

Date

___ / ___ / ___

Subject ID.

ERICA – WP1

Source Data Worksheet

**To be completed by a
member of the
research team**

This study is sponsored by Cambridge University Hospitals Foundation NHS Trust and the University of Cambridge

Subject ID.

Please ensure that all boxes are ticked throughout the worksheet

If a mistake is made, please cross out and initial and date, writing the correct answer next to the mistake.

Questionnaires can be completed in between exercise tests to ensure recovery

A post-bronchodilator spirometry must have been carried out within the last 3 months. If not, patients will have to consent into the study first and this assessment will need to be performed on visit 1 **before any measurements are undertaken in order to satisfy the study inclusion criteria and for the patient to continue into the ERICA study. (Entering the measurements on page 4)**

All patients should be entered onto the screening log, but no I.D. should be given until the patient is consented and enrolled into the study.

Eligibility criteria check – please tick if checked

Inclusion criteria

- ☐ • Aged ≥ 40 years
- ☐ • Able to provide consent
- ☐ • Post-bronchodilator spirometry FEV_1/FVC ratio < 0.7 and $FEV_1 \leq 80\%$ of predicted normal (undertaken within last 3 months)
 FEV_1/FVC ratio _____
 FEV_1 _____

If post-bronchodilator spirometry is undertaken at this visit, fasting measurements should not be undertaken at the same visit and if possible, patients asked to return for a second visit.

- ☐ • Current or ex-smoker with a smoking history of at least 10 pack years
- ☐ • Clinical stability > 4 weeks from any exacerbation requiring treatment with oral steroids or anti-biotics or hospitalization

Patients will not be eligible for inclusion in the study if any of the following criteria apply: (please tick if check has been carried out)

Exclusion criteria:

- ☐ • Pregnancy
- ☐ • Current participation in an ongoing CTIMP
- ☐ • Known diagnosis of alpha1 anti-trypsin deficiency
- ☐ • Known neurological co-morbidities with skeletal muscle involvement

Questionnaires completed?

ERICA ☐
participant
questionnaire

NOTE: Question 9B is the 'MRC Dyspnoea Score' The value to be entered corresponds to the box ticked (E.g. Box 1. = Score 1)

COPD ☐
Assessment
test/CAT score

(Please check that scores are correctly added)

St. ☐
George's
Respiratory
Questionnaire
for COPD
patients
(Refer to SGRQ-C Manual)

Subject ID.

Please bear in mind that arterial stiffness, BP, SNIP ideally need to be done having withheld inhalers for > 6 hours.

Please bear in mind that venepuncture, urine sample collection, arterial stiffness and BP ideally need to be done having fasted for 4 hours. Please refer to investigator manual

Please consider rescheduling a visit if the patient is planned for one of these measurements and has not fasted / withheld inhalers. Two visits are allowed per patient.

Before the 6MWT, SPPB and QMVC, usual inhalers can be offered if the patient has withheld inhalers so that they are fully prepared for the exercise tests.

NOTE: If a patient has had a FEV₁ Post-bronchodilator spirometry assessment performed within the last 3 months in either the ECLIPSE Extension study, ARCADE, PROACTIVE, MRC WP4 Consortium or Skeletal Muscle dysfunction study, this does not need repeating and the results should be recorded. However, if a patient has had this measurement in a different study (not mentioned above) within the last 3 months, this measurement will be accepted to enter the study, but will need repeating at some point during the visit/s.

Informed Consent?

Yes ☐ No ☐

Date / /

Once consented, the patient can be allocated a subject I.D. and entered on the enrolment log.

Name

Subject I.D.

Questionnaire follow-up: Phone ☐ Post ☐

Date of Birth / /

Gender

NHS number

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CHI number

--	--	--	--	--	--	--	--	--	--	--	--

Address

Postcode Telephone

Comments

Subject ID.

Anthropometry - please refer to Investigator Manual

Does the patient have a pacemaker? Yes ☐ No ☐

If the patient does have a pacemaker, please use alternative standard clinical scales for weight. Please ask the patient if they can provide a urine sample before bioimpedance and record on page 6.

Segmental impedance (STANDARD):

Height: . cm Fat mass: . kg

Weight, TANITA: . kg Fat free mass: . kg

Body fat%, TANITA: . % Total body water kg

Impedance, whole: Ω

*** Staple the TANITA printouts to this form ***

Date / /

Comments

Spirometry - undertaken at this visit? Yes ☐ No – done as part of ARCADE / ECLIPSEetc ☐

NOTE– please ensure this is post-bronchodilator spirometry– see Investigator Manual. If undertaken at this visit, please avoid 'fasting measurements', stated in Investigator Manual, if possible.

Date / /

Comments

If no, please enter previous values if spirometry was taken within the last 3 months and record the date.

