

## **RISING POWERS POLICY WORKSHOP**

### **Regulatory challenges of personalised medicine: a transnational perspective**

on

22 June 2015

at

Room SW 1.09 (Somerset House East Wing), Strand, London

by

Members of the ESRC Rising Powers Research project, KCL

The workshop will explore the regulatory challenges of personalised medicine from a transnational perspective, as part of the ESRC project *State strategies of governance in global biomedical innovation; the impact of China and India*. The focus will be on two critical issues: the challenges associated with rapid technological advances in next generation sequencing, and the changing regulatory status of laboratory-developed tests. The workshop will bring together a variety of experts from government, industry and academia from Europe, North America, India and China.

#### **Schedule**

- 09:30** Arrival and refreshments
- 09:45** Introductions
- 10:00** **Session 1:** Next generation sequencing
- Introductory overview – technological advances and new regulatory challenges.
  - Validating analytic performance.
  - Validating clinical performance
- 13:15 – 14:15** Lunch
- 14:15** **Session 2:** Laboratory-developed tests
- Introductory overview – evolving business models and regulatory responses.
  - Pathways, standards and transnational harmonization.
  - Options and next steps.
- 16:15 – 17:00** Final discussion and roundup
- 17:00** Discussion will continue informally over drinks and dinner.