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Genomics England

Cancer Sample Tracking

Document Management

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Version Control

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# Introduction

Purpose

The purpose of this document is to describe the data that Genomic Medicine Centres are asked to supply to accompany the samples submitted for analysis. The GMC laboratory will provide a set of sample metadata, and a set of test results, for each sample successfully processed. The complete set should be supplied and accepted by Genomics England at or before the time at which the derived products for example, the extracted DNA, are dispatched to the Genomics England Biorepository.

Audience

This document is primarily written for informatics leads within the GMCs and those involved in the collection and submission of data for the UK 100,000 Genomes Project.

Related Documents

This document should be read in conjunction with:

• Genomics England Data Model Catalogue ([Genomics England Sample Tracking](https://gelmc.extge.co.uk/catalogue/dataModel/40407@3.0.0))

• Example CSV Files

• NHS England GMC Service Specification

* Appendix A, B, C, D, E, F and G (contained in this release pack)

How to use this document

This document is split into sections that describe the information we expect to receive within the context of each csv submission. The document is primarily split by file type. Within each csv, we expect to receive a set of rows of data. Within each row we expect to receive a number of data elements, each of which is associated with a name, a brief explanation, a multiplicity, a datatype and often a business rule. The business rule reference refers to the rule id at the back of the document,

NOTE: this document should be used in conjunction with the User Guidance for Cancer Data Specification Document. In particular see the sample tracking related appendices for more information on

CSV file definitions:

A list of data elements included in each csv submission. Each data element describes the information within the corresponding rows the constraints on the values and the header text (first row of the csv) which is the name of the data element.

Each data element has a data type and some have business rules. Click on the hyperlinks in the document to navigate to each of these.

Data types:

Types, rules and enumerations that constrain the value of a data element.

*Rules* are expressed as regular expressions and/or groovy code.

*Enumerations* are described by their code and description.

NOTE: Enumerations in grey are deprecated. Although deprecated codes will continue to be accepted they will be removed from the next release and users are encouraged to use other suitable codes.

Business rules:

Contains business rules that apply across data elements within the context of a csv file submission i.e. if the we submit a test of type is x we expect test result value of y.

NOTE: this document should be used in conjunction with the User Guidance for Cancer Data Specification Document.

Completeness:

A value is ‘mandatory’ as part of the csv submission if the corresponding data element has a multiplicity of 1..1.

Where an item has a multiplicity of 0..1 it is considered ‘non-mandatory’ **however**, please see the business rules associated with each data element as many of the ‘optional’ columns are mandatory in certain contexts.

# Glossary

|  |  |
| --- | --- |
| FF | Fresh Frozen |
| FFPE | Formalin-Fixed Paraffin Embedded |
| LIMS | Laboratory Information Management System |
| GMC | Genomic Medical Centre |
| CSV | Comma separated variable |
| NHS | National Health Service |
| GeL | Genomics England |
| ODS | Organisation Data Service |
| QC | Quality Control |
| XML | Extensible Markup Language |
| EDTA | Ethylenediaminetetraacetic Acid |
| GS1 (data matrix) | 2 Dimensional Bar-code |
| ICD | International Classification of Diseases |
| SNOMED | Systemized Nomenclature of Medicine |
| CT | Clinical Terminology |
| RT | Reference Terminology |
| LOINC | Logical Observation Identifiers Names and Codes |
| BuRST | Genomics England Logging Service |

# Sample Tracking Validation

Validation to take place before submission of file

NHS GMCs should only submit files that are deemed valid by the current standards contained in this document.

It is expected that NHS GMCs who are submitting CSVs will have validated them before submission.

Validation after submission of file

An additional layer of validation takes place after file submission. If the CSV is invalid, one the following types of errors will be raised:

## Header errors

An error in the headers of the CSV fields means that we cannot determine what type of CSV has been submitted. The headers for each CSV type are determined by the definition within the Genomics England Model Catalogue. Headers are case-insensitive, and may include whitespace before or after the field name, but must otherwise appear exactly as specified within the Catalogue. The ordering of fields is not important. If any header errors are found, a message is sent via the Basic Report Subscription Tool (BuRST) and processing stops.

## Field syntax errors

If the headers are correct, then processing continues on each row. Each value must conform to the field definition given in the Genomics England Model Catalogue. Enumerations (the values within the fields) are checked to ensure conformance; these are case insensitive. If any syntax errors are found, a message is sent to BuRST and processing stops.

## Validation error

If the headers match a CSV definition and every row is syntactically valid, then the message is stored in the database staging tables to aid debugging. Each row is now checked to ensure semantic conformance to database consistency rules and business rules specific to sample tracking processes. In most cases, this is carried out row-by-row, but some rules require a consistency check across all rows received. All validation error messages are collated and a single response is sent to BuRST; processing then **stops**.

## Warning Message

If the headers match a CSV definition and every row is syntactically valid, then the message is stored in the database staging tables to aid debugging. Each row is now checked to ensure semantic conformance to database consistency rules and business rules specific to sample tracking processes. In most cases, this is carried out row-by-row, but some rules require a consistency check across all rows received. In addition if an enumeration has been deprecated but continues to be submitted, the data will be processed and a warning message will be generated. All warning messages are collated and a single response is sent to BuRST; processing then **continues.**

All headers and field datatypes are described in the Genomics England Model Catalogue as well as this document. Validation rules generating error and warning messages are informally described in this document, ordered by CSV file type.

Submissions failing validation

Submissions that fail validation will be rejected and a message will be sent to BuRST, as well as an email advising any individuals subscribed to warning messages for that GMC.

If no validation error messages are found, checking proceeds to find potential inconsistencies that may require further investigation. The contents of the CSV are checked row-by-row, and then further consistency checks are applied across all rows.

All warning messages are collated, and a single message sent to BuRST. Processing continues as normal. It is important to note that where successful data transfer has not taken place, samples must not be sent to the biorepository

General CSV Validation Rules

* If the order of the columns within the CSVs is incorrect then a *Header Error* is raised.
* If a CSV column header titles don’t match the titles of data elements in the current data model a *Header Error* is raised
* If a CSV column header title is missing a *Header Error* is raised
* If the data submitted for a data element which is defined as mandatory in the data model is missing a *Field Syntax Error* is raised
* If the data submitted for a data element does not validate against the constraints (string, integer etc.) a *Field Syntax Error* is raised

General CSV Validation Rules for incoming GMC\_GEL\_Sample\_Metadata\_Cancer.csv

* When a tumour or germline sample is dispatched there should be a minimum of 2 samples for every cancer participant i.e. ***Clinic Sample Type*** from the CONSTITUTIONAL DNA classification and one from the TUMOUR DNA classification
  + The **exceptions** are:
    - The submission of circulating tumour cells (Streck plasma/EDTA plasma) required for cancer **omics**
    - If there is a metachronous tumour sample from a patient i.e. if there were previously successfully sequenced tumour and germline samples there is no requirement to send a further germline sample. For haematological malignancies where the tumour sample type would be ‘DNA Blood Tumour’ or ‘DNA\_Bone\_Marrow\_Aspirate\_Tumour\_Sorted\_Cells’, FF or FFPE samples are not expected.

General CSV Validation Rules for incoming GMC\_to\_GeL\_test\_result csv

* The Metadata file will be accepted but a warning message is sent via BuRST if a sample has not had a QC result submitted

# Sample Tracking Submission FAQs

## How are files date stamped?

Unix Timestamp

**GMC\_GEL\_Sample\_Metadata\_Cancer\_[UNIX Timestamp]\_[Version].CSV**

*i.e. GMC\_GEL\_Sample\_Cancer\_Metadata\_1427703622\_3.0.0*

**GMC\_to\_GEL\_Test\_Results\_Cancer\_[UNIX Timestamp]\_[Version].csv**

*i.e. GMC\_to\_GEL\_Test\_Cancer\_Results\_1427703622\_3.0.0*

## How are organisational details included?

The Laboratory ID value is detailed in Genomics England Data Model**.**  Files are submitted to an end point only available to that organisation.

