The Wellcome Trust, UK

Introduction

1. The Wellcome Trust (the “Trust”) is an independent research-funding charity, established under the will of Sir Henry Wellcome in 1936. It is funded from a private endowment, which is managed with long-term stability and growth in mind. The Trust’s mission is to foster and promote research with the aim of improving human and animal health.

2. The Trust is a leading player in the Human Genome Project (HGP) and the Wellcome Trust Sanger Institute (WTSI) in Hinxton, Cambridgeshire has taken responsibility for sequencing and annotating one third of the genome sequence. The Trust believes that genomics research offers exceptional potential to enhance our understanding of the major diseases affecting human kind and our ability to develop new preventive and therapeutic approaches for their control.

3. The Trust recognises the key importance of research that aims to elucidate how variations in genome sequence between individuals influence disease susceptibility and the effectiveness of therapeutic interventions. In 1999, the Trust brokered the SNP Consortium, and the WTSI will also participate in the International Haplotype Mapping Project. The Trust considers that these genome variation maps will enhance our ability to identify genetic susceptibility factors, and our ability to employ pharmacogenetics approaches to enhance the development and safe use of medicines.

4. The development and progression of most common diseases results from the interplay of the environment to which an individual is exposed with a variety of genetic susceptibility factors. In order to dissect these complex interactions, researchers in both academic and commercial settings are increasingly initiating longitudinal studies of large patient cohorts over extended periods of time. The Trust supports several such projects, including the Avon Longitudinal Study of Parents and Children (ALSPAC).

5. In April 2002, the Trust earmarked £20 million funding for the UK Biobank project. This resource will support scientists in investigating the pathology of common diseases.

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1 The Human Genome Project is the international collaborative project to sequence the entire three billion base pairs constituting the human genome. The sequence data generated is released immediately into the public domain with no terms or conditions on its use, so it can be used by scientists the world over.

2 The SNP consortium is a unique partnership between the Wellcome Trust, 13 pharmaceutical and biotechnology companies and four genomics research centres to generate a map of single nucleotide polymorphisms (SNPs), which are sites of single base pair variation, across the human genome. Further information is available at: http://snp.cshl.org/

3 The haplotype mapping project is a three year $100 million project to characterise blocks of linked SNPs across the human genome.

4 The UK Biobank will be funded by the Wellcome Trust, Medical Research Council and Department of Health. It will collate genotype information with medical and lifestyle data for a
complex diseases and potentially enable them to gain new insights on how genetic and environmental factors influence the effectiveness of medical interventions. As the project proceeds, the funders are working to ensure that the wider implications of the project are addressed fully. An interim advisory group has been established to advise on the development of an ethical framework through which the resource will operate. Several rounds of consultation with key stakeholder groups, including healthcare professionals, scientists and the general public, have been undertaken to date. This crucial process will continue as the project progresses.

6. Genetics research and its healthcare applications are raising an increasing number of complex ethical, legal, social and economic issues for society to address. These advances will require the development of appropriate policy frameworks at both a national and international level to regulate the use of these technologies in the public interest. The Trust believes strongly that policy makers must strive for a balance where the considerable potential of this research to improve health may be realised, whilst setting in place robust ethical and regulatory safeguards that protect both research participants and the general public, and ensure that the benefits are realised equitably.

7. In 1997, the Trust launched a Biomedical Ethics programme to support research exploring the ethical, legal, social and public policy implications of advances in biomedical science. In 1999, the Trust made a dedicated call for proposals for projects addressing the implications of human biomedical sample collections and pharmacogenetics. In the same year, it funded workshops for researchers on each of these issues to explore emerging themes and develop potential research questions. Through this initiative, the Trust funded five research groups to undertake studies on the implications of pharmacogenetics, and these grants are listed in Annex A. Many of these projects directly explore issues addressed in the consultation document.

