

Cancer Research UK Stratified Medicine Programme Calls: Frequently Asked Questions

These FAQs include queries received before 12pm on the Thursday before circulation. For queries that are received after this time, responses will be included in the FAQ update the following week but we will endeavour to send individual responses prior to this.

Click on the links below to find answers to questions surrounding particular themes:

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General Questions

What is the role of AstraZeneca and Pfizer?

Our commercial partners AstraZeneca and Pfizer are co-funding the Stratified Medicine Programme. They are represented on the Governance Board and have oversight of the programme's activities. They share our excitement about the potential of stratified medicine, and in particular the opportunities to identify patients for targeted clinical trials, to develop a national model for molecular diagnostics, to further analyse stored DNA and to develop research hypotheses from consented patient datasets.

Can the results of testing be used for clinical care?

The results of testing done by this programme cannot be used for clinical care. NICE-approved testing should be done separately and within the clinical pathway and regulatory framework. By the end of two years, we hope that the service demonstrated is of a standard that could be adopted into clinical care, but we cannot guarantee it and therefore clinicians must not rely on the results until they are proven to be appropriate.

Technology Hubs

NEW and REVISED Questions

REVISED: I represent an NHS lab. Are costings VAT exempt as research and NHS/diagnostic component to this project?

It is assumed that the £300 allowance for testing costs will not be subject to a VAT charge from NHS labs. Based on our initial assessment of the programme (which has not been shared with HM Revenue & Customs), we believe that the activities of Phase One of the Stratified Medicine Programme can be interpreted as research. As such, funding for NHS applicants should be exempt from VAT.

We expect that private labs will charge VAT on the cost of this work.

The recoverability of VAT on laboratory consumables will flow from the underlying VAT treatment of the testing costs income. But we must stress that this VAT treatment is the responsibility of the body carrying out the work.

If you consider your circumstances are different to the ones we have envisaged please let us know.

REVISED: Can you provide further information on how the samples will be provided to Technology Hubs?

The details of this will be developed between the Clinical and Technology Hubs following selection. FFPE material may be provided by the Clinical Hubs as a microtome-cut section(s) either as a 'scroll' or 'ribbon' of sections in a sterile tube. Alternatively, if it is agreed that micro- or macro- dissection is required for samples then sections will be provided on appropriate slides. A matching pathology (e.g. H&E stained) slide or an electronic pathology image will accompany samples, but again details of this will be agreed between selected hubs. Technology Hubs will need to consider this pathology assessment prior to DNA/RNA extraction.

Where possible, sufficient tumour should be provided by Clinical Hubs to enable extraction of over 2µg of genomic DNA, so that the Technology Hub can both run the necessary tests and store DNA for future analysis. It is estimated that Clinical Hubs would need to provide 6-8 five micron sections of a FFPE block with 4mm² biopsy sample to provide a total of over 2µg DNA. The quantity of DNA extracted will vary, depending on the size of the sample, tissue type and cellular composition, and therefore the amount of material provided may have to be adjusted accordingly

It is acknowledged that this quantity (of 2µg genomic DNA) may not be achievable with certain biopsies and resections that result in particularly small samples. Applicants are advised to highlight any sample types they propose to collect that will yield less than 1µg DNA in their application. An absolute minimum quantity may be agreed between selected Clinical and Technical Hubs at a future workshop.

Clinical Hubs may also choose to extract DNA locally from patient tumour and matching blood samples and sent this to the appropriate Technology Hub (though no additional funding will be provided to the Clinical Hub if they choose to do this). Over 2µg (or less for

some sample types - as above) of genomic DNA would need to be provided in appropriately labelled microfuge tubes in an appropriate volume (e.g. 20-30µl) of water.

REVISED: What data will be derived from the blood samples?

DNA must be extracted from all matched blood samples and stored by the Technology Hubs. For some tumour types, this will be used to analyse polymorphisms in some pharmacogenetic markers as part of the list of genes to be tested as part of the Programme.

A further aim of collecting blood (germline) DNA is to future proof the programme for research and allows the samples to be analysed for whole genome sequencing when appropriate. However this is not within the scope of this call and so the ability to perform next generation sequencing on these samples does not need to be incorporated into the application.