## How is version numbering handled for re-submission?

For any updates please contact Genomics England Service Desk.

## How are header rows identified?

The top row of the file is the header row.

## How are data rows identified?

Rows beneath the top row (the header row) are the data rows.

## Are there any special “end of data” identifiers?

No

## Types of data items?

Data items and their types are all defined at length in the Genomics England Data Model Catalogue. Access to Genomics England Data Model Catalogue is available through your NHS GMC Lead Organisation

## Are trailing spaces accepted?

No

## Are leading spaces accepted?

No

## Are future dates allowed?

Yes – in the case of the dispatch date

## Are historic dates allowed?

Only to the start of the 100,000 project - 2014

## How are punctuation and special characters to be managed?

Use of delimiters and other characters which need to be managed in a comma separated values file are covered in the [RFC 4180](http://tools.ietf.org/html/rfc4180) specification which is explained via this link;

[https://super-csv.github.io/super-csv/csv\_specification.html](https://super-csv.github.io/super-csv/csv_specification.html%20) .

Note that as of the current release the system cannot process double quotes

## Comment Lines in CSV files

Do not add comment lines in CSV files.

There is a specific field for Fixation Comments.

## Blank Lines

Blank lines in a comma separated values file will terminate the processing of that file in the Genomics England system.

## Are Omics processed differently?

Submission of circulating tumour cells (Streck plasma/EDTA plasma) required for cancer **omics** do not need to be dispatched with a minimum of 2 samples for every cancer participant

## Sample Metadata FAQs

The following time points appear in the dataset related to cold ischaemic time and should be filled in accordingly:

* Clinic Sample DateTime
* Fixation Start DateTime
* Snap Freezing Start DateTime

### FFPE Samples – Macrodissection

In this context, the definition of macrodissection is dissection of tumour for tumour enrichment and removal from slide or H&E section.

### Pre-invasive elements

Description of atypia or in situ disease, if present, e.g. DCIS for breast, adenomas for colorectal, and PIN for prostate.

## Sample Quality FAQs

### Tumour Content - Assessment

Tumour content should be assessed in an H&E stained section as follows:

* Percentage of tumour cell nuclei present expressed as a proportion of all cell nuclei present (including admixed inflammatory and stromal cells) to the nearest 10%
* It should be noted that the assessment should be based on nuclear size/volume as a surrogate marker of DNA content rather than surface area of tumour on the slide, such that a small cluster of lymphocytes will yield more DNA than an equivalent sized nest of tumour cells, in which each cell will be larger.
* This model does not take into account the 3-dimensional nature of the tissue in the block (and how this is represented in serial sections) or tumour cell hyperdiploidy/aneuploidy
* Within the marked area only if macrodissection is to be performed
* Viable tumour only, excluding necrotic areas or apoptotic cells
* It may be useful to apply a ‘binary’ decision map: ie < or > 50% tumour, if more, then < or > 75%.

### Test Result Type – Cellularity - Assessment

Cellularity is defined as the total number of cells (neoplastic and non-neoplastic) in the tumour sample from which DNA was harvested.

Cellularity should be estimated according to the following categories:

|  |  |
| --- | --- |
| **Category** | **Number of cells** |
| Very low | <700 cells |
| Low | <4,000 cells |
| Medium | 4,000-10,000 |
| High | >10,000 cells |
| Very high | >50,000 cells |

This can be achieved by quickly counting the cells present in a small representative area of the slide and then multiplying this up to estimate the total cellularity of the section. In order to take account of 3D nature of the tissue, and given the size of tumour cell nuclei (on average), numbers of tumour cells in a 10um section can be calculated by counting (as described) and then adding a multiplication factor of 0.5.

