Researchers from the Robertson Centre for Biostatistics made a significant contribution to a study that was published on-line on 03/09/2013 in the New England Journal for Medicine and presented on the same day at a Hot Line Session of the Conference of the European Society of Cardiology (ESC) in Amsterdam. Ian Ford was a member of the study Executive Committee and the RCB was the independent Statistical Centre for the Study.

The study (ECHOCRT) was a randomised clinical trial to evaluate the benefit of cardiac resynchronisation therapy on top of an implantable cardiac defibrillator in patients with heart failure (primarily NYHA IV) and left ventricular dysfunction. Previous studies had confirmed the significant life-saving benefits of this approach in patients with a broad QRS measured on an ECG. The aim of this trial was to study whether these benefits were also seen in an extension to the existing indication, in patients who had a narrow QRS (< 130ms) and had evidence of mechanical dyssynchrony as measured on an echocardiogram. The primary endpoint of the trial was all-cause mortality or hospital admission for worsening heart failure.

One of the largest studies of its type, the trial recruited 809 patients in the United States, Canada, Australia, Israel and Europe (including the UK) but was stopped prematurely on the advice of the independent data monitoring committee (IDMC) 'because of futility with a potential for harm'. There was a trend to an increase in the primary endpoint in the CRT group compared to the control (102 in the control group versus 116 in the CRT group, \( p=0.15 \)) and an increase in deaths in the CRT group that reached nominal statistical significance (26 in the control group versus 45 in the CRT group, nominal \( p \)-value=0.02).

Professor Ian Ford said: 'Although the apparent increase in deaths in the intervention group should be treated cautiously and needs further investigation, especially as the IDMC were monitoring deaths on an ongoing basis and the nominal \( p \)-value is not corrected for this process, there was clearly no evidence of benefit from this intervention. The trial is important as this treatment strategy is being used in some patients with a narrow QRS and this trial will provide important information for cardiologists on who should not receive this device. The trial also reminds us of the important role that IDMCs play. A number of studies that were presented at ESC this year were stopped prematurely on the advice of their IDMCs.'