient has been listed under “other” as a “housewife” or “househusband” on this question this should be entered into the database under the category “looking after home”.	

Data ruling		
Baseline CRF QB7 (Employment status)	If "other" and job title has been completed this should be converted into a job category (e.g. skilled manual) before entry into the database. The trial office team will contact the health economists if there is any doubt as to what category a particular job fits under.	
Baseline CRF QB7 (Employment status)	If patient ticks both "working" and "retired/looking after home/inactive", enter the most active, i.e. "working".	MC 27/Sep/2018 (email)
Baseline CRF Section C (Questionnaire guidance to patient from site staff)	If all four tick boxes have been left blank, do not query with site. This is a guide for site staff only. Ruling is consistent with Visual Data Check TSI for Baseline Questionnaire.	SW 04/Jul/2018
ATRS Baseline questionnaire Pre-injury	If it is self-evident that a patient has answered the score incorrectly by mistake, the data can be inverted i.e. if a patient has entered scores of 0 (worst score) across the questionnaire then these can be entered into the database as 10. However, if there is any doubt as to what the score should have been recorded as then the site should be contacted. In this case, if the patient has entered one score as close to 0, and the rest as 0, the non-zero value can be inverted as well, e.g. "3" to "7". Trial statistician raised potential inconsistent answers in cases of responses to ATRS in range 20-35 and EQ-5D Mobility = 1. Trial team should attempt to contact the patient, even over a year after injury, to ask for clarification of how they were before injury. If the patient cannot be contacted or cannot clarify, enter the data as provided by the patient.	Clarified by MC 07/Mar/2018 ST-SAL-1146 (Baseline) Clarified by MC 18/May/2018 e.g. ST-CHX-1404, DT-DBH-1059 (Baseline pre-injury)
8 Week CRF (Intervention)	Question A2 can be answered by the study office when intervention was indicated and the section for that intervention was completed.	SW 09/Mar/2018
8 Week CRF (Intervention)	The database allows for either Boot or Cast details but not both. If patient has crossed over at baseline and then crossed over again during the 8 weeks: 2nd crossover at 1 week: enter data for weeks 2-8 (ST-ABD-1405) 2nd crossover at 7th week: enter data for weeks 1-7 (ST-ENH-1368)	MC 21/Mar/2018 (email) ST-ABD-1405 (8 wk) ST-ENH-1368 (8 wk)

Data ruling		
8 week CRF (Intervention)	If the patient was in a boot (or cast) before randomisation, and was randomised to the same arm, sites may enter the date of the initial appointment as before randomisation, when they consider that treatment began. If this is the case, change the date to the randomisation date. Annotate to explain.	SW 22/Mar/2018 ST-ABD-1408 (8 wk) (following precedent of OUH patient)
8 Week CRF QB3 (Number of wedges used in walking boot)	For sites who use a Vacoped boot and record the data in "degrees" rather than number of wedges this following conversions should be used and entered into the trial database as follows: - 30 degrees = 2 wedges - 20 degrees = 2 wedges - 15 degrees= 1 wedge - 10 degrees = 1 wedge	
8 Weeks Questionnaire (number of wedges)	If the patient had 'No wedges' at 6 weeks and 8 weeks was not answered, study office can assume 'No wedge' at 8 weeks.	SW 08/03/2018
8 Weeks Questionnaire (number of wedges)	If the site has left earlier dates blank but stated 3 wedges later (e.g. at 4 weeks), it can be assumed that the patient had 3 wedges up to that point.	MC 24/04/2018
8 Week Questionnaire Pack (Page 7-18)	If the patients were missed and it will be too late to complete the questionnaire, the site staff will be asked to complete the CRF part and send on (striking through the first page of the questionnaire and annotating why it was not done if this is the case). If the CRF was sent to study office but the first page of questionnaire was not annotated, this could be done by study office if a reason was given. AL email to Salisbury site 23/01/2018	AL 23/Jan/2018
8 Week CRF QB4 (Weight-bearing timepoint)	If a site answers this as "baseline" then annotates "during first week" this is to be entered into the database as "baseline".	
8 Week CRF QB4 (Weight-bearing timepoint	If the patient was allowed to fully weight bear but commenced weight bearing weeks later this should be recorded as the time when they were allowed to and not when they started.	SW 26/Jun/2018 ST-CHX-1472