# GMC to GeL Sample Metadata Cancer

For each sample successfully processed, the GMC laboratory will provide a set of sample metadata to Genomics England, at the point when the derived products are dispatched to the Biorepository. Sample metadata must be successfully transferred before the samples are dispatched, GMCs must ensure they have no 'fail' burst warnings before samples are dispatched. This information will be supplied in csv format with each row of data containing the following values:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Description** | **Multiplicity** | **Data Type** | **Business Rules** |
| **Participant ID (12502@1.0.0)** | Participant Identifier (supplied by Genomics England) | 1..1 | [participantId](#34495) | [Participant ID GMC-ID-Range Check (41961) Participant-Clinic-Sample-ID Uniqueness (42061) GMC Test Result Rule (42080) Participant Tumour Sample Type Dispatched (42222) Participant Tumour Extraction Protocol Dispatched (42223)](#41961) |
| **Clinic ID (12503@1.0.0)** | ODS code for GMC clinic where the sample was taken. | 1..1 | [odsCode](#42020) | [Participant-Clinic-Sample-ID Uniqueness (42061) Clinic Sample Datetime Uniqueness (42073)](#42006) |
| **Sample ID (12607@1.0.0)** | The barcode from the sample tube used for sample collection at the GMC clinic. Different clinics may use different identifiers within their local LIMS to identify the sample collected in their clinic, so this identifier is not globally unique across programme. However, within the context of a single clinic, this id must be used to identify the samples collected in that clinic and must be unique within the context of that clinic. NOTE, CSV files can contain multiple rows with the same sample id and different laboratory sample id. | 1..1 | [sampleId](#34515) | [Participant-Clinic-Sample-ID Uniqueness (42061) Clinic Sample Datetime Uniqueness (42073) GMC Test Result Rule (42080)](#42061) |
| **Clinic Sample Type (12616@1.0.0)** | The type of the sample (against specified enumeration) | 1..1 | [gmcSampleType](#34458)  >10 enumerations, please click link above to view full list. | [Sample Volume Rule (42128) Tumour Morphology Mandatory (42140) Tumour Clinic Sample Type Mandatory Elements (42149) Fresh Frozen Tumours Mandatory Elements (42152) Participant Tumour Sample Type Dispatched (42222) Participant Tumour Extraction Protocol Dispatched (42223) Sample Submission (42224) Sample Metadata Sample Type Required QC Results (42240) FFPE Tumour Mandatory Elements (42146)](#42128) |
| **Clinic Sample DateTime (12617@1.0.0)** | Timestamp containing the date and time the sample was taken in clinic. This must be captured on the sample linkage form and transferred into the GMC LIMS. | 1..1 | [xs:dateTime](#59) | [Clinic Sample Datetime Uniqueness (42073) Clinic Sample Datetime Post Consent (42075) Clinic Sample Datetime Not Future (42076)](#42073) |
| **Laboratory ID (12619@1.0.0)** | ODS code of the laboratory organisation used for sample processing i.e. extraction, QC, collection or dispatch N.B. this could relate to a Blood Extraction Facility for QC data, otherwise we expect this to be a GMC Laboratory | 1..1 | [odsCode](#42020) |  |
| **Laboratory Sample ID (12621@1.0.0)** | The 2D barcode from the FluidX tube used for dispatch from the Laboratory to the GeL Biorepository. This identifier must be unique. | 1..1 | [laboratorySampleId](#34471) | [Laboratory Sample ID Uniqueness (42079) GMC Test Result Rule (42080) Laboratory Sample ID Dispatch Rule (42082)](#42079) |
| **Laboratory Sample Volume (12622@1.0.0)** | Volume of the product in the laboratory sample tube as dispatched | 0..1 | [volumeInMicroliters](#34534) | [Sample Volume Rule (42128)](#42128) |
| **Laboratory Remaining Volume Banked (12624@1.0.0)** | Amount of additional product remaining at the laboratory (which may be zero) N.B. DNA concentration must be > 30ng/ul for normal germline samples and >10ng/ul for tumour DNA | 0..1 | [volumeInMicroliters](#34534) | [Sample Volume Rule (42128)](#42128) |
| **GMC Sample Dispatch Date (12626@1.0.0)** | Datetime at which the sample is dispatched to the GeL Biorepository | 1..1 | [xs:dateTime](#59) | [GMC Consignment Post Consent (42130) GMC Consignment Dispatch (42131)](#42130) |
| **GMC Sample Consignment Number (12627@1.0.0)** | The consignment number used by the transport service.  NHS BT Consignment Number always starts with an ODS Code [a-zA-Z0-9]{3,9} and then "-" clinic number \d{2} and then "-" and then week number \d{1,2} and then "-" and then year number \d{2} and then "-" and then \d{1,2} This is only unique across a particular week - not unique to a dispatch | 1..1 | [gmcConsignmentNo](#42005) | [GMC Rack ID Well Consignment Uniqueness (42132) GMC Consignment Dispatch (42131) Participant Tumour Sample Type Dispatched (42222) Participant Tumour Extraction Protocol Dispatched (42223)](#42132) |
| **GMC Rack Well (12893@1.0.0)** | The GMC must record the position of the sample in the Rack they send to the biorepository. Each rack has 96 wells.  The position of a sample in these wells is coded from A-H on the x-axis (short side) and 1-12 on the y-axis (long side) i.e. A3 | 1..1 | [rackWell](#34510) | [GMC Rack ID Well Consignment Uniqueness (42132)](#42132) |
| **GMC Rack ID (12625@1.0.0)** | Barcode on the containing rack as dispatched | 1..1 | [rackId](#34509) | [GMC Rack ID Well Consignment Uniqueness (42132)](#42132) |
| **Tumour Type (14721@3.1.2)** | The type of the tumour sampled and sent for sequencing  For haematological cancers only 'primary' is applicable. | 0..1 | [tumourType](#32950)   |  |  | | --- | --- | | **primary** | Primary; source of cancer tumour sample | | **recurrence\_of\_primary\_tumour** | Recurrence; a tumour has returned at the site of the original cancer | | **metastatic\_recurrence** | Metastatic (different cancer site) which developed and was sampled after presentation | | **metastases** | Metastatic (different cancer site) which was present and sampled at diagnosis instead of the primary tumour | | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |
| **Excision Margin (14904@3.1.2)** | An indication of whether the excision margin was clear of the tumour and if so, by how much.  Where there is more than one measurement, record the closest or closest relevant margin.  Where actual measurements are not taken use options 01, 05 or 06 as applicable. | 0..1 | [excisionMargin](#589)  [>10 enumerations, please click link above to view full list.](#589) |  |
| **Tumour Size (29075@3.1.2)** | Maximum dimension in mm on the histopathology report | 0..1 | [diameterInMm](#40396) |  |
| **Morphology (ICD) (14871@3.1.2)** | The morphology code for the diagnosed cancer as defined by ICDO3. This can be recorded as well as or instead of MORPHOLOGY (SNOMED). Allows for multiple codes delimited by a comma surrounded by double quotes: e.g "M/9876,M/49587". | 0..1 | [multipleMorphologyICD](#42115) | [Tumour Morphology Mandatory (42140)](#42140) |
| **Morphology (SNOMEDRT) (31243@3.1.2)** | The morphology code for the diagnosed cancer as defined by SnomedRT. This can be recorded as well as or instead of MORPHOLOGY (ICD). Allows for multiple codes delimited by a comma surrounded by double quotes: e.g. "xxxxxx,xxxxxxx" | 0..1 | [multipleMorphologySnomedRT](#42120) | [Tumour Morphology Mandatory (42140)](#42140) |
| **Morphology (SNOMEDCT) (31244@3.1.2)** | The morphology code for the diagnosed cancer as defined by SNOMED CT. This can be recorded as well as or instead of MORPHOLOGY (ICD). Allows for multiple codes delimited by a comma surrounded by double quotes: e.g."xxxxxx,xxxxxxx" | 0..1 | [multipleMorphologySnomedCT](#42124) | [Tumour Morphology Mandatory (42140)](#42140) |
| **Tissue Source (14724@3.1.2)** | Tissue Source of Sample | 0..1 | [tissueSource](#32928)  [>10 enumerations, please click link above to view full list.](#32928) | [Tumour Clinic Sample Type Mandatory Elements (42149) Needle Core Biopsies Mandatory Elements (42166) Mandatory for Biopsy (42232) Tissue Source applicable to Disease Type (42263)](#42149) |
| **Pre-invasive Elements (14872@3.1.2)** | Description of atypia or in situ disease, if present. Input needs to be surrounded by double quotes i.e. "xxxx, xxxx xxxx" | 0..1 | [xs:string](#38) |  |
| **Topography (ICD) (31228@3.1.2)** | This is the topographical site of the tumour as categorised by ICD03 | 0..1 | [topographyIcdo3](#414) |  |
| **Topography (SNOMEDCT) (14876@3.1.2)** | This is the topographical site of the tumour as categorised by SNOMED CT. | 0..1 | [topographySnomedCt](#573) |  |
| **Topography (SNOMEDRT) (31227@3.1.2)** | This is the topographical site of the tumour as categorised by SNOMED RT | 0..1 | [topographySnomed](#571) |  |
| **Macrodissected (14888@3.1.2)** | Was macrodissection used for tumour enrichment? | 0..1 | [yesNo](#34541)   |  |  | | --- | --- | | **yes** | Yes | | **no** | No | | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |
| **Macrodissection Details (14889@3.1.2)** | Any details of the macrodissection, if applicable. Input needs to be surrounded by double quotes i.e. “xxxxx,xxxxxxx” | 0..1 | [xs:string](#38) |  |
