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| **Project Settings** |
| **Implement the following settings for the project:*** Use Surveys in this project
* Use longitudinal data collection
* Repeating Instruments
* Auto-numbering of records
* Enable Data Resolution Workflow
* Require a reason when making changes to existing records
* Prevent branching logic from hiding fields that have values
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| **Event Names** |
| **Add the following events:*** Screening Visit
* Baseline & Randomisation Visit
* 6-Month Follow-up Visit
* Adverse Events
* Medications
* Change of Status
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| **Designate Instruments for events** |
| **Create the following Data Collection Instruments and designate them to the event in brackets:*** Visit Date (Screening Visit, Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* Inclusion/Exclusion (Screening Visit)
* Screening Visit (Screening Visit)
* Contact Details (Screening Visit)
* Baseline Visit (Baseline and Randomisation Visit)
* Eligibility Review (Baseline and Randomisation Visit)
* Randomise (Baseline and Randomisation Visit)
* Randomisation Result (Baseline and Randomisation Visit)
* EQ5D5L (Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* BPI (Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* HAQ (Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* PQSI (Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* SF36 (Baseline and Randomisation Visit, 6-Month Follow-up Visit)
* 6-Month Visit (6-Month Follow-up Visit)
* Weekly Blood Pressure Readings (6-Month Follow-up Visit)
* Adverse Event (Adverse Events)
* Concomitant Medications (Medications)
* Withdrawal (Change of Status)
* Death (Change of Status)
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| **Instrument Name**  | **Field Name** | **Field Type**  | **Validation** | **Branching Logic**  |
| **Visit Date** | Visit Date  | Text  | DateMax: Today | None |
| **Screening Visit**(subsection PISCF and Consent) | Date PISCF given to Participant | Text | DateMax: Today | None |
| **Screening Visit** (subsection PISCF and Consent) | PISCF Version No | Text | Number (1 decimal place) | None |
| **Screening Visit** (subsection PISCF and Consent) | PISCF Version Date | Text | DateMax: Today |  |
| **Screening Visit** | Did the participant and investigator both sign the Consent Form? | Yes/No | None | None |
| **Screening Visit** | Investigator Name) | Text | None | Field appears if ‘Did the participant and investigator both sign the consent form?’ is ‘Yes’ |
| **Screening Visit** | Date of Consent | Text | DateMax: Today | Field appears if ‘Did the participant and investigator both sign the consent form?’ is ‘Yes’ |
| **Screening Visit** (sub-section Participant Details/Demographics) | Gender | Drop-down* Male
* Female
* Prefer not to say
 | Required | None |
| **Screening Visit** (sub-section Participant Details) | Date of Birth | Text | DateMax: Today | None |
| **Screening Visit** (sub-section Participant Details/Demographics) | Age | Calculated FieldCalculated between Date of Birth and Consent Date  | None | None |
| **Screening Visit** (sub-section Participant Details/Demographics) | Participant is aged <40. Participant is Ineligible for study | Descriptive field (Red) | None | Field appears if ‘Age’ is <40 |
| **Screening Visit** | Ethnicity | TBCUse the groups as listed here to create ethnicity options https://www.ethnicity-facts-figures.service.gov.uk/style-guide/ethnic-groups | None | None |
| **Screening Visit**(in sub-section Current Conditions) | Diabetes Mellitus | Yes/No | None | None |
| **Screening Visit**(in sub-section Current Conditions) | Type | Drop-down* Type 1
* Type 2
 | None | Field should only appear if ‘Diabetes Mellitus’ is ‘Yes’ |
| **Screening Visit**(in sub-section Current Conditions) | Atrial Fibrilation | Yes/No | None | None |
| **Screening Visit**(in sub-section Current Conditions) | Chronic Kidney Disease | Yes/No | None | None |
| **Screening Visit**(in sub-section Current Conditions) | High Cholesterol (requiring treatment with medication) | Yes/No | None | None |
| **Screening Visit**(in sub-section Current Conditions) | High Blood Pressure (requiring treatment with medication) | Yes/No | None | None |
| **Screening Visit**(in sub-section Previous Conditions) | Previous malignancy/cancer | Yes/No | None | None |
| **Screening Visit**(in sub-section Previous Conditions) | If Yes, please specify details | Text | Include Field Note ‘Specify type of malignancy, year of diagnosis and treatment type if known’ | Field should only appear if ‘Previous malignancy/cancer’ is ‘Yes’ |
