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Genomics England

Rare Disease Sample Tracking

Document Management

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Version Control

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| Version | Date | Summary of Changes |
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| 1.1.0 | 28/08/2015 | update |
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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 B, C, D (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.

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.

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\_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\_[Timestamp].csv**

*i.e. GMC\_GEL\_Sample\_Metadata\_1427703622*

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

*i.e. GMC\_to\_GEL\_Test\_Results\_1427703622*

## 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.

### GMC\_to\_GE\_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)** | 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](#54292) |  |
| **Test Result Type (12608)** | QC test result type | 1..1 | [gmcTestResults](#54233) |  |
| **Test Result DateTime (12609)** | The date and time that the test results were obtained | 1..1 | [xs:dateTime](#59) |  |
| **Test Result Value (12610)** | The value obtained | 1..1 | [xs:string](#38) |  |
| **Participant ID (12502)** | Participant Identifier (supplied by Genomics England) | 1..1 | [participantId](#48455) |  |
| **Laboratory ID (12619)** | 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)** | 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](#48427) |  |

### GMC\_GE\_Sample\_Metadata

For each blood sample successfully processed, the GMC laboratory will provide a set of sample metadata to Genomics England, at or before the point when the derived products 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** |
| **Participant ID (12502)** | Participant Identifier (supplied by Genomics England) | 1..1 | [participantId](#48455) |  |
| **Sample ID (12607)** | 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](#48479) |  |
| **Clinic ID (12503)** | ODS code for GMC clinic where the sample was taken. | 1..1 | [odsCode](#42020) |  |
| **Clinic Sample Type (12616)** | The type of the sample (against specified enumeration) | 1..1 | [gmcSampleType](#48412) |  |
| **Clinic Sample DateTime (12617)** | 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) |  |
| **Laboratory ID (12619)** | 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)** | 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](#48427) |  |
| **Laboratory Sample Volume (12622)** | Volume of the product in the laboratory sample tube as dispatched | 1..1 | [volumeInMicroliters](#48500) |  |
| **Laboratory Method (12623@0.0.9 )** | Version of Genomics England protocol used for sample handling and processing | 1..1 | [gelSampleProtocolVersion](#11453) **v1**:v1 of the Genomics England sample handling and processing protocol **v2**:v2 of the Genomics England sample handling and processing protocol |  |
| **Laboratory Remaining Volume Banked (12624)** | 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 | 1..1 | [volumeInMicroliters](#48500) |  |
| **GMC Rack ID (12625)** | Barcode on the containing rack as dispatched | 1..1 | [rackId](#48471) |  |
| **GMC Sample Dispatch Date (12626)** | Datetime at which the sample is dispatched to the GEL Biorepository | 1..1 | [xs:dateTime](#59) |  |
| **GMC Sample Consignment Number (12627)** | 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](#48410) |  |
| **GMC Rack Well (12893)** | 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](#48472) |  |

# Data Types

**gelSampleProtocolVersion**

**(Genomics England Shared)**

Version of the Genomics England Protocol used for sample handling and processing

|  |  |
| --- | --- |
| **Code** | **Description** |
| v1 | v1 of the Genomics England sample handling and processing protocol |
| v2 | v2 of the Genomics England sample handling and processing protocol |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

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

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

**gmcSampleType**

**(Genomics England Shared)**

GMC Sample Type

|  |  |
| --- | --- |
| **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 CD128 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)* |
| dna\_bone\_marrow\_aspirate\_tumour\_cells | DNA Bone Marrow Aspirate Tumour Cells (TUMOUR DNA) (Haem Onc samples) |
| bone\_marrow\_rna\_gtc | Bone Marrow RNA stored in GTC buffer (OMICS SAMPLES) |
| blood\_rna\_gtc | Blood RNA stored in GTC buffer (OMICS SAMPLES) |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

**gmcTestResults**

**(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* |
| tapestation\_din\_value | Tapestation DIN Value (0 to 10) |
| tapestation\_din\_percent\_over\_23kb | Tapestation Percent Over 23kb |

**Usages**

[GMC\_to\_GE\_Test\_Results](#55398)

**laboratorySampleId**

**(Genomics England Shared)**

Laboratory Sample ID (GS1 Data Matrix)

|  |  |
| --- | --- |
| Regular Expression | \d{10} |
| Rule based on  xs:string (XMLSchema 0.0.1) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

[GMC\_to\_GE\_Test\_Results](#55398)

**odsCode**

**(NHS Data Dictionary GEL Subset)**

All valid ODS Codes

|  |  |
| --- | --- |
| Regular Expression | [a-zA-Z0-9]{3,9} |
| Rule based on  xs:string (XMLSchema 0.0.1) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

[GMC\_to\_GE\_Test\_Results](#55398)

**participantId**

**(Genomics England Shared)**

Genomics England participant identifier (supplied by Genomics England)

|  |  |
| --- | --- |
| Regular Expression | \d{9} |
| Rule based on  xs:string (XMLSchema 0.0.1) | import static javax.xml.bind.DatatypeConverter.\*  true && (x = parseString(string(x))) |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

[GMC\_to\_GE\_Test\_Results](#55398)

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

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

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

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

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

**Usages**

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**volumeInMicroliters**

**(Genomics England Shared)**

Volume in microliters

|  |  |
| --- | --- |
| Unit of Measure | microliters (Volume in microliters |
| Regular Expression | ^[+]?\d+([.]\d+)?$ |
| Rule based on  xs:double (XMLSchema 0.0.1) | import static javax.xml.bind.DatatypeConverter.\*  parseDouble(string(x)) in Double |

**Usages**

[GMC\_GE\_Sample\_Metadata](#55397)

**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\_GE\_Sample\_Metadata](#55397)

[GMC\_to\_GE\_Test\_Results](#55398)

**xs:string**

**(XMLSchema)**

Character strings in XML.

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

**Usages**

[GMC\_to\_GE\_Test\_Results](#55398)