| **Snap Freezing Start DateTime (29081@3.1.2)** | Date and time sample frozen | 0..1 | [xs:dateTime](#59) | [Snap Freezing DateTime Post Consent (42138) Fresh Frozen Tumours Mandatory Elements (42152)](#42138) |
| **Type of Fixative (29080@3.1.2)** | Type of fixative used during pre-processing | 0..1 | [fixativeType](#32788)   |  |  | | --- | --- | | **formal\_saline** | Formal saline | | **neutral\_buffered\_formalin** | Neutral buffered Formalin | | **umfix** | UMFix | | **paxgene** | Paxgene | | **other** | Other | | [FFPE Tumour Mandatory Elements (42146)](#42146) |
| **Fixation Start DateTime (14750@3.1.2)** | The date and time that the sample was put into fixative | 0..1 | [xs:dateTime](#59) | [Fixation Start DateTime Post Consent (42143) FFPE Tumour Mandatory Elements (42146)](#42143) |
| **Fixation End DateTime (14883@3.1.2)** | Date and time the sample was removed from fixative | 0..1 | [xs:dateTime](#59) | [Fixation End DateTime Post Consent (42144) FFPE Tumour Mandatory Elements (42146)](#42144) |
| **Fixation Comments (29076@3.1.2)** | Any additional comments regarding fixation surrounded by double quotes i.e. "xxxx, xxxx xxxx" | 0..1 | [xs:string](#38) |  |
| **Processing Schedule (29079@3.1.2)** | Fixation time on processor | 0..1 | [processingSchedule](#32889)   |  |  | | --- | --- | | **overnight** | Overnight (routine) | | **urgent** | Rapid run | | **extended** | Extended (>48hrs) | | **extra\_large\_program** | Extra Large Program (prostate only) | | [Processing Schedule Prostate Only (42145) FFPE Tumour Mandatory Elements (42146)](#42145) |
| **Time in formalin on processor (35516@3.1.2)** | Time in formalin while on processor, recorded as a decimal value | 0..1 | [timeInHours](#32926) | [FFPE Tumour Mandatory Elements (42146)](#42146) |
| **Number of Biopsies (35525@3.1.2)** | Number of biopsies, applicable if Genomics England sample tissue source is a biopsy | 0..1 | [xs:nonNegativeInteger](#50) | [Mandatory for Biopsy (42232)](#42232) |
| **Gauge of Biopsies (35524@3.1.2)** | Gauge of biopsy, applicable if Genomics England sample tissue source is a biopsy | 0..1 | [gaugeOfBiopsy](#32794) | [Needle Core Biopsies Mandatory Elements (42166)](#42166) |
| **DNA Extraction Protocol (30637@3.1.2)** | DNA extraction protocol for tumour sample. For FFPE please distinguish between extraction protocol. For fresh frozen no distinction is necessary | 0..1 | [dnaExtractionProtocol](#32765)   |  |  | | --- | --- | | **covaris** | GeL Covaris 65 (FFPE) | | **qiagen\_80** | GeL Qiagen 80 (FFPE) | | **qiagen\_90** | GeL Qiagen 90 (FFPE) | | **fresh\_frozen** | Fresh Frozen | | **cell\_pellet\_extraction** | Cell Pellet Extraction | | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |
| **Prolonged Sample Storage (30640@3.1.2)** | Prolonged sample storage method, if applicable | 0..1 | [sampleStorage](#32913)   |  |  | | --- | --- | | **refrigeration** | refrigeration (2-8 C) | | **vac\_pack** | vacuum pack at room temperature | | **refrigeration\_and\_vac\_pack** | refrigeration (2-8 C) and vacuum pack | | **room\_temp** | room temperature | |  |
| **Tumour Sample Type (35507@3.1.2)** | This applies only to FFPE samples and describes the tumour sample type that DNA was extracted from. Does not apply for FF samples. | 0..1 | [tumourSampleType](#32949)   |  |  | | --- | --- | | **sections** | section | | **cores** | cores | | **scrolls** | scrolls | | **blocks** | blocks | | [FFPE Tumour Mandatory Elements (42146) Tumour Sample Type Scroll Element Mandatory (42254) Tumour Sample Type Section Mandatory Data Elements (42256) Tumour Sample Type Block Mandatory Data Element (42258) Tumour Sample Type Core Mandatory Data Elements (42257)](#42146) |
| **Scroll Thickness (35512@3.1.2)** | Thickness of Scrolls, applicable if sample type is scrolls | 0..1 | [thicknessInMicrometres](#34532) | [Tumour Sample Type Scroll Element Mandatory (42254)](#42254) |
| **Number of Scrolls (35509@3.1.2)** | Number of scrolls, applicable if sample type is scrolls | 0..1 | [xs:nonNegativeInteger](#50) | [Tumour Sample Type Scroll Element Mandatory (42254)](#42254) |
| **Number of Sections (35508@3.1.2)** | Number of sections, applicable if sample type is sections | 0..1 | [xs:nonNegativeInteger](#50) | [Tumour Sample Type Section Mandatory Data Elements (42256)](#42256) |
| **Section Thickness (35511@3.1.2)** | Thickness of section, applicable if sample type is section | 0..1 | [thicknessInMicrometres](#34532) | [Tumour Sample Type Section Mandatory Data Elements (42256)](#42256) |
| **Number of Blocks (35517@3.1.2)** | Number of blocks, applicable if sample type is blocks | 0..1 | [xs:nonNegativeInteger](#50) | [Tumour Sample Type Block Mandatory Data Element (42258)](#42258) |
| **Core Diameter (35513@3.1.2)** | Core Diameter, applicable if sample type is core | 0..1 | [diameterInMm](#40396) | [Tumour Sample Type Core Mandatory Data Elements (42257)](#42257) |
| **Number of Cores (35510@3.1.2)** | Number of cores, applicable if sample type is cores | 0..1 | [xs:nonNegativeInteger](#50) | [Tumour Sample Type Core Mandatory Data Elements (42257)](#42257) |
| **Tumour ID (42230@3.1.2)** | A locally allocated identifier for the participant's tumour. This should be unique for each tumour submitted from a patient. Two tumours resected at the same time would have unique Tumour IDs.  All sample reports and event reports that relate to a Genomics England tumour sample must have a locally allocated Tumour ID. Tumour IDs must be unique within the context of a GMC Clinic and should conform to the following convention: Clinic ID proceeded by "\_" proceeded by the local tumour identifier used to refer to a tumour, which must be between 1 and 16 alphanumeric characters i.e. RN3\_A098BC | 0..1 | [tumourID](#42261) | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |
| **Disease Type (12834@3.1.2)** | The cancer type of the tumour sample submitted to Genomics England.  The list of disease types will be validated against the types contained in Appendix A. These may be subject to change and GMCs are requested to ensure that data capture systems are flexible enough to accommodate future changes to the list of diseases contained in Appendix A.  If this is unknown at registration, it can be updated as part of the patient information in the core data submissions. | 0..1 | [xs:string](#38) | [Processing Schedule Prostate Only (42145) Disease Type and Subtype Consistency (42262) Tumour Clinic Sample Type Mandatory Elements (42149) Tissue Source applicable to Disease Type (42263)](#42145) |
| **Disease Subtype (42236@3.1.2)** | The subtype of the cancer in question, recorded against a limited set of supplied enumerations.  The list of disease subtypes will be validated against the subtypes contained in Appendix A. These may be subject to change and GMCs are requested to ensure that data capture systems are flexible enough to accommodate future changes to the list of diseases contained in Appendix A.  This is to enable high-level grouping and analysis of the tumour type. It is understood that this may not be available at Registration or may change between Registration and submission of Core data.  If the diagnosis is not listed as a subtype it can be entered under “other”.  A tumour comprised of more than one subtype should be entered as follows: The predominant tumour subtype in the sample sent for whole genome sequencing should be entered first. The remaining subtypes should be entered in descending order with the most prevalant subtype in the whole tumour listed second. It is helpful to include “mixed tumour type” as a subtype but this should not be entered alone.  Allows for multiple subtypes delimited by a comma surrounded by double quotes i.e. "xxxxxx,xxxxxxx" | 0..1 | [xs:string](#38) | [Tumour Clinic Sample Type Mandatory Elements (42149) Disease Type and Subtype Consistency (42262)](#42149) |
| **Retrospective Sample (42264@3.1.2)** | Has the sample been stored and retrospectively dispatched? If the dispatched sample has been stored from previous testing please answer true. If the dispatched sample is a new sample for GeL please answer false. | 0..1 | [xs:boolean](#34)   |  |  | | --- | --- | | **0** | False | | **1** | True | | **true** | True | | **false** | False | | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |
| **Previous Treatment (42268@3.1.2)** | Record if the participant has had anti-cancer treatment (chemotherapy, radiotherapy, endocrine therapy) for this cancer or any other site prior to this sample collection. | 0..1 | [previousTreatment](#42269)   |  |  | | --- | --- | | **neoadjuvant** | Previous treatment (neoadjuvant) for this cancer (chemotherapy / radiotherapy or endocrine therapy) | | **historic\_treatment** | Previous historic treatment for this cancer type (chemotherapy / radiotherapy or endocrine therapy) | | **historic\_treatment\_other** | Previous historic treatment for another cancer type (chemotherapy / radiotherapy or endocrine therapy) | | **no\_previous\_treatment** | No previous treatment for this or any other cancer type (chemotherapy / radiotherapy or endocrine therapy) | | [Tumour Clinic Sample Type Mandatory Elements (42149)](#42149) |

