




# Cancer Model 3.2.0

## Release Note

### 100,000 Genomes Project Release Notes

<b>Functional Area</b>	Participants	<b>Document Key</b>	-
<b>Document Owner</b>	Amanda O'Neill	<b>Status</b>	Final
<b>Document Author</b>	Sam Hubble	<b>Version</b>	1.0
<b>Document Reviewer(s)</b>	Adam Milward – Metadata Engineer	<b>Version Date</b>	13/03/2017
	Clare Craig – Cancer Programme GMC liaison	<b>Next Review Date</b>	n/a
	Joanne Mason – Director of sequencing and sample acquisition		
<b>Document Approval</b>	Amanda O'Neill – Director of clinical data quality		
	Clare Craig – Cancer Programme GMC liaison		
	Tom Fowler – Project Lead		
<b>Electronic Signature</b>	 Tom Fowler (Mar 15, 2017)	<b>Approval Date</b>	Mar 15, 2017
	 amanda oneill (Mar 16, 2017)		16/03/2017
	 Clare Craig (Mar 15, 2017)		15/03/17
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## 2 Document Control

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### 2.1 Version History

Version	Author	Date	Description
0.1	Sam Hubble	10/03/2017	Initial document creation and content population
1.0	Sam Hubble	13/03/2017	Template completed and sent for electronic signature

## 3 Introduction

### 3.1 Purpose

The purpose of this document is to provide a brief summary of the 3.2.0 Cancer Data Model Package.

### 3.2 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.

## 4 What's New?

Summary of the main changes:

NOTE: specific changes can be found in the change tab of the Excel data specifications

### 4.1 Additions

- none

### 4.2 Removals

- Gauge of Biopsy Rule removed
- 1,0 removed from Retrospective sample enumeration

### 4.3 Changes

- Final Figo Stage enumeration updated
- Changed constraint from 3-35 chars to 1-50 chars and allow apostrophes for personGivenName, personFamilyName, personFamilyNameAtBirth
- Rules for macro dissection completion in sample tracking guidance
- Previous treatment changed to allow multiple responses
- New disease subtype added
- Tumour Type enumeration definition updated
- New Consent Forms Added (Appendix F)
- Multiplicity for metastatic site changed from 0..1 to 1..\*
- ReasonsSampleNotSentCancer-v3.2.0 schema-name changed
- Updated sample tracking business rules, appendices C and D
- Update presentations mapping, appendix G

- Additional findings questions in consent made optional to accommodate deceased participants
- Disease information updates made 1..\* to support more than one update in a submission
- New consignment number format added
- Constraint for drug regimen relaxed
- Descriptions for Underlying Cause, Condition, Immediate Cause, Significant changed
- Pathology investigation type and tissue source enumerations updated

## 5 Package Contents

### 5.1 Cancer Model Overview

- 1) **Cancer Model Conceptual Overview-3.2.0.pdf** – General overview and conceptual model for the data structures in the specification

### 5.2 Cancer Clinical Data Specifications for XML Submissions and Open Clinica Forms:

- 2) **Cancer Model-3.2.0.docx** - Cancer Clinical Data Specification as a Word Document describing the XML message definitions for Genomic Medicine Centres (GMCs) to provide clinical data for the programme from registration, to the description of their cancer diagnosis and stage, through their treatment pathway.

- 3) **Cancer Model-3.2.0.xlsx** - Cancer Clinical Data Specification AND CHANGE LOG as an Excel Document describing the XML message definitions for Genomic Medicine Centres (GMCs) to provide clinical data for the programme from registration, to the description of their cancer diagnosis and stage, through their treatment pathway.

CHANGES: New Additions to the model are highlighted in Green, Removals are highlighted in Red, Superficial changes (such as descriptions) are highlighted in blue.

### 5.3 Cancer Clinical Data XSDs and examples

- 1) **XSDs** - Contains the XML Schemas used to validate the XML messages submitted by GMCs.

