

# STUDY NEWSLETTER



Issue No. 6, 15<sup>th</sup> June 2020

## A welcome from the NCC Principal Investigator

Dear Study Teams,

We hope that you and your families are happy and healthy despite the strange times that we are living through the coronavirus pandemic.

Many of our sites have been placed on hold because of the coronavirus pandemic, but we were able to get an exemption for FOURIER LEGACY at Imperial College, since this is an observational study.

We are happy to tell you that both the UK and the Netherlands are now actively recruiting for FOURIER LEGACY.

We are now at 101 PARTICIPANTS enrolled, that's 10% of our national target.



Dr Judy Mackay

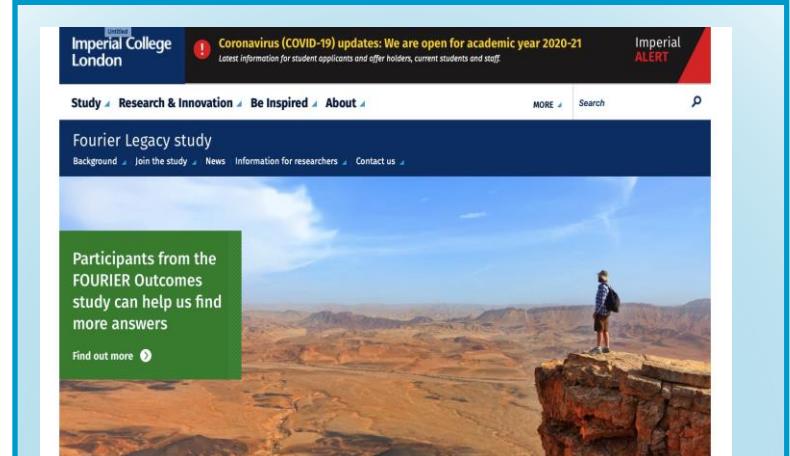
We are happy to be the first country to be activated for FOURIER LEGACY on 7<sup>th</sup> February 2020 (though the Netherlands narrowly beat us to consenting the first patients, as we were delayed by IT issues).

The first patient consented was in the Netherlands, on March 11<sup>th</sup> 2020 and the first UK patient consented was on April 24<sup>th</sup> 2020.

Our first UK patient from Whitby Group Practice was contacted on 6<sup>th</sup> April 2020, and our first consent was on 23<sup>rd</sup> April 2020 by a subject from Royal Bournemouth Hospital.

Barnsley Hospital is our first completed site, with 89% of their potential participants enrolled on the study.

We have the equal highest target globally and all our sites and their patients will make a valuable contribution towards achieving our national target.



## FOURIER Legacy Imperial Website

If you have not already had a look, please check out Imperial's FOURIER Legacy website.

[www.imperial.ac.uk/medicine/fourier-legacy](http://www.imperial.ac.uk/medicine/fourier-legacy)

With interesting background, news, participant information and a meet the team section.

Thank you to the following sites who have already started contacting and sending us details of their assented participants:

*Arrowe Park Hospital*

*Whitby Group Practice*

*Barnsley Hospital*

*Royal Bournemouth Hospital*

*Sherbourne Medical Centre*

*Ormeau Clinical Trials*

*New Cross Hospital*

*Rowden Surgery*

*South Axholme Practice*

*Ashfields Primary Care Centre*

*Mounts Bay Medical*

*Imperial College Healthcare NHS Trust  
(Hammersmith Hospital)*

*Northwick Park Hospital (North West London NHS Trust)*

*Bradford-on-Avon and Melksham Health Centre*

*Torbay Hospital*

**18 SITES ACTIVATED**

**5 SOON TO BE OPEN**

**36 SITES TO GO**

The following sites have also been activated recently and will be contacting their Fourier Outcomes participants soon:

*Swansea Bay Clinical Research Unit*

*Brannel Surgery*

*Sandwell and West Birmingham Hospitals NHS Trust*

We have a few sites with SIVs scheduled for this month:

*Nottingham City Hospital*

*Worcester Royal Hospital*

*Ninewells Hospital, Dundee*

*Portmill Surgery*

*Queen Alexandra Hospital*

101  
patients  
enrolled



If any other sites are being given the green-light to resume non-covid-19 studies or have capacity to take on FOURIER Legacy again, please do let us know. We will be delighted to have you on board and activated.

## Consenting experiences

Our experience so far indicates that around 70% of potential participants progress to registration. Most patients we have phoned have been very happy to be contacted and enthusiastic about taking part. Of course, we recognise that it has been easier to make contact with patients during lockdown. Under the current circumstances, many patients have generally been happy to have someone to chat to on the phone.