What time on the 8th March does the competition to be a Technology Hub close?

The deadline is midnight on the 8th March. However, please note that once an applicant has pressed the submit button in eGMS it will pass to your administrative authority and they must fully submit it before it is counted as received by CR-UK. It is therefore important to ensure that your administrative authority is available when submitting the application. To ensure fairness and give enough time for the selection process, this deadline cannot be extended.

Who is my Administrative Authority and how do they approve my application?

If you cannot find your administrative authority in eGMS, you must contact us as soon as possible to set this up.

You need to identify the appropriate people to form this workgroup and provide the names and email addresses of everyone, plus a generic email address that they can all access. As a general guideline the workgroup should include members of the finance department and/or R&D office) as this is an administrative approval step.

Please send this to grants.help@caner.org.uk as soon as possible.

When you click submit on your application, an email notification is sent to the generic email address. People in the workgroup will see this, but you should also make sure they are available and aware that you are going to submit the application. They should then log into eGMS (the individuals should be sent passwords for their individual accounts when the administrative authority is set up) and click on the tab “workgroup tasks”, where the task for approving your application is situated. They should assign it to their personal tasks, and complete it.

Please note that the administrative authority must approve your application and submit this task before the end of Tuesday, as Cancer Research UK does not receive your application until they have done this.

Please could you clarify a point under section 5.2 e.g. ‘Consultant/Medical staff training in improvement methodology

NHS Improvement is a national programme designed to drive improvements in the way services are delivered in the NHS. There may be an opportunity to work with them to identify how improvements could be made across the genetic testing pathway. Part of this

work would provide the opportunity for staff to be trained in service improvement methodology such as “the LEAN approach”. This is a separate opportunity from the Stratified Medicine Programme and involvement in this is not mandatory for being selected as a Technology Hub.

Will repeat testing or DNA extraction need be undertaken for failed samples and what will the expected level of this be?

If sufficient high quality tumour sample is available we would expect repeat DNA extractions or tests at no additional cost to the programme and hubs should include expected failure rates into their cost calculations. If the DNA extraction/ test fails repeatedly the hubs will be expected to address failures according to local GLCP policies and CPA standards. If the test/DNA extraction fails because the sample was of insufficient quality we would not expect it to be repeated.

The cost of providing tests is dependent on the number of samples that can be tested at once. Will I receive samples in batches? How should I deal with this in costs section of the application?

The processes for transfer and storage of samples between Clinical Hubs and Technology Hubs will be determined by the selected Hubs at processes workshops that will occur in June. Therefore, it is not possible to provide guidance on exactly how/whether samples will be batched, however we do appreciate that the cost of the test will be affected by this.

Section 1.6 of the application form should be used to describe how the costs provided (in section 1.5) have been derived, and how this could change for example through batching samples. For example, if costs based on an average batch size have been provided, this can be outlined in section 1.6 and an indication given of how this is dependent on the number of sample being tested together.

The Application Process for the Technology Hubs

This is a laboratory bid to become a Technology Hub; do the details on the application form relating to CV, publications & research abstract relate to the lead applicant - or a group of individuals who will be involved?

CVs: The details requested in the contact information, applicant information, CV sections and equal opportunity (including “CV publications”) relate to the lead applicant. You can use the “supporting roles” section to identify other staff involved such as co-investigators.

Publications: In the application form (the word document upload) you have the opportunity in the track record section to provide an appendix with publications demonstrating the expertise of the whole laboratory.

Research Abstract: The research abstract should relate to your proposal as a whole, and should briefly outline the approach you will take to providing the genetic testing.

Can institutions apply as a consortium to become a Technology Hub?

It is possible for laboratories to submit an application as a consortium. Applicants should consider the following:

- All locations which will carry out genetic analysis must be CPA accredited
- A lead applicant should be identified within the consortium, who will be the recipient of the Grant Award Letter if successful
- The consortium would be responsible for meeting any extra costs associated with multiple sites i.e. shipping samples between sites
- The consortium must demonstrate a clear workflow including how the sites will work together and how clinically relevant turnaround times will be achieved by the end of the two years.

