

# STUDY NEWSLETTER



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

## *A welcome from the Chief 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.

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

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

Recruitment is progressing well, and we have 319 participants enrolled.



*Professor Peter Sever*

### **Netherlands experience**

The Netherlands is running the study using a different model, in that sites are doing their own recruiting and follow up, and the Netherlands NCC is coordinating and facilitating this.

Some sites have preferred not to use the participant communicator system to store their subjects' confidential data, whilst other sites are using this. Although there have been many teething problems in setting up the system and in training, it is a potentially useful tool in enabling participant surveys to be sent electronically.

### **United Kingdom**

The UK started recruitment later than the Netherlands, about the same time as the UK went into lockdown for the coronavirus pandemic. This has meant that many NHS sites have had to delay study activation as they have been placed on hold for non-COVID studies.

However, at Imperial, we were granted an exemption from this 'on-hold' position, since the study involves no risks to participants and did not involve front-line NHS staff.

We now have 24 sites activated and recruitment, though slow, is progressing.

One advantage of lockdown was that it was easier to catch participants on the telephone, as they were largely confined to their homes!

### **South Africa**

The South Africa NCC has completed contracts and has submitted to ethics. We are now in the process of setting up the study IT systems for them and arranging data systems training.

### **Other NCCs**

We are still in the process of arranging contracts with Poland, Czech Republic, Russia and Hungary, but we are hoping that these countries will be activated in 2020, so that they can obtain at least one survey per participant.

## STUDY RECRUITMENT

### Global recruitment update:

The global figures as of 18<sup>th</sup> June 2020 are as follows:

### Country breakdown

	No. pts assented	No. pts consented
<i>UK</i>	141	104
<i>Netherlands</i>	220	215

319  
participants  
enrolled



### Participant status

<b>Contacted for assent</b>	<b>401</b>
- Declined assent	38
- Site declined	12
- Assented	361
- Consented	319
- Deceased	29
- Withdrawn	4

### Survey collection

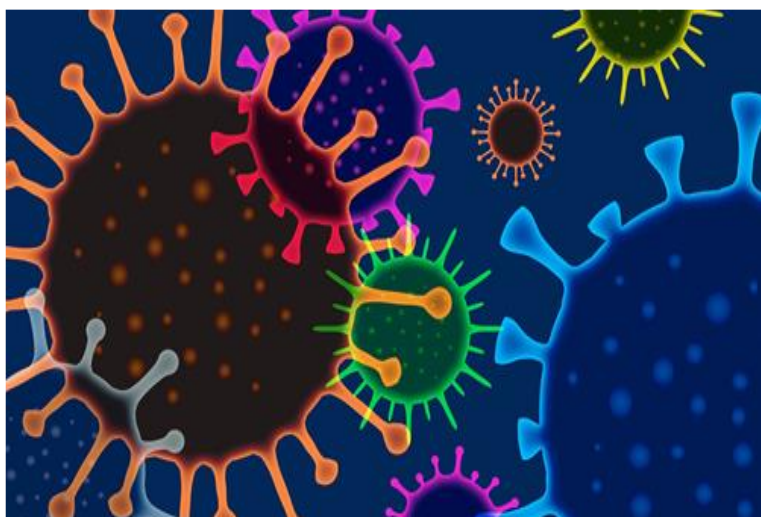
<b>Collected</b>	<b>275</b>
- Completed	204
- Incomplete	71
<b>Method of collection</b>	<b>(3 not recorded)</b>
Letter	150
Online	4
Clinic visit	13
Phone	108

### Outcome events

<b>Number of outcome events</b>	<b>117</b>
- Death	14
- Selected for adjudication	22

