Welcome to our first newsletter for people taking part in REVEAL. With this and future newsletters we hope to keep you up to date with the progress of REVEAL, and pass on any tips that might make taking part in the study easier and more enjoyable.

However, the first thing we need to say is an enormous ‘thank you’ for joining the REVEAL study. We initially planned to recruit 30,000 people worldwide. We are delighted to say that we have exceeded our target, recruiting 30,624 participants, across ten countries.

REVEAL is the largest study looking into the possible benefits of boosting good cholesterol and further lowering bad cholesterol to prevent heart attacks and strokes, in people who have suffered these conditions before and who are already taking statins.

It is anticipated that the study will continue until around the end of 2016, and we may wish to keep in touch with you from time to time after that, just to see how you are doing. We need to know how you get on, even if you are no longer taking the tablets. So it is important that you keep going to your clinic appointments every six months, where study staff can check how you are and update you on the progress of the study.

Thank you once again for participating in REVEAL. With your help, we hope we will be able to answer a really important scientific question that could improve treatment for many thousands of people around the world.

Dr Martin Landray and Dr Louise Bowman are the senior doctors leading the REVEAL study from the University of Oxford, UK. Both are consultant physicians and regularly treat patients in their cardiology (Martin) and diabetes and lipidology (Louise) clinics.

Which fats to avoid?

Everyone wants to eat a little healthier to reduce their bad cholesterol – and here’s a good tip to pass on to the rest of the family: minimise your intake of saturated fats because they are the ones likely to do the most damage to your heart. A good rule of thumb is to avoid those fats that are solid at room temperature (like lamb and bacon fat), although don’t ditch the healthier spreads. Do keep an eye out for healthier unsaturated and – better still – polyunsaturated fats on labels. Adding more fruits and vegetables (fresh, tinned, frozen and dried all count) to your meals and taking regular exercise will also help.
30,624 people have joined the REVEAL study from 10 countries. Here are the number of people enrolled from each country:

- Canada: 752
- China: 8629
- Denmark: 1850
- Finland: 613
- Germany: 1529
- Italy: 1660
- Norway: 844
- Sweden: 861
- UK: 8382
- USA: 5504

474,670 samples from study participants have been collected so far and sent to Oxford.

190,383 study interviews have taken place at study clinics so far, totalling 5,769,063 minutes of visit time, which is equivalent to 11 years!

Drugs that should generally NOT be taken with one or other of the study treatments

1. For lowering cholesterol
   Statins: if your own doctors wish to change the atorvastatin dose you are receiving in REVEAL, or change to a different statin, please contact your study clinic first.

2. Antibiotics
   - Erythromycin (Arpamicin, Erymax, Erymin, Erythrocin, Erythroped, Ilosone, Tiloryth)
   - Clarithromycin (Biacin, Clacid, Claridar, Claripen, Clarixin, Crixan, Fromilid, Klabax, Klacid, Klacid, Vikrol)
   - Telithromycin (Ketek)
   - Daptomycin (Cubicin)

3. Antifungals (excluding creams or eye/ear drops)
   - Itraconazole (Sporanox)
   - Posaconazole (Noxafl)

4. Protease Inhibitors
   - Atazanavir (Reyataz)
   - Fosamprenavir (Telzir)
   - Lopinavir (Kaletra)
   - Darunavir (Prezista)
   - Nelfinavir (Viracept)
   - Ritonavir (Norvir)
   - Saquinavir (Invirase, Fortovase)
   - Tipranavir (Aptivus)
   - Indinavir (Crixivan)

5. Other
   - Ciclosporin (Neoral, Sandimmun, SangCya)
   - Fusidic acid (excluding creams or eye/ear drops)
   - Nefazodone (Serzone, Nefadar)
**Why this Logo?**

REVEAL is led by medical scientists at Oxford University’s Clinical Trial Service Unit (abbreviated to CTSU) – a world leader in big studies testing new approaches to prevent and treat chronic diseases such as cancer, heart attack or stroke.

One of the main interests at CTSU is the prevention of cardiac disease. The first Heart Protection Study (HPS) showed the beneficial effect of taking statins by people with pre-existing heart and circulatory diseases. The second study (HPS2) tested whether raising levels of good cholesterol using the drug niacin was beneficial. Unfortunately the use of niacin was limited by some unwelcome side effects. REVEAL (HPS3) is the third study in this series.

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### Keeping in contact

- Are you continuing to attend your regular 6-monthly REVEAL clinics? Remember, you are a valued and important member of the REVEAL study and we are interested in you, even if you no longer take the study medication. Without YOU, the study would not be possible.

- Hopefully most people will be able to continue taking the study tablets, however, if you do think about stopping, please discuss this with your study clinic first or call the doctors in Oxford: **0800 585323** (toll free in the UK).

- When you come to the study clinic please bring a list of any other tablets you are taking.

- Stay in touch, even if you are not able to attend the clinic; a telephone call will suffice, we just want to know how you are getting on. It’s important to the team and the study.

- Remember: doctors from the Oxford REVEAL team are available 24 hours a day to discuss ANY concerns you may have regarding REVEAL or the study tablets, so please don’t worry in silence, call us on the numbers mentioned above.
At every clinic visit, your blood is taken and measured by the nurse to check you can continue taking the study medications. In addition to this local blood test, you have occasionally provided samples for analysis at CTSU’s laboratories in Oxford. Data from the central analysis will significantly contribute to the overall study results. These samples are frozen in your clinic, transported all the way to Oxford, and are processed by CTSU lab staff. The photographs show what happens to your samples.

From April to October 2014 at your follow-up visit, we are going to ask you to provide another sample for central analysis, as we will be about half-way into the study. Even if you do not regularly visit the study clinic for an interview, it would be very helpful if you could visit your clinic so that the study staff can collect your samples. Every patient and every sample is important. If you have any questions or would like further information about the samples, please contact the study staff at your REVEAL clinic.

Where do your samples go?

1. Set of blood and urine samples collected at the beginning of the study. Samples are labelled with a barcode only, not your name or study ID.

2. Samples are frozen to about -40°C and kept frozen at the clinic site.

3. Samples are packed with dry ice (to keep them frozen) and transferred to Oxford by air or by land.

4. At the CTSU laboratory, samples are unpacked and inspected to make sure they have arrived in good condition.

5. Laboratory staff “check-in” the samples on their electronic system. This allows us to carefully record information about where every sample is kept.

6. Samples are defrosted and tested on our automatic analyser machines.

7. The samples for long term storage are kept in CTSU’s liquid nitrogen tanks at a very low temperature of -196°C. One tank can store 70,000 tubes!

We hope you have found this newsletter interesting and helpful. Please let us know if you have any ideas about subjects you would like us to cover in future editions. Please write or email to the following address.

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