| **Screening Visit**(in sub-section Previous Conditions) | Previous treatment with blood transfusion | Yes/No | None | None |
| **Screening Visit**(in sub-section Previous Conditions) | If Yes please specify details | Text | Include Field Note ‘Specify reason for treatment and year of treatment’ | Field should only appear if ‘Previous treatment with blood transfusion’ is ‘Yes’ |
| **Screening Visit**(in sub-section Previous Conditions) | Previous surgical interventions | Yes/No | None | None |
| **Screening Visit**(in sub-section Previous Conditions) | If Yes, please complete the section below | Descriptive field (blue) | None | Field should only appear if ‘Previous surgical interventions’ is ‘Yes’ |
| **Screening Visit**(in sub-section Previous Conditions) | Matrix of fields with title Previous SurgeriesMatrix Rows as follows:* Angioplasty
* CABG
* Transplant Surgery (any type)
* Bowel resection
* Oophrectomy
* Surgical removal of malignant tumour
* Stent insertion (any type)
 | Single Answer Radio Buttons – Column Choices Yes/No | None | Matrix should only appear if ‘Previous surgical interventions’ is ‘Yes’ |
| **Screening Visit** (in sub-section Vital Signs) | Systolic Blood Pressure | Text | NumberMin: 50Max: 250 | None |
| **Screening Visit** (in sub-section Vital Signs) | Diastolic Blood Pressure | Text | Number:Min: 50Max: 250 | None |
| **Screening Visit** (in sub-section Vital Signs) | Participant BP is >150/90. Participant is Ineligible for study | Descriptive field (red) | None | Field should appear is Systolic BP is >150 and Diastolic BP is >90 |
| **Screening Visit** (in sub-section Vital Signs) | Height (cm) | Text | NumberMin: 120Max: 220 | None |
| **Screening Visit** (in sub-section Vital Signs) | Weight (kg) | Text | Number (1 decimal place)Min: 35.0Max: 220.0 | None |
| **Screening Visit** (in sub-section Vital Signs) | BMI | Calculated Field Calculated between Height and Weight | None | None |
| **Screening Visit** (in sub-section Vital Signs) | Temperature (Celsius) | Text | Number (1 decimal place)Min: 35.0Max: 40.0 | None |
| **Screening Visit** (in subsection Medications) | Is the participant currently taking any concomitant medications? | Yes/No | None | None |
| **Screening Visit** (in subsection Medications) | Please complete details in Concomitant Medications | Descriptive field (Red) | None | Field appears if ‘Is the participant currently taking any concomitant medications?’ is ‘Yes’ |
| **Contact Details** | First Name | Text | Required  | None |
| **Contact Details** | Last Name  | Text | Required | None |
| **Contact Details** | Preferred Contact Method | Drop-down * Email
* Post
* Telephone
 | Required | None |
| **Contact Details** | Email Address | Text | Email | Field should only appear if ‘Preferred Contact Method’ is ‘Email’ |
| **Inclusion/Exclusion** (subsection Inclusion Criteria) | Inclusion Criteria: All must be answered YES to be eligible for the study | Descriptive (blue) | None | None |
| **Inclusion Exclusion** (subsection Inclusion Criteria) | 1. Aged 40 and over at Consent Date?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Inclusion Criteria) | 1. Currently treated with ACE Inhibitors (for at least six months prior to Consent Date)?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Inclusion Criteria) | 1. Able and willing to have wearable BP monitoring device fitted for at least 6 Months?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Inclusion Criteria) | 1. Able and willing to give Informed Consent to take part in the study?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Inclusion Criteria) | One or more Inclusion Criteria is answered ‘No’. The participant is Ineligible | Descriptive field (Red) | None | Field appears if any Inclusion Criteria 1-4 is ‘No’ |
| **Inclusion Exclusion** (subsection Exclusion Criteria) | Exclusion Criteria: All must be answered NO to be eligible for the study | Descriptive (blue) | None | None |
| **Inclusion Exclusion** (subsection Exclusion Criteria) | 1. Currently pregnant or breastfeeding?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Exclusion Criteria) | 1. Blood Pressure > 150/90 at **Screening Visit**
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Exclusion Criteria) | 1. Currently or previously treated with Angiotensin-2 Receptor Blockers (within the last six months)?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Exclusion Criteria) | 1. Already enrolled on another **Randomise**d IMP trial for blood pressure treatment?
 | Yes/No | Required | None |
| **Inclusion Exclusion** (subsection Exclusion Criteria | 1. Known or suspected to be non-compliant with currently prescribed blood pressure treatment?
