

Genomics England

EARNING TRUST

Public Engagement and Patient Involvement Strategy
2015-17

Earning and maintaining public confidence

Ensuring a lasting legacy by

putting participants at the centre
engaging with our partners
initiating debate and understanding

Summary

This document outlines the Genomics England strategy to build trust and public confidence in the 100,000 Genomes Project and in the security and privacy of its data.

To support this overarching aim and ensure our legacy, there are three main objectives:

1. Putting participants at the centre

- to involve participants at the centre of our work, establishing a participant panel in order to listen and learn from them and act on their advice on a range of matters
- to specifically involve participants, through the panel and GMC PPI programmes, in the assurance of our data access policies

2. Engagement with our partners

- to actively work with our different partners to understand concerns, to communicate and to develop strategies to mitigate them
- to develop strategies with them to ensure that our legacy is a lasting one
- to develop relationships which ensure that key messages about genomics are aligned, with a range of funders and those with special interests but particularly with NHS Genomic Medicine Centres
- to engage with as diverse a range of SMEs as possible in order to ensure the greatest insights and developments from the data services
- to engage with regulators to ensure that regulatory frameworks will be in place to enable rapid adoption of new diagnostics and treatments which come from insights enabled by the data

3. Initiating debate and understanding to ensure a lasting legacy

- to contribute to a raised awareness of genomics
- to catalyse discussion and debates on ethical issues in genomics across society
- to create a commitment amongst government, the NHS and the scientific communities to take account of the outcome of these debates when framing future genomics applications and initiatives
- to foster international links for a wider profile for the 100,000 Genomes Project

Background

During 2014, Genomics England's attention was focused on setting up its services and infrastructure including sequencing, biorepository, bioinformatics and informatics; on the initiation of pilots and in developing its policies and protocol for Research Ethics Committee approval. These dauntingly complex workstreams have proceeded, in parallel, at enormous speed to extremely challenging deadlines.

Engagement to date has necessarily largely had to focus inwards; on what needed to be done in order to get the project infrastructure up and running – for instance, working with potential participants to find out their views in order to inform our ethical policies or the involvement of potential participants in the development of consent forms and patient information. Another important strand has been building public trust and confidence.

Now, with the main phase starting it is time to pause and reflect what needs to be undertaken over the final three years of the project. Whilst continuing to retain the trust of the public remains our overarching concern, the focus now must be on ensuring the lasting legacy for patients, the NHS and the UK economy of the 100,000 Genomes Project.

Whilst the public was not involved in decisions in how the 100,000 Genomes Project was initiated, there is now an opportunity for genuinely open-ended engagement about what comes next; through the NHS Genomic Medicine Centres (GMCs) and participants, who can help shape NHS genomic medicine for the future and, through the public and our partners on a broader societal level .

For informed national debates to take place, there needs to be a wider understanding of genomics (currently recognition of the term amongst the public stands at just 12%¹).

This cannot be achieved by Genomics England alone. Much of what we need to do now will involve collaborative working with our main partners in the NHS, PHE and HEE. We also have an important role as a catalyst bringing together many different groups to start national conversations about genomics whilst also ensuring that activities complement and extend one another, rather than compete for audiences.

We are acutely aware that although Genomic England's sequencing objectives will be complete by 2017, the 100,000 Genomes data will endure as a national asset for decades beyond this. The foundations must be laid now to ensure that it continues to deliver benefits for patients for generations to come. In particular, Genomics England must engage with industry and with regulators to make sure that the 100,000 Genomes Project delivers its potential for new treatments and diagnostics.

¹ Wellcome Trust Monitor Report Wave 2 (2013). Full report: http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053113.pdf

Genomics England's partners

In addition to participants², potential participants and the public, Genomics England has an unusually diverse range of partners; relevant patient groups and medical charities, special interest groups (data, privacy, genetics/genomics), teachers, NHS healthcare professionals, including those in clinical genetics and working in NHS Genomic Medicine Centres, researchers through the Genomics England Clinical Interpretation Partnership (GeCIP), academic and professional bodies, research funders such as MRC and the Wellcome trust, industry including pharma, biotech, informatics and data analysis companies of all sizes, regulators such as MHRA and HRA, our directly involved partners (NHSE, HEE, PHE,), Government (principally DH but also BIS), parliamentarians and finally a wide range of digital, print and broadcast media.