# GMC to GeL Test Results

For each sample successfully processed, the GMC laboratory will provide a set of test results to Genomics England, at or before the point when the derived products (in particular, the extracted DNA) are despatched to the GeL Biorepository. This information will be supplied in csv format with each row of data containing the following values:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Description** | **Multiplicity** | **Data Type** | **Business Rules** |
| **Sample ID (12607@1.0.0)** | The barcode from the sample tube used for sample collection at the GMC clinic. Different clinics may use different identifiers within their local LIMS to identify the sample collected in their clinic, so this identifier is not globally unique across programme. However, within the context of a single clinic, this id must be used to identify the samples collected in that clinic and must be unique within the context of that clinic. NOTE, CSV files can contain multiple rows with the same sample id and different laboratory sample id. | 1..1 | [sampleId](#34515) | [Participant-Clinic-Sample-ID Uniqueness (42061) Clinic Sample Datetime Uniqueness (42073) GMC Test Result Rule (42080)](#42061) |
| **Test Result Type (12608@1.0.0)** | QC test result type | 1..1 | [gmcTestResults](#34459)  >10 enumerations, please click link above to view full list. | [Test Results Type Value (42241) Sample Metadata Sample Type Required QC Results (42240)](#42241) |
| **Test Result DateTime (12609@1.0.0)** | The date and time that the test results were obtained | 1..1 | [xs:dateTime](#59) |  |
| **Test Result Value (12610@1.0.0)** | The value obtained | 1..1 | [xs:string](#38) | [Test Results Type Value (42241)](#42241) |
| **Participant ID (12502@1.0.0)** | Participant Identifier (supplied by Genomics England) | 1..1 | [participantId](#34495) | [Participant ID GMC-ID-Range Check (41961) Participant ID Clinic Check (42006) Participant-Clinic-Sample-ID Uniqueness (42061) GMC Test Result Rule (42080) Participant Tumour Sample Type Dispatched (42222) Participant Tumour Extraction Protocol Dispatched (42223)](#41961) |
| **Laboratory ID (12619@1.0.0)** | ODS code of the laboratory organisation used for sample processing i.e. extraction, QC, collection or dispatch N.B. this could relate to a Blood Extraction Facility for QC data, otherwise we expect this to be a GMC Laboratory | 1..1 | [odsCode](#42020) | [Laboratory ID Consistency (42077)](#42077) |
| **Laboratory Sample ID (12621@1.0.0)** | The 2D barcode from the FluidX tube used for dispatch from the Laboratory to the GEL Biorepository. This identifier must be unique. | 1..1 | [laboratorySampleId](#34471) | [Laboratory Sample ID Uniqueness (42079) GMC Test Result Rule (42080) Laboratory Sample ID Dispatch Rule (42082)](#42079) |

# Data Types

**diameterInMm**

**(Genomics England Shared)**

diameter in mm

|  |  |
| --- | --- |
| Unit of Measure | millimeter (meter\*10^-3 |
| Rule | x==~/\d\*\.?\d\*/ |
| Rule based on  xs:decimal (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseDecimal(string(x)) in BigDecimal |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**dnaExtractionProtocol**

**(Cancer Model)**

protocol for DNA extraction

|  |  |
| --- | --- |
| **Code** | **Description** |
| covaris | GeL Covaris 65 (FFPE) |
| qiagen\_80 | GeL Qiagen 80 (FFPE) |
| qiagen\_90 | GeL Qiagen 90 (FFPE) |
| fresh\_frozen | Fresh Frozen |
| cell\_pellet\_extraction | Cell Pellet Extraction |

**Usages**

[GMC to Gel Sample Metadata Cancer](#40558)

**excisionMargin**

**(Cancer Outcomes and Services Dataset)**

An indication of whether the excision margin was clear of the tumour and if so, by how much.  
  
Where there is more than one measurement, record the closest or closest relevant margin.  
Where actual measurements are not taken use options 01, 05 or 06.  
Note that not some values are applicable to specific tumour types

|  |  |  |  |
| --- | --- | --- | --- |
| Rule | string(2) | | |
| **Code** | | **Description** |
| 01 | | Excision margins are clear (distance from margin not stated) |
| 02 | | Excision margins are clear (tumour >5mm from the margin) |
| 03 | | Excision margins are clear (tumour >1mm but less than or equal to 5mm from the margin |
| 04 | | Tumour is less than or equal to 1mm from excision margin, but does not reach margin |
| 05 | | Tumour reaches excision margin |
| 06 | | Uncertain |
| 07 | | Margin not involved =>1mm |
| 08 | | Margin not involved <1mm |
| 09 | | Margin not involved 1-5mm |
| 98 | | Not applicable |
| 99 | | Not Known |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**fixativeType**

**(Cancer Model)**

fixative type used pre-processing

|  |  |
| --- | --- |
| **Code** | **Description** |
| formal\_saline | Formal saline |
| neutral\_buffered\_formalin | Neutral buffered Formalin |
| umfix | UMFix |
| paxgene | Paxgene |
| other | Other |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**gaugeOfBiopsy**

**(Cancer Model)**

.

|  |  |
| --- | --- |
| Rule based on  xs:nonNegativeInteger (XMLSchema) | minInclusive(0) |
| Rule based on  xs:integer (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseInteger(string(x)) in BigInteger |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**gmcConsignmentNo**

**(Genomics England Shared)**

GMC NHS BT Sample Consignment Number. An NHS BT Consignment Number always starts with an ODS Code [a-zA-Z0-9]{3,9}  
and then "-" clinic number \d{2} and then "-" and then week number \d{1,2} and then "-" and then year number \d{2} and then "-" and then \d{1,2}

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z]{3,9}-\d{2}-\d{1,2}-\d{2}-\d{1,2} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**gmcSampleType**

**(Genomics England Shared)**

GMC Sample Type

|  |  |  |  |
| --- | --- | --- | --- |
| Based On | SampleType (Genomics England Shared) | | |
| **Code** | | **Description** |
| dna\_blood\_germline | | DNA Blood Germline (CONSTITUTIONAL DNA) |
| dna\_saliva | | DNA Saliva (CONSTITUTIONAL DNA) |
| dna\_fibroblast | | DNA Fibroblast (CONSITUTIONAL DNA) |
| dna\_ff\_germline | | DNA FF Germline (CONSTITUTIONAL DNA) - non tumour tissue |
| dna\_ffpe\_tumour | | DNA FFPE Tumour (TUMOUR DNA) |
| dna\_ff\_tumour | | DNA FF Tumour (TUMOUR DNA) |
| dna\_blood\_tumour | | DNA Blood from blood in Haematological malignancy Tumour (TUMOUR DNA) |
| dna\_bone\_marrow\_aspirate\_tumour\_sorted\_cells | | DNA Bone Marrow Aspirate Tumour Sorted Cells (TUMOUR DNA) (Haem Onc samples) |
| tumour\_tissue\_ffpe | | Tumour Tissue FFPE (OMICS SAMPLES) |
| lysate\_ffpe | | Lysate FFPE (OMICS SAMPLES) |
| lysate\_ff | | Lysate FF (OMICS SAMPLES) |
| lysed\_tumour\_cells | | Deparaffinised Lysed Tumour Cells in RNA-stabilised buffer (OMICS SAMPLES) |
| buffy\_coat | | Buffy Coats (OMICS SAMPLES) |
| streck\_plasma | | Streck Plasma (OMICS SAMPLES) |
| edta\_plasma | | EDTA Plasma - Plasma for ctDNA (OMICS SAMPLES) |
| lihep\_plasma | | LiHep Plasma (OMICS SAMPLES) |
| serum | | Serum (OMICS SAMPLES) |
| rna\_blood | | RNA Blood (OMICS SAMPLES) |
| tumour\_tissue\_ff | | Tumour\_Tissue\_FF (OMICS SAMPLES) |
| tumour\_scrapings | | FFPE Tumour scrapings or slides (OMICS SAMPLES) |
| additional\_tumour\_material | | Additional Tumour material for research (OMICS SAMPLES) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**gmcTestResults**