 | Yes/No | Required | None |
| **Baseline Visit**(subsection Pregnancy Test) | Is the participant of child-bearing potential? | Yes/No | None | None |
| **Baseline Visit**(subsection Pregnancy Test) | If Yes, was a pregnancy test performed? | Yes/No | None | Field appears if ‘Is the participant of child-bearing potential?’ is ‘Yes’ |
| **Baseline Visit**(subsection Pregnancy Test) | Result | Drop-down* Negative
* Positive
 | None | Field appears if ‘If Yes, was a pregnancy test performed?’ is ‘Yes’ |
| **Baseline Visit**(subsection Pregnancy Test) | Participant has returned a positive pregnancy test and cannot continue in the study. Please complete Change of Status | Descriptive field (Red) | None | Field appears if ‘Result’ is ‘Positive’ |
| **Baseline Visit**(subsection Vital Signs) | Build all fields in this section as built in Vital Signs section at **Screening Visit** | As before | As before | As before  |
| **Baseline Visit**(subsection Medications) | Have there been any changes to the participants medications since the last visit? | Yes/No | None | None |
| **Baseline Visit** (in subsection Medications) | Please complete details in Concomitant Medications | Descriptive field (Red) | None | Field appears if ‘Have there been any changes to the participants medications since the last visit?’ is ‘Yes’ |
| **Baseline Visit** (in subsection Adverse Events) | Has the participant experienced any adverse events since the last visit? | Yes/No | None | None |
| **Baseline Visit** (in subsection Adverse Events) | Please complete details in Adverse Events  | Descriptive (Red) | None | Field appears if ‘Has the participant experienced any adverse events since the last visit? |
| **Eligibility Review** (in subsection Confirmation of Eligibility) | Is the participant eligible to proceed to randomisation? | Yes/No | Required | None |
| **Eligibility Review** (in subsection Confirmation of Eligibility) | If No, please specify reason | Drop-down* Participant did not comply with one or more of the Inclusion Criteria
* Participant did not comply with one or more of the Exclusion Criteria
* Participant declined to continue with study
* Other
 | None | Field appears if ‘Is the participant eligible to proceed to randomisation?’ is ‘No’ |
| **Eligibility Review** (in subsection Confirmation of Eligibility) | Eligibility Confirmed By (Name) | Text | Required | None |
| **Eligibility Review** (in subsection Confirmation of Eligibility) | Date Eligibility Confirmed | Text | DateMax: Today | None |
| **Eligibility Review** (in subsection Confirmation of Eligibility) | Participant is Ineligible. Please complete Change of Status | Descriptive field (Red) | None | Field appears if Field appears if ‘Is the participant eligible to proceed to randomisation?’ is ‘No’ |
| **Randomise** (in subsection Randomisation Details) | **Randomise** Now | Yes/No | None | Field should only appear if: * All Inclusion Criteria in **Inclusion Exclusion** is answered ‘Yes’
* All Exclusion Criteria in **Inclusion Exclusion** is answered ‘No’
* ‘Is the participant eligible to proceed to randomisation?’ in **Eligibility Review** is ‘Yes’
* ‘Eligibility Confirmed By (Name)’ in **Eligibility Review** is completed
* ‘Date Eligibility Confirmed’ in **Eligibility Review** is completed
 |
| **Randomise** (in subsection Randomisation Details) | Date of Randomisation | Text | DateMax: Today | Field should only appear if: * All Inclusion Criteria in **Inclusion Exclusion** is answered ‘Yes’
* All Exclusion Criteria in **Inclusion Exclusion** is answered ‘No’
* ‘Is the participant eligible to proceed to randomisation?’ in **Eligibility Review** is ‘Yes’
* ‘Eligibility Confirmed By (Name)’ in **Eligibility Review** is completed
* ‘Date Eligibility Confirmed’ in **Eligibility Review** is completed
 |
| **Randomise** (in subsection Randomisation Details) | Please ensure this page is set to ‘Complete’ when saved. This will populate the **Randomisation Result** on the next page | Descriptive field (Red) | None | Field should only appear if: * All Inclusion Criteria in **Inclusion Exclusion** is answered ‘Yes’
* All Exclusion Criteria in **Inclusion Exclusion** is answered ‘No’
* ‘Is the participant eligible to proceed to randomisation?’ in **Eligibility Review** is ‘Yes’
* ‘Eligibility Confirmed By (Name)’ in **Eligibility Review** is completed
* ‘Date Eligibility Confirmed’ in **Eligibility Review** is completed
 |