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Best</u>
FVC	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> L
	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> %predicted
FEV ₁	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> L
	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> % predicted
FEV ₁ /FVC	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/>

*** Staple the Spirometry printouts to this form if available ***

Record values from the manoeuvre with the highest FEV₁ on the eCRF

Subject ID.

ECG - undertaken? Yes ☐ No ☐

Signed by a clinician? Yes ☐ No ☐

Date / /

Comments

Short Physical Performance Battery (SPPB) – Guideline 4 should be the assessment preceding the 6MWT

SPPB - undertaken? Yes ☐ No ☐

Date / /

i) Balance: 3 separate position, each performed once

Side-by-side: seconds points **Semi-tandem:** seconds points

Tandem: seconds points

Sum of above points: {Maximum 4 points}

ii) 4m gait speed: perform 2 x tests and use best effort for calculating points

Effort 1: seconds converted points

Effort 2: seconds converted points

Converted points for the best gait speed: {Maximum 4 points}

iii) Chair stand: Total time taken for 5 x standing up from a chair, unaided

Time seconds

Converted points for chair stand: {Maximum 4 points}

Total Sum for SPPB (sum of points for balance test, gait speed & chair stand)

{Maximum 12 points}

Record all the 'point' measurements on eCRF

Subject ID.

Comments

6 Minute Walk Test – please refer to Investigator Manual

Guideline 2– 6MWT must be an hour apart from QMVC

Guideline 4 – 6MWT should be the assessment after SPPB

Please allow patients to use their inhalers if they wish

Note: Resting ECG undertaken in the previous 6 months should be reviewed before testing (Precautions – please refer to Investigator Manual – page 58)

6MWT- undertaken? Yes ☐ No ☐

Date / /

Distance walked: metres

Pre-walk O₂ Saturation: % Post-walk O₂ Saturation %

Pre-walk Borg Rating: (0-10) Post-walk borg rating (0-10)

Did the patient require O₂ supplementation? Yes ☐ No ☐

If so, please specify the amount Litres

Record all measurements on eCRF

Comments

Venepuncture/urine sample – please refer to Investigator Manual

Note: This should be ideally undertaken after fasting for 4 hours

Time elapsed since last eaten: hours ago

Blood sample taken? Yes ☐ No ☐

Date / /

Urine sample collected? Yes ☐ No ☐

Date / /

Comments

Subject ID.

Blood pressure and arterial stiffness – Please refer to Investigator Manual

Note: This should be ideally undertaken after withholding salbutamol for 6 hours and after fasting for 4 hours

Time elapsed since last eaten: _____ hours ago

Time elapsed since inhaler/salbutamol: _____ hours ago

Seated brachial blood pressure

Cuff size: Small ☐ Medium ☐ Large ☐

First

Second

Third

Average

Systolic mmHg

Diastolic mmHg

Average of second and third reading – record on eCRF

Seated Central Blood pressure

First

Second

Third (if needed)

Average

Systolic mmHg

Diastolic mmHg

Average reading recorded on eCRF

Seated Mean Arterial Pressure

First

Second

Third

MAP

mmHg

Record measurement on eCRF

Seated heart rate (from sphygmoCor system)

First

Second

Average

Heart rate bpm

Average reading recorded on eCRF

Subject ID.

Seated Augmentation Index

First

Second

Average

Augmentation Index %

Average reading recorded on eCRF

Comments

Supine readings – pulse wave velocity

Notch-carotid (proximal) mm Notch-femoral (distal) mm

Supine blood pressure

First

Second

Third

Average

Systolic mmHg

Diastolic mmHg

Average of second and third reading – record on eCRF

Pulse wave velocity

First

Second

Average

PWV m/sec

Heart rate from SphygmoCor bpm

Average reading recorded on eCRF

Comments

Subject ID.

Carotid Intima-Media Thickness (IMT) – please refer to Investigator Manual

IMT undertaken? Yes ☐ No ☐

Date / /

Comments

Sniff Nasal Inspiratory Pressure (SNIP) - Please refer to Investigator Manual

SNIP undertaken? Yes ☐ No ☐

Date / /

Please perform for each nostril; continue testing until there is no longer an increase in measurement.

Left:

--	--	--	--	--	--	--	--	--	--

Right:

--	--	--	--	--	--	--	--	--	--

cmH₂O

Extra boxes:

--	--	--	--	--

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cmH₂O

Highest value

Record the highest/best measurement on eCRF

Comments

Subject I.D.

QMVC - Guideline 2 – must be an hour apart from 6MWT.
QMVC - undertaken? Yes ☐ No ☐

Date / /

Please use the right leg. (Unless there is a particular reason not to)

Please perform a warm-up of 4 contractions at approx 50% effort, followed by 4 contractions at 75% effort.

Please perform 6 tests, (maximal contraction) allowing a 20-30 second interval between contractions

 . Kg

Best effort
Record the highest/best measurement on eCRF
Comments on measurements:

Name of measurement	Comment