

ECFS CTN LCI Core Facility submission requirements for certification

LCIs must be performed according to the SOP on the CTN website with a minimum of 3 traces per subject. If you have concerns over the quality of one of the traces, you may submit 4 traces.

We require a minimum of 10 subjects per site for the initial submission. At least 6 of whom are CF patients with FEV₁<80%. NB. ***An exception can be made for paediatrics, where higher FEV₁ will be allowed for CF subjects.***

If an operator from a previously certified site submits we only require 5 subjects per operator.

Newer sites might find it easier to submit only adult traces initially; in this event, we would offer to certify at a later date for paediatrics on a smaller data set or vice versa.

Submission:

Please submit to Jordan Tuyindi at this email address: lci-over-reading@imperial.ac.uk

- Send **SPX** files containing no patient identifying information (see file identification and exporting below)
- Send the ECFS CTN LCI qualification submission form (appendix A)

SUBMISSION REQUIREMENTS – School Age to Adult			QUALIFICATION REQUIREMENTS		
Number of Operators per Site	Number of Test Occasions required PER OPERATOR	TOTAL Number of Test Occasions required PER SITE	Number of Successful Test Occasions required for INDIVIDUAL Qualification	TOTAL Number Successful Test Occasions required for SITE Qualification	MINIMUM Number of QUALIFIED OPERATORS required per site for SITE Qualification
1	10	10	8/10	8/10	Adult/School Age = 1operator (6 years to adult)
2	5 each	10	4/5 per operator	8/10	
3	5 each	15	4/5 per operator	12/15	
4	5 each	20	4/5 per operator	16/20	

❖ **ADULT OR PAEDIATRIC ONLY SUBMISSION**

1 operator = at least 6 CF and up to 4 HC.

2 or more operators = at least 3 CF and 2 HC each

NB At a later date the operator may submit a further 3 subjects (at least 2 CF) in either adults or paediatrics to qualify in both. (At least 2 of which must pass)

❖ **BOTH ADULT AND PAEDIATRIC SUBMISSION**

1 operator = at least 6 CF and up to 4 HC. **At least 4 need to be paediatric and at least 2 CF.**

2 operators or more = at least 3 CF and up to 2 HC. **At least 2 need to be paediatric and at least 1 CF..**

Ideal examples:

No. of operators	Adults		Paediatric	
	3 CF	2 HC	3 CF	2 HC
1	3 CF	2 HC	3 CF	2 HC
2 or more	Up to 2 CF	1 HC	Up to 2 CF	1 HC

Ideally submit the group characteristics you will be testing for i.e. 6-11years for a specific trial

Qualification Process:

Traces will be graded according to our quality control protocol

We will aim for a 2-3 week turnaround of traces

If successful each operator will receive a certificate of qualification for their site as proof of validation from the ECFS CTN.

If traces are deemed unacceptable, feedback will be given and an opportunity to re submit corrected traces or additional subjects.

Under circumstances where additional traces are also unsuccessful, further training may be required and we will discuss this on a case by case basis.

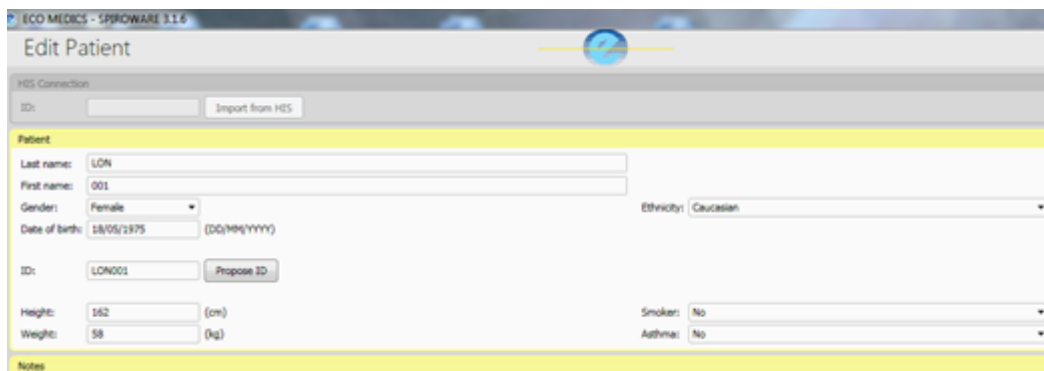
NB. If you are aware that your site will shortly be participating in a clinical trial using LCI, please expedite your measurements and indicate on the submission form, so that we can prioritise you.

It is essential that the operator can show they observe testing events such as leak or end of test criteria not being met and act on this accordingly. Thus we encourage operators to include comments on any issues of the test in the notes section in Spiroware and /or on the submission form.

File identification and exporting

Please submit SPX files

- The SPX files must be non-identifiable and saved as a draft. **DO NOT CONCLUDE YOUR TESTS**
- Enter the 1st 3 letters of your site into Last name e.g. LON for London
- Enter each patient as 001,002 consecutively into First name. Therefore for 10 sets of data it should go up to 010
- Click on propose ID and delete the DOB from the centre of the ID sop you are left with e.g. LON001
- If you are sending traces that contained patient information please re-run the file under a new non-identifiable subject.



ECO MEDICS - SPIROWARE 1.1.6

Edit Patient

HIS Connection
ID: Import from HIS

Patient

Last name:
 First name:
 Gender:
 Date of birth: (DD/MM/YYYY)
 Ethnicity:

ID:

Height: (cm)
 Weight: (kg)
 Smoker:
 Asthma:

Notes

How to export an SPX file

- Select export data from the administration menu of Spiroware
- This will bring up the entire patient list. All files are selected by default
- Uncheck patient number and place a check by the patient you wish to export
- Select export patient files in upper right corner of screen
- Select a pre-existing or create a new folder to sort exported SPX files. You can export it straight to a USB stick
- The SPX file will now be exported to the selected folder
- The SPX file can now be emailed to ICI-over-reading@imperial.ac.uk