NHS ENGLAND

INVITATION TO TENDER

STAGE TWO ITT

NHS GENOMIC MEDICINE CENTRE SELECTION - WAVE 1

NHS England - Invitation to Tender

Stage Two ITT: NHS Genomic Medicine Centre Selection - Wave 1

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The following documents are provided as separate attachments:

Annex 2 Section A 1	*Initial Response - Technical Issues Log*
Annex 2 Section A 2	*Initial Response - Sample Trajectory*
Annex 2 Section A 3	*Initial Response - EQA Assessment Scheme Questionnaire*
Annex 2 Section C	*Initial Response - Financial Response*
Annex 4 1A	*Specification*
Annex 4 1B	*Appendices to the Specification*
Annex 5	*Heads of Terms (provided to Applicants directly)*
Annex 6 1A and 1B	*Tech Fund - Capital Investment Forms*

1 Introduction

1.1 General

1.1.1 In this Stage Two ITT, terms shall have the same meaning given to them in the Prospectus and in the Stage One ITT. Other terms are defined in the Glossary in Annex 1.

1.1.2 This Stage Two ITT relates to the 100,000 Genomes Project ("the Project"), which has been established to deliver on the Government's commitment to sequencing 100,000 whole human genomes by the end of 2017.

1.1.3 In the context of the Project, NHS England is selecting Applicants to participate in the Project as NHS Genomic Medicine Centres, by way of this Procurement.

1.1.4 This Stage Two ITT is issued to those Applicants who have been successful in the Stage One ITT for this Wave 1 of the Procurement of NHS Genomic Medicine Centres. It sets out:

1.1.4.1 details of the process which will be followed with Applicants;

1.1.4.2 details of the requirements, contract and environment in which the NHS Genomic Medicine Centres will be operating, so as to allow Applicants to submit their Initial Responses and Final Applications in this Procurement;

1.1.4.3 the response requirements which Applicants must adhere to; and

1.1.4.4 the evaluation process which will be followed to select the Wave 1 NHS Genomic Medicine Centres.

1.1.5 The purpose of this Stage Two ITT is to provide this detail to Applicants, enable constructive engagement during this Stage Two and to set out the basis on which contracts will be awarded to successful Wave 1 NHS Genomic Medicine Centres. The Stage Two ITT is split into two phases - an Initial Response phase as detailed in paragraph 2.1 and a Final Application phase as detailed in paragraph 2.2.

1.2 Overview of what is required from an NHS Genomic Medicine Centre

1.2.1 Applicants that successfully pre-qualify as NHS Genomic Medicine Centres will retain pre-qualification status indefinitely. However, in order to be designated full status and become a contracted GMC Lead Organisation, Applicants must also state all of their intended GMC Local Delivery Partners, whether commencing operational readiness on January 1st 2015 or as part of a later phasing-in. Applicants will need to demonstrate ability to meet all parts of the service specification in one or all organisations that constitute the local NHS Genomic Medicine Centre, with a clear

mobilisation plan. The mobilisation plan should include details of which GMC Local Delivery Partners commence at which time in the lifecycle of the Project.

1.2.2 Applicants should provide the level of detail set out in the Specification regarding its proposed GMC Local Delivery Partners dependent on the timing of them commencing the provision of NHS Genomic Medicine Centre services, as set out in their plan for the phasing in of GMC Local Delivery Partners. For GMC Local Delivery Partners commencing on or shortly after 1 January 2015 then all of the detail in the Specification is required. For GMC Local Delivery Partners commencing later on in the phasing then less detail is required at this time, as set out in the Specification, and as colour coded in it. Once the contract is operational, when new GMC Local Delivery Partners are introduced then then GMC Lead Organisations will be responsible for obtaining NHS England's agreement to the relevant GMC Local Delivery Partner(s) commencing service, and NHS England will require the full detail to be provided before that agreement is granted.

1.2.3 For Wave 1 and operational readiness on January 1st 2015 Applicants will be expected to demonstrate capacity, capability and existing delivery infrastructure in the following areas (as more fully described in the Specification):

1.2.3.1 ability to obtain Board commitment to the project from the Applicant and all intended GMC Local Delivery Partners within an NHS Genomic Medicine Centre by 1st January 2015;

1.2.3.2 evidence of capacity and capability to support the Project in terms of eligible patients/families in the specific disease areas of focus, the sample numbers and systems to deliver significant sample flows per annum focused on Rare Diseases and cancer;

1.2.3.3 clear commitment to work to specified protocols for blood and tissue samples and their collection, processing, storage and transport;

1.2.3.4 clear commitment to participate in the established UKNEQAS scheme for the Project to ensure that DNA extraction quality requirements are fully met throughout the lifetime of the Project;

1.2.3.5 commitment to record and upload patient characteristics and all data sets according to defined minimum defined data fields and guidance contemporaneously with sample acquisition;

1.2.3.6 commitment to transfer samples and associated data with agreed identifiers, according to national standards set by NHS England, to the Genomics England Central Biorepository, and a clear commitment where possible to re-supply samples where initial samples fail quality control;

1.2.3.7 capabilities and capacity within proposed operational models to validate results from whole genome sequencing and feedback to patients within clinical care;

1.2.3.8 clear management support and clinical, laboratory and informatics leadership;

1.2.3.9 informatics plans with details of any necessary technical or organisational change;

1.2.3.10 resource plans for any activities in addition to routine care;

1.2.3.11 local delivery structure including project management and monitoring of transformational impact.

