

## **TB043 and TB044 studies, Jenner Institute, Nuffield Department of Medicine**

**Professor Helen McShane, Chief Investigator**

### **What was your study about?**

**The TB043 study** is a human challenge study to evaluate innate and adaptive immune responses to a controlled human infection with BCG administered by the aerosol inhaled route in healthy, BCG-naïve, UK adult volunteers. In this study we plan to enrol 65 healthy volunteers aged 18 to 50 who have not previously received the BCG vaccine. On the day of the challenge, the volunteers will be randomised to either inhale BCG or to inhale saline, allocated to one of the 5 study groups and will undergo a bronchoscopy either on day 2, day 7, day 14, day 28 or day 56 post-challenge. The volunteers will be followed up for 6 months post-challenge.

**The TB044 study** is a clinical challenge study to evaluate controlled human infection with BCG administered by the aerosol inhaled route in historically BCG vaccinated healthy adult volunteers. In this study we plan to recruit 12 healthy volunteers aged 18 to 50 who had received the BCG vaccine in the past. The volunteers will be allocated to one of the 4 study groups and receive either a very low dose, a low dose, a medium dose or a higher (standard) dose of inhaled BCG. All volunteers will undergo a bronchoscopy 14 days post- BCG challenge. Volunteers will be followed up for 6 months post-challenge.

### **How did you involve patients and/or the public?**

We have recently established a collaborative working partnership with Oxford Vaccine Group (OVG) and we are currently developing the strategy to make patient and public involvement an integral and routine part of research across both departments. For the purpose of the TB043 and TB044 studies, we contacted the existing PPI group which had previous experience in vaccine research projects run by OVG. We asked the PPI contributors to review the Volunteer Information Sheets (VIS), consent forms and advertisement materials (posters). The draft documents were sent to the contributors via email for feedback and comments and any further correspondence with them was also via email.

### **What was the impact of involving patients and/or the public?**

It can be hard to efficiently explain the reason, purpose and often the methodology behind research projects. In both TB043 and TB044 studies, it was particularly challenging to explain the key concept of the BCG being given as a type of weak bacteria to mimic an infectious response to TB, as opposed to being given as a vaccine.

We received very valuable feedback from the PPI contributors, which highlighted to us the need to revise the wording and terminology used and the layout of the VIS. Some of the changes we incorporated including: adding a brief summary on the first page of the VIS,

underlining the key aspects of both studies, using pictures and bullet points; and adding a 'key concept box' explaining what the BCG vaccine is, how it is routinely used and how it is being used for the purpose of these two studies.

Having a lay audience's viewpoint on our study documents, we are ensuring that the information given to research volunteers is clear, understandable and jargon-free, which in itself can help improve recruitment.

### **What were the challenges and how did you overcome these?**

The main challenge was to compile, consider and incorporate the feedback from the PPI contributors within tight research project timelines, as this can be quite time consuming.

However, if this is well planned and all members of the study team value the importance of the PPI feedback, then this can be achieved.

In addition, the existing PPI group consists mostly of contributors above the age of 50, whereas our pool of research volunteers are aged between 18 and 50. Therefore, while the PPI feedback is valuable to improving lay understanding of our research, we need to ensure in future that our PPI group also contains representatives of our target population.

We are planning an advertising campaign to recruit PPI members and hope this will ensure a more representative and diverse group.

### **What advice do you have for other researchers considering patient and public involvement activities?**

Our research aims to benefit the wider public and relies on the general public to volunteer, therefore it is essential that we strive to involve the public in our research.

Within our group, some of the research team initially felt that PPI was another "tick box" exercise. However, they found the PPI feedback on the study VIS was extremely useful and insightful. They changed their perception of the process and are now extremely positive about incorporating it into all future studies.