The consent process is rather lengthy, as everything is done over the phone and via post. As we are currently mostly working from home during the lockdown, we are only able to collect our post twice a week.

## Study surveys

We have been completing the first questionnaire by telephone for most participants as we can then explain all the questions. However, in the future, we would refer any participants who can do so, to complete the survey electronically.

About 50-60% of participants so far contacted are happy for future questionnaires to be sent by email or text and completed electronically.

## Steps to avoid potential data breaches

When sending confidential information to the Imperial team, we ask you to think carefully:

### ***Has the patient given assent for this information to be sent?***

Only send confidential data (name, address, telephone number, DOB) for patients who have given verbal assent for this. Please do not send identifying information for deceased patients - just let us know that they are deceased.

### ***Am I sending this information safely?***

Identifying information can only be sent from nhs.net to nhs.net emails. If you do not have access to an nhs.net email, we can advise you on alternative safe methods of transmission e.g. using encryption.

When you send an email containing participants' personal details, please make sure that the only people copied in are those with nhs.net emails. Emails sent to an imperial.ac.uk account which contain personal details will be a potential data breach.

### ***How do I send it securely?***

Patient identifiable details should **only** be sent to a nhs.net email account and **not** an Imperial College email account. A reminder to please send these to:

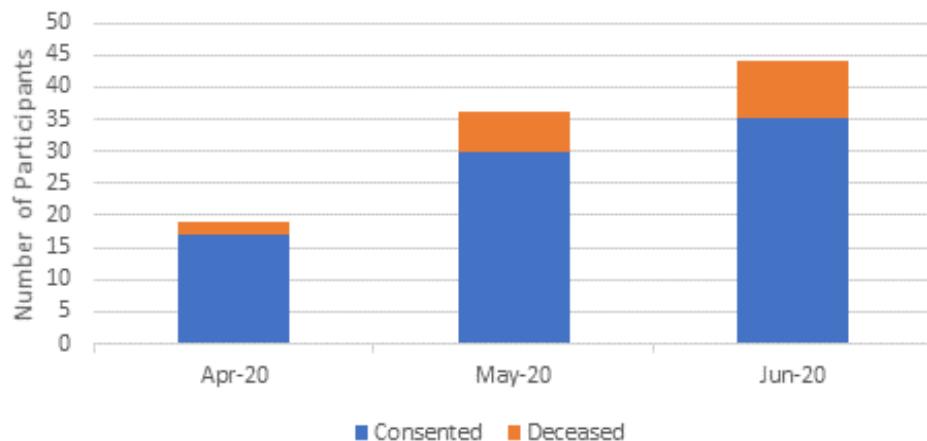
Candy Coghlan at [c.coghlan@nhs.net](mailto:c.coghlan@nhs.net)

Andrew Whitehouse at [andrew.whitehouse2@nhs.net](mailto:andrew.whitehouse2@nhs.net)

Judy Mackay at: [judith.mackay1@nhs.net](mailto:judith.mackay1@nhs.net)

