



Meeting:	Brighton and Sussex University Hospitals NHS Trust Board of Directors
Date:	23rd February 2017
Board Sponsor:	Steve Holmberg, Medical Director
Paper Author:	Scott Harfield, Head of R&D
Subject:	The Wessex Genomic Medicine Centre - 100,000 Genome Local Delivery Partner

Executive summary

Genomics England is creating a lasting legacy for patients, the NHS and the UK economy through the sequencing of 100,000 genomes, all with the consent of participants. This is known as the 100,000 Genomes Project. The main goal of the Project is to transform the application of genetics to healthcare in the NHS. The Project is run by Genomics England, a company owned by the Department of Health.

The Kent, Surrey and Sussex (KSS) region is the one remaining geographical location that does not have a Genomic Medicine Centre or close relationship with one. This is largely due to a lack of expertise and infrastructure to establish a service. Brighton & Sussex University Hospitals NHS Trust has been given an opportunity by University Hospitals Southampton to become a strategic delivery partner in 100,000 Genome Project.

Participation in the project would ensure that the Trust has an opportunity to play an active role in the delivery of this potentially game changing area of medicine. By establishing a partnership with a leading centre for genomic medicine we have the added opportunity to learn from experts and potentially establish a stand-alone centre in Brighton in the future.

Action required by the Board of Directors

Consider the financial implications of this work with a view to supporting the development of a strategic delivery partnership with the Wessex Genomics Medicine Centre.

Links to corporate objectives

This proposal does have potential to meet the Trust corporate objective of delivering excellent outcomes for patients where treatment options may be available. As a result of this initiative longer term participation in genetic medicine or research may become routine so delivering a service at BSUH could empower help attract skilled staff.



Identified risks and risk management actions	<p>The risks of not proceeding are at present unquantifiable in the sense that there would be no direct impact on patients as downstream benefits such as improved treatment options are still in their infancy. However, genomic medicine is gathering at a pace and the role it will play in healthcare in the future will be significant. Therefore, participating in the development of this network at an early stage will ensure that the technology is adopted and embedded into practice ready for patients to benefit from in the future. The Trust may not be given another chance to participate in an established network if this opportunity is turned down.</p> <p>To ensure the project delivers the Trust needs to identify a clinical genetic champion to drive it forward. Additionally the right level of financial investment will be needed to get the project off the ground. The estimated annual running costs are £39,500. This is offset in the first two years by a possible income stream of up to £16,000 (£160 for each patient sample sent for processing). A long term commitment to invest in this project will need to be made to ensure there is no risk of the project folding in later years.</p>
Resource implications	<p>The resource implications associated with this project predominantly relate to the amount staff time required to support the activity. Dedicated time will need to be found for Consultant Oncologists, Histopathologists, Nurses, HCAs and laboratory technicians</p> <p>Over time this could be factored into existing job plans, if the service becomes mainstream. In the initial stages specific time will need to be set aside to support the collection and processing of 104 samples per year.</p>
Report history	Not applicable
Appendices	None

Report to the Board of Directors, 23rd February 2016
The Wessex Genomic Medicine Centre - 100,000 Genome Local Delivery Partner

1. Introduction/purpose

The purpose of this paper is to inform the Board of the role of the NHS Genomic Medicine Centre in supporting the delivery of the 100,000 Genome Project, and seek support to become a collaborator in this project with the Wessex genomic Medicine Centre.

Rapid genome sequencing and analysis is already transforming our approach to medicine and providing improved outcomes for patients. This technology will be key to transforming future patient care through personalised medicine. In December 2012, the Prime Minister set out an ambitious vision for genomics in the UK, and committed to sequencing 100,000 whole human genomes, focussing on patients with inherited/rare diseases and cancer.

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.

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.

It was the intention of NHS England to ensure that all of the NHS was represented by a Genomic Medicine Centre. The Kent, Surrey and Sussex (KSS) region is the one remaining geographical location that does not have a Genomic Medicine Centre or close relationship with one. An invitation to apply for Genomic Medicine Centre status was passed to the Trust, however, the organisation lacked the expertise and equipment to establish and lead a centre. There were no other KSS organisations better placed to take the initiative forward.

The Wessex Genomic Medicine Centre (WGMC) is led by University Hospitals Southampton (UHS). It is one of 13 centres nationally commissioned to collect, decode and analyse genomes from people with cancer and rare diseases. Recruitment of patients to this project has been progressing well. UHS are now in a position to extend patient recruitment out from Southampton, and are working with several other Trusts regionally. BSUH has been invited to join the 100,000 genomes project by enrolling as a Local Delivery Partner with WGMC, with some commitment of staff time towards recruiting and consenting patients and collecting samples for DNA analysis.

2. Role of Delivery Partner

The Trust has been invited to be a 'Delivery Partner' to the WGMC. The role of the delivery partner differs from that of the host in that there are not requirements to have a full genetic laboratory service to undertake sequencing.

Our main role as a delivery partner would be to facilitate sample collection from potential donors and provide feedback on clinically relevant results to patients. We have examined the feasibility of becoming a delivery partner to WGMC for the rare disease collection as well as cancer. Following an audit of our activity and assessment of the current pathway for patients with the nominated rare condition it was decided that we would have insufficient numbers to contribute to the rare diseases aspect of the project. .