How samples will be provided to Technology Hubs

Can you provide a clearer estimate of the likely breakdown of the 9000 samples, i.e. roughly what number would you expect for each of the six disease types?

The Programme expects to collect and test a minimum of 1500 samples each for breast, colorectal, lung and prostate cancer. No minimum levels have been set for ovarian cancer or malignant melanoma.

Technology of Tests

Is the Programme aimed at certain technologies such as arrays or next generation sequencing?

No, the Programme is explicitly technology neutral. Our Technology Advisory Group has recommended that we leave the technology choice to the applicants. We expect those applying to be Technology Hubs to suggest how they could deliver the service best.

Will the tests be standardised across the hubs or will the tests be divided between them so that only one centre is performing a particular test.

The purpose of Phase 1 is to demonstrate a uniform network of collecting centres and technology hubs. Each Clinical Hub will be assigned to a specific Technology Hub by the Stratified Medicine Team to keep the samples flow to each hub as equal as possible. By having all three Hubs carrying out all the tests we can ensure that genetic testing provision is uniform across the network. This supports the ultimate aim of the programme which is for a standardised panel test to be used across the hubs.

However, we recognise that different Technology Hubs may have different expertise and we will encourage the sharing of these skills during the programme particularly in the validation of new tests which may be led by specific hubs and shared with the other hubs.

Is there any further funding for developing a new method/approach for screening genetic abnormalities and would publication of the data be permitted?

The CRUK programme will not supply further funding for development of new methods. The Technology Strategy Board is funding this.

We would encourage the publishing of any data generated and we are keen for labs to work together to share best practice and expertise with each other.

Only a small subset of the genetic marker panel is currently available as validated tests. What control material resource will be available to validate the remainder? How will the programme ensure consistency and quality across different multiple technologies that may be applied?

The Technology Hubs will be required to agree how tests will be validated between themselves and we anticipate that these discussions will start in the workshops that all chosen Hubs will be required to attend. The Technology Hubs will be encouraged to share their expertise and the workload between them. We anticipate that this work may take time and in the first few months that samples from the ECMCs may have their DNA extracted and stored until the tests are available or that the available tests will be carried out and the 'extra' tests will be run at a later date.

Histopathology of samples

Can you give more detail on the histopathology assessment required, and whether this is required at the Clinical Hubs or Technology Hubs?

Histopathology assessment of samples will be conducted at the Clinical Hubs. Sufficient information will need to be provided to the Technology Hubs to cover:

1. Confirmation that the sample is tumour
2. Ideally we would like the unique pathology number assigned to the sample on the slides/samples sent to the Technology Hubs – so any queries can be cross referenced back to the original sample/report
3. The percentage tumour content in the marked area should be indicated
4. Samples need to be accompanied by a marked H&E and ideally unmarked slides to enable microdissection (which will take place at the Technology Hub), if required.

Data analysis at Technology Hubs and data exchange with Clinical Hubs

Is it expected that each Hub (or combination of Clinical & Technology Hub) will develop its own XML data exchange schema, or will there be some co-ordination of this more centrally?

One of the aims of the programme is to share best practice and to formulate some draft standards for adoption by the NHS. The exact format of any data exchange between Clinical Hubs and Technology Hubs (including XML schemas if appropriate) will be agreed during the workshops to be held once the Technology and Clinical Hubs are chosen. However, a starting point for this will probably look at adopting or extending any existing methods or standards where they exist.

Is the genetic analysis result reporting time to be specified by Cancer Research UK, or is this open to applicants to state what they can achieve?

At this point it is open to applicants to state what they can achieve but ultimately the target is for Technology Hubs to provide results to Clinical Hubs within clinically relevant timescales – we have been advised that turnaround times of 5-15 days are reasonable dependent on the test. These targets will be agreed through workshops held with the chosen Technology Hubs and Clinical Hubs to facilitate joint working and Standard Operating Procedures.

