

**Senior Research Associate in Medical Statistics**  
**Further Particulars**  
**Ref: A918**

**The project**

Randomized trials of novel drugs, health technologies and non-drug interventions are usually designed to test average treatment effects. In the analysis of these trials it is therefore typically assumed that treatment effects are constant across individuals. This strong assumption is often neither supported by empirical evidence nor the theories undergirding the intervention. While heterogeneity in intervention effects is often expected, the assessment of differential treatment effects is limited by available statistical methods. When differences in treatment effects are examined, limitations with existing methodology normally result in an examination of a few interaction terms.

This project will develop a novel approach for testing differential effects that is inspired by ideas in causal modelling (Holland, 1986; Rubin, 1974) and involves the use of missing data techniques to create a predicted individual treatment effect (PITE) for each respondent. This approach is motivated by related work by Cai et al. (2011) but its detailed implementation is largely undeveloped.

This proposal brings together researchers from Lancaster University and the University of South Carolina, Columbia (USA) and aims to develop statistical methods for identifying differential effects and to contrast them.

**The Investigators**

Dr Thomas Jaki is a Reader in Statistics at Lancaster University and a co-investigator of the MRC's North-West Hub for Trials Methodology Research and the current leader of the Adaptive Designs Working Group of the MRC network of Hubs. He is a Career Development Fellow of the NIHR and the director of Lancaster University's Medical and Pharmaceutical Statistics Research Unit ([www.mps-research.com](http://www.mps-research.com)) which develops and evaluates novel statistical methods of study design and data analysis relevant to medical research institutes and pharmaceutical companies. His main research is in adaptive designs for early phase clinical trials and methods for identifying differential effects.

Prof. M Lee Van Horn is Associate Professor for Quantitative Psychology at the University of South Carolina, Columbia (USA). He is one of the leading experts in applied regression mixture modelling – one of the alternative approaches to be investigated under this projects - and has led several substantial research projects on this topic.

Dr Jaki and Prof Van Horn have a long standing history of joint research on methods for identifying differential effects and regression mixture models in particular.

## The Departments

Dr Thomas Jaki is based in the Department of Mathematics and Statistics at Lancaster University (<http://www.maths.lancs.ac.uk/departments/>). Lancaster's Statistics Group is an internationally recognised centre of research excellence. For over twenty years the Group has been at the forefront of the UK research effort in Statistics, establishing a strong track record of theoretical innovation arising from real- world challenges. The Group has a vibrant research environment consisting approximately 20 staff, with in excess of 40 RAs and PhD students. Lancaster is also home of the Medical and Pharmaceutical Research Unit (<http://www.mps-research.com/>) which has a long standing history of developing novel statistical methods of study design and data analysis relevant to medical research institutes and pharmaceutical companies.

The University of South Carolina, USA (USC) is one of only 62 public universities in the USA to receive the highest ranking by the Carnegie Foundation as an institution with "very high research activity", with more than US\$ 238 million in sponsored research awards in 2012. The Department of Psychology, housed within the College of Arts and Sciences, has a strong commitment to advancement of basic and applied psychological research and interdisciplinary collaboration. There is a strong history of securing prestigious research awards and large research grants from the National Institutes for Health (NIH), the National Science Foundation and the Institute of Education Sciences.

## References

1. Holland, PW. 1986. Statistics and causal inference. *Journal of the American Statistical Association*, 81, 947–960.
2. Rubin, DB. 1974. Estimating causal effects of treatments in randomized and nonrandomized studies. *Journal of Educational Psychology*, 66, 688–701.
3. Cai, T, Tian, L, Wong, PH, & Wei, LJ. 2011. Analysis of randomized comparative clinical trial data for personalized treatment selections. *Biostatistics*, 12(2), 270–282.