1.2.4 In line with NHS England's legal duties for equality, NHS Genomics Medicine Centres shall enable equity of access for all patients under the care of the NHS in England to receive access to participation in the Project if clinically appropriate and if they are fully consenting.

1.2.5 Each NHS Genomic Medicine Centre should demonstrate:

1.2.5.1 that it is representative of a defined referral population as well as a geography;

1.2.5.2 credibility of pipeline trajectory to act at scale and pace in line with the monthly sample accrual targets of the Project;

1.2.5.3 sufficient geographical spread that will drive transformation at scale across the NHS demonstrating mapping against AHSN geographical footprints. Where there are patient flows that transcend AHSN geographical boundaries NHS Genomic Medicine Centres should demonstrate engagement with multiple networks to substantiate and evidence the sample pipeline and benefit realisation across these geographies.

1.2.6 Except as expressly stated otherwise in this Stage Two ITT or where the context implies otherwise, the provisions in Stage One ITT are hereby deemed to be incorporated into this Stage Two ITT, including but not limited to the conditions of the Procurement.

1.2.7 This Stage Two ITT is published on the NHS England website except for Annex 5 and 6 which is sent direct to Applicants only.

1.3 Important matters

1.3.1 Each successful Applicant will enter into an agreement with NHS England to manage its element of the delivery of the Project. It is also mandatory that each successful Applicant ensures that each entity it is working with (whether as partners, consortium members, sub-contractors or otherwise) also agrees to the terms of the contract which are relevant to them, and NHS England reserves the right to require copies of all such agreements.

1.3.2 Applicants should also ensure that when providing their Final Application that they cover all GMC Local Delivery Partners as more fully set out in the Specification in Annex 4. Applicants should provide the level of detail set out in the Specification regarding its proposed GMC Local Delivery Partners dependent on the timing of them commencing the provision of NHS Genomic Medicine Centre services, as set out in their plan for the phasing in of GMC Local Delivery Partners. For GMC Local Delivery Partners commencing on or shortly after 1 January 2015 then all of the detail in the Specification is required. For GMC Local Delivery Partners commencing later on in the phasing then less detail is required at this time, as set out in the Specification, and as colour coded in it. Once the contract is operational, when new GMC Local Delivery Partners are introduced then then GMC Lead Organisations will be responsible for obtaining NHS England's agreement to the relevant GMC Local Delivery Partner(s) commencing service, and NHS England will require the full detail to be provided before that agreement is granted.

1.3.3 Applicants should only submit Initial Responses and Final Applications for this Stage Two ITT if they are confident that they can meet the delivery timetable below, namely contract award in mid-December and operational readiness commencing from 1 January 2015, i.e. actively seeking participants and gaining their consent. If Applicants consider that they cannot meet these timescales then in the first instance they should contact england.genomics@nhs.net and inform NHS England, and then consider whether their application would be better timed for future Waves.

1.3.4 As Applicants are aware there is the opportunity for capital investment funding to be made available via the Department of Health's Tech Fund. When the contract award decision is made for this Procurement of NHS Genomic Medicine Centres, Applicants will be aware of whether their capital investment funding request has been granted. This funding can be drawn down from April 1 2015 but GMC Lead Organisations will need to have demonstrated that they have undertaken a local procurement by that time. Applicants should complete the form provided to them by NHS England at Annex 6 and use no more than 10 pages.

1.4 Timetable

1.4.1 The Prospectus and the Stage One ITT set out an outline of the timetable for this Procurement. The anticipated timetable is now set out below:

Date	Stage
Friday October 10 2014	Stage Two ITT issued
Friday October 10 2014 to Friday October 24 2014	Applicants engage with their intended GMC Local Delivery Partners to create aggregated Initial Responses
Friday October 24 2014 at 3pm	Submission of Initial Responses by each Applicant to NHS England (not evaluated) - see paragraph 2.1
Friday October 24 2014 to	NHS England review the Initial Responses

Date	Stage
Wednesday October 29 2014	
Wednesday October 29 2014	NHS England host aggregated legal and technical discussions with all Applicants together for legal and technical. Financial feedback may be in written form.
Friday October 31 2014	NHS England republishes the documents to inform the Final Applications - see paragraph 2.2
Tuesday November 4 2014 at noon	Opportunity for Applicants to raise clarifications ends
Friday November 7 2014 at 3pm	Deadline for submitting Stage Two ITT Final Applications ("Deadline")
Friday November 7 2014 to Friday December 5 2014	The evaluation of Final Applications is undertaken, including site visits to moderate and confirm the successful Final Applications received. ***The site visits will take place on the dates set out below this timetable. Please ensure that you organisations have availability on these dates - NHS England will contact you to confirm which date(s) are applicable to you.***
week beginning Monday December 8 2014	Results for Stage Two ITT released
following release of results	Standstill period - 10 calendar days
prior to contract award	Final clarifications with successful Applicants
prior to Christmas 2014	Contract award
1 January 2015	Contract begins - operational readiness to commence - i.e. start of process of patient enrolment and consent only, and samples to be provided for analysis following these processes