The diversity of our partners reflects the wide interest and potential impacts of genomics across society. On the one hand genomics is seen as revolutionary, delivering new diagnostics, drugs and insights for the benefit of patients and as a boost to the UK's world leading life sciences industries, but on the other, genomics is little understood and may even be feared. Genomics raises many ethical issues such as feedback of results and implications for family beyond the patient, but there are also important concerns about data privacy and security or potential personal detriments relating to insurance, access to financial products like mortgages or even jobs. It is vital that society debates these issues in an open and informed way as society decides whether and how genomics is used more widely in medicine. As noted earlier, whilst Genomics England can engage and involve participants and enable the wider use of genomics within the NHS, it cannot undertake these important debates across society alone. However it can and should act as a catalyst for these conversations and this will be an important element of our engagement work over the next three years. And if Genomics England can collaborate effectively with partners, it will be able to extend its reach through effective partnership working.

In addition we will need to work closely with the 11 NHS Genomic Medicine Centres (and any additional ones added over the life of the project) each of whom have their own public engagement activity, as well as an extensive Public and Patient Involvement (PPI) programme.

² We deliberately use the term participants rather than patients because about 35,000 of those involved in the 100,000 Genomes Project will not be patients, but the healthy relatives of an individual affected by rare disease.

Public and patient engagement and involvement to date

Genomics England undertook a range of work in 2014 to ensure that potential participant's views were included in the formulation of the ethical policies submitted for research ethics approval and in the development of patient information. The views of different groups of potential participants (those affected by cancer, or rare disease, or those from BAME groups) in relation to ethical issues raised by the 100,000 Genomes Project were sought in a series of deliberative events. A separate piece of work involved patients in the development of participant literature and consent forms. There was a particularly high degree of co-production in material intended for young adults. A range of events, debates, surveys have also been organised by Genomics England and by independent third parties. Reports on the deliberative work for the different groups is available on the Genomics England website. Several hundred potential participants and their families have been directly engaged in informing our ethical policies or involved in the development of literature to date, with close to 1,000 members of the public attending public events. We are enormously grateful for all the help and support we were given to complete this work by patients and their carers, by Genetic Alliance UK, Cancer Research UK and by all their staff and supporters,

Our engagement strategy for the remaining three years of the life of the project sits beneath our overarching aim of retaining public trust. A key element of this is the involvement of our participants through a participant panel and through PPI work in each of the NHS Genomic Medicine Centres.

Building trust and confidence

- to continue to earn and maintain public trust and confidence in the 100,000 Genomes Project and in the security and privacy of its data

Beneath this are three elements which contribute to our overarching aim and help ensure our legacy

Putting participants at the centre to ensure a lasting legacy

- to involve participants at the centre of our work, establishing a participant panel in order to listen and learn from them and act on their advice on a range of matters
- to specifically involve participants, through the panel and GMC PPI programmes, in the assurance of our data access policies

Engagement with our partners to ensure a lasting legacy

- to actively work with our different partners to understand concerns, to communicate and to develop strategies to mitigate them
- to develop strategies with them to ensure that our legacy is a lasting one
- to develop relationships which ensure that key messages about genomics are aligned, with a range of funders and those with special interests but particularly with NHS Genomic Medicine Centres
- to engage with as diverse a range of SMEs as possible in order to ensure the greatest insights and developments from the data services
- to engage with regulators to ensure that regulatory frameworks will be in place to enable rapid adoption of new diagnostics and treatments which come from insights enabled by the data

Initiating debate and understanding to ensure a lasting legacy

- to contribute to a raised awareness of genomics
- to catalyse discussion and debates on ethical issues in genomics across society
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Ethical approval and data access

Our Board and particularly our Ethics Advisory Committee, with input from potential participants, have put a great deal of thought into the protocol approved by the Research Ethics Committee in February 2015. We have developed a series of policies on data security and other matters. All our policy documents and protocol are publicly available on our website.