As indicated in the call and guidance documents, please note that:

- Existing NICE recommended genetic testing should continue to follow existing pathways using existing testing services, as these tests are not covered in this Programme to avoid duplication.
- Results of genetic analysis obtained as part of the Stratified Medicine Programme **should not** be used by clinicians to inform treatment decisions.

During the first research phase of the project can the Technology Hubs report test data in batched format to the Clinical Hubs, understanding that clinical reports will be issued where appropriate?

The main concern with batching data transfers from the Technology Hubs to the Clinical Hubs is that this is likely to introduce delays in the overall clinical timeline for a single patient.

As a main aim for the programme is to prove clinically relevant timelines as part of Phase One, the benefits of having fewer, but larger batches of results transmitted to the Clinical Hubs would need to be weighed off against the negative effect on timelines.

Will reporting/data transfer be genotype only or require an element of clinical/scientific interpretation?

The reporting data will be genotype only and clinical interpretation will only be included if it becomes relevant and can be provided by the Technology Hubs within the original per sample costs.

Recruitment

Additional scientific staff will be needed to carry out the assay development and bench work. Is recruitment of postdoctoral research fellows permitted?

Provided the programme standards and requirements are met, we are happy for individual Technology Hubs to decide how they will assign the funding and what staff they choose to recruit. However, given the importance of the CPA accreditation it is important that the staff recruited would be deemed appropriate in that process too.

Funding

The amount of work for each tumour type would be different since the number/nature of genetic abnormalities to be screened differs hugely among these tumours so how will this be reflected in the funding?

Each Clinical Hub will be assigned to a specific Technology Hub by the Stratified Medicine Team to keep the samples flow to each hub as equal as possible. The ECMCs are likely to provide a combination of tumours so we would anticipate the Technology Hubs analysing most of the tumour types although we can't guarantee the numbers will be exactly the same. We are asking Hubs to state what tests they can do out of the list provided for a set amount of £300 so it is up to the individual lab to decide how many and which tests they can do for that amount. We recommend that individual Hubs assume that they will test 3,000 samples, with 600 each of lung, breast, colorectal and prostate, and 300 each of ovarian and melanoma: please indicate this or any other assumptions underlying your application.

Hubs will be DNA RNA resource centres for the SMP. Are there likely to be calls for sample sorting/export for additional projects and if so how will this be funded?

The programme partners may request access to DNA, but this would be funded separately to the programme and they would be required to cover all costs associated with exporting the samples.

Will significant IT solutions and upgrades be funded by the programme?

The Phase One informatics solution will wherever possible build on existing NHS or research systems, although there is a small central funding stream for providing extract routines, clinical messaging formats, import routines and a centrally provided research database; to meet the needs of the programme. Therefore the programme will not be funding in-hospital or in-lab data systems.

The per sample funding is designed to include the necessary resource time for local capture of the data, and the programme will separately design, fund and deliver the extraction and central storage of that data. The results of our Requirements Gathering which have been shared with all ECMCs indicate that the majority of ECMCs would be able to meet the requirements of the programme without significant investment.

The Technology Strategy Board call for data handling will separately fund the development of hospital and lab data handling systems in this area.

Please can you clarify the position on funding and access to equipment as stated in Appendix 1?

Appendix 1 states a standard policy for CRUK on what is considered eligible costs for grants.

The Stratified Medicine Programme will provide up to £300 per sample. However, it is up to the discretion of individual hub to choose where they spend this funding and the programme will not provide any additional money specifically for equipment.

An outline funding model for the Clinical Hubs is discussed in the FAQs does this also apply to the Technology Hubs?

Yes, the exact nature of the how the grants will be structured is being determined, but we expect that a certain % of the funding will be guaranteed in advance to allow any staff required to be hired.

Is the per sample funding expected to cover costs for attendance/travel for steering and working group meetings, or will there be a separate funding of this?

The programme will cover travel costs for delegates attending any steering and working group meetings, in addition to the “per sample” costs. These travel costs will be separately reimbursed in line with Cancer Research UK’s standard practice. Attendance costs (ie per diems, honorariums) will not be funded.

Clinical Hubs

NEW and REVISED Questions

REVISED: At what point in the patient cycle will samples be taken?