**(Genomics England Shared)**

GMC Constrained List of Tests

|  |  |  |  |
| --- | --- | --- | --- |
| Based On | GMCLaboratoryTests (Genomics England Shared) | | |
| **Code** | | **Description** |
| absolute\_cell\_count | | Absolute cell count (number of cells) |
| agarose | | Agarose (Pass / Fail) |
| cellularity | | The total number of cells (neoplastic and non-neoplastic) in the tumour sample from which DNA was harvested Very low (<700 cells), Low (<4,000 cells), Medium (4,000-10,000 cells), High (>10,000 cells), Very high (>50,000 cells) |
| delta\_cq | | delta Cq |
| nanodrop\_od\_260\_280 | | Nanodrop OD 260/280 |
| *nanodrop\_concentration* | | *Nanodrop concentration ng/ul* |
| percent\_necrosis | | Proportion of the submitted tumour sample that is necrotic (0-100) |
| picogreen\_concentration | | Picogreen Concentration ng/ul |
| *picodrop\_concentration* | | *PicoDrop Concentration ng/ul* |
| picodrop\_od\_260\_280 | | PicoDrop OD 260/280 |
| qubit | | Qubit ng/ul |
| summary\_qc | | Summary QC Pass / Fail |
| tumour\_content | | Proportion of the total number of nuclei in the submitted sample that are neoplastic nuclei (Low, Medium, High) – Low <40%; Medium 40-60%; High>60%. |
| trinean\_od\_260\_280 | | Trinean OD 260/280 |
| glomax\_concentration | | Glomax concentration ng/ul |
| *trinean\_concentration* | | *Trinean Concentration ng/ul* |

**Usages**

[GMC to GeL Test Results](#40559)

**laboratorySampleId**

**(Genomics England Shared)**

Laboratory Sample ID (GS1 Data Matrix)

|  |  |
| --- | --- |
| Regular Expression | \d{10} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**multipleMorphologyICD**

**(Cancer Sample Tracking GeL GMC)**

Morphology ICD03 code. Allows for multiple codes delimited by a comma.

|  |  |
| --- | --- |
| Rule | x ==~/([a-zA-Z0-9.\-\/]{5,7},)\*([a-zA-Z0-9.\-\/]{5,7})/ |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**multipleMorphologySnomedCT**

**(Cancer Sample Tracking GeL GMC)**

For use in pilot project only at present. Please contact cosd@ncin.org.uk for further details. This is the morphology of the tumour as categorised by SNOMED CT. Allows for multiple codes delimited by a comma.

|  |  |
| --- | --- |
| Regular Expression | (\d{6,18},)\*\d{6,18} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**multipleMorphologySnomedRT**

**(Cancer Sample Tracking GeL GMC)**

This is the morphology of the tumour as categorised by SNOMED RT. Allows for multiple codes delimited by a comma.

|  |  |
| --- | --- |
| Regular Expression | ([a-zA-Z0-9]{6,8},)\*[a-zA-Z0-9]{6,8} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**odsCode**

**(NHS Data Dictionary GEL Subset)**

All valid ODS Codes

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z0-9]{3,9} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**participantId**

**(Genomics England Shared)**

Genomics England participant identifier (supplied by Genomics England)

|  |  |
| --- | --- |
| Regular Expression | \d{9} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**previousTreatment**

**(Cancer Sample Tracking GeL GMC)**

Previous treatment for cancer

|  |  |
| --- | --- |
| **Code** | **Description** |
| neoadjuvant | Previous treatment (neoadjuvant) for this cancer (chemotherapy / radiotherapy or endocrine therapy) |
| historic\_treatment | Previous historic treatment for this cancer type (chemotherapy / radiotherapy or endocrine therapy) |
| historic\_treatment\_other | Previous historic treatment for another cancer type (chemotherapy / radiotherapy or endocrine therapy) |
| no\_previous\_treatment | No previous treatment for this or any other cancer type (chemotherapy / radiotherapy or endocrine therapy) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**processingSchedule**

**(Cancer Model)**

processing schedule

|  |  |
| --- | --- |
| **Code** | **Description** |
| overnight | Overnight (routine) |
| urgent | Rapid run |
| extended | Extended (>48hrs) |
| extra\_large\_program | Extra Large Program (prostate only) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**rackId**

**(Genomics England Shared)**

Barcode on the containing rack as dispatched (128 Barcode)

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z]{2}\d{8}|\d{8}|\d{10} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**rackWell**

**(Genomics England Shared)**

The GMC must record the position of the sample in the Rack they send to the biorepository.  
Each rack is has 96 wells. The position of a sample in these wells is coded from A-H and 1-12

|  |  |
| --- | --- |
| Regular Expression | [A-H][1-9]|[A-H][1][0-2] |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**sampleId**

**(Genomics England Shared)**

The sample id i.e the barcode from the sample tube used for sample collection at the GMC clinic.  
This will be a Code-128 Barcode

|  |  |
| --- | --- |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**sampleStorage**

**(Cancer Model)**

Sample storage method

|  |  |
| --- | --- |
| **Code** | **Description** |
| refrigeration | refrigeration (2-8 C) |
| vac\_pack | vacuum pack at room temperature |
| refrigeration\_and\_vac\_pack | refrigeration (2-8 C) and vacuum pack |
| room\_temp | room temperature |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**thicknessInMicrometres**

**(Genomics England Shared)**

Double-precision 64-bit floating point type legal literals {0, -0, INF, -INF and NaN} Example, -1E4, 12.78e-2, 12 and INF

|  |  |
| --- | --- |
| Regular Expression | ^[+]?\d+([.]\d+)?$ |
| Rule based on  xs:double (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseDouble(string(x)) in Double |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**timeInHours**

**(Cancer Model)**

Time in hours, recorded as a decimal number

|  |  |
| --- | --- |
| Unit of Measure | hour (time in hours |
| Regular Expression | ^[+]?\d+([.]\d+)?$ |
| Rule based on  xs:double (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseDouble(string(x)) in Double |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**tissueSource**

**(Cancer Model)**

Tissue source

|  |  |
| --- | --- |
| **Code** | **Description** |
| bma\_tumour\_sorted\_cells | Bone marrow aspirate tumour sorted cells |
| ct\_guided\_biopsy | CT-guided biopsy |
| endoscopic\_biopsy | Endoscopic biopsy |
| endoscopic\_ultrasound\_guided\_biopsy | Endoscopic ultrasound guided biopsy |
| endoscopic\_ultrasound\_guided\_fna | Endoscopic ultrasound guided fine needle aspirate |
| laparoscopic\_biopsy | Laparoscopic biopsy |
| laparoscopic\_excision | Laparoscopic excision |
| mri\_guided\_biopsy | MRI-guided biopsy |
| non\_guided\_biopsy | Non-guided biopsy |
| surgical\_resection | Surgical resection |
| stereotactically\_guided\_biopsy | Stereotactically guided biopsy |
| uss\_guided\_biopsy | USS-guided biopsy |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**topographyIcdo3**

**(Cancer Outcomes and Services Dataset)**

The topographical site code for the tumour as defined by ICDO3. This will normally be derived by Registries.

