

## **Management of the Clinical Trial**

### **What is your role in the project?**

We will make sure that the clinical trial will be run safely, effectively and efficiently and in compliance with all relevant regulations.

### **How do you plan to do that?**

We will ensure that patients and their families have all the information they need to participate in the trial, that researchers in all the trial sites have clear guidelines so the research is rigorous and that the research meets all the necessary regulatory and ethical requirements. We will carry out all necessary governance functions, and act as monitor for the clinical trials at all participating sites.

### **What are the challenges you could be facing?**

The trial will be taking place in 4 different countries. Coordination of all the different research sites and researchers will require effective communication, monitoring and ensuring compliance with clinical trials regulations, information governance regulations and other regulatory demands.

### **How does your work contribute to the overall objectives of the project?**

Effective management of the clinical trial is essential for two main reasons. First to ensure that the benefits are maximized, and risks minimized, for those taking part. Second to ensure that the results are robust and can confidently be used to influence care and policy into the future. Our work includes governance of research, development and innovation from regulatory perspectives, as well as the clinical operation of trials themselves, so we are very well placed to support this activity.

### **How do you think the project will improve the quality of life of older people with complex chronic conditions?**

Quality of life is enhanced by person-centered care; care that 'sees' the individual. This project will improve the identification of older people with chronic life-limiting illnesses, promote individualized assessment and enable sensitive communication with them.