Data ruling		
	If the patient was allowed to fully weight bear after '6' or '8' weeks, or 'still not allowed', query with site to provide a reason for this.	SW 04/Jul/2018 (Ruling made by AL prior to Feb 2018)
8 Week CRF QB4 (Weight-bearing timepoint)	If site writes "other" and "7 weeks", enter as 8 weeks	MC ruling in email 06/Dec/2018
8 Week CRF QB7 and QC6 (Why did the patient switch between interventions?)	If this has been answered as two different answers (patient request and clinician decision) this should be entered into the database as patient request only.	
8 Week CRF Section D (VTE Prophylaxis)	If the patient has received VTE prophylaxis that is not in addition to their current medication (e.g. prescribed Aspirin 75mg but has already taken Aspirin for 30 years), then do not enter this data. Select 'No' for 'D1: Did the patient receive treatment with VTE prophylaxis'. Add an annotation describing which VTE prophylaxis medication the patient was prescribed, for how many weeks they were prescribed and the number of years the pt had already taken this medication.	Ruling made by MC via email 16/07/2018
3, 6 and 9 month questionnaires		
3, 6 and 9 month questionnaires	If patient returns two questionnaires for the same time point the first questionnaire should be used. However, if one questionnaire was answered online before the other was received in the post, the answers already recorded online will be retained. If one was entered into OpenClinica before the other was received or data was entered, the answers already recorded in the database will be retained.	MC [07/Mar/2018) ST-RTH-1022 (9m)
3, 6 and 9 month questionnaires	If no response is received from the participant within the timeframe that can be counted towards the 3 month or 6 month timepoint (see "Dataset Closure" for limits) then that timepoint is "skipped". If no response is received within the timeframe for the 9 month questionnaire (before 366 days), the participant is deemed lost to follow-up for the 9 month timepoint (primary outcome).	

Data ruling		
Questionnaires received in the post from patients	Date to be used for "today's date" when a questionnaire is returned from a patient without a date on it should be 3 days before the date received e.g. a questionnaire received on 6th April then date completed would be entered as 3rd of April.	
Questionnaires received via online data entry when patients are sent a link via LimeSurvey or OXSMS	Questionnaires received via online link do not have a date value in "date questionnaire pack completed" section in OpenClinica. OpenClinica also holds a "Start date" field for each questionnaire, which is the date that data was first entered in that record, including data completed via Lime Survey. Data from LimeSurvey is uploaded overnight from the previous day. 1. When aware that the "date questionnaire pack completed" is blank, Trial office staff complete this date manually from the date present in Lime as "date completed" 2. For those that remain blank after this process, after data entry, Trial Statistician uses for analysis purposes ("start date" – 1 day).	IM email 19/Feb/2019
Complications	If patient answers one or more of the questions in 1. and leaves the others blank, those left blank should be recorded an "No" for the other complications. This includes answering "No" to "Did you fall" and leaving "did you injure yourself" blank, which should be recorded as "No". Annotate as "patient left blank – completed as in data ruling"	MC 07/03/2018 ST-UHS-1187 ST-RTH-1022 (9m)
Complications, Q2, pain under the heel today	If patient marks neither box and writes "occasionally" take this to mean No	SW 02/Oct/2018 ST-ABD-1019 (9M)
Complications	If patient writes "No" in the text field for Q3, this can be taken as "No" for all the complications questions (1, 2) that have been left blank. Annotate as "patient left blank – completed as in data ruling"	MC 07/03/2018
Complications	Re-ruptures and DVTs to be reviewed during data cleaning by CI against evidence provided by sites.	MC

Data ruling		
Resource use questionnaire p. 7-10 all amounts	If cost is given in another currency, enter the figure as given and add a discrepancy note e.g. “amount in US dollars”	MM via email 03/04/2018
Resource Use questionnaire p8-9	If the patient has left the entire double page spread blank, assume the patient has missed the page completely. Contact patient for clarification. If patient cannot be contacted for clarification, enter as missing data.	MC 07/03/2018 ST-LDS-1072
Resource Use questionnaire Q1 (Inpatient Care) and Q2 (Outpatient Care)	If patient lists a speciality which is clearly unrelated to the injury this should not be entered into the database. If there are no costs related to the injury, enter as “No” in OpenClinica.	MC email 18/04/2018
Resource Use questionnaire Q2 (Outpatient Care)	If patient puts “other - fracture clinic” under outpatient care this should be recorded as an “orthopaedics” clinic visit.	
Resource Use questionnaire Q2 (Outpatient Care)	If patient puts “NHS Referral” against “Physiotherapy (Private)” change this to “Physiotherapy (NHS)”	MC 07/03/2018 ENH-1100 (9m)
Resource Use questionnaire Q2 (Outpatient Care)	If patient has entered “weekly”, calculate the number of visits, e.g.4 weeks x 3 months =12	MM email 19/Apr/2019 (1133 9M)
Resource Use questionnaire Q4 (Medications)	If patient lists medications which are clearly unrelated to the injury, change the answer to ‘No’ and enter “No” into the database. If in any doubt check with the CI.	Signed off in V1.0 of DMP. Clarified by SW 16/03/2018
Resource Use questionnaire Q4 (Medications)	If the Medications section is not completed, and the patient has completed other sections of the double page spread, assume no medications.	MC 07/03/2018 ST-MYH-1202
Resource Use questionnaire Q4 (Medications)	If patient lists VTE prophylaxis, do not enter into the database. This data is captured in Section D of the questionnaire. Change the answer to ‘No’ and enter into the database.	SW 16/03/2018
Resource Use questionnaire Q4 (Medications)	If number of days of medication recorded by patient exceeds the number of days since their injury then enter the value given by patient, but record it as a discrepancy note.	

