Terms of Reference

Genomics Test Evaluation Working Groups

1. Introduction and background

The Genomics Programme co-ordinates and oversees genomics across the NHS in England. The NHS Long Term Plan (LTP) sets out a clear commitment for the NHS to invest in genomics to transform patient care and provide access to cutting-edge genomic technology for patient benefit.

The NHS Genomic Medicine Service (GMS) was launched in October 2018 to provide consistent and equitable care for the country's 55 million population. The NHS GMS is working towards full implementation of:

- A national genomic laboratory network;
- A National Genomic Test Directory to direct the national laboratory network;
- National whole genome sequencing provision and supporting informatics infrastructure; and
- An integrated clinical genomic medicine service built from existing clinical genetics services and evolved NHS Genomic Medicine Centre infrastructure.

Fundamental to delivering the genomics LTP commitments and the future vision for the NHS GMS is to embed genomics across care pathways and within clinical specialities.

2. Purpose

As part of the NHS GMS, a National Genomic Test Directory has been developed. The National Genomic Test Directory specifies which genomic tests are commissioned by the NHS in England, the technology by which they are available, and the patients who will be eligible to access a test. NHS England and NHS Improvement has introduced a Genomics Clinical Reference Group (CRG) to oversee an annual evidence-based process to ensure that the National Genomic Test Directory is kept up to date with current testing and technologies.

The Genomics CRG will be supported by three test evaluation working groups for rare and inherited disease, cancer and pharmacogenomics. The role of the test evaluation working groups will be:

- To support the genomic test evaluation process by providing recommendations to the Genomics CRG;
- Review applications for updates to the National Genomic Test Directory and highlight any areas of clarification required from the laboratories; and
- To ensure that the National Genomic Test Directory is kept in line with current evidence, and that where appropriate, tests are removed if they are superseded or no longer relevant for clinical care.

To ensure each UK nation retains the ability to determine their own commissioning decisions, applications for amendments to the National Genomic Test Directory and review of applications by the Test Evaluation Working Group will be conducted on a UK-wide basis, however any review of impact of implementation will be conducted

for England only, leaving the flexibility for each nation to develop their own methodology for determining which tests are commissioned for their populations.

3. Duties and Responsibilities

Test evaluation working group Chairs and members will provide impartial, evidence-based clinical and scientific advice to inform the development of the National Genomic Test Directory. Members of the Genomics Test Evaluation Working Groups will have the following key responsibilities:

- Using an ethical, evidence-based approach, provide impartial clinical and scientific advice to support the development of National Genomic Test Directory including:
    - participating in the development of genomic test evaluations – including economic impact assessments;
    - evaluating protocols for new clinical indications;
    - evaluating proposals to alter the eligibility criteria, constituent tests or technology for existing clinical indications;
    - evaluating changes to contents of gene panels;
    - establish the criteria for evaluating impact for patient benefit including diagnostic yield;
    - evaluation clinical outcomes from the National Genomic Test Directory; and
    - inform impact and cost effectiveness assessments

- Attend face-to-face meetings of the working group (extraordinary meetings can be organised using teleconferencing and web-conferencing technology) and ensure effective relationships between working group members;
- Undertake sufficient preparation prior to meetings to fully understand and consider all the documentation provided;
- Identify and draw on additional national or international expertise as required;

Any documentation, discussions and meeting outputs as part of the test evaluation working groups remain **confidential** and not for discussion and circulation outside of the working group.

3. Membership

The Genomics Test Evaluation Working Groups will each have a chair/co-chair and will be made up of key representatives and clinical specialties from cancer, rare and inherited disease, and pharmacogenomics.

Clinical specialties may include:

- Clinical genetics;
- Genetic counselling;
- Cancer, covering solid tumour, haematological malignancies and paediatric cancer;
- Primary care;

- Rare and inherited disease;
- Mainstream clinical specialties such as cardiology, reproductive medicine, neurology, ophthalmology and renal disease;
- Clinical scientists;
- Nursing;
- Public health; and
- Pharmacogenomics

4. Meetings

The Genomics Test Evaluation Working Groups will meet in person quarterly. The Chair of the meeting may convene additional *ad hoc* meetings (in person or via teleconference), as necessary.

A minimum of 50% of members must be present for the meeting to be deemed quorate.

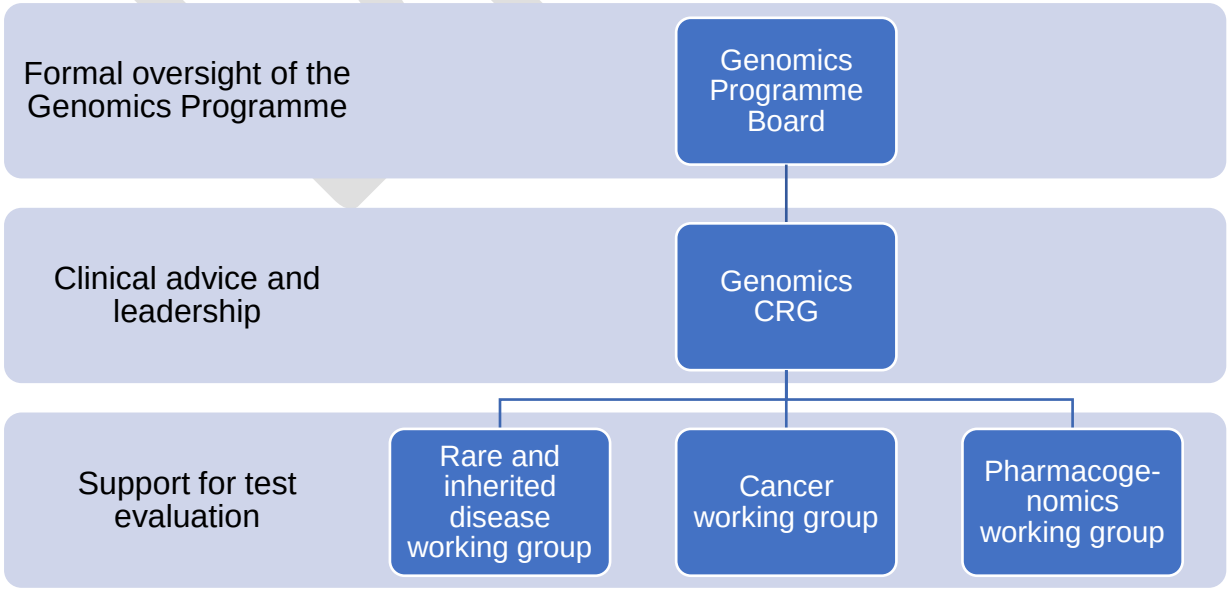
The Chair may invite additional experts to attend meetings and participate in discussion where this is relevant to specific agenda items.

5. Conflicts of interest

All members are required to declare conflicts of interest and the receipt of gifts, hospitality and/or sponsorship, in line with the national guidance to the NHS. Conflicts of interest should be declared in writing to the secretariat and specific conflicts should be raised at the start of any agenda item or discussion for which that conflict arises. A conflict of interest and a hospitality register will be maintained by the secretariat.

6. Reporting and governance

The Genomics Test Evaluation Working Groups will report into the Genomics CRG and the Chairs of the Test Evaluation Working Groups will also sit on the Genomics CRG.



7. Secretariat

Secretariat will be provided by the Genomics Unit within NHS England and NHS Improvement.

Minutes and actions from each meeting will be written up and agreed with the Test Evaluation Working Group Chairs prior to circulation.

The secretariat can be contacted on: England.Genomics@NHS.net