

BOARD PAPER - NHS ENGLAND

Title: Genomics: Update on NHS Preparedness for Delivery of the 100,000 Genomes Project

Clearance:

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Purpose of Paper:

To update the Board on the work underway to deliver the 100,000 Genomes Project, in particular:

- The designation of the first wave of NHS Genomic Medicine Centres (NHS GMCs);
- Operational readiness and 'Go live'; and
- Next steps.

The Board is invited to:

- Note the considerable progress made by the NHS and NHS England in delivering a complex programme within ambitious timescales; and
- Agree to receive a paper at a future meeting on plans for realising a new era of personalised, genomic medicine, after completion of the 100,000 Genomes Project.

Genomics: Update on NHS Preparedness for Delivery of the 100,000 Genomes Project

Introduction

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, focusing on patients with inherited and rare diseases and certain cancers.
2. NHS Genomics Medicine Centres (NHS GMCs), which will collect the 90,000 genomes required for the main programme, started to become operational from March 2015. NHS England is on course to complete its commitment to putting in place appropriate arrangements to enable the acquisition of a maximum of 90,000 samples and accompanying clinical data of sufficient quality to enable whole genome sequencing under the contractual arrangements between Genomics England and Illumina (the company Genomics England has procured to deliver the sequencing and support the analysis of the genomes).
3. Successful delivery of the Project stands to position the NHS as a global leader 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.
4. This paper updates the Board on the designation of the NHS GMCs, their operational readiness and 'Go live' position. It also sets out next steps for the Project and beyond.

NHS Genomic Medicine Centres - Designation

5. Since summer 2014, NHS England has led a robust procurement exercise and contracting process to select and ensure the operational readiness of the first wave of NHS GMCs.
6. Stage One of the Invitation to Tender (ITT) ran over the summer to assess potential applicants for pre-qualification for Stage Two. At Stage Two, applicants were required to demonstrate how they would meet the service specification and the contract between the NHS GMCs and NHS England, as approved by the NHS England Genomics Programme Board. Applicants were provided with the opportunity to request further clarification and discuss specific issues relating to the documentation.
7. Applicants were also invited to attend Provider Information Days (since July 2014). These events ensured all potential providers received consistent, accurate information to support them through the procurement and contracting process. They also provided an opportunity to share experiences, understand challenges, and learn from those involved in Genomics England pilot sites. (Since the designation of the NHS GMCs these have become NHS GMC Network Meetings focussing, for example, on the ITT2, the contract, patient consent and eligibility, informatics and data, and governance and partnership working).
8. An Evaluation Team was established to assess all the applications at both Stage One and Stage Two of the process. This was a cross-delivery partner team, chaired by the Chief Scientific Officer, with relevant experience and expertise drawn from across NHS England, Genomics England and the Department of Health (DH).
9. As part of the assessment process, a cross-section of the Evaluation Team (with expert representation from NHS England, Genomics England and DH) undertook a site visit to each of the Stage Two applicants to confirm and clarify the content of the applications submitted. These were very well attended, averaging 25 members of NHS staff, in addition to attendance

from patients in some cases. These site visits have evidenced considerable innovation in the NHS in relation to:

- patient and public co-production in designing the genomics service;
- the creation of cross-specialism genomics multi-disciplinary teams;
- workforce training, particularly in relation to consent requirements;
- collaboration across multiple trusts and with academic partners; and
- linkage with Academic Health Science Network priority areas.

10. The Genomics Procurement Board formally ratified and approved the Evaluation Team's recommendations in full on 8 December 2014. A press conference attended by the Minister for Life Sciences and representatives from Genomics England and NHS England was held on 22 December 2014 to publicly announce the 11 designated first wave NHS GMCs (**Annex A**). More than 25 journalists attended the briefing session which resulted in positive press coverage across the national press.

Operational Readiness

11. NHS England has further demonstrated its commitment to the successful implementation of the 100,000 Genomes Project through the establishment of an Implementation Unit comprising the following expertise:

- Programme management coordination with the national partners involved in the 100,000 Genomes Project;
- Programme Delivery Unit working with each of the NHS GMCs;
- Contracts and finance management to monitor performance of the NHS GMCs;
- Communications, media, Network of Best Practice, and Patient Participation;
- Laboratory improvement;
- Informatics and data quality; and
- NHS service improvement and pathway transformation.

12. Additionally, the Patients and Information Directorate will recruit national expertise to provide strategic policy support in informatics architecture, data security and annotation capability for the Project, and a national strategic media and external communications lead has been identified.