Site visit dates	
November 10th	All Day
November 11th	PM
November 12th	AM
November 18th	All Day
November 19th	All Day
November 20th	All Day
November 25th	AM
November 26th	All Day
November 27th	All Day
November 28th	AM
December 1st	All Day
December 4th	All Day
December 5th	All Day

1.4.2 NHS England reserves the right: (i) not to consider any Final Application which is received later than the Deadline or after any extension has expired, if granted, and/or (ii) to amend the timetable of the Procurement process.

1.4.3 NHS England will publish a Contract Award Notice at the end of the Procurement, no later than forty eight (48) days after the contracts have been awarded.

1.5 Structure and relevant organisations

1.5.1 The following terminology and relationships apply in this Stage Two ITT.

1.5.1.1 NHS Genomic Medicine Centres - is the designation used by permitted users by way of branding for the services which are the subject of this Procurement;

1.5.1.2 GMC Lead Organisation - is the successful Applicant with whom NHS England enters into a contract following this Procurement;

1.5.1.3 GMC Local Delivery Partners - the entities with whom the GMC Lead Organisation works to provide the NHS Genomic Medicine Centre Services;

1.5.1.4 GMC Delivery Entities - means a GMC Lead Organisation and its GMC Local Delivery Partners; and

1.5.1.5 Delivery Sites - means the locations from which the GMC Delivery Entities provide the NHS Genomic Medicine Centre Services.

1.5.2 The Specification in particular has many requirements which must include detail on all of these, requiring Applicants to set out which entity/entities provide particular elements of the services. Applicants should read the guidance and the Evaluation Criteria carefully, and ensure that their Initial Application and their Final Response are compliant.

2 Stage Two ITT Phases

2.1 Initial Response

2.1.1 This Stage Two ITT is divided into two phases.

2.1.2 In the **Initial Response** phase, each Applicant must provide the documents set out below for that Initial Response in the formats specified below. This will assist NHS England with finalising the specification and developing the final contract document set, and also to ensure that the Applicant's proposal is complete and accurate. This phase is not evaluated.

2.1.3 During the Initial Response phase, NHS England expects each Applicant to work together within their organisation (i.e. the Applicant and its potential

GMC Local Delivery Partners) to collate the documents required as set out in the remainder of this paragraph relevant to the Initial Response. This will ensure best use of limited resources and best value for money.

2.1.4 Technical - each Applicant should work together within their organisation (i.e. the Applicant and its potential GMC Local Delivery Partners) should submit their collated Initial Response for the Technical Review in accordance with the template set out at Annex 2, Section A with their **top 10 issues** to inform the meetings described in paragraph 2.1.7.

2.1.5 Legal - each Applicant should work together within their organisation (i.e. the Applicant and its potential GMC Local Delivery Partners) should submit their collated Initial Response for the Legal Review of the Heads of Terms in accordance with the template set out at Annex 2, Section B to inform the meetings described in paragraph 2.1.7.

2.1.6 Financial - Applicants should submit their Initial Response for the Financial review in accordance with the template set out at Annex 2 Section C.

2.1.7 NHS England will then review the comments on the documents provided for review by each Applicant and undertake a feedback meeting regarding the Legal and Technical areas collectively with all Applicants as set out in the timetable in paragraph 1.4.1. Financial feedback may be provided in writing to Applicants.

2.2 Final Application

2.2.1 In the **Final Application** phase, NHS England may reissue any or all of the Specification, the Heads of Terms (or the contract document set which will replace it), this Stage Two ITT and/or the response requirements. Applicants must then complete and submit Final Applications before the Deadline, working together within their organisation (i.e. the Applicant and its potential GMC Local Delivery Partners). The Final Application phase is evaluated.

2.2.2 Technical - each Applicant should submit its own Final Application in accordance with the template set out at Annex 3, Section A (as updated by NHS England if required), working together within their organisation (i.e. the Applicant and its potential GMC Local Delivery Partners).

2.2.3 Legal - each Applicant should submit its own Final Application in accordance with the template set out at Annex 3, Section B for the contract document set to be provided by NHS England, working together within their organisation (i.e. the Applicant and its potential GMC Local Delivery Partners).

2.2.4 Financial - Applicants should submit their Final Application for the Financial review in accordance with the template set out at Annex 3 Section C.

2.2.5 NHS England will only maintain one standard document set - i.e. Applicants may have different comments but there will not be Applicant-specific specifications.

3 Key Documents

3.1 Specification

3.1.1 The current draft of the Specification is included at Annex 4. It sets out how the Applicants must provide the services in question if they are awarded a contract to become an NHS Genomic Medicine Centre. The Specification will become part of the contract which is awarded.