The Trust would be well placed to take on the cancer component of the project although this is a little more complex as it involves the collection of fresh tumour tissue from participants, in addition to blood samples. As a delivery partner the expectation is that two cancer patients will be recruited per week. We believe this is well within our capability, initially few could focus on the recruitment of gynaecological cases due to pragmatic reasons i.e. surgery lists, histopathology capacity and expertise.

From a practical perspective, potential cancer participants will need to be identified within standard NHS clinics or at medical decision making meetings. Patients would need to be sent information and consented at the pre-operative clinic appointments, where a genomics project blood sample will be taken. Tissue for the project will be collected on the day of surgery. The consent process is very involved and in some cases could take up to two hours to go through the detailed information sheet and questions that may arise. This would need to be undertaken by a dedicated nurse. The processing and preparation of the tissue will need to be done to a specific protocol. It is estimated that this will take one hour of a Consultant Histopathologist time and one hour of a Band 6 Histopathology Technician, per sample.

3. IT Requirements

The ultimate aim of this project is to set up a service that provides results in short time over an integrated IT platform. Therefore, information technology connectivity between partners is critical the successful delivery of this project. We are dependent on the WGMC to set out the exact IT requirements of the project. In broad terms the data extracted through the sequencing process needs to be transferred via IT systems (not email) back to the local partner site so that it can be accessed by the treating physician who can discuss the implications and possible treatment options with the patients.



A protocol that enables database information to be transferred between centres will need to be designed and BSUH will be given a laptop to which we need to apply a Trust build and configuration with smartcards. This is something that is used very lightly by BSUH users, but achievable. BSUH will also need to provide an ODBC connection to the Somerset Cancer Register.

Exact requirements are not yet confirmed, as no other Delivery Partners for the cancer aspect of the project are yet live. Bournemouth NHS Trust is due to go live within the next 3 months; following this the Wessex team will be able to provide better assessment of the IT requirements and cost.

4. Benefits of participating in this project

The overarching aim of 100,000 genome project is to position the UK and NHS as the first country to introduce genetic technology in its mainstream health system, ultimately leading to better tests, better drugs and above all better, more personalised care.

At present the delivery of this project is centred on 13 core NHS centres with expertise in genetic testing and medical application of the results. The lack of a genetic medicine centre in the South East of England could see Brighton & Sussex University Hospitals, and more importantly the patients it serves, being left behind as the rest of the NHS adopts this technology.

The opportunity to become a local delivery partner is particularly attractive as it offers the Trust expert mentorship to support the development of a local genetics service, which could be formally rolled out into practice once the technology becomes main stream.

5. Benefits to patients

The 100,000 Genomes Project offers no concrete benefits to patients in terms of their personal healthcare as the technology is still in its infancy. However, participation in the programme does provide wider societal benefits through a greater understanding of disease, its prevention and treatment.

After a patient's genome is sequenced, the results will be sent to the clinical team who will discuss them with the patient. The results may provide information that helps guide treatment, but alternatively it is also possible that there will be no information to report. Results could also provide information about changes to patient's cells which may lead to further actions to help reduce the chances of developing other cancers in the future.

6. Funding for Delivery Partner Work

Genomics England and WGMC cannot reimburse NHS Trusts for the work involved to support this project. Therefore the long term costs need to be met by the Trust. However, there is time limited funding from Wessex Academic Health Sciences Network to support WGMC delivery partners in the form of £160 per patient. The maximum available would be £16,000 per annum for the first two years assuming the Trust is able to meet its recruitment target of two patients per week. The rationale for this funding was to provide support for a nurse to manage the consent process.

7. Resource Requirements & Financial Implications

In order to deliver this project a number of staff will need to be involved in the process. The table below sets out the key players who will be required to support the patient pathway. Critical to the project's success is the consent process; it is recommended that this is carried out by a specialist nurse with a sound understanding of the project and its risks and benefits. The suggestion from active sights is that this process can take up to two hours per patient depending on the number of questions they may have around the procedure and implications of the findings.

A Consultant Oncologist will need to be identified to lead and champion the project this could take up to 2 hours per week. Clinics to feedback results to patients may initially take longer as the results are explained and new treatment options may be considered.

Additional Consultant Histopathologist and technician time will also need to be identified to manage the on-site preparation of samples prior to shipment to WGMC.

Post	Role	Hours per week	Approximate Cost over 1 year period
Consultant <u>Histopathologist</u>	Point of contact for WGMC Preparation of 2 samples a week as per project protocol	3	£8,000
Histopathology Technician	Prep of sample/ support consultant Histopathologist	2	£2,000
Consultant Oncologist	Overall Clinical Project Lead Point of contact for WGMC	2	£6,000
Nurse Co-ordinator (Band 6)	Oversees all study processes <ul style="list-style-type: none"> • Screens for patients • Approaches and consents patients at a ratio to 1 in 5 agreeing 	19	£20,000
Consumables			£2,000
Sample Courier			£1,500
Annual Cost			£39,500
IT hardware/Software	Not yet known		Possibly up to £10,000
IT support	Not yet known		Possibly up to £1,000
Fixed Costs			£11,000



The annual costs of supporting this work have been estimated at £39,500, set against a potential income stream of £16,000 over the first 2 years.

6. Conclusion/action required by the Board of Directors

The Board are requested to support the development of this initiative to and consider options for funding for the project.

Scott Harfield
Head of Research & Development
February 2017