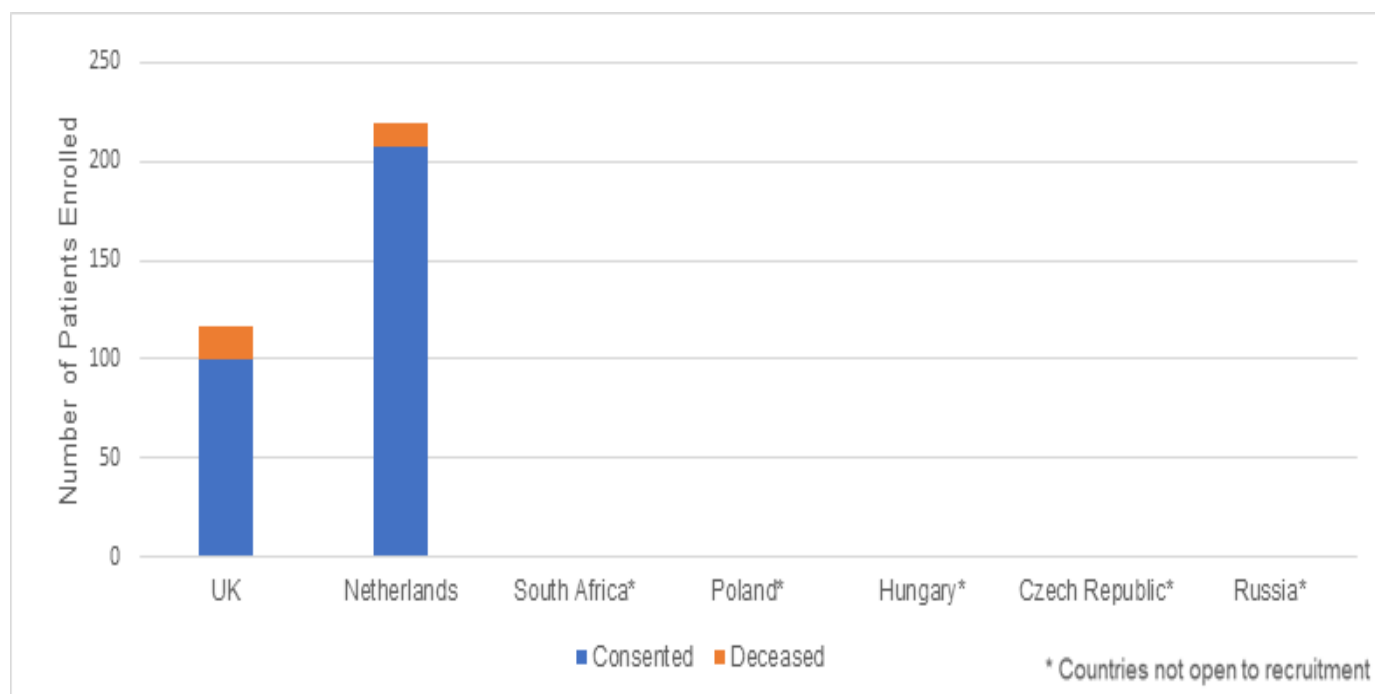
### UK RCC REMOTE WORKING

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!