3.1.2 Applicants should note that Genomics England is also publishing its draft Genomics England Protocol for stakeholder consultation shortly. Applicants should note that they should respond to the Specification and Heads of Terms contained within this Stage Two ITT. Genomics England will be providing copies of their protocol for stakeholder consultation.

3.2 Heads of Terms

3.2.1 The current draft of the Heads of Terms is included at Annex 5 and will be provided to Applicants directly. It sets out how the Applicants must comply with various requirements in order to provide the services in question if they are awarded a contract to become an NHS Genomic Medicine Centre. The Heads of Terms will be developed into a full contract, including the Specification, and it will be this full contract which Applicants must respond to in their Final Application, and which successful Applicants will be required to sign to become an NHS Genomic Medicine Centre.

4 Award Criteria and Process

4.1 Overview of Criteria for Stage Two ITT

4.1.1 The Evaluation Criteria for Stage Two ITT Final Applications are divided into three sections:

4.1.1.1 Section A - ITT2 - Technical, representing 80% of the overall score;

4.1.1.2 Section B - ITT2 - Legal, representing 10% of the overall score; and

4.1.1.3 Section C - ITT2 - Financial, representing 10% of the overall score.

4.1.2 Initial Responses to this Stage Two ITT are not evaluated. The Initial Response is intended to be used to inform engagement with Applicants and updating the documents for this Procurement, as described in paragraph 2.1.

4.1.3 Final Applications to this Stage Two ITT will be evaluated in accordance with this Stage Two ITT.

4.1.4 Governance of the Procurement is overseen by the NHS England Genomics Programme Board and reporting within the NHS England Board Assurance Framework. For the purposes of oversight of the Procurement of NHS Genomic Medicine Centres an NHS England Genomics Procurement Board has been established. The NHS Genomic Medicine

Centres Evaluation Team will comprise of representatives of the 100,000 Genomes Project Delivery Partners and other stakeholders, including but not exclusive to NHS England, Genomics England and the Department of Health. The Evaluation Team will make recommendations to the NHS England Procurement Board in accordance with the process set out in paragraph 4.1.15 of this document.

4.1.5 The Evaluation Criteria for this Stage Two ITT are set out in this paragraph. This is principally concerned with each Applicant's ability to successfully operate a NHS Genomic Medicine Centre and meet the accompanying requirements and objectives demanded by the Project, if the Applicant is awarded a contract.

4.1.6 Once Final Applications are received and opened following the Deadline specified in paragraph 1.4, they shall be assessed according to this paragraph. If a Final Application is successful under the Stage Two ITT Evaluation Criteria in this paragraph and is not excluded, the Applicant will be awarded a contract to become a NHS Genomic Medicine Centre under Wave 1 of this Procurement process.

4.1.7 NHS England reserves the right to consider the number of samples proposed by each Applicant and re-allocate these between Applicants dependant on the quality of their Final Applications, the overall number of samples required to meet the overall even balance between samples for cancer and rare diseases, the prices bid in the Final Applications and the outcome of the site visits. Applicants should also note that the Heads of Terms also sets out how NHS England may reallocate these samples between GMC Lead Organisations during the life of the contracts.

4.1.8 For the Stage Two ITT Evaluation Criteria under this paragraph, evaluators will undertake the following process.

4.1.9 Each criterion within this paragraph is given a scoring method and a weighting (which may be a pass/fail criterion). When scoring a Final Application, evaluators will give a score using the applicable scoring method but not apply the weighting for that criterion at that stage - weightings shall be applied later once the score is finalised. The criteria, scoring methods and weightings are set out below.

4.1.10 The scores shall be allocated to reflect the quality of the Final Application provided and the evidence which is provided with it. Individual evaluators will provide reasons for their decision-making, taking into account all of the elements within the criteria. Evaluators should also log any concerns they have regarding the risk profile of the Final Application, potential delays in implementing the NHS Genomic Medicine Centres and/or any material areas of concern and/or non-compliance (**"Concerns"**).

4.1.11 Once all of the scores are completed and after review and approval of responses to the Service Specification for operational readiness for a 1st January 2015 commencement, site visits shall be undertaken as part of the evaluation process, as follows. A joint NHS England/Genomics

England/Department of Health team will conduct this, which may take the form of an interview and/or site visits, in accordance with the timetable in paragraph 1.4.1 to discuss plans and local capabilities.

4.1.12 NHS England will develop a generic set of criteria to be considered on the site visit, relating to any or all of the evaluation criteria for the Final Application, operational readiness for a 1st January 2015 commencement, paying particular attention to the operational commitment at all levels of the organisation, the Applicant's ability to follow the required consent and sample handling protocols, and their capacity to record and export required clinical data. Evaluators will note observations/issues for each of these as applicable.

4.1.13 The outcome will either be to:

4.1.13.1 confirm that the evaluation of the Final Application is not impacted, or;

4.1.13.2 advise on areas which need to be re-assessed as a result of a material issue which arises at the site visit. This makes the Final Application of that Applicant non-compliant until that issue is resolved, and NHS England reserves the right to re-score downwards only any element of an Applicant's bid as a result of information arising from the site visit. Where a Final Application remains non-compliant as an issue has not been resolved, an Applicant may be disqualified in accordance with paragraph 4.1.16.5.