| **Randomise** (in subsection Randomisation Details) | Participant cannot be Randomised as one or more of the Inclusion Criteria in Inclusion Exclusion has been answered ‘No’ | Descriptive field (Red) | None | Field should only appear if any of the Inclusion Criteria in **Inclusion Exclusion** are answered ‘No’ |
| **Randomise** (in subsection Randomisation Details) | Participant cannot be Randomised as one or more of the Exclusion Criteria in Inclusion Exclusion has been answered ‘Yes’ | Descriptive field (Red) | None | Field should only appear if any of the Exclusion Criteria in Inclusion/Exclusion are answered ‘Yes’ |
| **Randomise** (in subsection Randomisation Details) | Participant cannot be Randomised as ‘Is the participant eligible to proceed to randomisation?’ in Eligibility Review is answered ‘No’ | Descriptive field (Red) | None | Field should only appear if ‘Is the participant eligible to proceed to randomisation?’ in **Eligibility Review** is answered ‘No’ |
| **Randomisation Result** (in subsection Randomisation Result) | **Randomisation Result** | Drop-down* Standard BP monitoring
* BP monitoring via wearable device
 | None | None |
| **Randomisation Result** (in subsection Randomisation Result) | Participant has been Randomised to Standard BP monitoring | Descriptive field (Blue) | None | Field appears if ‘**Randomisation Result**’ is ‘Standard BP monitoring’ |
| **Randomisation Result** (in subsection Randomisation Result) | Participant has been Randomised to BP monitoring via a wearable device | Descriptive field (Blue) | None | Field appears if ‘**Randomisation Result**’ is ‘BP monitoring via a wearable device’ |
| **EQ5D** | Build all fields as specified in questionnaire | At 6-Month Follow-up Visit, enable these questionnaires as a survey to be issued to those whose preferred contact is ‘Email’. Surveys should be sent out automatically to the email address provided in Contact Details. The questionnaires should be sent six months (180 days) after the Date of Randomisation +/- 2 weeks (14 days). The questionnaires should not be sent if the participant has died or been withdrawn from all aspects of the study. A reminder should be sent only once every 14 days. |
| **BPI** | Build all fields as specified in questionnaire |
| **HAQ** | Build all fields as specified in questionnaire |
| **PQSI** | Build all fields as specified in questionnaire |
| **SF36** | Build all fields as specified in questionnaire |
| **6-Month Visit** | Build all fields the same as in **Baseline Visit** | As before | As before | As before |
| **Weekly Blood Pressure Readings instrument should be created as a Repeating Instrument, labelled with the Week Beginning Date** |
| **Weekly Blood Pressure Readings**  | Week Beginning Date | Text | DateMax: Today | None |
| **Weekly Blood Pressure Readings**  | Week Ending Date | Text | DateMax: Today | None |
| **Weekly Blood Pressure Readings** | Please record the **lowest** reading for this week | Descriptive field (Blue) | None | None |
| **Weekly Blood Pressure Readings** | Systolic Blood Pressure | Text | NumberMin: 50Max: 250 | None |
| **Weekly Blood Pressure Readings** | Diastolic Blood Pressure | Text | NumberMin: 50Max: 250 | None |
| **Weekly Blood Pressure Readings** | Please record the **highest** reading for this week | Descriptive field (Blue) | None | None |
| **Weekly Blood Pressure Readings** | Systolic Blood Pressure | Text | NumberMin: 50Max: 250 | None |
| **Weekly Blood Pressure Readings** | Diastolic Blood Pressure | Text | NumberMin: 50Max: 250 | None |
| **Adverse Events instrument should be created as a Repeating instrument labelled with the Description of Event**  |
| **Adverse Event**  | Description of Event | Text | None | None |
| **Adverse Event** | Start Date  | Text | DateMax: Today | None |
| **Adverse Event** | Is this an SAE? | Yes/No | None | None |
| **Adverse Event** | Please complete an SAE form and submit this to ACCORD | Descriptive field (Red) | None | Field appears if ‘Is this is an SAE?’ is ‘Yes’ |
| **Adverse Event** | Severity | Drop-down* Mild
* Moderate
* Severe
 | None | None |
| **Adverse Event** | Causality | Drop-down* Unrelated
* Possibly Related
 | None | None |
| **Adverse Event** | Expectedness | Drop-down* Expected
* Unexpected
 | None | None |
| **Adverse Event** | Date of Assessment | Text | DateMax: Today | None |
| **Adverse Event** | Assessed By (Initials) | Text | None | None |