13. Final draft contract and service specification documentation was issued to all NHS GMCs week commencing 26 January 2015. During February, conversations were held with individual NHS GMCs to agree sample trajectories and other operational matters pertaining to their contractual obligations, prior to contract completion.

14. Sample trajectories by both cancer and rare disease were allocated to each individual NHS GMC across the term of the contract. A reserve of 10,000 samples was held back for allocation to the second wave of NHS GMCs and to expand the remit of the North East and North Cumbria GMC (currently designated for rare disease only) to include cancer sample collection. From the submissions at the second stage of the first wave procurement, it has been identified that there is additional activity potentially available (at least 30,000 more samples overall), should any short fall become apparent. This has been carefully matched to the sample supply with the signed Illumina contract requirements, such that there should be a slight oversupply.

15. A team, again led by the Chief Scientific Officer with representation from Genomics England, has visited each NHS GMC to discuss the bespoke elements of their contracts and assess

operational readiness to commence rare disease participant recruitment to 'Go live' from March 2015. Three groups of NHS GMCs were identified:

- those that were operationally ready;
- those not operationally ready; and
- those that were not able to sign contracts due to reconsideration of their business model.

16. Final contracts were issued to all NHS GMCs on 25 February 2015. Contract signature for those NHS GMCs that were operationally ready to 'Go live' commenced during March. Where NHS GMCs were not operationally ready, the Implementation Unit provided significant support to enable commencement.

17. The SRO for 100,000 Genomes Project will update the Board on the most recent position in relation to contract signature and 'Go live' at the Board meeting.

18. The 'Go live' date to commence cancer sample supply has been delayed as Genomics England continues to conduct pilot studies to determine the optimal processing arrangements to provide successful whole genome sequencing. Discussions have been held as to how the 10 NHS GMCs providing the cancer samples will be involved in a pilot phase before a Genomics England/NHS England agreed 'Go live' date. This will ensure that the samples the NHS GMCs provide in any enhanced sample processing arrangement will yield whole genome sequencing of the right quality before commencing full-scale recruitment to the main programme.

Operational Readiness – Dependencies

19. Contract signing and 'Go live' was dependent on the Research Ethics Committee (REC) providing its approval of the Genomics England Protocol. In light of the recent Health Research Authority (HRA) decision to pilot a new category and submission mechanism for the REC review of those projects wishing to establish large datasets associated with Biorepositories, Genomics England pursued REC approval for the 100,000 Genomes Project under this category.

20. REC approval was received on 19 February 2015. Following this, NHS GMCs required a short period (2-3 weeks) to allow for printing and booking clinics.

21. Operational readiness was also dependent upon Genomics England confirming:

- finalised data set requirements;
- the data interface and tools they will provide NHS GMCs;
- the securing of N3 connectivity;
- the data quality assurance processes that they will put in place; and
- each NHS GMC agreeing to the final terms of the Genomics England Material Transfer Agreement and Data Sharing Agreement.

22. A programme of work was put in place to address NHS GMC concerns in relation to IT functionality and clinical governance, in particular, to provide confidence, technical assurance and functionality between Genomics England and the NHS systems. The NHS GMC Improvement Day on 5 March 2015 provided clarity and resolution on these issues.

Next Steps

23. The designation process for the second wave of NHS GMCs will start from April 2015.
24. Focus is now being given to how to best use the catalyst the Project provides to engage with the NHS on the emerging science and clinical utility of genomics, and the potential improvements in clinical care it offers in relation to the prediction and prevention of disease, precise diagnosis and personalised treatment.

Recommendation

25. The Board is invited to:
 - note the considerable progress made by the NHS and NHS England in delivering a complex programme within ambitious timescales;
 - agree to receive a paper at a future meeting on plans for realising a new era of personalised, genomic medicine, after completion of the 100,000 Genomes Project.

Tim Kelsey
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National Medical Director

March 2015

Designation of first wave NHS Genomic Medicine Centres

The Genomics Procurement Board formally approved the designation of the first wave of NHS Genomics Medicine Centres (NHS GMCs) on 8 December 2014 as follows:

- East of England NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- South London NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- North West Coast NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- Greater Manchester NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- University College London Partners NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- North East and North Cumbria NHS GMC - **designate** this as an NHS GMC for rare disease only;
- Oxford NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- South West Peninsula NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- Wessex NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- Imperial College Health Partners NHS GMC - **designate** this as an NHS GMC for both cancer and rare disease;
- West Midlands NHS GMC – **designate** as an NHS GMC for both cancer and rare disease.