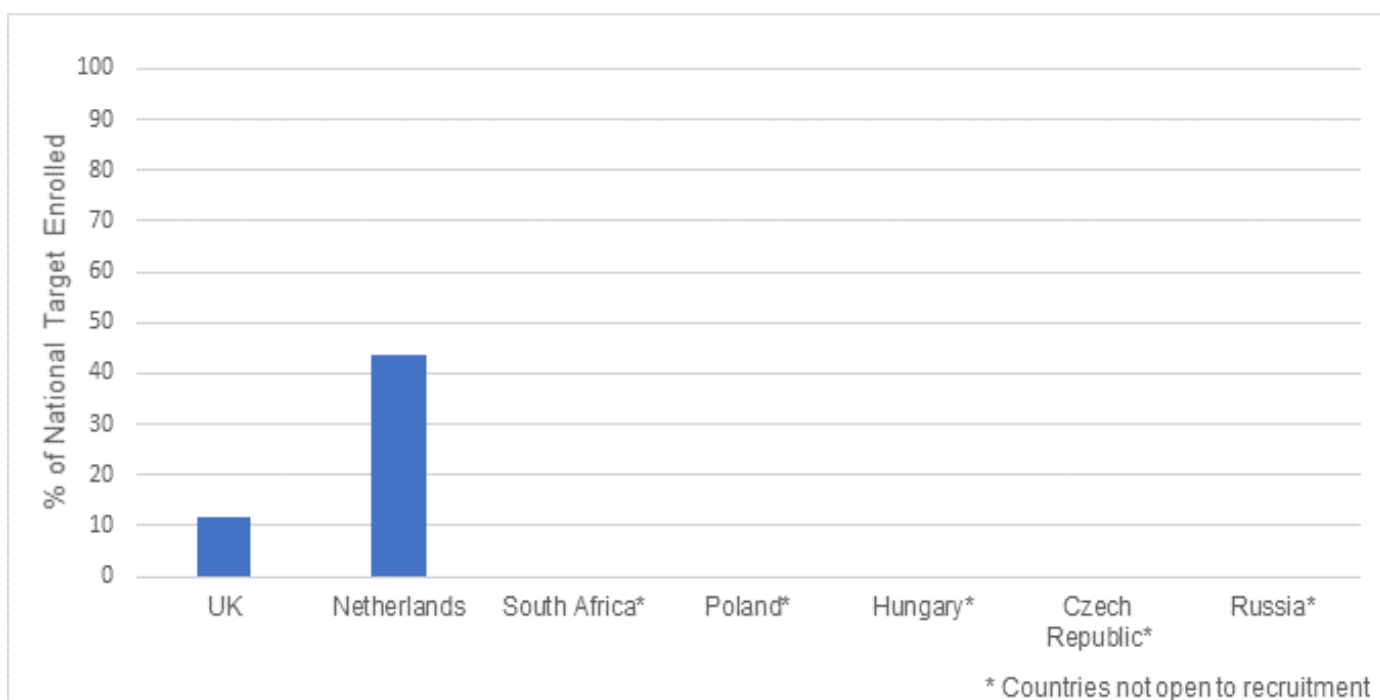


## STUDY RECRUITMENT

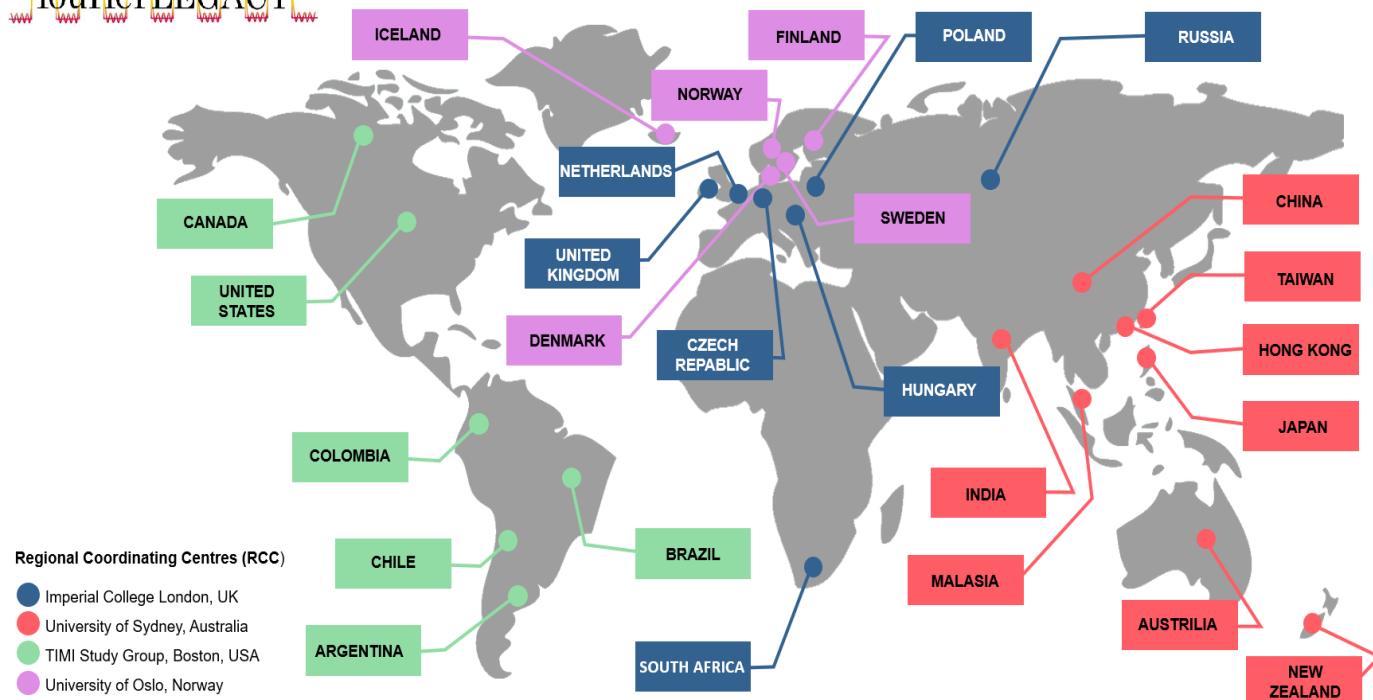
### Total Recruitment Numbers for the Europe/South Africa NCC:



