

# Methods for the evaluation of biomarkers in patients with kidney and liver diseases: multicentre research programme including ELUCIDATE RCT

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†In memoriam

**Declared competing interests of authors:** Peter J Selby has an international patent (application no. PCT/GB2014/050768; biomarker; University of Leeds) issued. Rosamonde E Banks reports grants from various non-commercial funding sources during the conduct of the study; in addition, she has a international patent (application no. PCT/GB2014/050768; biomarker; University of Leeds) issued. Jenny Hewison is a panel member of the National Institute for Health Research (NIHR) Clinical Trials Unit Standing Advisory Committee. Grant D Stewart has a patent (1408091.5) pending to the Medical Research Council (MRC) Human Genetics Unit (HGU). James Neuberger is a consultant to Astellas Pharma, Inc., and has received speaker support funding from Astellas and Novartis UK. Claire Hulme has received grants from the NIHR during the conduct of the study and is a panel member of the Health Technology Assessment (HTA) Commissioning Board. Andrew Lewington has received personal fees from Fresenius Medical Care, Baxter Healthcare Ltd, AM-Pharma, BioPorto Diagnostics A/S and GE Healthcare, outside the submitted work; in addition, he has a patent (ACY-1 biomarker) pending. Naveen S Vasudev has received personal fees from Bristol-Myers Squibb and GlaxoSmithKline plc, outside the submitted work. William Rosenberg was an inventor of the enhanced liver fibrosis (ELF) test when he was an employee of the University of Southampton. His rights were transferred to Siemens Healthcare Diagnostics Ltd by the University of Southampton. He does not receive any payment in relation to sales of the test by the manufacturer Siemens Helathcare Diagnostics. He has received grant support and speaker fees from Siemens Healthcare Diagnostics and is a director of iQur Ltd (Southampton, UK), a company that provides ELF testing.

In the context of this NIHR-funded study, all ELF testing provided by iQur Ltd was performed on a not-for-profit, cost-recovery basis. William Rosenberg is married to Julie Parkes, who is a co-investigator on the programme. Julie Parkes reports receiving support from the Speakers' Bureau for Siemens Healthcare Diagnostics, outside the submitted work, and is married to William Rosenberg (co-applicant). Jonathan J Deeks is a panel member of the HTA Commissioning Board.

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## Plain English summary

### **Evaluation of biomarkers in patients with kidney and liver diseases**

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## Plain English summary

**P**rotein biomarkers are substances that can be measured, often in body fluids, to provide information about patients and their illness. Measuring biomarkers in blood or urine is simple and safe and may help diagnose disease and its severity and help choose treatment. New research is discovering more biomarkers but there is no quick way to decide how useful they are.

Our research was aimed at methods to assess the clinical usefulness of biomarkers as quickly and efficiently as possible:

- We identified the best research methods for monitoring disease or treatment with biomarkers. We showed that the literature is modest in scale and of variable quality. We made recommendations for improvements.
- We created a sample 'banking' system for collecting and storing patient samples and relevant clinical data from large numbers of patients, for renal cell carcinoma and renal transplantation. Biomarkers were identified and analysed and the system was used to show their value.
- We conducted a trial of the 'enhanced liver fibrosis' test in 878 patients. We showed that it alters patient care but longer follow-up is needed to show if this results in improvements in long-term outcomes.

Our experience is part of the basis of a new framework for evaluating diagnostic tests in four centres in England.

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