## UK RECRUITMENT NUMBERS (AS OF 15<sup>TH</sup> JUNE 2020)

### FOURIER Legacy - UK Monthly Recruitment



### FOURIER Legacy - UK Cumulative Recruitment Actual v Target



### UK FIGURES:

**15 sites have sent patient details: total 222 potential participants**

**163 processed by sites**

**17 deceased (10%)**

**143 assented**

**136 patients interested in participating**

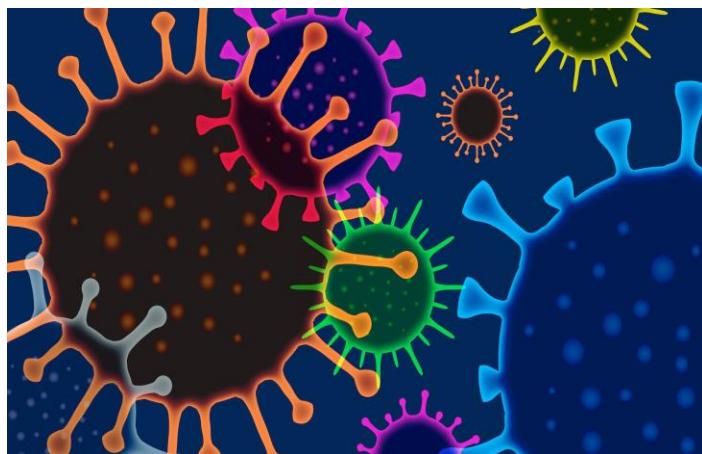
**8 declined**

**84 consented**

**101 enrolment (consented + deceased)**

**67 questionnaires completed (82% of those enrolled)**

**0 withdrawn**

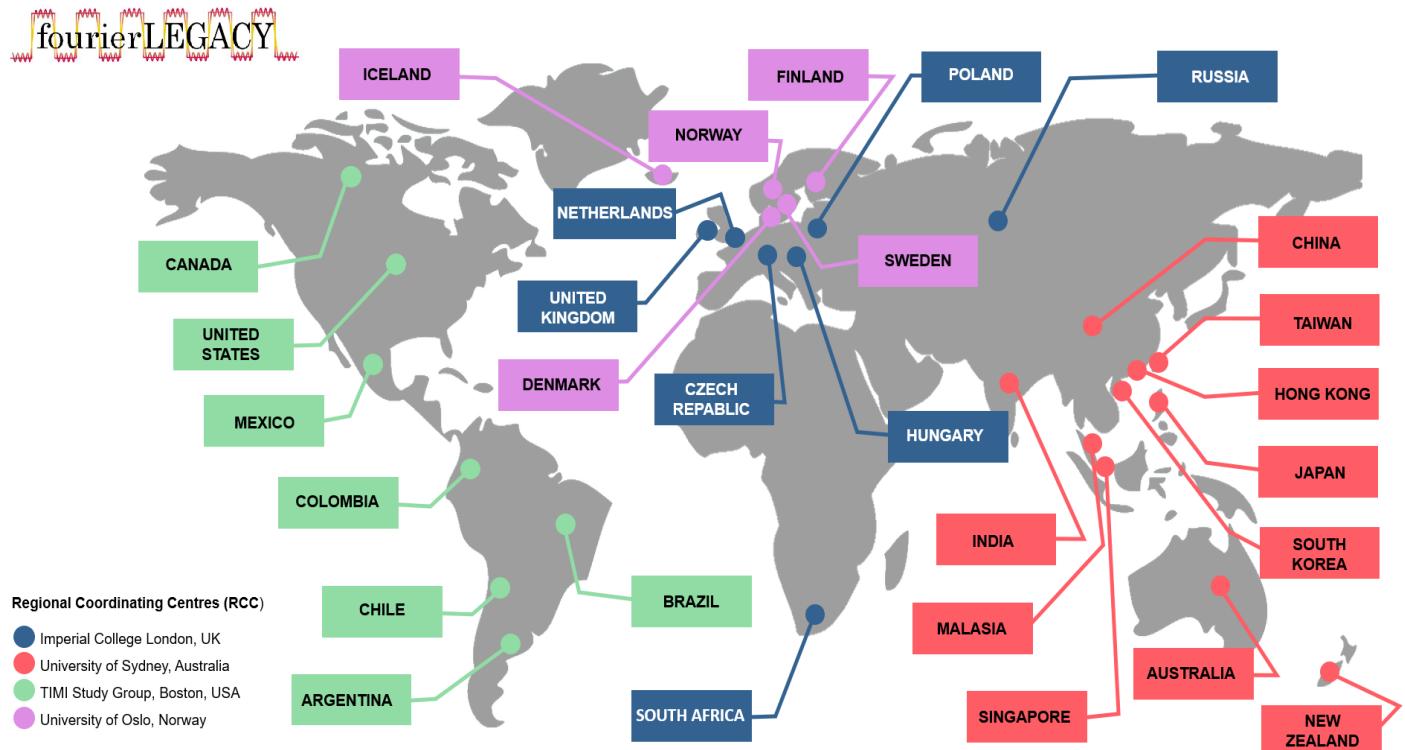


### COVID-19

We would like to say a big thank you to our sites, for their amazing efforts during the current covid-19 pandemic. We understand there are sites on hold as resources are allocated to covid-19 management, and others with resourcing issues. We also appreciate those who have been able to start work on Fourier Legacy.

Thank you!

# GLOBAL SITE LOCATIONS



## GLOBAL FIGURES:

289 assented

25 deceased

239 consented

4 withdrawn

235 baseline  
questionnaires

96 outcome  
events

2 countries activated  
and recruiting (UK  
and Netherlands)

## NCC REMOTE WORKING



Whilst we are all working from home currently, it's business as usual.  
We're busy working together and meeting regularly on Zoom.

## UK NATIONAL COORDINATING CENTRE CONTACT LIST

Our Imperial Teams have been very busy and we have some new staff who have returned or come to join us. Our updated contacts list is below:

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**We are here to help! Please do not hesitate to contact us if you have any queries or questions about the study.**

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