

BOARD PAPER - NHS ENGLAND**Title:**

Genomics: NHS Preparedness for Delivery of the 100,000 Genome Project

Lead Directors:

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Purpose of paper:

To inform the Board of the work underway to deliver the 100,000 Genome Project, and to highlight the areas of responsibility that fall to NHS England. The paper also seeks agreement from the Board to the process and timetable for selecting initial '*NHS Genomic Medicine Centres*' and, as part of this, approval to publish a Prospectus setting out NHS England's requirements around sample acquisition and inviting interest from potential providers.

Key issues and recommendations:

The immediate priority for NHS England is to launch a process for selecting *NHS Genomic Medicine Centres*. NHS England is required to have sufficient contracts in place with participating providers to enable sample acquisition to start from 1 January 2015. We therefore intend to embark on a process of '*NHS Genomic Medicine Centres*' selection, where successful providers will enter into a contract with NHS England for the supply of services to support the 100,000 Genome Project.

In order to ensure a high degree of confidence in the ability of the selected sites to supply the sufficient quantity and quality of samples, it is crucial that we develop a clear and robust specification of our requirements to underpin that process and a rigorous and transparent process for selecting participating clinical sites for the duration of the Project.

Actions required by the Board:

The Board is asked to:

- note NHS England's role in delivery of the 100,000 Genome Project and the supporting governance arrangements that have been put in place;
- agree the timetable and process for selecting '*NHS Genomic Medicine Centres*';
- approve the Prospectus document for publication; and
- agree to receive a paper at a future meeting on plans for realising a new era of personalised, genomic medicine, post completion of the 100,000 Genomes Project.

Genomics: NHS Preparedness for Delivery of the 100,000 Genome Project

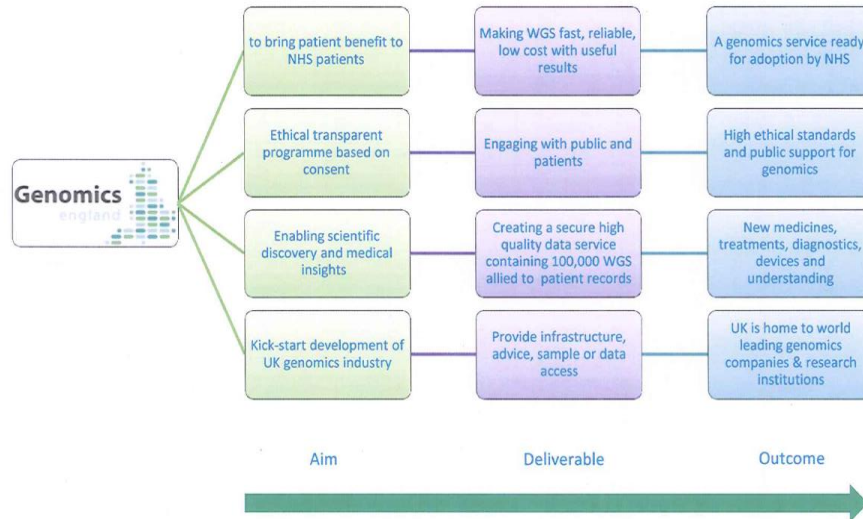
Issue

1. On 10 December 2012, the Prime Minister set out an ambitious vision for genomics in the UK, and committed to sequencing 100,000 whole human genomes by the end of 2017, focussing on patients with inherited/rare diseases and cancer.
2. Successful delivery of the project stands to position the NHS as global leaders in realising a new era of personalised medicine for the benefit of patients. The project also stands to make a major contribution to economic growth through establishing the UK as the international base for genomics science and industry.
3. To oversee delivery of the project, the Department of Health has established Genomics England- a company wholly owned by the Secretary of State for Health. NHS England is the major delivery partner for the project and is principally responsible for securing a sufficient quantity and quality of samples from consenting patients.
4. This paper asks the Board to:
 - note the potential benefits of the 100,000 Genome Project, NHS England's role in supporting delivery and the governance arrangements we have put in place;
 - agree the process and timetable for selecting 'NHS Genomic Medicine Centres';
 - approve a Prospectus document inviting interest from potential providers; and,
 - agree to receive a paper at a future meeting on plans for realising a new era of personalised, genomic medicine, post completion of the 100,000 Genomes Project.