An Access Review Committee, which will include members of our participant panel, will provide a further level of assurance on data access requests. We will publish all requests for data access, both those granted and those refused, on our website. A high level summary of the area of interest will be included.

We will respond to requests for information as soon as possible.

We will ask our Participant Panel to regularly audit the quality and transparency of our materials and information.

1. Putting participants at the centre of our work

The 100,000 Genomes Project could not succeed without the generosity of participants. Although some will benefit personally from whole genome sequencing, most, particularly in the cancer arm of the project, will not, yet they are still prepared to take part because they hope their involvement will benefit generations to come. We owe them a great deal. The 100,000 Genomes Project is built on their data so we think that participants should be the people most closely involved in assuring that the data is being properly protected and that access to it is appropriate. We also want to find the best way to recognise participant's involvement, to communicate with them and to use their experience and expertise to continually improve the project and the experience of future participants as well as advising us on legacy.

We wish to establish a participant panel which we see as having several important roles. The outline given here is not prescriptive nor finalised. We would expect it to be further refined by the participant panel itself once it is established.

Participant interests

- To ensure that participant's interests remain centre stage and that any issues are brought quickly to Genomic England's notice and addressed promptly
- To ensure appropriate patient representation and involvement in GeCIP domains
- To help continually improve the experience of future participants

Data access

- To provide advice and oversight on data governance through membership of the Access Review Committee
- To make recommendations to the Board in respect of exceptional requests for data access
- To assure, through its oversight, that applications granted and refused for data use are put in the public domain through the Genomics England website.

Communication

- To ensure that research arising from use of the data is freely accessible to all with summaries in appropriate clear and simple language
- Working with PPI groups in the GMCs, to review existing patient information and, where necessary, to commission additional guidance or literature
- To monitor, evaluate and advise on website content and accessibility
- To ensure regular communications with participants who wish this and to review and develop effective methods for recognising participant involvement

Engagement

- To help prioritise those issues which should be the subject of public debate
- To be involved in decisions as to how best to advance this

We envisage a wider group of perhaps as many as 40 participants in order that a core group of some 10 – 12 members could be assembled. They would have the ability to co-opt additional expertise where necessary and call members of Genomic England's staff to report to them. We would expect some members to be co-opted to other key oversight bodies within Genomics England such as the Access Review Committee. We envisage that this panel will report directly to the Board, through its Chair with the support of Vivienne Parry, Head of Engagement.

We will advertise nationally for potential members through NHS Genomic Medicine Centres and there will be a formal application, interview and appointment process undertaken with the involvement and oversight of Genomics England's present patient representatives. We will be looking for thoughtful individuals who can put themselves in other's shoes and see problems from the perspective of other participants who may not be like them, even though they have a condition in common.

Participants will be paid a daily rate and travel expenses in line with Involve guidelines (<http://www.invo.org.uk/wp-content/uploads/2014/11/10002-INVOLVE-Budgeting-Tool-Publication-WEB.pdf>).

We would expect to appoint at least equal numbers from the rare disease and cancer side of the project. A chair will be appointed from amongst those members expressing an interest in this post.

Training will be provided for members of this panel.

2. Engagement with our partners to ensure a legacy

In addition to non-participant members of the public, Genomics England has numerous partners. For some, specific work programmes are appropriate (for instance with regulators) but for others developing a relationship and working together to align messages about genomics and its uses is the principal aim of engagement.

NHS Genomic Medicine Centres

There are three major strands of work with Genomic Medicine Centres (GMCs). All GMCs have engagement activities in place or planned as well as an extensive PPI programme. We plan to bring together the principals involved in engagement and involvement from each Centre on a regular basis and would also hope to include the participant panel, at least three times a year, with a different GMC hosting on every

occasion, to share best practice, exchange information, ideas and potential opportunities as well as keeping in regular contact about the bigger picture.

