**Approved list of cancers and their eligibility criteria**

**Updated April 2018**: The information on this page is taken directly from the “Cancer Eligibility Criteria Version 4.0” document. The aim of this page is to provide an up-to-date list of eligibility criteria for cancer types approved for recruitment.

**Note**: It is important to recognise that conventional clinical**diagnosis** and clinical**trials samples** for these cancers take priority.

Where it is possible to take sufficient material or an additional sample, this can be submitted through existing NHS GMC pathways and processes for inclusion in the 100,000 Genomes Project.

[**General Guidance on Inclusion and Exclusion**](https://www.webarchive.org.uk/wayback/archive/20210325120604mp_/https:/www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/information-for-gmc-staff/cancer-programme/eligibility/)

* All participants must receive all usual clinical care.
* Tumour samples should be obtained as **fresh** or **fresh frozen** and not FFPE and pathways of care to facilitate this collection should be established.  
  In a limited number of allowed circumstances optimised FFPE (see [sample handling guidance](https://www.webarchive.org.uk/wayback/archive/20210325120604mp_/https:/www.genomicsengland.co.uk/information-for-gmc-staff/sample-handling-guidance/)) will be accepted (note the genomic interpretation will be lower quality).
* Access to appropriate **high quality DNA** from both tumour and germline samples enabling Whole Genome Sequencing is required.
* Samples must have been **processed** according to the requirements set out in Annexes F and H, and any other standard operating procedures issued during the Term.
* Potential participants not wanting to **consent** for the study or participate in all aspects of the Project should be excluded. The patient may opt out of receipt of secondary findings not relevant to their cancer diagnosis.
* Recruitment after negative results from **another research project** – a patient who has had whole genome sequencing as part of another project should not be recruited to the 100,000 Genomes Project (unless otherwise agreed) as this will be unlikely to provide additional information.
* Patients may be recruited in parallel to a clinical trial provided the clinical trial sample will not be compromised and the sample will not undergo Whole Genome Sequencing. If the trial involves Whole Exome Sequencing please contact the service desk to discuss the appropriateness of also Whole Genome Sequencing the tumour.
* There is a requirement to provide Essential Sample Data and Core Data, therefore potential participants seen from another centre for specialist care, or where only Samples are received, cannot be recruited unless **sufficient data** will be obtainable from local centres.
* All potential participants must be residents of England, Scotland, Northern Ireland or Wales and be under the care of and be followed up by the NHS in England. Those in England and Wales must have an **NHS number**and those resident in Scotland or Northern Ireland their country equivalent.

[**Inclusion Criteria for Cancer**](https://www.webarchive.org.uk/wayback/archive/20210325120604mp_/https:/www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/information-for-gmc-staff/cancer-programme/eligibility/)

* Patients must have a **diagnosis** from a WHO/IARC cancer classification
* Ability to collect the specified **dataset** within agreed timescales.
* Provision of informed **consent** in accordance with the Services Specification, Annex N – consent and patient recruitment and the Genomics England Protocol.
* **Previously treated patients**: (including those with haematological malignancies (see below)), are now eligible who:
  + present with a recurrence of a previously treated tumour (with chemotherapy, hormone therapy and/or radiotherapy). This may be a local or metastatic recurrence.
  + have undergone chemotherapy, hormone therapy and/or radiotherapy for their cancer, but fail to respond to this treatment and progress.
  + have received neoadjuvant therapy (treatment before intended surgical resection) for their tumour.
  + have undergone chemotherapy, hormone therapy and or radiotherapy for a previous tumour.

Collection of pre-treated tumour samples (e.g. from biopsy) and subsequent treated tumour samples in a time course series will be of particular value.

* **Stored samples** can be used providing that all of the following conditions apply:  
  1. Samples are Fresh Frozen (not FFPE);  
  2. Samples were taken after 1 January 2015;  
  3. Patients must have the potential to benefit from inclusion in the project;  
  4. Where the stored sample numbers do not exceed 10% of contracted volumes; and  
  5. Where all other aspects of the contractual requirements can be met including:
  + Consent for inclusion specifically in the 100,000 Genomes Project;
  + The specified dataset can be collected;
  + Samples have been processed in accordance with the applicable Annexes and sample handling guidance and have passed the relevant QC requirements.

Where collections of DNA or samples exist and consist of **more than 20** individuals or were obtained **before 1 January 2015** but meet other criteria outlined, permission on a case by case basis can be given by Genomics England and NHS England for inclusion in the main programme, subject to NHS GMCs completing a proforma

[**Exclusion Criteria for Cancer**](https://www.webarchive.org.uk/wayback/archive/20210325120604mp_/https:/www.genomicsengland.co.uk/about-genomics-england/the-100000-genomes-project/information-for-gmc-staff/cancer-programme/eligibility/)

**Ineligible** **cancer types** (plans are being developed to introduce many of these during the lifetime of the Project):

* Cervical, vaginal and vulval carcinomas other than melanomas
* Endocrine malignancies (except thyroid cancers)
* Squamous and basal skin carcinoma
* Haematological malignancies (see below)
* Malignancies from, placenta, heart, male genital tract other than prostate and testis or melanoma
* Benign tumours
* Carcinoma*in situ* (except bladder) and borderline ovarian tumours.

Please also see the separate page on [haematological malignancies](https://www.webarchive.org.uk/wayback/archive/20210325120604mp_/https:/www.genomicsengland.co.uk/information-for-gmc-staff/cancer-programme/haematological-malignancies/)

Where a patient is found to be ineligible on the basis of these criteria after initial recruitment, **the patient must be informed** that they can no longer be included in the project.

**Currently approved cancer conditions**

* Unless otherwise specifically excluded, all samples from **invasive malignancies** are eligible.
* Samples may be from the **primary** lesion, or from a **metastasis**.
* Samples collected at **re-occurrence** will only be considered for whole genome sequencing if there is a primary sample available: either stored or previously submitted.
* **Recurrent tumours** without a primary sample may be submitted where advised in writing, and will be considered if:

1. The time scale from primary tumour to the recurrent tumour is such that a strong clinical case could be put that this is in fact a second primary.
2. There was no opportunity to store frozen tissue from the primary when it was resected.

* **Multiple samples** can now be accepted from a single patient. These can be from synchronous tumours; metastatic and primary samples; samples from different locations within a tumour or samples taken at different time points. Detailed guidance can be accessed in the Sample Handling Guidance.
* **Small tumour size** is not a contraindication to recruitment and guidance on techniques for sampling small tumours is available in the Sample Handling Guidance.

Approved cancer conditions to date are **invasive forms** of the following cancer types. Any **rare malignancy** within these organs are eligible unless specifically excluded.

**View list of cancer types**

* Gynaecological cancers encompassing several anatomical descriptions/sites including fallopian, endometrial, ovarian and primary peritoneal
* Lung cancer
* Prostate cancer
* Colorectal cancer
* Breast cancer
* Sarcoma (including paediatric and adult sarcoma)
* Renal cancer
* Adult Brain Tumours
* Bladder cancer
* Melanoma
* Upper gastrointestinal (GI) tumours
* Hepatopancreatobiliary tumours
* Testicular cancer
* Head and Neck Cancers
* Cancer of Unknown Primary
* Childhood Solid Tumours
* Neuroendocrine tumours (except benign)
* Haematological Malignancies (see below)
* Thyroid cancers (except micropapillary thyroid carcinoma with no metastases)