4.1.14 NHS England will undertake site visits for successful Applicants only, but if as a result of the site visits other Applicants become entitled to be a successful Applicant then NHS England will also undertake site visits for those Applicants, so as to preserve equality.

4.1.15 Following the site visits, NHS England will collate the scores, make recommendations and reports to the Procurement Board, and the Procurement Board will consider each of the Applications along with the recommendations and reports.

4.1.16 NHS England reserves the right to exclude Applicants for the following reasons:

4.1.16.1 an Applicant scoring 0 or 2 in any criteria, scoring less than 60% overall for all the marks available in the Technical category (therefore 48% of the available 80%) and/or less than 50% overall when all of the weighted scores are added together for the three categories (in which case feedback shall be provided in a debrief session to assist Applicants in competing for future Waves);

4.1.16.2 Applicants making one or more material amendments to key principles and/or failing on any pass/fail or mandatory requirement;

4.1.16.3 Applicants effecting a material change in the risk profile of NHS England or its partners,

4.1.16.4 an Applicant's Final Application being incomplete or not capable of evaluation;

4.1.16.5 an Applicant failing to clarify a material issue arising from a site visit to NHS England's satisfaction, as set out in paragraph 4.1.13.2;

4.1.16.6 the grounds set out in paragraphs 6.1.1 and/or 6.1.2 of the Stage One ITT;

4.1.16.7 an Applicant failing to notify NHS England of changes in accordance with paragraph 6.6.4 of the Stage One ITT; and

4.1.16.8 in accordance with paragraph 5.3.3.

4.2 Contract Award

4.2.1 NHS England reserves the right to apply conditions to each contract awarded where the Procurement Board has concerns about that Applicant, including but not limited to the circumstances in paragraph 4.1.7 and in respect of existing Genomics England pilot sites where those pilot sites must complete their existing allocation of required samples in their pilot site arrangements prior to providing samples through this contract with NHS England.

4.2.2 NHS England also reserves the rights to amend the number of samples awarded to any successful Applicant as a result of this process, including but not limited to in the circumstances set out in paragraph 4.1.7.

4.2.3 Contracts will be awarded to either an Applicant as one GMC Lead Organisation (ideally) or to two Applicants but forming one designated NHS Genomic Medicine Centre in name, with a partnership agreement required between them, and additional details as set out in the Specification, Heads of Terms and the contract document set.

4.3 Section A - ITT - Technical Evaluation Criteria

The scoring applied to each category in the Technical response to the Final Application is as follows. The technical evaluators will score each individual question in the Specification then consider on that basis what score applies to the whole grouping. There are no sub-weightings or averaging of scoring, and evaluators will therefore base their overall score for a criterion based on their view of an Applicant's overall performance in that category.

It is particularly important that Applicants include detail from all entities which will form part of the proposed NHS Genomic Medicine Centre. Please see the Specification for further detail of what detail is required where. If Applicants fail to complete their Final Response with the details required across their Lead Organisation and GMC Local Delivery Partners then they will be scored down as set out below.

Score	Criteria
10	a comprehensive answer with excellent detail and strong supporting evidence of delivery provided for the GMC Lead Organisation and all GMC Local Delivery Partners
8	a comprehensive answer with some detail and an acceptable level of evidence of delivery provided for the GMC Lead Organisation and all GMC Local Delivery Partners or a good answer with excellent detail and strong supporting evidence of delivery provided for the GMC Lead Organisation and all GMC Local Delivery Partners
6	a good answer with some detail and an acceptable level of evidence of delivery provided for the GMC Lead Organisation and all GMC Local Delivery Partners **(and to score 6 or more in a criterion, a Final Application must have details of all GMC Local Delivery Partners for that criterion to the extent set out in the Specification, particularly taking into account the phasing of each GMC Local Delivery Partner (i.e. for earlier phased GMC Local Delivery Partners, more detail would be required than for GMC Local Delivery Partners due to be phased in later in the contract)**
4	a good answer with little detail and little evidence of delivery provided for the GMC Lead Organisation and only some GMC Local Delivery Partners

Score	Criteria
	or a weak answer with some detail and an acceptable level of evidence of delivery provided for the GMC Lead Organisation and only some GMC Local Delivery Partners **(and a score of 4 or less will apply to criteria within Final Applications which do not have details of all GMC Local Delivery Partners for that criterion)**
2	a weak answer with little detail and little evidence of delivery provided for the GMC Lead Organisation and only some GMC Local Delivery Partners
0	little or no answer provided, with little detail and/or no evidence of delivery provided for the GMC Lead Organisation and only some GMC Local Delivery Partners

Specification Category	Weighting (out of the 80% available for Technical)
Recruitment of patients and Consent and Patient and Public Involvement (3.1 of the Specification)	15
Informatics and Participant Data (3.2 of the Specification)	20
Sample collection, processing and logistics, post annotation, reporting and validation (3.3 of the Specification)	20
Return of results to participants and clinical care; transformation and outcomes; workforce (3.4 of the Specification)	10
Organisational governance and partnership arrangements (3.5 of the Specification)	15

4.4 Section B - ITT - Legal Evaluation Criteria

4.4.1 NHS England sets out here additional background detail which should assist Applicants in providing their legal responses to this Stage Two ITT.