The following XSDs are included:

- RegistrationAndConsentsCancer-v3.2.0.xsd

- RiskFactorAssessmentsCancer-v3.2.0.xsd
- DiagnosesCancer-v3.2.0.xsd
- DiseaseInformationUpdatesCancer-v3.2.0.xsd
- CarePlansCancer-v3.2.0.xsd
- ConsentUpdatesCancer-v3.2.0.xsd
- InterventionsCancer-v3.2.0.xsd
- InvestigationsCancer-v3.2.0.xsd
- PresentationsCancer-v3.2.0.xsd
- ReasonsSamplesNotSent-v3.2.0.xsd
- Withdrawals-v3.2.0.xsd
- DeathsCancer-v3.2.0.xsd

## 2) **Example XML Files**

The following XML files are included:

- example\_3.2.0\_reason\_sample\_not\_sent\_2.xml
- example\_3.2.0\_presentations\_1.xml
- example\_3.2.0\_disease\_information\_update\_2.xml
- example\_3.2.0\_death\_1.xml
- example\_3.2.0\_withdrawals\_2.xml
- example\_3.2.0\_care\_plans\_1.xml
- example\_3.2.0\_care\_plan\_2.xml
- example\_3.2.0\_riskfactors\_1.xml
- example\_3.2.0\_consent\_updates\_2.xml
- example\_3.2.0\_diagnoses\_2.xml
- example\_3.2.0\_diagnoses\_1.xml
- example\_3.2.0\_interventions\_1.xml
- example\_3.2.0\_registration\_and\_consent\_1.xml
- example\_3.2.0\_investigations\_1.xml

## 5.4 Cancer Sample Tracking Data Specifications – CSV Submissions and examples:

- 1) **Cancer Sample Tracking-3.2.0.docx** - Cancer Sample Tracking Specification as a Word Document describing the csv message definitions for Genomic Medicine Centres (GMCs) to provide sample tracking data for the programme.

- 2) **Cancer Sample Tracking-3.2.0.xlsx** - Cancer Sample Tracking Specification AND CHANGE LOG as an Excel Document describing the csv message definitions for Genomic Medicine Centres (GMCs) to provide sample tracking data for the programme. New CHANGES: Additions to the model are highlighted in Green, Removals are highlighted in Red, Superficial changes (such as descriptions) are highlighted in blue

### 3) **Example CSV Files**

The following csv files are included:

- example\_3.2.0\_metadata\_1

## 5.5 Cancer Appendices: Reference Data and Guidance

- 1) **Cancer Model v3.2.0\_Appendix A\_Disease\_Type\_Subtype\_Matrix\_v2**- Disease Type / Subtype Matrix
- 2) **Cancer Model v3.2.0\_Appendix B\_Tissue\_Source\_Disease\_Type\_Matrix\_v2** - Tissue Source / Disease Type Matrix
- 3) **Cancer Model v3.2.0\_Appendix C\_Sample\_Type\_Test\_Result\_Type\_Matrix\_v2** - Sample Type / Test Result Type Matrix
- 4) **Cancer Model v3.2.0\_Appendix D\_Sample\_Metafile\_Completion\_Guidance\_v3**- Sample Metadata File Completion Guidance for each Sample Type
- 5) **Cancer Model v3.2.0\_Appendix E\_Test\_Result\_Type\_Test\_Result\_Value\_v2** - Test Result Type / Test Result Value
- 6) **Cancer Model v3.2.0\_Appendix F\_Consent\_Forms\_Participant\_Info\_Additional\_v4** - Consent Forms, Participant Information Sheets, Additional Materials and Consent Update Enumerations
- 7) **Cancer Model v3.2.0\_Appendix G\_Presentation\_v2** – Disease Type / Presentations

**NB:** More example xml files and csv files will be issued in due course.

## 6 Known Deficiencies

### 6.1 Inherent Defects

none

## 7 Impact of Release

### 7.1 GMC Impact

Valid processing of CSV files for Gear 2 against the published model.

Valid processing of XML submissions for Gear 2 against the published model.

### 7.2 Biorepository Impact

none

### 7.3 Sequencer Impact

none

### 7.4 Support Impact

None anticipated beyond existing considerations.


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END OF RELEASE NOTE





# Cancer Model 3.2.0

## Release Note

### 100,000 Genomes Project Release Notes

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	Chris Long - Cancer Programme (Onc)	Next Review	N/A
	Sam Poole - Director of Engineering and sample acquisition		
Document Approval	Sam Poole - Director of clinical data		
	Chris Long - Cancer Programme (Onc)		
	Sam Poole - Project Lead		
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Impact on Compendium Personnel		Read and understood	Y
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










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