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z0-9.\-\/]{3,7} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**topographySnomed**

**(Cancer Outcomes and Services Dataset)**

This is the topographical site of the tumour as categorised by SNOMED RT

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z0-9]{6,8} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**topographySnomedCt**

**(Cancer Outcomes and Services Dataset)**

For use in pilot project only at present. Please contact cosd@ncin.org.uk for further details.  
  
  
This is the topographical site of the tumour as categorised by SNOMED CT.

|  |  |
| --- | --- |
| Regular Expression based on  snomedCt (Cancer Outcomes and Services Dataset) | \d{6,18} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**tumourID**

**(Cancer Model)**

Genomics England Tumour Identifier

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z0-9]{3,9}\_[a-zA-Z0-9]{1,16} |
| Rule based on  xs:string (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**tumourSampleType**

**(Cancer Model)**

|  |  |
| --- | --- |
| **Code** | **Description** |
| sections | section |
| cores | cores |
| scrolls | scrolls |
| blocks | blocks |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**tumourType**

**(Cancer Model)**

|  |  |
| --- | --- |
| **Code** | **Description** |
| primary | Primary; source of cancer tumour sample |
| recurrence\_of\_primary\_tumour | Recurrence; a tumour has returned at the site of the original cancer |
| metastatic\_recurrence | Metastatic (different cancer site) which developed and was sampled after presentation |
| metastases | Metastatic (different cancer site) which was present and sampled at diagnosis instead of the primary tumour |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**volumeInMicroliters**

**(Genomics England Shared)**

Volume in microliters

|  |  |
| --- | --- |
| Unit of Measure | microliters (Volume in microliters |
| Regular Expression | ^[+]?\d+([.]\d+)?$ |
| Rule based on  xs:double (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseDouble(string(x)) in Double |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**xs:boolean**

**(XMLSchema)**

Binary-valued logic legal literals

|  |  |
| --- | --- |
| **Code** | **Description** |
| 0 | False |
| 1 | True |
| true | True |
| false | False |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**xs:dateTime**

**(XMLSchema)**

Specific instant of time. ISO 8601 extended format YYYY-MM-DDThh:mm:ss. Example, to indicate 1:20 pm on May the 31st, 1999 for Eastern Standard Time which is 5 hours behind Coordinated Universal Time (UTC): 1999-05-31T13:20:00-05:00.

|  |  |
| --- | --- |
| Rule | import static javax.xml.bind.DatatypeConverter.\*  parseDateTime(string(x)) in Calendar |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**xs:nonNegativeInteger**

**(XMLSchema)**

Infinite set {0, 1, 2,...}. Sign omitted, “+” assumed. Example: 1, 0, 12678967543233, +100000.

|  |  |
| --- | --- |
| Rule | minInclusive(0) |
| Rule based on  xs:integer (XMLSchema) | import static javax.xml.bind.DatatypeConverter.\*  parseInteger(string(x)) in BigInteger |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

**xs:string**

**(XMLSchema)**

Character strings in XML.

|  |  |
| --- | --- |
| Rule | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

[GMC to GeL Test Results](#40559)

**yesNo**

**(Genomics England Shared)**

Boolean, yes no response

|  |  |
| --- | --- |
| **Code** | **Description** |
| yes | Yes |
| no | No |

**Usages**

[GMC to GeL Sample Metadata Cancer](#40558)

# Business Rules

### Clinic Sample Datetime Post Consent (42075)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **A Clinic Sample DateTime must be a date after the original date of consent** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-01** |
| Status | **FINAL** |

### Participant Tumour Extraction Protocol Dispatched (42223)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample Type** **Participant ID** **GMC Sample Consignment Number** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Multiple tumour samples/multiple regions dispatched at the same time must have the same DNA Extraction Protocol**  **Essential for all tumour samples taken at the same time from the same participant to have the same clinic sample type and DNA extraction protocol.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-14** |
| Version Created | **2016-09-13** |
| Status | **FINAL** |

### Clinic Sample Datetime Not Future (42076)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GEL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **The Clinic Sample Datetime should not be in the future** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-01** |
| Status | **FINAL** |

### Laboratory Sample ID Uniqueness (42079)

|  |  |
| --- | --- |
| Data Elements | **Laboratory Sample ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GEL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Laboratory Sample ID must be unique across the programme** |
| Error Condition | **VALIDATION RULE** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-14** |
| Version Created | **2016-09-02** |
| Status | **FINAL** |

### Fresh Frozen Tumours Mandatory Elements (42152)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample Type** **Snap Freezing Start DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Mandatory for all Fresh Frozen Tumour (DNA FF Tumour) samples – see Clinic Sample Type** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-03** |
| Version Created | **2016-09-09** |
| Status | **FINAL** |

### Needle Core Biopsies Mandatory Elements (42166)

|  |  |
| --- | --- |
| Data Elements | **Tissue Source** **Gauge of Biopsies** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **If Tissue Source is Needle Core Biopsy then Gauge of Biopsies Mandatory otherwise not required. Please refer to user guidance for needle core biopsy tumour tissue sources.** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-12** |
| Status | **FINAL** |

### Tumour Sample Type Section Mandatory Data Elements (42256)

|  |  |
| --- | --- |
| Data Elements | **Number of Sections** **Tumour Sample Type** **Section Thickness** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL submissions** |
| Trigger | **Sample Tracking CSV's Received** |
| Description | **If Tumour Sample Type is Section then the linked Data Element is Mandatory** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-03** |
| Version Created | **2016-09-26** |
| Status | **FINAL** |

### Sample Submission (42224)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Samples can only be dispatched if a germline sample is dispatched within the same submission OR if the sample is a longitudinal sample, when a germline sample has already been dispatched and passed post-sequencing QC** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-13** |
| Status | **FINAL** |

### Participant ID GMC-ID-Range Check (41961)

|  |  |
| --- | --- |
| Data Elements | **Participant ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **For each row, the Participant ID must be in the range allocated to the submitting NHS GMC** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-13** |
| Version Created | **2016-08-03** |
| Status | **FINAL** |

### Tumour Sample Type Core Mandatory Data Elements (42257)

|  |  |
| --- | --- |
| Data Elements | **Core Diameter** **Number of Cores** **Tumour Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **If Tumour Sample Type is core then the linked Data Elements are Mandatory** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-11** |
| Version Created | **2016-09-26** |
| Status | **FINAL** |

### Processing Schedule Prostate Only (42145)

|  |  |
| --- | --- |
| Data Elements | **Processing Schedule** **Disease Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **extra\_large\_program processing schedule can only be submitted if the participant is registered with a Disease Type (Registration) of Prostate - if not a warning needs to be generated** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-04** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Tumour Sample Type Block Mandatory Data Element (42258)

|  |  |
| --- | --- |
| Data Elements | **Number of Blocks** **Tumour Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **If Tumour Sample Type is Block then Data Element is Mandatory** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV Rejected** |
| Notification Target | **GMC Submitter, GeL service management** |
| Last Updated | **2016-10-03** |
| Version Created | **2016-09-26** |
| Status | **FINAL** |

### Sample Volume Rule (42128)

|  |  |
| --- | --- |
| Data Elements | **Laboratory Sample Volume** **Laboratory Remaining Volume Banked** **Clinic Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Laboratory Sample Volume AND Laboratory Remaining Volume Banked Mandatory for all Blood, Saliva (Constitutional DNA) and Tumour (extracted Tumour DNA) samples – see Clinic Sample Type (12616.3 - https://gelmc.extge.co.uk/#/40548/dataElement/34408/history )**  **Optional for all other samples** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-16** |
| Version Created | **2016-09-07** |
| Status | **FINAL** |