Benefits of the Programme to Patients and the Economy

5. The potential of genomics is huge, leading to more precise and faster diagnostic tests, the development of new medical devices helping people lead independent lives, faster clinical trials, new drugs and treatments and potentially, in time, new cures. The research opportunities and mainstream use of genomic medicine across the NHS also has a major contribution to make to wealth creation and economic growth in this country.
6. The diagram below helpfully illustrates the purpose of the 100,000 Genome Project and the legacy it is aiming to leave for patients in this country.

Genomics England aims, outcomes and deliverables



7. NHS England's opportunity is to take this legacy and ensure it benefits all patients and all clinicians, not just those involved in the early part of the project.
8. Some patients involved in the 100,000 Genomes Project (which will focus on inherited/rare diseases and cancer) are likely to have immediate clinical benefit, because a better treatment is identified for them or their condition is diagnosed for the first time. For most, the benefit will be in knowing that they will be helping people like them in the future through research on the genome data they generously allow to be studied. But, all will know that because of their involvement, an infrastructure will be developed which, in the future, will enable the NHS to offer genomic services much more widely, to any patient who might benefit.

NHS England's Role and Supporting Governance Arrangements

9. There are a number of specific deliverables NHS England is responsible for:
 - Identification, collection and supply of samples of sufficient quality and quantity to support the ambition of the 100,000 Genome Project
 - Ensuring clinical advocacy and supporting the cohort of clinicians in those disease areas where the 100,000 Genome Project will focus to be at the vanguard of leadership, recognising scientific importance and acting as thought leaders.

- A Data Maturity Assessment to determine from existing clinical data capability where the maximum opportunity lies
 - Modification and improvement of clinical data capability to enable the 100,000 Genome Project and then appropriate modification to support whole genome sequencing being transformational and sustainable beyond the 100,000 Genome Project.
 - Developing an effective clinician and patient feedback mechanism
 - Ensuring the NHS is operationally geared up to use whole genome sequencing routinely
 - Contributing to a comprehensive stakeholder engagement process – clinical, academic, commissioners/providers, industrial and public/patient voice
 - Contributing to a comprehensive media and consumer engagement process that mitigates risk for the 100,000 Genome Programme and instils public trust and investor confidence
10. Accountability for overall project rests with the Department of Health and is overseen by an Assurance Board chaired by the DH Permanent Secretary, Una O'Brien. Tim Kelsey and Professor Sir Bruce Keogh represent NHS England on this assurance board. In addition to this, Professor Sir Malcolm Grant represents NHS England on the Genomics England Board.
11. An internal programme board has been established, with representation across all key directorates, to ensure rigorous governance arrangements are in place for our specific responsibilities and deliverables.
12. Furthermore, to support this programme board, we are in the process of establishing a Genomics Clinical Advisory Group which will be chaired by Professor Sir Bruce Keogh. This group will support NHS England in maximising the clinical benefits of the project, promote clinical advocacy with clinicians and leaders, and provide advice on preparing the NHS for the mainstream introduction of genomic medicine. This group will hold its first meeting in September.

The Board is asked to note the role of NHS England in supporting delivery of the 100,000 Genome Project and the supporting governance arrangements that have been put in place to assure and drive delivery.

NHS Genomic Medicine Centres Selection Process

13. NHS England is required to have sufficient contracts in place with participating providers to enable sample acquisition to start from 1 January 2015. We therefore intend to embark on a process of clinical site selection, where successful providers will enter into a contract with NHS England for the supply of services to support the 100,000 Genome Project.
14. We intend to use the selection and contracting process to provide assurance and a high degree of confidence in the ability of the selected sites to supply the sufficient quantity and quality of samples. A track record of providing similar

services and/or activities that the 100,000 Genome Project requires will be essential.