8. The Trust believes very strongly that the potential of biomedical research to deliver real benefits to health will not be realised unless the public are aware of, and engaged with, the issues it raises. Public engagement is one of the Trust’s four key corporate aims, and, through its Medicine in Society Programme, it promotes a diverse range of innovative approaches to public engagement. These activities include: advocating curriculum changes in schools to encourage the exploration of the issues raised by advances in scientific research; promoting the use of theatre as a means of engagement; cohort of half a million individuals aged between 45 and 69 years. See: http://www.ukbiobank.ac.uk/

5 The Trust’s Biomedical Ethics Programme provides funding for biomedical ethicists via research grants, personal support and symposia awards. It currently focuses on three areas - genetics, neuroscience and mental health, and the ethics of research in developing countries. Further details can be found at: http://www.wellcome.ac.uk/en/1/pinbio.html

6 A report on the pharmacogenetics workshop and a commissioned background review paper can be accessed from: http://www.wellcome.ac.uk/en/1/pinbiobnkpha.html

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and working to support health professionals and scientists in their interactions with the public.

9. The Trust welcomes the opportunity to respond to the Nuffield Council on Bioethics on the important issues raised in its consultation document. In preparing this response, the Trust contacted the five research teams whom it funds through its Biomedical Ethics programme to explore the implications of pharmacogenetics to gain their expert perspectives on these issues. All five groups provided inputs, and the information they submitted is cited within the response below. The Trust also consulted Dr David Bentley at the Wellcome Trust Sanger Institute and a research group it funds at Liverpool University, led by Professors Munir Pirmohamed and Kevin Park.

Responses to Consultation Questions

| Q1 | What do you think will be the likely economic impact of pharmacogenetics on the development of new medicines? |
| Q2 | Do you think that further regulatory measures will be needed to encourage the development of clinically desirable but economically unprofitable medicines? |

10. The Trust believes that the application of pharmacogenetic approaches holds exciting potential to ultimately enhance the drug discovery and development process. It could result in a greater number of new products reaching the market, which could be targeted to those patients in which they will work safely and effectively. It could also result in the more effective use of previously-marketed drugs and potentially enable candidate drugs that have previously failed clinical trials due to adverse effects in a minority of patients to be reinvestigated and used safely in a targeted fashion.

11. The Trust considers, however, that it is extremely difficult to predict the extent of the economic impact that pharmacogenetics will have at the present time, or the timeframe over which these will occur. Indeed, it does not seem that there is clear consensus, even within the pharmaceutical industry, as to the extent of any benefits that may arise.

12. The Trust would highlight two responses it received from researchers working in this area as demonstrating the current uncertainties surrounding these issues:

- Dr Oonagh Corrigan at the University of Cambridge highlighted the divergence of views in a survey of industry scientists that she conducted. Whilst many thought pharmacogenetics would radically alter drug development and make drugs cheaper to produce, some were sceptical of the idea of “segmentation of the market”, noting that to date most pharmaceutical companies have relied on profits from blockbuster drugs.
The Pharmacogenetics Evaluation Policy (PEP) Project at Cambridge University notes that initially pharmacogenetics will be cost-additive whilst companies invest in new equipment, staff, educational requirements and administrative costs. PEP argues that whilst cost savings will result from clinical trials, the market for each product is likely to be more limited, which could induce industry to charge a premium for the higher efficacy and safety to these individuals. Finally, incremental costs may fall as pharmacogenetics is integrated into the drug development process.

13. The Trust would suggest that further research evidence and more detailed economic analyses are required before we can begin to assess reliably the economic implications that pharmacogenetics may have.

14. As regards regulatory measures to incentivise the development of medicines where a sufficient market incentive does not exist for the pharmaceutical industry, the Trust considers that a variety of mechanisms must be developed if the benefits of genomics research are to be delivered equitably. This applies not just to patient groups defined as a result of pharmacogenetics characteristics, but to neglected diseases which primarily affect the world’s poor. Governments, research funders and other international organisations must continue to work with the pharmaceutical industry to develop appropriate incentives, controls and partnerships to overcome these challenges.

15. Orphan drugs legislation is one important tool which is already well established in the US and Europe. The PEP Project team point out that regulators are currently extremely cautious about using this route for subsections of the disease group defined by pharmacogenetics. They state that, in general, new regulatory measures for drugs are deemed unnecessary for patient benefit, but it may be that in certain cases the applications of orphan drug status may need to be flexible for particularly well-targeted pharmacogenetics drugs.

Q3 In your view, should pharmacogenetic testing of participants in trials be a regulatory requirement for the development of medicines in the future?

16. The Trust interprets this question to refer to the pharmacogenetic testing of participants during clinical trials rather than testing as a prerequisite to screen out unsuitable participants.