### GMC Rack ID Well Consignment Uniqueness (42132)

|  |  |
| --- | --- |
| Data Elements | **GMC Sample Consignment Number** **GMC Rack Well** **GMC Rack ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **The combination of GMC Rack Well and GMC Rack ID must be unique per GMC Sample Consignment.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-14** |
| Version Created | **2016-09-07** |
| Status | **FINAL** |

### GMC Consignment Post Consent (42130)

|  |  |
| --- | --- |
| Data Elements | **GMC Sample Dispatch Date** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **GMC Sample Dispatch Date must after the original date of consent** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-07** |
| Status | **FINAL** |

### Clinic Sample Datetime Uniqueness (42073)

|  |  |
| --- | --- |
| Data Elements | **Sample ID** **Clinic ID** **Clinic Sample DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **All samples submitted with the same (Sample ID and Clinic ID pair) need to have the same Clinic Sample Datetime** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-13** |
| Version Created | **2016-09-01** |
| Status | **FINAL** |

### Tumour Morphology Mandatory (42140)

|  |  |
| --- | --- |
| Data Elements | **Morphology (SNOMEDRT)** **Morphology (SNOMEDCT)** **Morphology (ICD)** **Clinic Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **For each row, if the Clinic Sample Type is of DNA\_FF\_Tumour or DNA\_FFPE\_tumour tumour type, then one of the Morphology fields (Morphology (ICD), Morphology (Snomed RT), Morphology (SnomedCT)) must be completed** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GEL service management** |
| Last Updated | **2016-09-13** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Laboratory Sample ID Dispatch Rule (42082)

|  |  |
| --- | --- |
| Data Elements | **Laboratory Sample ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **For each row, the Laboratory Sample ID must not have already been dispatched.** **The Laboratory Sample ID must not be repeated in the submission.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-26** |
| Version Created | **2016-09-02** |
| Status | **FINAL** |

### FFPE Tumour Mandatory Elements (42146)

|  |  |
| --- | --- |
| Data Elements | **Tumour Sample Type** **Time in formalin on processor** **Processing Schedule** **Fixation End DateTime** **Fixation Start DateTime** **Type of Fixative** **Clinic Sample Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Data Elements Mandatory for all tumour DNA sample with Clinic Sample Type of dna\_ffpe\_tumour. Optional for samples that are not DNA FFPE Tumour Type** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Tumour Sample Type Scroll Element Mandatory (42254)

|  |  |
| --- | --- |
| Data Elements | **Scroll Thickness** **Tumour Sample Type** **Number of Scrolls** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSV's Received** |
| Description | **If the Tumour Sample Type is Scroll then the linked Data Element is Mandatory otherwise it is Optional** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-03** |
| Version Created | **2016-09-26** |
| Status | **FINAL** |

### Test Results Type Value (42241)

|  |  |
| --- | --- |
| Data Elements | **Test Result Value** **Test Result Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **The rules contained in Appendix D will be applied across the test result type and test result value data points i.e. a test value where the test result type is Agarose should fail validation unless the value is Pass or Fail. Please see Appendix D for further details.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-30** |
| Version Created | **2016-09-14** |
| Status | **FINAL** |

### Snap Freezing DateTime Post Consent (42138)

|  |  |
| --- | --- |
| Data Elements | **Snap Freezing Start DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **A Snap Freezing Start must be a date after the original date of consent - this should trigger a validation error** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Fixation End DateTime Post Consent (42144)

|  |  |
| --- | --- |
| Data Elements | **Fixation End DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **A Fixation End DateTime must be a date after the original date of consent** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Tumour Clinic Sample Type Mandatory Elements (42149)

|  |  |
| --- | --- |
| Data Elements | **Tissue Source** **Clinic Sample Type** **Macrodissected** **Tumour Type** **DNA Extraction Protocol** **Tumour ID** **Disease Subtype** **Retrospective Sample** **Previous Treatment** **Disease Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Elements Mandatory for all Tumour (Tumour DNA) samples – see Clinic Sample Type** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Disease Type and Subtype Consistency (42262)

|  |  |
| --- | --- |
| Data Elements | **Disease Type** **Disease Subtype** **Disease Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **GMC GeL Sample Metadata CSV Received, Registration, Disease Information Received** |
| Description | **Combination of disease type and subtype submitted must be consistent with the combinations marked within Appendix A.** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-28** |
| Status | **FINAL** |

### Mandatory for Biopsy (42232)

|  |  |
| --- | --- |
| Data Elements | **Tissue Source** **Number of Biopsies** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **Mandatory data elements if tissue source is biopsy** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-14** |
| Status | **FINAL** |

### Tissue Source applicable to Disease Type (42263)

|  |  |
| --- | --- |
| Data Elements | **Tissue Source** **Disease Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **GMC GeL Sample Metadata CSV Received** |
| Description | **Tissue source submitted for each disease type should match Appendix B.** |
| Error Condition | **WARNING MESSAGE** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-28** |
| Status | **FINAL** |

### Fixation Start DateTime Post Consent (42143)

|  |  |
| --- | --- |
| Data Elements | **Fixation Start DateTime** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **A Fixation Start DateTime must be a date after the original date of consent** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-08** |
| Status | **FINAL** |

### Sample Metadata Sample Type Required QC Results (42240)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample Type** **Test Result Type** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **GMC GeL Sample Metadata CSV Received** |
| Description | **Metadata file will be accepted but a warning message is sent via BuRST if a sample has not had a QC result submitted.** **Please see Appendix C for sample test result matrix. All combinations of sample type / test result that are marked with an R are required. If a metadata file has been sent prior to receiving all the test results marked with an R a warning message will be sent.** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-14** |
| Status | **FINAL** |

### Participant Tumour Sample Type Dispatched (42222)

|  |  |
| --- | --- |
| Data Elements | **Clinic Sample Type** **Participant ID** **GMC Sample Consignment Number** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **All tumour samples dispatched in the same consignment, from the same participant should have the same clinic sample type i.e. they should all be ff or ffpe.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-14** |
| Version Created | **2016-09-13** |
| Status | **FINAL** |

### Participant-Clinic-Sample-ID Uniqueness (42061)

|  |  |
| --- | --- |
| Data Elements | **Sample ID** **Clinic ID** **Participant ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **A Sample ID for a participant (ID) should be unique within a clinic. i.e .no two participants can have the same Sample ID and Clinic ID.** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-13** |
| Version Created | **2016-09-01** |
| Status | **FINAL** |

### GMC Consignment Dispatch (42131)

|  |  |
| --- | --- |
| Data Elements | **GMC Sample Dispatch Date** **GMC Sample Consignment Number** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **All samples with the same GMC Sample Consignment Number must have the same GMC Sample Dispatch Date.** **NOTE - this is a warning as consignment numbers are only unique per week (not per dispatch)** |
| Error Condition | **WARNING** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission processed, warning logged** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-10-12** |
| Version Created | **2016-09-07** |
| Status | **FINAL** |

### GMC Test Result Rule (42080)

|  |  |
| --- | --- |
| Data Elements | **Participant ID** **Laboratory Sample ID** **Sample ID** |
| Component | **Sample Tracking** |
| Rule Focus | **GMC to GeL Submissions** |
| Trigger | **Sample Tracking CSVs Received** |
| Description | **If the Laboratory Sample ID AND Sample ID has already had test results submitted then the Participant ID must match the Participant provided in that submission** |
| Error Condition | **VALIDATION ERROR** |
| Issue Record | **Email, BuRST** |
| Notification | **Submission Failing Validation, CSV rejected** |
| Notification Target | **GMC submitter, GeL service management** |
| Last Updated | **2016-09-26** |
| Version Created | **2016-09-02** |
| Status | **FINAL** |