4.4.2 The legal evaluation of the Final Application will review the contract document set as published later in this process. Following discussion with Applicants, certain contract provisions will become mandatory, as advised by NHS England. If an Applicant seeks to amend or reject these provisions then their bid may be disqualified by NHS England in accordance with paragraph 4.1.16.2. Other parts of the contract will be assessed on a compliance basis, as set out below.

4.4.3 Evaluation approach:

4.4.3.1 This part focuses on the scoring methodology for assessment of the legal elements of Applicants' Final Applications. Where appropriate and/or specifically referenced, the legal advisers will refer matters to the other evaluators.

4.4.4 Scoring:

4.4.4.1 The contract document set to be evaluated will be divided into a number of sections for scoring purposes, and NHS England will provide this division after the contract document set has been issued.

4.4.4.2 The evaluators will review the comments provided on the contract document set submitted by each Applicant by way of the Issues Log submitted with their Final Application. The evaluators will score each section referenced in the table to be provided pursuant to paragraph 4.4.4.1 according to the scoring guidelines in the table in paragraph 4.4.6.

4.4.4.3 The evaluators will then agree scores and complete reasons for those scores, which will be moderated to ensure fairness between Applicants.

4.4.4.4 A weighting will be provided for each of the sections. The purpose of applying a weighting is to make the scores for the more important legal criteria worth more than the scores for less fundamental criteria. Each agreed score of the evaluators will be multiplied by the weighting to give the total score for the Applicant for that criteria, and these scores will then be added together to give an overall weighted score, which will form the percentage of the Applicant's overall score as set out in paragraph 4.1.1.2.

4.4.5 Reporting to NHS England Procurement Board:

4.4.5.1 The evaluators will report to the Procurement Board on the scoring indicating in respect of each Applicant all points of material concern. The evaluators will indicate in their report if the points of material concern are such that in their view proceeding with the bidder is likely to either cause significant delay to closing the project, be difficult to resolve in the light of the constraints of the competitive dialogue process or adversely affect the risk allocation as far as NHS England is concerned.

4.4.6 Scoring guidelines:

Score	**Explanation**
10	Comments indicate full acceptance of the provisions save for minor amends which do not increase NHS England's risk profile at all.
6	Comments indicate amendments to the provisions will be required but these amendments do not significantly increase NHS England's risk profile.
2	Comments indicate major amendments to the provisions will be required which very significantly increase NHS England's risk profile while retaining the substance of the original clause(s).
0	Comments indicate rejection of a provision or addition of an amendment which very significantly increases NHS England's risk profile and which removes the substance of the original clause(s).

4.5 Section C - ITT - Financial Evaluation Criteria

4.5.1 NHS England is making a limited investment and is prepared to make a maximum investment per successful sample (DNA sample and accompanying clinical data) of up to £200 based on an agreed monthly activity plan.

4.5.2 For cancers, this is up to £200 per successful sample and accompanying clinical data, of which there are up to two per patient (tumour and blood, so up to £400 in total), and for rare diseases this is also up to £200 per successful sample, of which there are up to three per patient (one from the patient and two from close family members, so up to £600 in total).

4.5.3 Activity plans will be capped and over performance will only be payable by prior agreement. Those suppliers that cost at lower than up to £200 per successful sample will receive a higher points award in the Evaluation Criteria (and therefore potentially a higher proportion of the sample pipeline in accordance with paragraph 4.1.7. Points will be awarded as follows:

Price per successful sample	**Financial evaluation score**
£200.01 or more	0 - paragraph 4.1.16.1 applies and Applicants may fail
£200.00	6
Price between £200.00 and the lowest of all prices from Applicants	A score between 6 and 10 to reflect the proportionate difference between £200 and the lowest of all prices, as set out in the example below
Lowest of all prices from Applicants	10

Example

Four Final Applications are received.

One is for £200. It scores 6.
One is for £150. It scores 10.
One is for £175. It scores 8, as its score is midway between £200 and the lowest of all prices at £150.
One is for £190. It scores 6.8, being calculated as follows: 10-((40/50)*4), being calculated as follows:

Score for £150 (being 10) - ((price increase from lowest price / price difference between lowest price and £200) * the score difference between 6 and 10).

5 Process

5.1 Format and content of Initial Responses

5.1.1 Initial Responses must be submitted in accordance with the requirements in paragraph 2 and in the format in paragraph 5.2, with references to Annex 3 replaced by references to Annex 2.