17. Whilst the Trust would leave detailed discussion of the regulatory issues surrounding clinical trials to those organisations with specific expertise in this area, its preliminary view would be that it would probably not be appropriate to introduce mandatory pharmacogenetics testing at this time. Our knowledge of pharmacogenetics is not sufficiently well advanced for us to make accurate predictions of likely drug responses based on genetic variation in the vast
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majority of cases. It is also likely that even when our knowledge of genetic factors underpinning pharmacogenetics responses is more advanced, it will still only be possible in most instances to establish the probability of adverse reactions or low efficacy action.

**Q4** Who should be responsible for providing a pharmacogenetic test? For individual therapy, should tests be available directly to patients over the counter or on the internet, or should they only be available through medical practitioners as part of a decision about the use of a prescribed medicine?

18. The Trust recently submitted a detailed response to the consultation of the Human Genetics Commission on Genetic Testing Services Supplied Direct to the Public in which it addressed these issues. Here the Trust stated the need for a regulatory framework that could categorise genetic tests into those that could be supplied direct to the public and those that should only be available through referral by medical practitioners, based on the impact that the information will have and the healthcare implications. It also stressed the need for ensuring provision of, and patient access to, appropriate counselling services, and the need to ensure that information on the implications of genetic tests was made readily available to the public.

19. The Trust considers that the requirements for pharmacogenetics tests do not differ from those of other types of genetic tests, and that these arguments apply equally to this situation. Wide-ranging consultations undertaken by the PEP Project have indicated that in almost all cases it was considered undesirable to have uncontrolled direct marketing of pharmacogenetics tests at this stage, particularly as the interpretation of the results will be complex and in most cases probabilistic rather than deterministic. The responses we received from scientists in the field also supported the argument that these tests should be conducted and interpreted by trained healthcare professionals in the context of clinical consultation.

**Q6** Should medicines which have been developed for administration in conjunction with a pharmacogenetic test be distributed to countries in which testing facilities are not available?

20. Whether a medicine that has been developed in conjunction with a pharmacogenetic test should be used in a country, or any given subsection of a population, where testing facilities are not available would depend on a number of factors. These would include: the frequency and seriousness of any adverse reactions associated with the drug; the cost of the treatment against the proportion of the population on which it would demonstrate

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7 Trust responses to consultation exercises may be accessed from: [http://www.wellcome.ac.uk/en/1/awtvspolsub.html](http://www.wellcome.ac.uk/en/1/awtvspolsub.html)
efficacy; and the severity of the healthcare need for that particular treatment. It might be unethical to provide a treatment without a test in a situation where it could only be used safely in a clearly defined subset of the population. On the other hand, in an extreme healthcare crisis, it might be considered unethical to withhold a treatment which would save lives, on the basis that it may cause limited adverse reactions in a small subset of the population.

21. Hopefully, as the technology advances, it should become increasingly feasible to offer pharmacogenetic tests in resource-poor settings. The World Health Organisation and other agencies have stressed the importance of international collaborations between developed and developing countries to promote the transfer of such technologies and provide poor countries with the basis on which to build clinical genetics services. The Trust is itself presently exploring strategic opportunities in this area.

Q7 How should predictions of efficacy and safety, as well as cost, be integrated in deciding whether to provide a particular treatment to patients in (a) a public healthcare system, and (b) a private healthcare system?

Q8 Do you think the application of pharmacogenetics might exacerbate inequalities in the provision of healthcare? Is it likely to challenge the principle of solidarity that lies at the basis of the provision of national healthcare in the UK? Will the benefits of pharmacogenetics only be affordable or available to the wealthy?

22. The implications of the increasing availability of pharmacogenetic testing on the decisions over which treatments to make available via the National Health Service (NHS) represents a hugely complicated issue. Responsibility will fall to the National Institute of Clinical Excellence (NICE) and other regulatory bodies to make these difficult judgements.

23. Of course, it should be noted that the provision of genetic services has serious resource implications for the NHS, and pharmacogenetics testing is just one component of this. It is to be hoped that the Department of Health’s forthcoming Green Paper on Genetics will address some of these issues. The Trust considers that this is a further issue on which robust research evidence is required.

