UKGTN Evaluation of New Gene Tests for NHS Service Documentation Required

Gene Dossier Form required

- Where a laboratory wants to provide testing for new disorder(s) or new group of phenotypes that is/are not currently listed on the Directory/online database (i.e. no other laboratory provides the disorder or group of phenotypes) a Gene Dossier will need to be submitted.

Additional Provider Form Required

- Laboratories will need to submit an Additional Provider for tests for conditions that are listed on the Directory/online database but where the submitting laboratory does not currently offer any component of the test.

No Gene Dossier or Additional Provider Form Required

Validation documentation only required:
Where a laboratory is adding genes to one of their existing NGS Panel tests then no additional provider form is required but validation documentation will need to be submitted and **will require scientific advisor approval**.

No documentation required:
Where a laboratory is adding genes to a test that the laboratory already offers and where these genes are listed on the directory/database for the same condition/s (i.e. offered by another laboratory) and the test uses Sanger Sequencing then no documentation is required.

Where a laboratory is moving from Sanger sequencing testing to NGS but the test listings remain the same on the UKGTN website, i.e. a straight swap from one technology to the other then no documentation is required.

Testing Criteria development where no Gene Dossier or Additional Provider is required:

In the two situations detailed above the following applies in relation to Testing Criteria development:

- If Testing Criteria requires amendment then Testing Criteria will need to be submitted by the laboratory. It will initially be reviewed by the Clinical Advisor and Chair of the GTEWG and subsequently signed off by the GTEWG.

Cytogenetic tests

Prior to completing either a Gene Dossier or Additional Provider Form for cytogenetic tests, please contact the UKGTN team as it may be more appropriate to add these tests to the core list of cytogenetic tests offered by all laboratories.