An additional strand of work with NHS GMCs relates to review of participant information and other materials at the 10,000 sequence mark. We would anticipate this beginning in June 2015 and involving GMC leads in this area plus members of our ethics teams and participant panel. We will also be working with them to develop strategies for engaging with hard to reach groups, to develop, where appropriate, central repositories such as translations or educational material.

The final strand involves regular engagement with the press and communications leads (usually of the host NHS Trust of each GMC), bringing them together at least once a year, perhaps in conjunction with an engagement leads meeting, together with DH, NHSE and HEE communication colleagues. We will develop the above three strands collaboratively with the Genomic Medicine Centres.

Clinicians and other NHS staff

NHSE will be largely responsible for managing relationships and engagement here but we will work with Health Education England to provide materials to help explain genomics in a simple way, such as slidesets and short video clips. We will also provide speakers for clinical meetings where possible.

Researchers

Engagement with researchers is through the Genomics England science workstream but we envisage organising and supporting one conference a year at which outcomes from the project are presented. See also [Genomics Summit](#).

Research funders and other bodies with interests in genomics

We have common interests in promoting the understanding of genomics and there is already excellent work undertaken by major bodies including the Wellcome Trust, Medical Research Council, Royal Society, Royal Institution, the Wellcome Trust Sanger Institute as well as a host of smaller organisations such as Nowgen, Progress Educational Trust, PHG.

Medical research charities and other patient support groups

There is a very important role for patient groups within specific domains of GeCIP. When these are finalised, we would expect all disease specific domains to have involvement of a relevant patient group. There will be representation of patients on the GeCIP board, both via the participant panel and from amongst those on disease

specific domains. We anticipate setting up a virtual forum for patient representatives involved in GeCIP domains.

We will be convening a workshop of relevant small patient groups with research portfolios such as Unique, to tease out what research questions they would most like to address through access to the data.

More widely, engagement with the numerous interested patient groups will be principally through the Association of Medical Research Charities, through Contact a Family and the Genetic Alliance UK. We will develop this work with our Participant Panel.

Policy makers

Genomics raises a number of policy issues in privacy, data security, insurance and bioethics both now and for the future. There are strong views about these matters which are of critical importance in public acceptance and confidence. Genomics England intends to work as a catalyst, collaborating with UCL's School of Public Policy to bring together academics from a wide range of disciplines including social scientists, computer scientists and bioethicists, with policy makers facilitated by UCLSP to work through and produce a range of independent evidence and position papers in areas of interest but particularly with a view to future security and global governance.

Regulators

Engagement with the Health Research Authority is through our Ethics leads.

Engagement with the Medicines and Healthcare Regulatory Authority (MHRA) and its subsidiary, the National Institute of Biological Medicines and Control (NIBSC) is extremely important. Genomics is a new area of medicine and will require a different regulatory landscape. It is essential that we begin to work with the MHRA and with companies to develop this. If this does not occur, patients may face unnecessary delays in obtaining the new medicines and diagnostics flowing from the project. There also needs to be a 'library' of validated genetic variants coming from the Project, mostly likely curated by NIBSC, against which future diagnostics can be assessed prior to market approval. We are working with colleagues at DH to engage with the MHRA and NIBSC to set up a genomics special interest group within the authority to consider how the regulatory landscape for this new area of medicine should be populated.

Industry

Genomics England has a wide range of potential partners in industry including pharmaceutical, biotech and diagnostic companies but also those working in companies developing better and more effective ways to analyse very large amounts of data. The Enterprise division of Genomics England has developed the GENE Consortium, a year long involvement of large and small companies and their staff, as a means of understanding what companies need to ensure that use of the data can develop into new understanding, medicines and diagnostics. We also need to be sure that we are reaching innovative small and medium enterprises as well as new start ups. More extensive engagement with this sector is planned through Medilinks and partnerships with Innovate UK and BIS.