24. The wider use of pharmacogenetics information in a private health care system raises different issues. An issue of particular concern would be the way in which health insurers would use this information, and whether it could

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8 A series of World Health Organisation reports have addressed issues of clinical genetic services in developing countries. The most recent is the report of the Advisory Committee on Health Research on Genomics and World Health, which can be accessed from: [http://www.who.int/health_topics/genomics/en/](http://www.who.int/health_topics/genomics/en/)

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result in reduced access to healthcare services for certain parts of the population. The conditions under which those with the ability to pay could access drugs which tests predict would have a low probability of working effectively or a high probability of an adverse reaction could also be problematic.

25. It is possible that pharmacogenetics tests will initially be expensive and accessible only to those with the ability to pay. It is to be hoped, however, that technological advances will result in cheaper and more efficient tests which could be made available to all via the health service, particularly if balanced against the cost-savings that would result from the more efficient use of expensive drugs. The Trust does not consider that pharmacogenetics will challenge “the principle of solidarity that lies at basis of provision of national healthcare in the UK” providing that prescribing decisions based on test results are made in a consistent manner. Indeed, physicians already make decisions on whether to prescribe a certain drug to a particular patient based on a variety of factors such as age, physiological condition and so forth.

26. Although the implicit emphasis of this question appears to be on inequalities within the UK, the Trust would note that there are already substantial inequalities in healthcare at a global level, both between and within countries. There is a danger that advances in genomics research, including the wider application of pharmacogenetics, could, initially at least, exacerbate such inequalities. Ensuring that the potential of this research is realised equitably constitutes a major challenge for the international community.

Q9 In your view, is the storage of genetic information for the purpose of pharmacogenetic analysis categorically distinct from storage of other kinds of genetic information, for example information about susceptibility to disease?

Q10 What level of anonymity should be accorded to genetic information stored as part of research in pharmacogenetics?

Q11 What kinds of consent should be required for the collection of samples for research in pharmacogenetics? Should pharmaceutical companies which collect samples in the course of research in pharmacogenetics be able to use such samples for any purpose, or should consent of the donor be restricted to allow usage only for specific kinds of research?

Q12 Do you think that researchers should provide individual feedback about genetic information obtained from participants in research in pharmacogenetics?

27. At this time, the Trust considers that the storage of genetic information for the purpose of pharmacogenetic testing should not be treated as categorically...
distinct from the storage of genetic information collected for other purposes, and the same standards for privacy should be applied. Indeed, whilst pharmacogenetics information may often have less serious implications for individuals than that arising from other types of genetic tests, it is not always distinct from disease susceptibility testing. Trust-funded researchers we consulted in developing this response noted the example of the APOE4 gene which has possible links with the efficacy of a number of drugs and is predictive of susceptibility to Alzheimer’s. Furthermore, pharmacogenetic test results may subsequently acquire much greater sensitivity for patients based on subsequent discoveries regarding disease susceptibility factors and so forth.

28. In pharmacogenetics research, as in other types of genetics research, a robust system to anonymise patient samples will often represent best practice, particularly where the information will feed into a resource to be accessed by other research users. In most cases, some form of reversible anonymisation might be appropriate, in which samples are de-identified through a coding process. This would enable the sample to be identified if: the protocol includes feedback to patients; if subjects’ records are to be updated from other sources (e.g. NHS information systems as in the case of the UK Biobank); or if a participant subsequently decided to opt-out and remove their information from the resource. Clearly the degree of anonymisation that is appropriate depends on the nature of the project under consideration and is a matter for scrutiny by ethical review bodies. Issues of anonymisation, with particular reference to secondary uses of research data, are discussed in a recent report published by the Nuffield Trust.9

29. Issues of consent and of feedback in the context of genetic database resources are still the subject of extensive discussion and have yet to be resolved. In the context of the UK Biobank, an interim advisory group has been established to advise funders as to how these issues should be addressed in the context of this resource and it would be inappropriate for the Trust to pre-empt the outcomes of these discussions. The Trust would note that issues surrounding consent were discussed at length at a UK Biobank Ethics Consultation workshop which was held in April 2002, and the Committee may find the report of this meeting of interest in considering this issue.10

30. The question of the appropriate level of feedback that should given to research participants will clearly depend on the nature of the study under question, and this should be covered in the consent process. The protocol for feedback must always respect the right of individuals not to know information

10 The report of the UK Biobank Ethics Consultation Workshop can be accessed from: http://www.ukbiobank.ac.uk/ethics.htm
if they so choose, and ensure that potentially sensitive results are given to individuals in the context of consultation with a suitably trained healthcare professional, with appropriate counselling support.