5.2 Format and content of Final Applications

5.2.1 All Final Applications must be submitted:

5.2.1.1 in electronic copy only, in editable word processing format;

5.2.1.2 using the template set out in Annex 3, with a maximum of the limits set out per criteria - any excess above the maximum will not be evaluated;

5.2.1.3 in a font size of 11 or more;

5.2.1.4 without any marketing material - this will not be evaluated;

5.2.1.5 by email to the following address england.genomics@nhs.net with the subject "NHS GMC WAVE 1 ITT STAGE TWO APPLICATION" with a delivery receipt requested - if Applicants do not receive a delivery receipt they should assume that their Final Application has not been received and try again;

5.2.1.6 without any assumptions except where specifically requested for trajectories, as potential Applicants who otherwise consider that items may need clarifying should do so in accordance with paragraph 5.3.1;

5.2.1.7 where Applicants are applying as consortia or partnerships, indicating which entities the relevant responses relate to; and

5.2.1.8 including all of the items set out in Annex 3, as supplemented by notice from NHS England;

5.2.1.9 the Applicant confirming that there have been no matters regarding which it should have informed NHS England, as set out in paragraph 4.1.16.7 (or indicating that such matters have already been notified, and that there are no further matters which should be notified); and

5.2.1.10 Applicants are required to include a single point of contact in their organisation for their Final Application. Applicants should ensure that their email addresses are monitored in the absence of that single point of contact to ensure that communications are addressed in appropriate timescales.

5.3 Receipt, Clarification and Validity of Final Applications

5.3.1 The period in which potential Applicants can raise clarification questions commences on the day the Stage Two ITT is issued. Applicants are urged to review the Prospectus, this Stage Two ITT and any other documents issued by NHS England immediately upon receipt and identify and submit any clarification questions as soon as possible. Should an Applicant submit clarification questions, these must be sent via email to england.genomics@nhs.net with the subject "ITT STAGE TWO CLARIFICATIONS". Clarification questions received by any other method may not receive a response. The deadline for submitting any clarification questions is five working days before the final date of submission of the Final Application, as outlined in paragraph 1.4.1.

5.3.2 As detailed further in paragraph 5.2.1.6, NHS England reserves the right to provide an anonymised copy of any clarification questions, and the answers to those questions, to all Applicants.

5.3.3 NHS England may require that Applicants clarify specific elements of their Final Application in writing within 3 working days (including that of their intended GMC Local Delivery Partners) and/or provide additional information within that same timescale. Any such clarification received shall then be added to that Applicant's response for the purposes of the evaluation and, should that Applicant be successful, the basis of their appointment. If any Applicant fails to respond within 3 working days or as required, NHS England shall have the right, in its sole discretion, to reject the applicable Final Application.

5.4 Security, Confidentiality and Permitted Disclosure

5.4.1 This Stage Two ITT is issued on the basis that all matters referred to in it are strictly confidential. No matter relating to this document or its contents or the proposed Project and/or Procurement shall be disclosed to any person, company or other legal entity without the prior written consent of NHS England (except as strictly necessary by the Applicant in order to obtain quotations necessary for the preparation of its Initial Responses and/or its Final Application in relation to insurance or professional advice). The information may not be used for any other purpose.

5.4.2 Applicants should ensure that they take steps to maintain such standards of security as are required by the conditions of this Stage Two ITT in order to prevent unauthorised disclosure of any confidential information.

5.4.3 Applicants acknowledge and agree that:

5.4.3.1 NHS England may disclose detailed information relating to Applicants' responses to the Stage Two ITT to NHS England's members, directors, officers, employees, agents or advisers and they may make Applicants' written responses available for private inspection by NHS England's members, directors, officers, employees, agents or advisers; and

5.4.3.2 NHS England reserves the right to disseminate information that is materially relevant to all Applicants, even if the information has only

been requested by one Applicant, subject to the duty to protect any Applicant's commercial confidence in its responses. Should Applicants wish to avoid such disclosure (for example, on the basis that the request or response contains commercially confidential information or may give another Applicant a commercial advantage) the request must be clearly marked "In confidence - not to be circulated to other Applicants" and the Applicant must set out the reason(s) for the request for non-disclosure to other Applicants. Subject to the provisions of this paragraph 5.4.3, NHS England will act reasonably as regards the protection of commercially sensitive information relating to the Applicant.

5.5 Jurisdiction and Governing Law

5.5.1 Any dispute arising in connection with the Procurement shall be governed by English law. The English courts shall have exclusive jurisdiction to settle any dispute arising in connection with this Procurement.

1 Annex 1: Glossary

The following definitions shall apply in this Stage Two ITT:

1.1.1 **Applicant** means an applicant to participate in the Procurement as described in the Prospectus and this Stage Two ITT.

1.1.2 **Deadline** means the timescale for Final Application receipt by NHS England, stated in paragraph 1.4.1.

1.1.3 **Delivery Sites** has the meaning given in paragraph 1.5.1.5.

1.1.4 **Evaluation Criteria** means the list of key Stage Two ITT evaluation criteria that is used to assess an Applicant's Final Application, as set out in paragraph 3 of this this Stage Two ITT.

1.1.5 **FFPE** means formalin fixed and paraffin embedded tissue.

1.1.6 **Final Application** means an application by an Applicant for this Stage Two ITT to become an NHS Genomic Medicine Centre using NHS England's templates to be submitted in accordance with the timetable in paragraph 1.4.1.