Data ruling		
Resource Use questionnaire Q4 (Medications)	If patient has selected that medication was both “prescribed” and “not prescribed” then “prescribed” will be entered onto the database.	
Resource Use questionnaire Q4 (Medications)	If patient has written ‘constant’ or “every day” for number of days used for medication then calculate number of days since last questionnaire/CRF, e.g. 3x3 = 90 Use 30 days per month. Do **not** enter the words as a discrepancy note.	MM email 19/Apr/2019
Resource Use questionnaire Q4 (Medications)	If patient or site staff has written “most days” for number of days used for medication then calculate number of days since last questionnaire/CRF as for “every day”, e.g. 8x7 = 56.	MC 18/May/2018
Resource Use questionnaire Q6 (Aids and adaptations)	If patient puts “one” crutch enter as one on the database, if they say a “pair/set” enter as two.	
Resource Use questionnaire Q6 (Aids and adaptations)	If patient lists “walking boot” or similar in Aids and Adaptations, cross it out and do not enter into the database. This is the intervention. If this is the only entry in that table, change the answer to “No”.	AL ~01/Feb/2018 ST-ENH-1368
Resource Use questionnaire Q6 (Aids and adaptations)	If patient lists more than one of an item, enter the unit cost under “cost”. E.g. Patient said 2 freezable ice packs, total £10” this is entered as freezable ice pack, number received = 2, cost = 5 (Pt 1368 3M)	MM email 19/Apr/2019
Resource Use questionnaire Q6 (Aids and adaptations)	If patient writes in 4 items, but there is only space for 3 in OpenClinica, enter the 4th as an annotation. (Pt 1173, 6M)	MM email 19/Apr/2019
Resource Use questionnaire Q7 (Work)	If patient selects more than one reason why they are not currently working then retired supersedes all responses and health reasons supersedes UKSTAR injury.	
Resource Use questionnaire Q7 (Work)	If patient has listed their days off work in weeks or months this should be converted into days. Assume a 7 day week.	AL ~01/Feb/2018 ST-ENH-1368 Clarified at TMG 28/Mar/2018

Data ruling		
Resource Use questionnaire Q7 (Work)	If patient enters a time off work greater than the time since the last timepoint, e.g. "4 ½ months" in the 8 week questionnaire, calculate the maximum time possible since the last timepoint and convert to days.	MC 07/Mar/2018 ST-SAL-1246 (8 wk)
Resource Use questionnaire Q7 (Work)	If patient enters number of days off work as "All", calculate the maximum time possible since the last timepoint using due dates and convert to days. E.g. for the 3 month questionnaire this will be 4 weeks since the 8 week timepoint.	MC 07/Mar/2018 ST-RCH-1319 (3m)
Resource Use questionnaire Q7 (Work)	If patient writes "Working" = "No", and the reason is because of injury, but leaves the number of days blank, enter the number of days as missing data.	MC 07/Mar/2018 ST-SAL-1146 (8 Wk)
Resource Use questionnaire (all questions)	If patient gives a range as an answer for any question the highest number should be used.	
Resource Use questionnaire (all questions)	If patient does not give a number of visits, or enters just a tick, assume one visit. If patient puts a word e.g. "referral", assume one visit.	Clarified by MC 07/Mar/2018 ST-ENH-1100
Resource Use questionnaire (all questions)	If patient enters "several" or "numerous" instead of a number then assume three.	
Resource Use questionnaire (all questions)	Where patient has listed the same visit across multiple parts of the questionnaire only one instance of the visit should be entered into the database to avoid double counting.	