3. Initiating debate and understanding

Contributing to a raised awareness of genomics

Public awareness of genes and genetics is high (more than 90%¹), despite the fact that DNA was not part of the GCSE curriculum until the 1980s. Genomics on the other hand only began to be included in the GCSE curriculum in 2015 so it is hardly surprising that, according to the latest biannual Wellcome Monitor survey¹, only 12% of the British population understand the term 'genomics'. People do not necessarily need to know about the genome but without some wider awareness and knowledge, it will be difficult to have the informed public debates that must take place over the next few years.

We are already working with HEE to raise awareness of genomics within the wider NHS workforce. We will continue to work with HEE and NHSE to this end.

As far as the wider public are concerned, despite the ubiquity of social media, most people still get their science knowledge from the mainstream media, particularly broadcast³. In order to ensure accurate reporting, we will work directly with journalists, with the Science Media Centre and with the press teams of our partners with an interest in genomics to increase the media's understanding of the basics of genomics and the 100,000 Genomes Project.

There are a number of organisations with existing public engagement programmes in genomics, many of which are excellent, for instance the Wellcome Trust Sanger Institute. We do not wish to replicate what is already being done, nor do we have the budget or reach to mount a large programme ourselves.

³ Ipsos Mori for Department of Business Innovation & Skills - Public Attitudes to Science Report (2014) <https://www.ipsos-mori.com/Assets/Docs/Polls/pas-2014-main-report.pdf>

We will instead adopt the role of catalyst, bringing together those already involved and together identify gaps and ensure that all our programmes are aligned in order that they can have the greatest impact. Organisations which will be involved include funders such as MRC and the Wellcome Trust, larger research charities (CRUK, BHF), museums (Science Museum, MOSI, Life Centres, Science Festivals (Edinburgh, Cambridge, Cheltenham), media partners such as the BBC, smaller specialist organisations (NowGen, PHG, Progress Educational Trust) along with the NHS and government (DH and BIS).

We are already aware of one particular gap; the lack of empirical evidence as to how best to communicate genomics and the issues around it. For example, what metaphors do publics best relate to? We will be partnering with the Wellcome Trust and social scientists from the Wellcome Sanger Institute in a short, joint project 'Socialising the Genome' to evidence the basis of understanding. We will then be using the type of online social media panels normally used to evaluate fast moving consumer goods to rapidly evaluate the best way to refine communications on genomics, based on sound evidence from the previous social science work. We will share the outcomes of this project with all our partners.

Catalysing debates

We will work with partners and the GMCs to ensure that there are opportunities for the public to engage in debate around the future of genomics. Many partners will have a role in encouraging these societal conversations to happen. We will be proactive in taking part in debate and discussions in existing forums as well as hosting our own events where we can encourage wider public dialogue on a range of ethical and scientific issues related to genomic medicine.

Ensuring a lasting legacy – Genomics Summit

Genomics has worldwide reach. For instance, on the research side, comparison of specific rare disease sets in the US and elsewhere in Europe may add immeasurably to knowledge if sufficient cases can be involved. New medicines and diagnostics will potentially have world markets. And many health systems are watching the UK, as the first health system in the world to adopt genomics into mainstream medicine, with great interest.

We will work with the Department of Health and the Genomics Enterprises division of Genomics England to firstly commission a report which will involve thought leaders from many different areas, research, clinical practice, health providers, governments with the aim of finding out how they envisage the genomics future of 2025. The report would include analyses of key challenges over the next decade.

We will launch this report at a global summit in 2015/16, organised with the United Kingdom government, with a small audience of world leading scientists, health ministers, industry CEOs and other global players which will highlight the UK's leading role and outline its experience so far. Using the analyses in the report, we envisage a Davos style event in which the route by which we get from our present experience to a global future is discussed. Challenges can be highlighted and where necessary, steps needed to overcome them, some of which may involve global collaboration, can be developed for action in the future.

We envisage allied 'satellite sessions' involving public debate, organised through the British Science Association and on the science, organised through the Royal Society.

About this document

First draft approved by the Genomics England Board 23/02/15

This document should not be considered final. It will continue to evolve as we explore options with our partners. We welcome further comment and suggestions on how to improve our plans.