15. We envisage a phasing of selecting *NHS Genomic Medicine Centres* with a small number identified in the first instance to commence enrolment of cases in January 2015.
16. The latest profile around likely sample numbers will ramp up from January 2015 to the end of 2017. This profile is not yet finalised. It is also worth noting that NHS England is only responsible for supplying sufficient samples to complete 90,000 whole genome sequences – the remaining 10,000 will be delivered via the current pilot phase which Genomics England are leading.
17. Simon Stevens announced earlier in June 2014 NHS England’s timetable for identifying participating providers:

Table 2- Competition Timetable

Activity	Date
Publish Prospectus	3 / 4 July 2014
Potential Provider Days	21 & 22 July 2014
ITT Launch	w/c 21 July
Application submission deadline	5 pm, 29 August 2014
Site Visits (ratification of mobilisation for 1 January 2015)	September 2014
Announcement of Likely First Wave Sites	w/c 6 October 2014
First Wave Site Contract Negotiations	October – December 2014

18. It may be that at the time NHS England announces the successful applicants of the first round of selection, a long list of NHS Trusts who have been selected as potential NHS Genomic Medicine Centres who will begin enrolment during the lifetime of the Project, between 2015 and 2017 (these may be pending further ratification of their application)

The Board is asked to agree the NHS Genomic Medicine Centres selection process and timetable.

Prospectus

19. We have developed a Prospectus setting out our needs and the requirements we expect providers to be meet in order to apply to support the 100,000 Genome Project. The Prospectus has been drafted in partnership with Genomics England and through a working group comprising of NHS England Commissioning Operations, Finance, Medical and Patients and Information directorate.
20. Recognising that a programme of this scale and complexity has never been attempted before in the NHS the Prospectus has also been informed by those providers currently participating in the pilot programmes run by Genomics

England Limited as the lessons they have learned are valuable in ensuring the success of the main programme.

21. Given the operational commitment required of interested providers, the Prospectus has also been informed by the experiences of some of our leading university teaching hospitals.
22. The Prospectus sets out the likely requirements any provider will need to demonstrate to deliver the first phase of the Programme from 1 January 2015. Successful providers will enter into a contract with NHS England to regulate the delivery of the following three elements required for successful delivery of the 100,000 Genome Project
 - a. Participation of patients and relatives
 - b. Achieve acquisition of adequate number of samples
 - c. Capture clinical phenotype information
23. As part of the selection process, interested providers will be expected to demonstrate working in partnership with their Academic partners, especially with the NIHR supported Biomedical Research Centres and Units, NIHR/Wellcome Trust funded Clinical Research Facilities and have processes in place to process samples to the required standards.
24. Successful providers selected as NHS Genomic Medicine Centres will need to demonstrate the robustness of local informational technology systems and the ability to integrate and upload patients' phenotypic and genomic data. NHS England and Department of Health have agreed a capital investment fund (approximately £10m in total), to be made available to a number of selected providers to further enhance the development of such information systems. The informatics system will need to capture clinical management data and patient-specific clinical, laboratory, imaging, etc. data compliant with NHS national data standards. These data need to be combined with the variant results obtained by Whole Genome Sequencing and presented to Clinical Care teams in a clinically relevant manner

The Board is asked to approve the publication of the Prospectus inviting providers to bid to become 'NHS Genomic Medicine Centres' (final draft to be tabled at the meeting).

25. There are however a number of issues that need to be resolved in parallel to the commencement of the NHS Genomic Medicine Centres' selection. These include issues of intellectual property, agreement of the evidence supporting selection of the initial disease areas the Programme will focus on, agreement of the optimal mechanisms in the system for ensuring high quality DNA extraction and the receipt of the approved Genomics England consent and ethics documentation.

26. We are working with Genomics England and the Department of Health to reach consensus on each of these issues. Of paramount importance is the issue of informed patient consent. The 100,000 Genome Project is based on the altruistic donation of data on the basis of informed consent. Along-side this we will need to ensure that we have a fully trained and developed clinical workforce able to apply genomic medicine within the NHS and raise awareness and understanding of the advantages genomic medicine can bring to patients. We are working closely with Health Education England to build the workforce capability and capacity.

Legacy beyond the 100,000 Genome Project

27. As set out in the diagram at paragraph 6, this project is about leaving a lasting legacy for patients. 100, 0000 whole genome sequences is just the start of realising a whole new era of personalised medicine supported by genomics. Ensuring that NHS England prepares the NHS for this paradigm shift over the coming years will be critical. The Board is therefore asked to agree to receive a paper at a future meeting setting out our approach to securing the benefits of the project in the medium to longer terms

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