Q13 What, in your view, would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?

31. Although the question of storage of pharmacogenetic information used in clinical practice is largely outside the Trust’s immediate area of expertise, it would like to emphasise, in response to the discussion in the consultation document, the potential importance of using this information in research. The Trust would suggest that research utilising anonymised, aggregated data on pharmacogenetic test results collated from medical records might be highly valuable to examine health service performance and inform future policy as pharmacogenetics becomes more widely applied in healthcare. The regulatory safeguards must therefore balance the need to protect patient privacy, whilst allowing valuable research of this type to proceed.

Q14 Do you think that the ethical and legal issues raised by the use of pharmacogenetic tests in primary care differ from those raised by other forms of genetic testing? What about non-genetic tests, such as tests for cholesterol?

Q15 What might be the psychological implications for individuals of pharmacogenetic tests? Are such tests likely to reveal information that is of relevance outside the context of testing for response to medicines?

Q16 What implications do you think pharmacogenetic tests might have for family members?

32. As stated above, the Trust’s current view is that information collected in the context of a pharmacogenetic test should be afforded the same status as information collected in other types of genetic tests with respect to patient confidentiality and so forth. It is of course true that the two types of tests may often be used in different medical contexts and the information generated will be used in different ways – i.e. disease susceptibility testing will mostly be used to inform lifestyle decisions and preventive action, whereas pharmacogenetic testing will be used to inform prescribing practice for patients with a particular condition. It is, however, not possible to delineate clearly between the two as pharmacogenetic testing may in some cases have implications for disease susceptibility. Some pharmacogenetics tests may therefore have implications for a patient’s family members in terms of revealing possible adverse drug reactions and predisposition to disease. Genetic information of this type which could directly impact on a patient’s
family members is therefore distinct from the results of cholesterol testing where no inheritance link is proven.

33. Pharmacogenetic tests might therefore have significant psychological implications for patients, if they are, for example, classed as non-responders to common classes of drugs or the test indicates susceptibility to disease. As with other types of genetic testing, counselling services will need to be provided for patients where the test results may have serious implications for that individual and their family. The Trust would suggest that there will be a need for a regulatory body to classify tests and provide guidance on which tests should only be provided with appropriate genetic counselling.

34. A Trust-funded research project undertaken by Dr Oonagh Corrigan involved interviews with a group of 23 volunteer subjects who had consented to pharmacogenetic testing for CYP2D6 as part of their participation in phase I clinical trials. Despite being informed of the implications of variants of this gene and that the availability of the information on request, not one was interested in knowing their CYP2D6 status. On the other hand, between 10 to 15 percent of healthy volunteers declined to give consent and some expressed a slight unease about such tests.

35. The Trust would also suggest that where pharmacogenetic testing is conducted by medical practitioners, there may be implications regarding the rights of the patient “not to know”. A physician would be subject to General Medical Council (GMC) requirements and would not necessarily be able to withhold relevant information, just because a patient asks them to. Paragraph 10 of the GMC booklet on consent states that, as regards withholding information:

“You should not withhold information necessary for decision-making unless you judge that disclosure of some relevant information would cause the patient serious harm. In this context, serious harm does not mean that the patient would become upset, or decide to refuse treatment”

Q17 In your view, are controversies likely to arise about who ultimately decides which treatment is prescribed in light of a pharmacogenetic test?

Q18 Should patients be able to refuse a genetic test to determine response to medicines but still expect to receive a prescription?

Q19 Do you think that the providers of health insurance should have access to pharmacogenetic information? What about other parts of the insurance industry, for example life insurance?

11 See “Seeking Patients’ Consent: The Ethical Considerations” (General Medical Council, November 1998), accessed from: http://www.gmc-uk.org/standards/default.htm
36. The Trust considers that there is some scope for controversies to arise if the tests are introduced without sufficient guidance for physicians and other healthcare professionals on how pharmacogenetic tests should be used in prescribing practice.

