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BOARD PAPER – NHS ENGLAND

Title: Legacy of the 100,000 Genomes Project and integration into the Personalised Medicine strategy
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Purpose of paper: To set out the key issues that will require Board level consideration pertaining to the legacy of the 100,000 Genomes Project and the future NHS England strategy for Personalised Medicine
Actions required by the Board: The Board are asked to note the contents of this paper and to nominate a number of Non Executive Directors to work with us and bring detailed recommendations back to a future NHS England Board meeting.

Legacy of the 100,000 Genomes Project and the Personalised Medicine Strategy

Introduction

1. This paper sets out the key strategic issues that the Board will need to consider and agree a position in the coming months in relation to planning for the legacy of the 100,000 Genomes Project. This will inform the evolving NHS England strategy for Personalised Medicine.

Recommendations

2. That the Board notes and agrees the way forward on plans to reach decisions required in relation to the legacy of the 100,000 Genomes Project as part of the future NHS England strategy for Personalised Medicine, as set out below.

Background

3. The NHS contribution to the 100,000 Genomes Project is being delivered by NHS Genomic Medicine Centres who are working in networks and partnerships and, developing the appropriate infrastructure including in informatics and data capture and sample processing to deliver at scale and to defined high quality standards across defined geographical populations.

4. The 100,000 Genomes Project is due to complete at the end of 2017The recent Department of Health (DH) Spending Round (SR) settlement, set out the intention to continue to fund Genomics England from 2018 (from the DH NIHR budget), with a focus on informatics and analytics and the continuation and further development of a national research and clinical genomics database. NHS England will assume responsibility for procuring whole genome sequencing and other multiomic investigations for diagnostic and clinical care purposes.

5. The pending NHS England Genetic Laboratory re-procurement will create a national genomic laboratory infrastructure, with a requirement to share data for both the commissioning system, and the enhancement of clinical interpretation and scientific endeavour, with a clear signal that NHS England are considering a WGS provision for NHS clinical care purposes.

Key issues that require a strategic position

6. The following text provides context for each of the key strategic business decisions required from the NHS England Board:

- **Informatics and Data**: The 100,000 Genomes Project has required the creation of a database to hold both clinical phenotypic and whole genome sequence information to enable interpretation for both clinical care and research purposes. This database is curated and has associated analytical platforms. As noted above the post 2017 plan as part of the SR settlement is to continue this database and expand it to become an national genomic database for all genomic data. The NHS currently holds genomic information within hospital systems as part of genetic and molecular pathology services. Genomic information will critically inform personalised treatment and intervention approaches and it would be our ambition to build a central repository for the data,

storage, curation, analytical and data linkage platforms required for the development of new models of diagnosis and treatment. In line with the National Information Board Strategy this will need to include integrated diagnostics data inclusive of clinical decision support systems and digital health solutions.

The NHS England Board will need to consider its position on :

a) **The inclusion of all NHS genomic data in the Genomics England database with the associated analytical capabilities post 2017**
b) **The capture of other diagnostic and phenotypic data and the implications for personalised medicine and its implementation in the NHS**
c) **The integration of information from digital health applications as part of the overall informatics solution and personalised medicine strategy**

- **Whole Genome Sequencing (WGS) provision**: The 100,000 Genome Project is providing low cost and high quality Whole Genome Sequencing and its annotation for eligible cases of cancer and rare diseases. There is both a current unmet clinical need and a post 2017 need to procure WGS provision and its annotation together with other elements of the functional genomics pathway to understand the expression of a genetic mutation within an individual as part of a comprehensive genomic diagnostic service for the NHS and to guide personalised treatments and interventions. Additionally emerging evidence from the 100,000 Genomes Project as well as the scientific literature is pointing towards the need toconsider within the time frame of the project other genomic advances that may better serve patients such as the introduction of Multi Gene Panel Testing in Cancer. .

  The NHS England Board will need to decide on the revenue and capital investment and commissioning strategy for Whole Genome Sequencing, multi-omic investigations and the introduction of broader Gene Panel Testing for acquired disease in the NHS.

- **Microbial Genomics :** At the direction of the Department for Health, PHE are investing significantly in microbial genomics as part of the infectious disease component of the 100,000 Genomes Project. As a result genomic technologies and their application in infectious disease are being integrated into a new infection service for Public Health England. These initiatives have implications for NHS microbiology services particularly in the adoption of genomic technologies and all of the benefits including in antimicrobial resistance detection and in cost saving potential. It will be important that NHS England understands the financial, clinical and service configuration impact of the PHE directed work.

  The NHS England Board will need to consider how best to introduce a new 'state of the art' microbiology genomics service for the NHS including plans to working with the leadership of PHE to develop a joint action plan and impact assessment of microbial genomics, infectious disease prevention and AMR work nationally and locally in line with the 5YFV.

- **NHS Genomic Medicine Centres :** The clinical transformation of the NHS is integral to the delivery of the 100,000 Genomes Project and central to the work of the NHS Genomic Medicine Centres and the partnerships and networks they have established across their geographies. Given the pace of scientific and clinical advances in the field of genomics and their application in clinical pathways retaining the infrastructure and expertise will be critical to the implementation of the NHS England personalised medicine strategy. , This is pertinent given the multi year and

whole health economy planning that is requested of the system for 2016/17 onwards. Those NHS organisations currently designated as NHS Genomic Medicine Centres are currently considering their financial, operational, capital and estates investment planning for the next five years. The requirement to continue this type of work and at what scale will influence these plans.

The NHS England Board will wish to consider what will happen to NHS Genomic Medicine Centres post 2017 and the opportunity for transformation into broader NHS Personalised Medicine centres

Actions required by the Board

The NHS England Board are asked to note the contents of this paper, to agree to a further discussion at a Board development day and to nominate a number of Non Executive Directors to work with us on these issues . Furthermore given future arrangements will need to be embedded in business as usual consideration will be given to the role that the Specialised Commissioning committee needs to be play.

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