Ideally consent would occur before the opportunity to biopsy, or when tissue/FFPE block is already held by the ECMC so that additional procedures are not required. The exact point will vary per tumour type and we are aware that there may be cases when a biopsy is taken before a cancer diagnosis. Whilst we were originally concerned that consenting for a Cancer Research UK study before a diagnosis of cancer could cause distress, we have been made aware of the possibility that consenting patients before diagnosis may be appropriate. We would encourage ECMCs to consider all possibilities for patients to be sensitively and appropriately approached for consent.

REVISED: When is consent permitted in this Programme – is pre-operative and/or post-operative consent permitted? What about pre-biopsy consent?

We appreciate the difficulties in fitting consent for the programme into the patient pathway and we are particularly aware of the sensitivities in consenting patients before cancer diagnosis. To help with this, we intend to provide two versions of the form along with a patient information sheet:

- A supplementary page that can be used with any existing biobanking consent forms allowing consent for Stratified Medicine to be taken at same time as biobanking,
- A full form for those hospitals that do not collect samples for biobanks.

If there is an existing process in the ECMC where consent for tissue for research purposes is obtained pre biopsy and the Stratified Medicine Programme consent forms can be integrated into this, we are happy for applicants to include this in their proposal. We were originally concerned that consenting for a Cancer Research UK study before a diagnosis of cancer could cause distress. We have been made aware of the possibility that consenting patients before diagnosis may be appropriate, and would encourage ECMCs to consider all possibilities for patients to be sensitively and appropriately approached for consent.

REVISED: Can we include more than one Lead Applicant?

In the application form, only one person should be named as Lead Applicant and this should be the named grant holder. However any joint Lead Applicants can be highlighted by inserting '(Lead Applicant)' after their name under the Co-Investigators section (1.4) of the application form. In eGMS, you can add a Joint Lead Applicant(s) in the Supporting Roles section.

When exactly is the submission deadline?

The deadline is midnight on the 8th March. However, please note that once an applicant has pressed the submit button in eGMS it will pass to your administrative authority and they must fully submit it before it is counted as received by CR-UK. It is therefore important to ensure that your administrative authority is available when submitting the application. To ensure fairness and give enough time for the selection process, this deadline cannot be extended.

What needs to be uploaded in the Uploads section of eGMS?

1. Completed main application form
2. Consent form(s) that may be suitable for the programme (single document).
3. Written referrals from relevant individuals (as described in Section 5 of the main applications form) collated into a single document.

Do we need to provide a research abstract?

eGMS is a system designed for research funding. There is therefore a section called “research abstract”. You should use this space to briefly outline your Clinical Hub proposal and how it meets the programme’s needs. It should not cover any local or central “research” aspects that you may be proposing.

Can we provide more information on our proposal in appendices?

We are not able to allow appendices as these could make the overall documents too complex or long for the committee members’ time to review. It’s also designed to minimise the work for applicants.

Will this funding enable the Trust to claim CLRN Service Support Costs and accrual on the NIHR Portfolio?

We hope that the programme will be adopted on the NIHR portfolio. We are working on our application at the moment and will let Trusts know once we have clarity on this.

What are the requirements for blood samples that we would provide – should they be anti-coagulated, spun down, frozen etc?

ECMCs should propose how they wish to send blood samples to Technology Hubs and if there are any feasibility issues with adopting an alternative approach, this should be outlined in the application. If for example, a Centres wishes to use provide spun down cells and keep the plasma for other research purposes, this should also be outlined. Agreement between selected Clinical and Technology Hubs on blood sample requirements will be finalised at a future workshop.

Can we routinely provide samples from patients where neoadjuvant treatment has been successful?

No. The material taken at the time of operation will often contain predominantly dead and dying cells, which may affect the quality of DNA extracted and introduce sample bias. Material from these patients taken prior to treatment (e.g. core biopsy for diagnosis) would however be acceptable.

The Application process for Clinical Hubs

Is it necessary that the existing ECMC Lead is the Lead Applicant?

The Lead Applicant does not have to be the ‘ECMC Lead’, but should be a senior healthcare worker and/or researcher based at the ECMC.