1.1.7 **FOIA Laws** means the Freedom of Information Act 2000 and the Environmental Information Regulations 2004 (as amended).

1.1.8 **GMC Delivery Entities** has the meaning given in paragraph 1.5.1.4.

1.1.9 **GMC Lead Organisation** has the meaning given in paragraph 1.5.1.2.

1.1.10 **GMC Local Delivery Partners** has the meaning given in paragraph 1.5.1.3.

1.1.11 **Initial Response** means the responses to the templates set out in Annex 2 in accordance with paragraph 2.1.

1.1.12 **NHS Genomic Medicine Centres** has the meaning given in paragraph 1.5.1.1.

1.1.13 **Procurement** means the procurement of NHS Genomic Medicine Centres.

1.1.14 **Procurement Board** means the NHS Genomic Medicine Centres Procurement Board of NHS England.

1.1.15 **Programme Board** means the Genomics Programme Board of NHS England. Reporting within the Board Assurance Framework of the NHS England Board, the Genomics Programme Board retains oversight of all aspects of NHS England accountabilities and contribution to delivery of the 100,000 Genomes Project.

1.1.16 **Project** has the meaning set out in paragraph 1.1.1 of this Stage Two ITT.

1.1.17 **Prospectus** means the 100,000 Genomes Project – NHS Genomic Medicine Centre Selection Prospectus which was made publicly available on 3 July 2014 and can be downloaded from http://www.england.nhs.uk/wp-content/uploads/2014/07/genome-medicine-centres-prospectus.pdf.

1.1.18 **Specification** means the specification of requirements which will underpin the process for awarding contracts to successful Applicants at stage two of the Procurement process.

1.1.19 **Stage One ITT** means stage one of two for this Invitation to Tender for the Procurement of NHS Genomic Medicine Centres as part of the Project, which was the pre-qualification stage designed to allow NHS England to assess each Applicant's previous experience that is relevant to the Project with the intention of selecting all those eligible to take part in Stage Two ITT. The Stage One ITT was published for this first stage on 28 July 2014.

1.1.20 **Stage Two ITT** means stage two of two for this Invitation to Tender for the Procurement of Wave 1 of the NHS Genomic Medicine Centres as part of the Project, with this document governing that part of the Procurement.

2 Annex 2: Initial Response Templates

The templates attached in this section are for Applicants to complete in the first few weeks following the Stage Two ITT being issued. They will inform the discussions with bidders and help develop the final documents.

Section A: Technical

Applicants should complete the following documents for this section of the Initial Response:

1. the issues log attached "Technical Issues Log", following the guidance for completion in it. Applicants do not need to complete the response columns in the Specification for this Initial Response, but they do need to do so for the Final Application;

2. the Sample Trajectory attached "Sample Trajectory" detailing the number of participants to be recruited and the number of samples to be delivered - with one copy for the Applicant's own organisation and then a further copy for each GMC Local Delivery Partner, detailing each of the Sites (with an extra copy of it as an "Other arrangement samples trajectory" where required);

3. the attached "EQA Assessment Scheme Questionnaire" must also be completed; and

4. any other documents referenced in the above documents which are to be completed.

Section B: Legal

Applicants should complete the columns for their responses and follow the instructions in the Heads of Terms at Annex 5.

Section C: Financial

Applicants should complete the Financial Response provided as a separate attachment - one copy for the Applicant and one copy for each intended GMC Local Delivery Partner.

3 Annex 3: Final Application Templates

These will be provided as separate documents for Applicants to complete and return by the deadline set out in paragraph 1.4.1. Applicants should ensure that they email the completed templates, and all information requested in them, in accordance with paragraph 5 of this Stage Two ITT.

Section A: Technical

The Final Application template for Technical will be in the format set out in the Specification, as updated by NHS England during this Procurement, including a final sample trajectory in the form set out in Annex 2 Section A part 2 unless otherwise advised.

Section B: Legal

The Final Application template will be an issues log in the format below, unless updated. The contract document set has not yet been issued but will be issued by NHS England along with final guidance on this response requirement.

Applicant ID and Issue number	***Reference (e.g. Heads of Terms, 3.2.1)***	***Applicant to explain the issue***	***Applicant to propose its resolution to the issue***

Section C: Financial

The Final Application template will be based on the form set out in Annex 2 Section C. NHS England will confirm this to Applicants, or provide an updated version.

4 Annex 4: Technical - Specification and other technical documents

1. Specification

This is provided as a separate document.

2. Genomics England Protocol

Applicants should note that Genomics England is also publishing its draft Genomics England Protocol for stakeholder consultation shortly. Applicants should note that they should respond to the Specification and Heads of Terms contained within this Stage Two ITT. Genomics England will be providing copies of their protocol for stakeholder consultation.

5 Annex 5: Legal - Draft Contract Documents for review

The Heads of Terms is provided to Applicants directly. As noted elsewhere in this Stage Two ITT, this will be developed into the full contract. Applicants should note that the specification as developed will become part of the full contract.

6 Annex 6: Capital Investment forms

These are provided as a separate document. Applicants should complete this form as set out in them and as required by paragraph 1.3.4.