| **Adverse Event** | Outcome | Drop-down* Ongoing
* Resolved
 | None | None |
| **Adverse Event** | Resolved Date  | Text | DateMax: Today | Field appears if ‘Outcome’ is ‘Resolved’ |
| **Concomitant Medications instrument should be created as a Repeating instrument labelled with the Medication Name** |
| **Concomitant Medications** | Medication Name | Text | None | None |
| **Concomitant Medications** | Indication | Text | None | None |
| **Concomitant Medications** | Frequency | Drop-downOnce dailyTwice dailyThree dailyFour dailyAs requiredOther | None | None |
| **Concomitant Medications** | If Other, please specify | Text | None | Field appears if ‘Frequency’ is ‘Other’ |
| **Concomitant Medications** | Dose | Text | None | None |
| **Concomitant Medications** | Unit | Text | None | None |
| **Concomitant Medications** | Route | Drop-down* PO (By mouth)
* IV (Intravenous)
* IM (Intramuscular)
* SC (Subcutaneous)
* TOP (Topical)
* TD (Transdermal)
* IH (Inhalation)
* IO (Intraosseous)
* Other
 | None | None |
| **Concomitant Medications** | Start Date (dd) | Drop-downUK12345678910111213141516171819202122232425262728293031 | None | None |
| **Concomitant Medications** | Start Date (mm) | Drop-downUK123456789101112 | None | None |
| **Concomitant Medications** | Start Date (yy) | Drop-downUK202520242023202220212020201920182017201620152014201320112010 | None | None |
| **Concomitant Medications** | Ongoing? | Yes/No | None | None |
| **Concomitant Medications** | Stop Date (dd) | Drop-downUK12345678910111213141516171819202122232425262728293031 | None | Field appears if ‘Ongoing?’ is ‘No’ |
| **Concomitant Medications** | Stop Date (mm) | Drop-downUK123456789101112 | None | Field appears if ‘Ongoing?’ is ‘No’ |
| **Concomitant Medications** | Stop Date (yy) | Drop-downUK202520242022 | None | Field appears if ‘Ongoing?’ is ‘No’ |
| **Withdrawal** | Date of Change of Status | Text | DateMax: Today | None |
| **Withdrawal** | New Participant Status | Drop-down* Withdrawn from intervention only – all follow-up to continue
* Withdrawn from all aspects of the study
 | None | None |
| **Withdrawal** | Withdrawn By | Drop-down* Participant
* Clinician
 | None | None |
| **Withdrawal** | Reason for Withdrawal | Drop-down* Clinician decision to discontinue
* Adverse Event
* Pregnancy
* Lost to follow-up
* No reason given
* Other
 | None | None |
| **Withdrawal** | If Other, please give details | Text | None | Field appears if ‘Reason for Withdrawal’ is ‘Other’ |
| **Death** | Date of Change of Status | Text | DateMax: Today | None |
| **Death** | Date of Death | Text | DateMax: Today | None |
| **Death** | New Participant Status | Drop-down* Deceased
 | None | None |
| **Death** | Cause of Death | Text | None | None |

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| **User Roles** |
| Create the following User Roles:**Site Researcher** – View and Edit Access to all instruments (including Edit access to Surveys), No Data Export rights to all instruments, Respond only to opened queries in Data Resolution Workflow, Create Projects only (not Rename or Delete), Lock/Unlock Records disabled. **Assign user [insert username] to this user role.****Trial Office** – Read Only access to all instruments, No Data Export rights to all instruments, View only queries in Data Resolution Workflow, Create Projects only (not Rename or Delete), Lock/Unlock Records disabled. **Assign user [insert username] to this user role.**  |

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| **Data Access Groups** |
| **Add the following sites (DAGs):*** Edinburgh
* Aberdeen
* Glasgow
* Manchester
* Cambridge
* Bristol
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| **Data Quality Rules and Notifications**  |
| 1. For all fields highlighted in yellow above, please add a Data Quality Rule if that field has not been completed
 |
| 1. Add a notification that will send an email once a participant has been Randomised. The notification should be set to send to dm.ectu@ed.ac.uk. The text of the notification should include the following:
* Record Id
* Site (DAG) Name
* Randomisation Result
 |

**<<<<<<<<<For template control only. Remove this page from live version>>>>>>>>**

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| **Template Revision History** |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | **Summary of Revisions**  |
| 1.0 |  | Lynsey Milne (Data Manager | * Initial Creation/New document
 |