Our Lead Applicant will not be the ECMC Lead. Can a separate box be added in the application form to include their details as well?

ECMC Leads can be named as Co-Investigators (Section 1.4 of the application form) and details provided accordingly. Their position can be highlighted by inserting '(ECMC Lead)' after their name in the application form.

Can the Lead Applicant be Director of Clinical of Research and Development?

Yes.

I am applying from an ECMC outside of England – does willingness to work NHS Improvement (Section 5.3 of the application) still apply?

NHS Improvement is a Health Department for England initiative only. However if there are similar initiatives for your devolved Health Department or you would like to be involved with the NHS Improvement work, this can be briefly described in the free text box provided.

Informatics Requirements

What is the CR-UK Informatics Requirements Gathering exercise, and do our responses to the data requirements gathering exercise affect the selection process?

The Informatics requirements gathering process is a separate piece of work within the programme, which aims to understand what the minimum informatics standards should be for the programme. It was run by Phil Rossiter and Monica Jones, who interviewed data specialists in 17 of the ECMCs to survey what informatics capabilities existed and used this information to define the informatics aspects of the Stratified Medicine Programme calls, as well as to help Cancer Research UK to start designing the central database for the Programme. The responses to the data requirements gathering exercise do not affect the selection process.

A summary anonymised report will be circulated next week for the purpose of information sharing. We will set up meetings to explore these findings and enable sharing of best practice, as requested by ECMCs. In the short term there will also be an opportunity to participate in a teleconference that will go through the report results in more detail. This date will be confirmed shortly.

Individual ECMCs will receive the results of the information that they submitted to us, which can indicate to them if it will be easy or difficult to meet the informatics need of the Stratified Medicine Programme, based on the information submitted. However this information does not form part of the selection process, and ECMCs will only be judged on the information they provide in the Clinical Hub application about how they intend to meet the informatics requirements.

Funding for Clinical Hubs

What funding commitments can we give to enable staff recruitment?

We are aware that organisations may need firm commitments for funding to employ staff such as research nurses or data managers. While the programme aims to incentivise both Clinical and Technology Hubs on the collection and analysis of samples and data, we will

need to commit sufficient funds as each organisation needs to participate. We are considering, for example, committing in advance half of the funds required for the sample collection predicted by the clinical hubs, and will keep hubs updated on this process.

Will the payments from CR-UK for Clinical Hubs or Technology Hub be made to the NHS Trust(s) involved or paid via University?

Payments will go to the Institution stated by the Lead Applicant in eGMS and the application form, which can either be the NHS Trust or the partner university, the Lead Applicant will be responsible for distributing funds to the appropriate partner trusts and departments (e.g. pathology) as appropriate. The programme will monitor funds actually received by the pathology department as we know that pathology resources and buy-in are important for the success of the programme.

Sample collection at the Clinical Hubs

Most of the samples we propose to collect are core/cytology biopsies that are will yield less than 1µg genomic DNA. Can these samples still be collected as part of the programme?

Where possible, we would like to collect 2µg genomic DNA per tumour sample, to ensure sufficient DNA is banked for any further genetic testing. However, we understand this may not be possible with all tumour sample types. Applicants are advised to highlight any sample types they propose to collect that will yield less than 1µg DNA in their application. An absolute minimum quantity may be agreed between selected Clinical and Technical Hubs at a future workshop.

Ethics and Consent

How should consent be organised and are there enough funds to cover the research nurse time for this?

Each individual ECMC should organise consent how they prefer, be it via a dedicated nurse (or other appropriate staff) or via a number of research nurses. A sum for nurse time to take consent has been included in the per sample funding rate; this figure was recommended by the Stratified Medicine Programme Service Delivery Advisory Group, but we will not be prescriptive about how each ECMC decides to allocate funds inside the overall per sample amount.

Is it intended that each centre does a separate ethics application or will there be central ethics?

The Stratified Medicine Programme needs to submit a central ethics application as part of the NIHR process. The programme will therefore supply a central consent form for use by the chosen ECMCs. If ECMCS can demonstrate that their consent forms adequately cover the same consent permissions as the Stratified Medicine Programme consent form, in principle we are happy for these to be used in place of the programme's consent form alongside the programme's Patient Information Sheet. Please note that this is based on NRES acceptance of this approach.