37. Whether a drug might be prescribed if a patient refuses a pharmacogenetic test will depend on a number of factors. A patient would have the right to refuse a pharmacogenetic test and this would in no way relieve a clinician of their legal and professional duty to provide what they feel to be the best available treatment for that patient based on their clinical judgement. It is important to note, however, that a clinician cannot be obliged to act against their clinical judgement, and would be under no obligation to prescribe a particular drug, if they believed that to do so would cause harm to the patient or be unlikely to benefit him or her. It is conceivable, therefore, that some clinicians may judge that certain drugs should only be prescribed in combination with a pharmacogenetic test, if, for example, there was a high risk of a serious adverse reaction.

38. As a number of experts whom the Trust consulted noted, it is possible that in the future, some drugs will only be licensed on the condition that an associated pharmacogenetic test is used. In such cases, clear guidance would be needed for clinicians on the circumstances, if any, in which it would be acceptable to provide such drugs in the absence of the test.

39. The Trust’s own public consultations, both in the context of the UK Biobank and more broadly, have indicated that the degree of access that insurance companies are granted to personal genetic data constitutes a major public concern with regard to genetic research and testing. A consultation undertaken by the Trust-funded PEP project found that there was a strong view that insurance companies should not have information about which a person has no control, including that concerning disease susceptibility and pharmacogenetics status. Various organisations, including the Human Genetics Commission, have stressed the need for legislation to prevent genetic discrimination by insurers and other potential users of this information, and for further research to explore the potential use of genetic data in insurance during the current moratorium.

12 See, in particular, paragraph 5 of the General Medical Council guidelines on Good Medical Practice (3rd Edition, May 2001) which states: “The investigations or treatment you provide or arrange must be based on your clinical judgement of patients' needs and the likely effectiveness of the treatment. You must not allow your views about patients’ lifestyle, culture, beliefs, race, colour, gender, sexuality, disability, age, or social or economic status, to prejudice the treatment you provide or arrange. You must not refuse or delay treatment because you believe that patients’ actions have contributed to their condition”. These guidelines may be accessed from:
http://www.gmc-uk.org/standards/default.htm

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Q20 Do you think that pharmacogenetics will increase the likelihood of the grouping of patients according to racial or ethnic groups for medical purposes? If so, what might be the ethical and social implications of such an outcome?

40. It is true that there is good evidence that some genetic variants are more common in certain ethnic or population groups reflecting geographical separation over long periods of time. However, research to date has suggested that there is more genetic variation within ethnic groups than between them. It does not necessarily follow therefore that pharmacogenetics will increase the grouping of patients according to race or ethnicity - the results of pharmacogenetics tests should be used to prescribe the most effective medicine for a particular individual, irrespective of their ethnic origin. There is a danger that, where such variants exist, pharmaceutical companies will tend to focus their drug discovery efforts to cater to genetic variants associated with populations in more wealthy parts of the world. However, global funding for research and development is already highly skewed towards the health needs of those in richer countries with the ability to pay, and there is already a pressing need to address these inequalities which pharmacogenetics does not change.
Annex A

Pharmacogenetics Projects Funded through the Wellcome Trust Biomedical Ethics Programme

The ethical and sociocultural implications of innovative genetics-based drug development. The application of pharmacogenetics in clinical drug trials - A case study.
Dr Oonagh Corrigan (Sponsor: Professor Nikolas Rose)
Goldsmith’s College, University of London

Pharmacogenetics and the genetic reclassification of common disease
Dr Adam Hedgecoe (Sponsor: Dr Brian Balmer)
University College London

Ethical factors in psychiatric drug development: an archival study of the ethical factors that influenced the development and production of Prozac in Eli Lilly & Company Ltd
Dr Mariam Fraser, Dr David Healy and Professor Nikolas Rose
Goldsmith’s College, University of London and University of Wales College of Medicine

The clinical and commercial development of pharmacogenetics: Issues for patients, professionals and public policy
Dr Paul Martin, Dr Alison Pilnick, Prof. Andrew Webster, Dr Graham Lewis and Dr Andrew Smart
University of Nottingham and University of York

Information policy for pharmacogenetics
Dr David Melzer
University of Cambridge

Further details of these projects may be accessed at:
http://www.wellcome.ac.uk/en/1/pinbiobnkgen.html