- **Data deviations**

Data deviations	
Item	*How will the trial deal with this/why this is important*
Inclusion/exclusion criteria not being met	The trial team will assess individual cases.

- **Data locks**

Datalocks during the trial
Any database lock will either be requested by the Trial Statistician for a DSMC or interim or final analysis, or the Trial Manager who will request a lock for the APR– this will be formally documented in Mantis and the OCTRU SOPs followed for the request and subsequent handling and distribution of the data.

- **Dataset closure**

Datasets to be closed during the trial	
Dataset	*Time point when this will be closed*
Screening logs	When recruitment is complete, all of the screening logs will be requested and the dataset closed
Whole dataset for a deceased patient	When a patient dies this dataset will be cleaned straight away rather than waiting until the end of the trial
Baseline data	Once all baseline data has been received, cleaned and all queries resolved (baseline assessment form and baseline patient questionnaire)
Follow-up (all points)	When all follow-ups have been completed and the data received and all data queries resolved. • Any response up to 10 weeks will be counted as part of the 8 week timepoint. • Any response from 10 weeks onwards until the end of 4 months (154 days) will be counted as part of the 3 month timepoint. • Any response from 5 months (155 days) onwards until the end of 7 months (245 days) will be counted as part of the 6 month timepoint. • Any response from 8 months (246 days) onwards until the end of 11 months (365 days) will be counted as part of the 9 month timepoint.

Datasets to be closed during the trial	
	• Any response that falls outside of the above timeframes will be counted as a non-responder for that timepoint.

- **Database documentation and metadata**

The initial and final approved data matrix and CRF matrix will be filed in the Trial TMF. PDFs of the approved CRFs and the CRF sign-off sheets/Log of Contributors and Reviewers will be filed in the Trial TMF along with the database validation and testing. CRF sign off sheets have been produced for all CRFs, the Randomisation System, Protocol and data matrix. Please refer to the central monitoring plan for frequency of review and items that will be checked.

- **Data Back-up and recovery procedures**

Data will be held on University of Oxford based and managed servers. The servers are backed up every night by MSD-IT and back-up copies are stored for 30 days. Checks that back-ups are functioning will be undertaken by OCTRU.

- **Dataset to be held by the site at the end of the trial**

Sites will be sent a full data set for their site (both for data entered directly by site and the data submitted directly by patients in patient completed questionnaires. The data set pulled from the database will be QC checked and then sent to site in an electronic format such as CDISC ODM. The study office will request confirmation of receipt of this data, and that the sites can open the files and they will record with the site where this data will be held and archived.

Part 5. Data security and confidentiality of potentially disclosive information

- **Confidentiality**

The trial staff will ensure that the patients' anonymity is maintained. The patients will be identified only by initials and a patients study number on the CRF and any electronic database. All documents will be stored securely and only be accessible by the central trial team and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

Personal data held by the central coordinating office in paper format to facilitate follow-up and results reporting will be sent and stored separately from any data collected and only accessed by authorised personnel. The consent form includes consent for this data to be held.

All data will be processed according to the Data Protection Act 1998 and General Data Protection Regulation 2016, and all documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent and the contact details used for follow-up, the patient will be referred to by the study patient number/code, not by name. Identifiable information will be stored separately from study data.

- **Security**

Responsible members of the University of Oxford or the NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations. The trial team will have access to a person's personal data and consent for this is sought. Data entry and statistical staff will not require access, apart from the staff using the randomisation database who will have access to some personal data (date of birth etc. but not names and addresses).

Access will also be granted for Trust, R&D audits and regulatory bodies should the trial be audited. Consent for this is included in the consent form.

Documents that have patient identifiable data on will be stored in either locked cabinets within the trial unit or on a password protected computer. Any paper documents that have identifiable data on that are no longer needed will be shredded.

- **Archiving**

Trial documentation must be retained for 5 years after completion of study-related activities. Collaborating sites are delegated the responsibility of archiving local essential documents in an appropriate secure environment locally. The central Trial Master File and associated documents in Oxford will be archived according to University of Oxford policy and this may include the use of an external professional archiving site. This complies with OCTRU SOP GEN-048 and archiving will be updated if the SOP revises key activities around archiving.

Part 6. Data sharing and access

- **Data use**

University of Oxford, OCTRU, the Lead statistician and the CI all have a role to play in data use as outlined in the UKSTAR ethics application.

- **Managing, storing and curating the data**

The data will be stored on the trial database, paper documents will be stored in locked filing cupboards throughout the trial. The final data set will be store at the university off site archive Centre. The trial database will be routinely backed up and managed by the trial manager.