### RCC recruitment (as percentage of target):



## GLOBAL SITE LOCATIONS



### GLOBAL FIGURES:

**361 assented**  
**29 deceased**  
**319 consented**  
**4 withdrawn**  
**275 baseline questionnaires**  
**117 outcome events**  
**2 countries activated and recruiting (UK and Netherlands)**

### UK RCC REMOTE WORKING



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

## GLOBAL COORDINATING CENTRE DETAILS: NHMRC

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## UK NATIONAL COORDINATING CENTRE CONTACT LIST

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

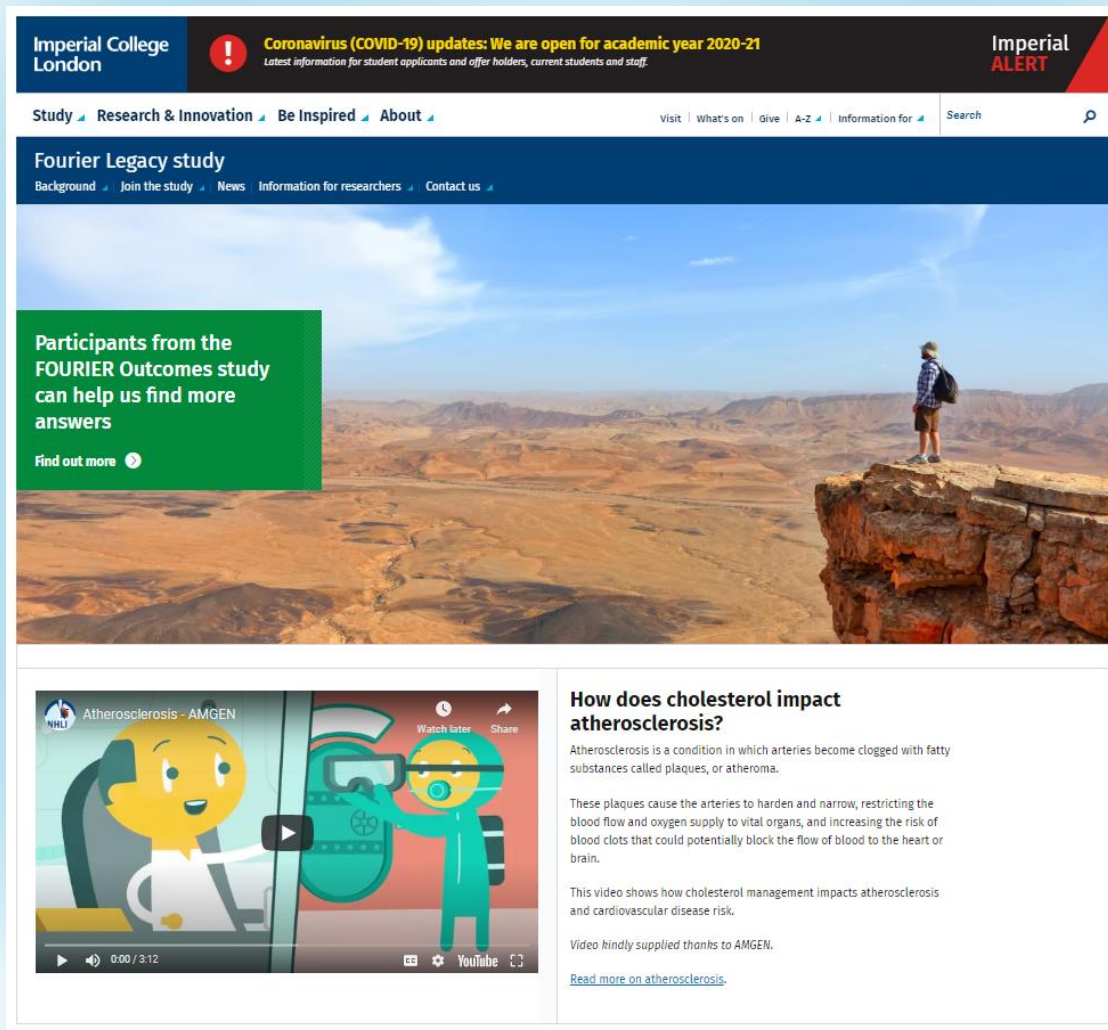
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# FOURIER Legacy Imperial Website

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.

**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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