Why are we not adapting existing forms used at the ECMCs?

It was initially hoped that the standard NHS consent form might provide adequate consent for the sample collections, but we collected a range of existing NHS consent forms from ECMCs and found that only 25% are suitable for the programme activities. Existing research consent forms, e.g. for tissue banking, from existing ECMCs were found to contain a high degree of variability. Whilst we appreciate this is frustrating for ECMCs who have existing and suitable consent forms, a central consent form presented the best option in order to cover all hospitals without delaying the start of sample collection. This also allows us to ensure the consent is standardised and future proofed across all samples as the programme is scaled up nationally.

Can we consent patients retrospectively, when they come to their first oncology clinic after their surgery and staging or even later?

Phase One of the programme aims to demonstrate a scalable model for the routine genetic testing of cancer patients, that in the future would inform treatment decisions. Therefore consenting patients shortly after surgery and staging would be acceptable but no later.

Transfer and storage of samples and data between Technology Hubs and Clinical Hubs

Should a patient's tumour and matching blood sample be sent together to the Technology Hub or as and when they are collected?

ECMCs should propose how they wish to send samples to Technology Hubs and if there are any feasibility issues with adopting an alternative approach, this should be outlined in the application. Agreement between selected Clinical and Technology Hubs on this is likely at a future workshop.

Should data exchange between the Clinical Hubs and Technology Hubs be anonymised?

It is expected that Clinical Hubs will be responsible for collation of genetic test results from the Technology Hubs, together with other patient, treatment and outcome data and will provide this to Cancer Research UK in an pseudonymised electronic format. There will ideally be no transfer of genetic results directly from the Technology Hub to the Stratified Medicine Programme at CR-UK.

This means that enough pseudonymised information regarding a patient and the source Clinical Hub must be provided to the Technology Hub to be able to return results to the correct Clinical Hub and associate results with the patient when they are returned. In addition, numbers and dates of samples sent to the Technology Hub responsible for the testing samples should also be sent to CR-UK by the Clinical Hubs, for management purposes.

Patients must also be traceable by the Stratified Medicine Programme, using pseudonymised identifiers held at the Clinical Hubs, Technology Hubs and Cancer Research UK. This will allow Cancer Research UK to provide access to cohorts of DNA samples held by the Technology Hubs without going back to the Clinical Hubs.

The exact detail of the format of the pseudonymised identifiers will be agreed during the workshops to be held once the Technology and Clinical Hubs are chosen, but could be a local patient ID number and/or date of birth for patient linking and Hospital Name and Technology Hub name for Organisation linking for example.

How, and in what format, are the Clinical Hubs going to receive genetic test results from the Technology Hubs?

It is expected that Technology Hubs will be able to transmit results to Clinical Hubs electronically in an agreed XML messaging format. Clinical Hub applicants should detail the proposed approach to receiving, processing and importing results in an electronic format from the Technology Hubs. This should include details of any system-based import functionality which exists in systems currently being used at the Clinical Hub.

Can Clinical Hubs use existing academic systems to store information in addition to the clinical systems used for patient care?

The expectation of the Stratified Medicine Programme is that the Clinical Hubs will be able to transmit data to Cancer Research UK in a standardised electronic format. This can be from a single system or a variety of linked clinical and research systems. If existing academic systems are to be used then they will need to demonstrate that they have the appropriate Information Governance and Data Protection arrangements in place. Details of these can be found in the NHS IG Toolkit <https://www.igt.connectingforhealth.nhs.uk> The process of utilising existing systems and any estimations on time and/or resource overheads in compiling data from multiple source systems should be outlined in your application. Any data transmitted to CR-UK should also be fully tested by the Clinical Hubs to ensure data is extracted accurately.

As part of the programme we will be looking to develop best practice guidance on how to adapt existing systems to meet the data capture and processing requirements of a national Stratified Medicine Initiative. The purpose of this is to ensure the resulting information flow/validation overheads do not quickly become over burdensome when scaling the process up to a national scale.